Rapports sur les problèmes de qualité des produits médicaux COVID-19

Numéro 12. Données de juin et juillet 2021

ANNEXE D: Informations sur le numéro d'identification (ID) des rapports et les articles sources

Ce document a été élaboré par le Medicine Quality Research Group, Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine, Université de Oxford

Annexe D. Informations sur le numéro d'identification (ID) des rapports et les articles sources

Cette annexe contient les rapports générés par "Medicine Quality Monitoring Globe (MQM Globe)" en utilisant des termes de recherche prédéfinis pour chacune des six catégories de produits. Au début de chaque rapport du "MQM Globe", les termes de recherche prédéfinis utilisés pour générer le rapport sont affichés.

Seuls les articles pertinents des rapports du "MQM Globe" ont été sélectionnés pour le présent rapport COVID-19. Pour chacun des numéros d'identification (ID) de rapport (code à six ou sept chiffres) abordés dans les sections "Articles sur les incidents dans la presse non spécialisée", des informations supplémentaires (y compris l'article source) peuvent être trouvées dans les rapports du "MQM Globe" dans les annexes D.1 à D.6 ou disponibles en ligne MQM Globe[1], en introduisant "reportID:XXXXXXX" dans le champ de recherche.

Comme la taille des annexes D.1 à D.6 est trop importante pour être incluse dans ce fichier, veuillez consulter la page du rapport sur la qualité des produits médicaux sur la page web de l'IDDO ou du MORU pour accéder aux rapports du "MQM Globe" par catégorie de produits.

Les articles dans le MQM Globe sont en anglais et ils contiennent les liens vers les articles de journaux originaux en anglais. En utilisant le numéro d'identification (ID) l'utilisateur peut rechercher le document en cliquant sur "article original". En utilisant Google Chrome, l'utilisateur peut générer une traduction de la page web anglaise en français.

Annexe D.1. Vaccins

Annexe D.2. Outils de diagnostic de la COVID-19

Annexe D.3. Equipements de Protection Individuelle

Annexe D.4. Désinfectants

Annexe D.5. Médicaments pour la COVID-19

Annexe D.6. Équipements et consommables de ventilation et d'oxygénation

[1]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 1, 2021. https://www.iddo.org/medicine-quality-monitoring-globe

Annexe D

D.1. Vaccins

Medicine Quality Monitoring Globe

September 20, 2021

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Filters applied for this report

Search ((”AZD1222” OR ”Tế bào Vero” OR ”BNT162b2” OR ”BBIBP-CorV” OR ”Sputnik V” OR ”Ad26.COV2.S” OR ”mRNA-1273” OR ”CoronaVac” OR ”EpiVacCorona” OR ”Covishield” OR ”Ad5-nCoV” OR ”Covaxin”) OR ((”vắc-xin” OR ”vaccine”) AND (”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Viện huyết thanh Ấn Độ” OR ”Oxford”)) OR ((”vắc-xin” OR ”vaccine”) AND (”COVID-19” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”SARS” OR ”CoV-2” OR ”vi rút corona”))) OR ((”BNT162b2” OR ”BBIBP-CorV” OR ”Ad26.COV2.S” OR ”CoronaVac” OR ”Covishield” OR ”Ad5-nCoV” OR ”AZD1222” OR ”FBRI” OR ”Sputnik V” OR ”mRNA-1273” OR ”EpiVacCorona” OR ”Vero Cells” OR ”Covaxin”) OR ((”vaccine”) AND (”Barat Biotech” OR ”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Serum Institute of India” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Oxford”)) OR ((”vaccine”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”CV19” OR ”CV-19” OR ”SARS” OR ”CoV-2”))) OR ((”AZD1222” OR ”BNT162b2” OR ”BBIBP-CorV” OR ”Ad26.COV2.S” OR ”mRNA-1273” OR ”Spoutnik V” OR ”CoronaVac” OR

”EpiVacCorona” OR ”Covishield” OR ”Ad5-nCoV” OR ”Covaxin” OR ”Cellules Vero”) OR ((”Vaccin”) AND (”Gamaleïa” OR ”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Bharat Biotech” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Oxford”)) OR ((”Vaccin”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”SRAS” OR ”CoV-2”))) OR ((”AZD1222” OR ”BNT162b2” OR ”FBRI” OR ”BBIBP-CorV” OR ”sputnik v” OR ”Células Vero” OR ”Ad26.COV2.S” OR ”mRNA-1273” OR ”CoronaVac” OR ”EpiVacCorona” OR ”Covishield” OR ”Covaxin”) OR ((”vacuna”) AND (”Barat Biotech” OR ”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Oxford” OR ”Instituto Suero de India”)) OR ((”vacuna”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”CV19” OR ”CV-19” OR ”SRAS” OR ”CoV-2”))) OR ({(″BNT162b2″ OR ″BBIBP-CorV″ OR ″Ad26.COV2.S″ OR ″克尔来福″ OR ″重组新型冠状病毒疫苗″ OR ″Covishield″ OR ″vero 细胞″ OR ″AZD1222″ OR ″FBRI″ OR ″卫星-V″ OR ″mRNA-1273″ OR ″非洲绿猴肾细胞″ OR ″Covaxin″) OR ((″疫苗″) AND (″牛津/阿斯利康″ OR ″Barat Biotech″ OR ″辉瑞″ OR ″牛津″ OR ″拜恩泰科″ OR ″阿斯利康″ OR ″北京科兴生物制品有限公司″ OR ″科兴生物″ OR ″强生″ OR ″中国医药集团″ OR ″辉瑞/拜恩泰科″ OR ″印度血清研究所″ OR ″Gamaleya″ OR ″Moderna″ OR ″国药″ OR ″康希诺生物″)) OR ((″疫苗″) AND (″新冠病毒″ OR ″武汉新型冠状病毒″ OR ″非典″ OR ″SARS″ OR ″CoV-2″ OR ″武汉肺炎″ OR ″新冠疫情″ OR ″COVID″ OR ″COVID-19″ OR ″新型冠状病毒肺炎″ OR ″SARS-CoV-2″ OR ″新型冠状病毒″ OR ″新冠″))})

Start date	2021-06-01
End date	2021-07-31
Language	
Report type	incident
Curation status	validated
Number of Reports	49

1 Fake Covid Certificates, Stolen Vaccines Sold on Darkweb for Bitcoin

Publication date	2021-07-01
Create date	2021-07-07
Score	323.26
Report id	1122035
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Fake Covid Certificates, Stolen Vaccines Sold on Darkweb for Bitcoin Yahoo Finance

Click here to see the Original Article

Table 1: Places for report 1122035

Region Name	Country	Location	Latitude	Longitude
		Earth	0	0

Table 2: Drugs for report 1122035

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 3: Other Stories

ID	Title	Link
1122443	Fake Covid Certificates, Stolen Vaccines Sold on Darkweb for Bitcoin - CoinDesk	Link
1122729	Fake Covid Certificates, Stolen Vaccines Sold on Dark Web for Bitcoin	Link
1129376	Blockchain company uncovers incredible details of online vaccine black market	Link
1129501	Italian police bust fake EU Covid-19 pass schemes	Link

Notes: Fake COVID-19 vaccination certificates, stolen vaccines and falsified doctors' signatures are being sold on the dark web for bitcoin.

According to a report on Thursday from blockchain analytics company Coinfirm, vendors have been selling the certificates and vaccines in exchange for a range of cryptos, including bitcoin, ether, dash, litecoin, tron, monero and zcash. [...] One particular dark web vendor, known as the "COVID-19 Vaccine Shop," appears to be selling vaccines in bulk from AstraZeneca, Pfizer-BionTech, Johnson & Johnson, Moderna and Sputnik V, Coinfirm reported. [...]

2 Pasay City police arrest fake nurse, cohort for illegal sale of COVID vaccines

Publication date	2021-07-07
Create date	2021-07-09
Score	169.67
Report id	1129126
Category	Vaccine
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Pasay City police arrest fake nurse, cohort for illegal sale of COVID vaccines Manila Bulletin

Click here to see the Original Article

Table 4: Places for report 1129126

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	City of Pasay	14.55	121

Table 5: Drugs for report 1129126

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 6: Other Stories

ID	Title	Link
1129375	Palace orders probe on COVID-19 vaccine sale	Link
1129387	Fake nurse caught selling COVID-19 vaccines in Pasay | Philippines Lifestyle News	Link
1129873	Fake nurse nabbed for offering COVID-19 vax for sale	Link

Notes: Two persons, one posing as a nurse, were arrested in an entrapment operation for selling

coronavirus disease (COVID-19) vaccines through social media at a very low price. [...] Esteban told police that Parejas was selling COVID-19 vaccines, Pfizer, AstraZeneca and Sinovac, through social media using her identity.

Esteban, after learning that Parajes was using her name in selling COVID-19 vaccines, immediately transacted with the suspect for 50 vials of COVID vaccines amounting to P120,000. [...] Estaban also told the police that Parajes claimed she was getting the supply of vaccines from a private hospital in Makati City and a government hospital in Quezon City. [...]

3 EU regulator flags contamination in some J&J COVID-19 vaccines

Publication date	2021-06-11
Create date	2021-06-15
Score	165.44
Report id	1095771
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: EU regulator flags contamination in some J&J COVID-19 vaccines Reuters

Click here to see the Original Article

Table 7: Places for report 1095771

Region Name	Country	Location	Latitude	Longitude
		Europe	48.69096	9.14062
Americas	United States	Baltimore	39.29038	-76.61219

Table 8: Drugs for report 1095771

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 9: Other Stories

ID	Title	Link
1095788	FDA expected to release 10 million doses of Johnson & Johnson's coronavirus vaccine from long-troubled Emergent plant	Link
1095789	BRIEF-EMA Aware Of Contamination In Batch Of Active Substance For COVID-19 Vaccine Janssen	Link
1095870	EU won't use J&J COVID shots from time of U.S. contamination issue	Link
1095904	FDA clears 10 million J&J vaccine doses from contaminated Baltimore plant	Link

Table 9: Other Stories(continued)

ID	Title	Link
1095907	AP source: J&J doses to be released, but many will be tossed	Link
1095911	Source: Millions of J&J doses to be released, but many more must be thrown out	Link
1095914	AP Source: J & J doses will be released, but many will be thrown	Link
1095926	US regulators order 60 millions Johnson & Johnson vaccines to be destroyed	Link
1095973	Johnson & Johnson vaccine from problem factory released for use	Link
1095982	U.S. FDA asks J&J to discard 60 million vaccine doses made at Baltimore plant: NYT	Link
1095988	FDA has decided at least 60 million doses of Johnson & Johnson's coronavirus vaccine must be be discarded; 10 million can be released	Link
1095989	J&J vaccine doses to be released, but many will be tossed	Link
1096018	Coronavirus: EU rejects some Johnson & Johnson COVID vaccines over contamination	Link
1096058	F.D.A. Tells J.&J. to Throw Out 60 Million Doses Made at Troubled Plant	Link
1096064	J&J Can't Use 60 Million Covid Doses Because of Possible Contamination: FDA	Link
1096073	FDA: Some J&J vaccine is good to go but some isn't	Link
1096084	EU won't use J&J COVID-19 shots from time of U.S. contamination issue	Link
1096134	Millions of J&J Doses Cleared for Use, But Many Remain in Limbo	Link
1096159	Some J&J vaccine doses can be used, but many must be tossed	Link
1096478	Contamination fears for millions of US vaccine doses	Link
1096595	US tells J&J millions of vaccine doses can't be used due to possible contamination	Link
1096653	EU Rejects Johnson and Johnson Vaccine batches Over Contamination	Link
1096696	EU Regulators Recommend Not Releasing Batches of Janssen COVID-19 Vaccine	Link
1096701	EMA orders 'millions' of Johnson & Johnson vaccines destroyed	Link
1097008	J&J doses to be released, but many will be tossed, AP reports	Link
1097048	J&J vaccine contamination 'takes roll out backwards' – Acting health minister	Link
1097524	UPDATE 1-EU won't use J&J COVID shots from time of U.S. contamination issue	Link

Table 9: Other Stories(continued)

ID	Title	Link
1097777	Germany demands that J&J make up Covid-19 vaccine gap in July	Link
1097867	US FDA clears J&J Covid-19 vaccine doses after months-long delay	Link
1097869	Coronavirus: Germany demands Johnson & Johnson replace spoiled COVID vaccine doses	Link
1098603	Millions of 'possibly contaminated' J&J vaccines to be discarded: four things you need to know	Link
1098663	Janssen COVID-19 Vaccine: one regulator blocks use, another promotes it	Link
1098726	Covid-19 roundup: Germany puts J&J on the hotseat for vaccine backorder; Top EMA official suggests forgoing AstraZeneca shot	Link
1098775	FDA: J&J Contaminated COVID-19 Vaccine Doses Must Be Discarded	Link
1098977	Germany demands replacement of 60 million contaminated J&J vaccine doses	Link
1099331	AP source: J&J doses to be released, but many will be tossed - Local 5	Link
1099476	FDA will release doses of J&J vaccine from Baltimore plant	Link
1100222	EMA officials are proposing to abandon AstraZeneca's jabs	Link
1101526	Millions of J&J doses unusable due to contamination	Link
1104023	EU officials 'expecting vaccine shortage for 3 months' but still lash out at J&J	Link
1104028	Problematic vaccine plant still lacks approval after some doses cleared	Link
1110121	US FDA asks J&J to discard millions of COVID-19 vaccine doses	Link
1111170	The FDA's weak drug manufacturing oversight is a potentially deadly problem	Link
1111339	The FDA's Weak Drug Manufacturing Oversight a Potentially Deadly Problem	Link
1112436	FDA's weak drug manufacturing oversight is a potentially deadly problem	Link
1116907	FDA's drug manufacturing oversight a potentially deadly problem	Link
1118475	EMA approves additional J&J vaccine manufacturing site	Link
1118494	How did 75M J&J vaccines get ruined? FDA details the manufacturing woes at Emergent's beleaguered site	Link
1120433	J&J to scrap about 60 million doses of its coronavirus vaccine	Link

Table 9: Other Stories(continued)

ID	Title	Link
1124108	F.D.A. Tells Johnson & Johnson That 60 Million Vaccine Doses Cannot Be Used	Link
1132838	J&J Can't Use 60 Million Covid Doses Because of Possible Contamination, FDA Rules	Link
1144991	The FDA's weak drug manufacturing oversight is a potentially deadly problem	Link

Notes: Europe's drug regulator said on Friday batches of Johnson & Johnson's (JNJ.N) COVID-19 vaccine made for the region around the time when contamination issues were revealed at a U.S. manufacturing site would, as a precaution, not be used. The European Medicines Agency (EMA) did not say how many shots were affected, but Reuters has reported it involves millions of doses, making it harder for J&J to meet a target of delivering 55 million to Europe by end of June. [...] Additional information report ID: 1095788 (https://www.washingtonpost.com/health/2021/06/11/fda-releases-johnson-johnson-vaccine-from-emergent-plant/): The Food and Drug Administration has decided at least 60 million doses of Johnson & Johnson's coronavirus vaccine made at the problem-plagued Emergent BioSolutions plant must be discarded, according to an individual familiar with the situation. [...]

4 Iran Cracks Fake COVID Vaccine Ring, Seizing Large Shipment

Publication date	2021-07-07
Create date	2021-09-15
Score	147.55
Report id	1216975
Category	Other, Vaccine
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: The Ministry of Intelligence of Iran (VAJA) arrested multiple individuals during an operation to seize a large shipment of fake and smuggled coronavirus vaccines.

Click here to see the Original Article

Table 10: Places for report 1216975

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Iran	Iran	32	53

Table 11: Drugs for report 1216975

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: The official IRNA news agency said in a report Wednesday, citing a VAJA statement, that the rings had been active in trafficking and counterfeiting vaccines which are in high demand throughout Iran. [...] The report said that the vaccines confiscated included major foreign brands like the Chinese Sinopharm or the British AstraZeneca as well as the US-made Pfizer, which is banned in Iran. The report, however, did not elaborate how much of the haul were fakes. [...] Iranian health ministry officials have repeatedly warned that vaccines offered in the black market for exorbitant prices are indeed fake. The VAJA statement explaiend it had also seized counterfeit COVID-19 drugs from the ringleaders' hideout places.

VAJA revealed that those arrested used ads on the social media to deceive "a significant number of people" to buy both the drugs and the vaccines. [...]

5 Le Canada ne distribuera pas les vaccins de Johnson & Johnson reçus

Publication date	2021-06-11
Create date	2021-06-18
Score	144.46
Report id	1096275
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Le Canada ne distribuera pas les vaccins de Johnson & Johnson reçus Le Journal de Québec

Click here to see the Original Article

Table 12: Places for report 1096275

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258
Americas	United States	Baltimore	39.29038	-76.61219

Table 13: Drugs for report 1096275

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 14: Other Stories

ID	Title	Link
1096276	Government of Canada : Mise à jour sur le vaccin contre la COVID-19 Janssen mis au point avec une substance médicamenteuse provenant d'Emergent BioSolutions	Link
1096299	Le Canada ne distribuera pas les doses reçues du vaccin de Johnson & Johnson | Coronavirus	Link
1097016	Vaccin Johnson & Johnson | Le Canada ne distribuera pas les vaccins reçus des États-Unis	Link

Table 14: Other Stories(continued)

ID	Title	Link
1097093	Les doses de Johnson & Johnson ne seront pas distribuées, dit Santé Canada	Link
1097349	Vaccin Johnson & Johnson: le Canada ne distribuera pas les vaccins reçus des États-Unis - Le Quotidien	Link
1099846	Le Canada ne distribuera pas les vaccins de Johnson & Johnson fabriqués à Baltimore	Link
1100239	Les doses de vaccin de Johnson & Johnson ne seront pas distribuées, dit Santé Canada	Link
1100297	Mise à jour sur le vaccin contre la COVID-19 Janssen mis au point avec une substance médicamenteuse provenant d'Emergent BioSolutions	Link
1115334	Vaccin Johnson & Johnson: le Canada ne distribuera pas les vaccins reçus des États-Unis - Le Nouvelliste	Link
1122299	Vaccin Johnson & Johnson: le Canada ne distribuera pas les vaccins reçus des États-Unis - Le Soleil	Link

Notes: Santé Canada ne distribuera pas les plus de 300 000 doses du vaccin contre la COVID-19 de Johnson & Johnson fabriquées dans une usine de Baltimore, au Maryland, en raison de préoccupations liées à une substance médicamenteuse mise au point dans l'installation d'Emergent BioSolutions. [...]

6 Gel-like substance found in 110 bottles of Sinovac's COVID-19 vaccine

Publication date	2021-06-29
Create date	2021-08-18
Score	131.71
Report id	1173183
Category	Vaccine
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: As many as 110 bottles of Sinovac COVID-19 vaccine have been found to contain a lump of transparent gel, which did not go away after being shaken. It is believed to be caused by the vaccine being stored at a temperature too low that recommended, according to Thailand's Food and Drug Administration (TFDA).

Click here to see the Original Article

Table 15: Places for report 1173183

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Thailand	Thailand	15.5	101

Table 16: Drugs for report 1173183

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: As many as 110 bottles of Sinovac COVID-19 vaccine have been found to contain a lump of transparent gel, which did not go away after being shaken. It is believed to be caused by the vaccine being stored at a temperature too low that recommended, according to Thailand's Food and Drug Administration (TFDA). [...] The TFDA has sent a letter, dated yesterday, informing all provincial health offices and hospitals across the country, administering Sinovac vaccine, to beware of the C202105079 batch, produced on May 10th and which expires on November 9th, and that it may contain a gel-like substance. [...]

7 First batch of J&J COVID vaccines won't be released in Canada

Publication date	2021-06-11
Create date	2021-06-17
Score	128.71
Report id	1096549
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: First batch of J&J COVID vaccines won't be released in Canada Toronto Sun

Click here to see the Original Article

Table 17: Places for report 1096549

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Baltimore	39.29038	-76.61219
Americas	Canada	Toronto	43.70011	-79.4163

Table 18: Drugs for report 1096549

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 19: Other Stories

ID	Title	Link
1096564	Health Canada not releasing Johnson & Johnson COVID vaccine	Link
1096606	First batch of Johnson & Johnson COVID vaccines won't be released in Canada	Link
1099089	Canada Rejects 300,000 Doses of J&J Vaccine Made in U.S.	Link
1099276	J&J will have to make up for tossed doses following quality control issue: gov't official	Link

Notes: More than 300,000 doses of the Johnson & Johnson single-shot COVID-19 vaccine will not be released for use in Canada.

The vaccines were quarantined in April before they were distributed to provinces because Health Canada was informed the drug substance in them was manufactured at the Emergent BioSolutions facility in Baltimore, Md., where there have been quality control issues. [...]

8 Police names suspects arrested over stolen Covid-19 vaccines

Publication date	2021-06-14
Create date	2021-07-13
Score	128.37
Report id	1129380
Category	Vaccine
Quality	Diverted/Unregistered
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Police names suspects arrested over stolen Covid-19 vaccines Independent

Click here to see the Original Article

Table 20: Places for report 1129380

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Uganda	Ntinda	0.35529	32.6142

Table 21: Drugs for report 1129380

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 22: Other Stories

ID	Title	Link
1129697	10 arrested over theft of COVID-19 vaccines	Link
1136292	Covid vaccines seized in private health units	Link

Notes: Uganda Police Force has named the twelve suspects picked up from two city pharmacies in connection to stolen COVID-19 vaccines. During the raids conducted by Crime Intelligence, more than 600 doses of AstraZeneca coronavirus vaccine were recovered at First Pharmacy Mulago-Wandegeya and Victoria Pharmacy in Ntinda. Police also picked up twelve suspects. [...]

9 Uganda: State House Says Over 800 People Vaccinated With Fake COVID-19 Jabs Kenya News

Publication date	2021-06-30
Create date	2021-07-02
Score	128.03
Report id	1119681
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Uganda: State House Says Over 800 People Vaccinated With Fake COVID-19 Jabs Kenya News Tuko.co.ke

Click here to see the Original Article

Table 23: Places for report 1119681

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 24: Drugs for report 1119681

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 25: Other Stories

ID	Title	Link
1119867	Over 800 vaccinated with fake Covid jab - State House	Link
1120279	800 in Uganda received fake COVID jabs: Officials | Daily Sabah	Link
1120812	Fake Vaccine Injectors Arrested In Uganda	Link
1120937	Over 800 people in Uganda get fake COVID-19 vaccine shots - Reports - Goa Chronicle	Link
1120960	800 people in Uganda vaccinated with fake COVID jab	Link

Table 25: Other Stories(continued)

ID	Title	Link
1121115	Ugandan police hunt phoney doctor, arrest two nurses in COVID vaccine scam	Link
1121231	Uganda: Over 800 Vaccinated With Fake Covid Jab - State House - AllAfrica	Link
1121232	Hundreds of people in Uganda vaccinated with fake COVID jab	Link
1121662	How 800 people were injected with water	Link
1122082	Alarm as 800 Ugandans get fake Covid-19 jab	Link
1122490	MPs Task Gov't to Investigate, Track Fake Covid-19 Vaccines	Link
1123007	Phoney doctor administers fake COVID-19 vaccines in Uganda	Link
1123588	Alarm as 800 Ugandans get fake Covid-19 jab - MyJoyOnline.com	Link
1127364	Ugandan-made COVID-19 drug now on black market | Daily Sabah	Link
1133959	ROGERS WADADA: Fake Covid-19 jabs, is this not an indictment to Uganda's entire vaccination campaign	Link
1137105	Experts Worry Fake COVID-19 Vaccine Scam Could Hinder Uptake :: Uganda Radionetwork	Link
1144235	800 Ugandans Injected With Fake Covid-19 Vaccine	Link
1146563	Experts confirm Ugandan fake COVID-19 vaccine doses were 99% water	Link
1147055	Ugandan State House confirms hundreds of Ugandans got water for COVID-19 vaccine	Link
1147303	Uganda: Experts Confirm Ugandans Got Water for Covid Vaccine	Link
1147523	Govt confirms 800 people received fake COVID-19 vaccine	Link
1147582	Experts confirm Ugandans got water for Covid vaccine	Link
1147649	Uganda: Experts Confirm Ugandans Got Water for Covid Vaccine - AllAfrica	Link
1147920	Hundreds of Ugandans given fake Covid jabs: health officials	Link
1147922	Fake vaccination: At least 800 people jabbed with WATER after buying 'Covid vaccine' from scammers in Uganda	Link
1147998	People paid for fake vaccines	Link
1147999	Hundreds of people in Uganda injected with water instead of Covid vaccine	Link
1148214	Ugandan medical workers accused of giving at least 800 people fake COVID-19 vaccines	Link
1148257	Hundreds of Ugandans given fake COVID jabs: health officials	Link

Table 25: Other Stories(continued)

ID	Title	Link
1148356	Ugandans injected with water instead of Covid-19 vaccine	Link
1148723	Hundreds of Ugandans given fake COVID-19 jabs: health officials	Link
1148919	Ugandan scandal: more than 800 people received fake coronavirus vaccines	Link
1150016	COVID-19 Vaccine Scam In Uganda Results In About 800 People Being Injected With Water	Link
1150130	Hundreds in Uganda given fake Covid shots	Link
1150391	Hundreds of Ugandans duped into paying for fake Covid-19 shots	Link
1150523	Ugandan workers injected with water instead of coronavirus vaccine: Report	Link
1150524	Hundreds of Ugandans injected with fake Covid-19 vaccines	Link
1150809	Hundreds of Ugandans given fake COVID-19 jabs – health officials	Link
1151497	Hundreds of Ugandans 'paid for fake coronavirus jabs in vaccination scam'	Link
1151746	How top city firms paid for fake Covid vaccines	Link
1155700	800 fake Covid-19 vaccine doses were 99% water - Monitoring Unit	Link
1160303	Fraudsters Injected 800 in Uganda With Water Instead of Covid Vaccines	Link
1166178	Three charged with administering fake Covid-19 vaccine	Link
1166281	Five charged over administering fake Covid-19 vaccines	Link
1167008	Five charged over fake Covid-19 jabs	Link
1186606	Hundreds of Ugandans given fake Covid jabs: health officials	Link

Notes: The fight against the dreaded coronavirus disease in Uganda has been dealt a blow after it emerged that some fake COVID-19 vaccines had found themselves on the counter. As Ugandans rush to take COVID-19 jabs, unscrupulous people are taking advantage of their desperate situation to administer fake vaccines at a fee. [...]

10 Ordenan a Johnson & Johnson tirar 60 millones de dosis

Publication date	2021-06-11
Create date	2021-07-22
Score	126.79
Report id	1095951
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Ordenan a Johnson & Johnson tirar 60 millones de dosis El Diario

Click here to see the Original Article

Table 26: Places for report 1095951

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	United States	Baltimore	39.29038	-76.61219

Table 27: Drugs for report 1095951

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 28: Other Stories

ID	Title	Link
1096045	Coronavirus.- El Gobierno de EEUU descarta 60 millones de dosis de vacunas Janssen por riesgo de contaminación	Link
1096243	EE.UU. ordena tirar millones de vacunas de Johnson & Johnson de una fábrica que tuvo problemas	Link
1096586	Estados Unidos ordenó descartar 60 millones de dosis de la vacuna de Johnson & Johnson. Estas son las razones	Link

Table 28: Other Stories(continued)

ID	Title	Link
1097026	Llegarán hoy más de 800 mil vacunas de AstraZeneca; Estados Unidos desechará millones de vacunas; Reducen v...	Link
1098284	FDA detalla fallas en planta de Baltimore por las que se produjeron 75 millones de vacunas J&J inutilizables	Link
1098655	Retira 2 millones de vacunas	Link
1100125	Johnson & Johnson desecha millones de dosis de su vacuna por contaminación – Escambray	Link
1100876	Johnson & Johnson ha tenido que desechar 75 millones de dosis de su vacuna anticovid por contaminación – CMKW Radio Mambí	Link
1101695	Vacunas anticovid de de Johnson & Johnson son desechadas por contaminación	Link
1116705	Intiman a Johnson & Johnson a que tire 60 millones de dosis de vacunas	Link

Notes: Después de semanas de revisión de una fábrica de Baltimore en problemas, los reguladores federales han decidido que alrededor de 60 millones de dosis de la vacuna contra el coronavirus de Johnson & Johnson producidas allí deben descartarse debido a una posible contaminación

11 Thai clinic shut down for selling fake Moderna vaccine: cops

Publication date	2021-07-14
Create date	2021-07-20
Score	122.36
Report id	1136434
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Thai clinic shut down for selling fake Moderna vaccine: cops Coconuts

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Table 29: Places for report 1136434

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Thailand	Prachin Buri	14.04992	101.36864

Table 30: Drugs for report 1136434

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 31: Other Stories

ID	Title	Link
1155821	Fake Vaccines In Thailand - Food, Drugs, Healthcare, Life Sciences - Thailand	Link

Notes: The owner of a Prachinburi province clinic was being dragged in for questioning today after patients said he was selling bogus Moderna COVID-19 vaccines. [...] A woman said she had transferred up to THB6,000 to vaccinate her family of four, but on the date of their scheduled inoculation, she said clinic staff never showed her the vaccine's packaging. She said she and her family members did not suffer any of the expected side effects, either. [...]

12 COVID-19 in Chhattisgarh: 70 doses of Covishield vaccine stolen in Durg's Ahirwara

Publication date	2021-07-18
Create date	2021-07-22
Score	122.14
Report id	1143378
Category	Vaccine
Quality	Diverted/Unregistered
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19 in Chhattisgarh: 70 doses of Covishield vaccine stolen in Durg's Ahirwara Free Press Journal

Click here to see the Original Article

Table 32: Places for report 1143378

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Ahirwāra	26.96502	81.20554

Table 33: Drugs for report 1143378

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: As the number of cases of delta variant started increasing in Chhattisgarh, the state witnessed another shocking incident, when 70 doses of Covishield vaccine were stolen from a COVID vaccination centre in Ahirwara in Durg district. [...]

13 WHO uncovers problems at Sputnik V Covid-19 vaccine at Russia's Ufa plant

Publication date	2021-06-24
Create date	2021-07-13
Score	117.19
Report id	1131615
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WHO uncovers problems at Sputnik V Covid-19 vaccine at Russia's Ufa plant Mint

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Table 34: Places for report 1131615

Region Name	Country	Location	Latitude	Longitude
Western Asia	Russian Federation	Ufa	54.74306	55.96779

Table 35: Drugs for report 1131615

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: The World Health Organization said Wednesday it had uncovered problems at a Sputnik V Covid-19 vaccine production site which Moscow insisted had been resolved. [...] The inspectors had concerns with the data integrity and testing results from monitoring during manufacturing and quality control, and with the monitoring and control of aseptic operation and filling.

The inspection identified issues with the traceability and identification of vaccine batches.

There were also concerns over the filling lines, sterility assurance, sterile filtration validation and the risks of cross-contamination. [...]

14 Sinovac shots confiscated in QC ‘unsafe,’ had dirty packaging – FDA

Publication date	2021-07-08
Create date	2021-07-13
Score	117.18
Report id	1130843
Category	Vaccine
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Sinovac shots confiscated in QC ‘unsafe,’ had dirty packaging – FDA INQUIRER.net

Click here to see the Original Article

Table 36: Places for report 1130843

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Republic of the Philippines	13	122

Table 37: Drugs for report 1130843

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: The 300 doses of COVID-19 vaccine supposedly manufactured by China’s Sinovac Biotech that were confiscated by the National Bureau of Investigation (NBI) in Quezon City had soiled packaging and are not safe to use, the Food and Drug Administration (FDA) said Friday.

FDA director Eric Domingo said the vaccines ”definitely” were being sold at the black market. He added that they are checking vaccine records and are coordinating with the Bureau of Customs to check if there were vaccine deliveries aside from those initiated by the government in the previous weeks. [...]

15 La FDA dit que les doses de vaccin J&J de 60 millions doivent être jetées: Dernières mises à jour COVID

Publication date	2021-06-11
Create date	2021-06-18
Score	116.89
Report id	1096003
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: La FDA dit que les doses de vaccin J&J de 60 millions doivent être jetées: Dernières mises à jour COVID News 24

Click here to see the Original Article

Table 38: Places for report 1096003

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Europe	48.69096	9.14062
Americas	United States	Baltimore	39.29038	-76.61219

Table 39: Drugs for report 1096003

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 40: Other Stories

ID	Title	Link
1095936	J&J: incident de contamination d'un lot de vaccins aux USA	Link
1096226	États-Unis - Soixante millions de doses inutilisables	Link
1096489	Johnson & johnson : Incident de contamination d'un lot de vaccins aux USA	Link

Table 40: Other Stories(continued)

ID	Title	Link
1096490	J&J : incident de contamination d'un lot de vaccins aux USA	Link
1096775	Covid-19: 60 millions de doses du vaccin J&J gâchées par une usine américaine	Link
1097163	Covid-19 - Des millions de vaccins Johnson&Johnson seront détruits en Europe suite à un problème de contaminat	Link
1097216	Des millions de jabs COVID-19 de J&J à jeter: États-Unis	Link
1119186	L'Agence européenne des médicaments ordonne la destruction de millions de vaccins Johnson&Johnson, suite à une contamination croisée	Link
1119558	Covid: la destruction de millions de vaccins J&J ordonnée par l'Agence européenne des Médicaments	Link
1125082	Johnson & Johnson : des millions de doses du vaccin vont être jetées	Link

Notes: [...] Le New York Times a rapporté que la FDA a décidé que 60 millions de doses du vaccin Johnson & Johnson COVID-19 produites dans une usine de Baltimore doivent être jetées en raison d'une éventuelle contamination. L'Associated Press a rapporté qu'environ 10 millions de doses seraient autorisées à être distribuées, mais, selon le Times, elles doivent inclure un avertissement que la FDA ne peut garantir que la société exploitant l'usine a suivi de bonnes pratiques de fabrication. [...]

16 Five fraudsters are arrested in Ecuador for selling fake Pfizer vaccines

Publication date	2021-06-15
Create date	2021-06-22
Score	106.36
Report id	1100787
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Five fraudsters are arrested in Ecuador for selling fake Pfizer vaccines Daily Mail

Click here to see the Original Article

Table 41: Places for report 1100787

Region Name	Country	Location	Latitude	Longitude
Americas	Ecuador	Republic of Ecuador	-1.25	-78.25

Table 42: Drugs for report 1100787

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Ecuadorian authorities arrested five people for allegedly selling jars filled with sea water that they claimed were Pfizer COVID-19 vaccines for $25. [...] Authorities confiscated a total of 43 syringes that were each filled with liquid as well as unknown number of small glass jars that contained ocean water. [...]

17 TMC MP Mimi Chakraborty falls for fake Covid-19 vaccination drive, gets accused arrested

Publication date	2021-06-23
Create date	2021-06-28
Score	106.10
Report id	1110971
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: TMC MP Mimi Chakraborty falls for fake Covid-19 vaccination drive, gets accused arrested India Today

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Table 43: Places for report 1110971

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kolkata	22.56263	88.36304

Table 44: Drugs for report 1110971

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 45: Other Stories

ID	Title	Link
1110904	Lok Sabha MP Mimi Chakraborty busts fake Covid-19 vaccination drive	Link
1111158	TMC MP Mimi Chakraborty gets vaccinated from fake vaccination centre; racket busted	Link
1111228	TMC MP Mimi Chakraborty gets COVID-19 jab at fake vaccination camp in Kolkata, informs police	Link
1111466	After TMC MP Mimi raises alarm, man arrested for running fake vaccination camp	Link

Table 45: Other Stories(continued)

ID	Title	Link
1111656	Fake vaccine centre in Kolkata busted after MP raises alarm	Link
1111657	Police trying to unmask the man behind many vaccination camps in city, suburbs	Link
1111940	'Fake' IAS man held after TMC MP Mimi Chakraborty duped into attending Covid-19 vaccination drive, getting jabbed	Link
1111942	Seized vials to be sent for testing, says Kolkata Police on fake COVID vaccination drive	Link
1112037	India: Police seize vials from alleged fake Covid vaccination drive	Link
1112083	Kolkata fake COVID-19 vaccination drive: Seized vials to be sent for testing, says Police	Link
1112144	Fake vaccination camp in Kolkata: Medical experts, vaccine recipients wonder what went into their bodies	Link
1112194	MP-actress Mimi Chakraborty takes COVID jab at fake vaccination camp in Kolkata, imposter arrested	Link
1112261	'Fake' Vaccine Probe After MP Mimi Chakraborty Gets Jab At Suspect Event	Link
1112270	Kolkata's Fake Vaccination Camp - People Are Wondering What Was Injected Into Them	Link
1112390	Mimi Chakraborty gets fake Covid-19 jab in Kolkata by a man named Debanjan Dev| TMC	Link
1112428	Vaccine fraud? Actor-MP Mimi Chakraborty allegedly duped; 'IAS impostor' held	Link
1112430	TMC leader claims she was jabbed at fake vaccination drive, man arrested	Link
1112614	At 'fake' COVID vaccination camp in Kolkata, recipients wonder what they were injected with	Link
1112618	Kolkata cops seize 'dust and liquid' vials from fake vaccination site where TMC MP Mimi Chakraborty took jab	Link
1112701	Vaccines administered did not contain anything harmful: TMC leader Mimi Chakraborty on fake vaccine racket	Link
1112719	Medicines found in office of fake officer who held camps not Covid vaccines	Link
1112720	Fake Covid Vaccination Drive, How Were 100s Duped Without Authorities Knowing? I The Urban Debate	Link
1112828	People may have got antibiotics at fake jab camp in Kolkata: Cops	Link
1112866	West Bengal: Fake vaccination camp busted in Kolkata, anti-bacterial jabs given in the name of COVID-19 vaccine	Link

Table 45: Other Stories(continued)

ID	Title	Link
1112868	Amikacin may have been used at fake Covid-19 vaccination camp in Kolkata	Link
1112870	People weren t jabbed with Covid vaccine at fake camp | Kolkata NYOOOZ	Link
1112956	Covid vaccination scam: Claims of lack of knowledge by CMC and police raise concerns among citizens	Link
1113003	Kolkata's Fake Vaccination Camp; Indians Skipping Masks + More Top News	Link
1113054	Kolkata: Fake vaccination camp participants may've got antibiotic shots	Link
1113199	Video: MP Mimi Chakraborty takes COVID jab at fake vaccination camp in Kolkata	Link
1113363	West Bengal MP Mimi duped in fake vaccination racket, one arrested	Link
1113447	Amikacin may have been administered in fake vaccination camps in Kolkata	Link
1113528	Fake vaccine racket mastermind's photos with TMC brass go viral, BJP attacks party	Link
1113601	'People weren't jabbed with Covid vaccine at fake camp'	Link
1113696	We Demand a Central Bureau of Investigation Inquiry in a Fake #COVID Vaccination ... - Latest Tweet by ANI	Link
1113798	Fake vaccination camp: What did we get, ask worried 'vaccine' recipients across Kolkata	Link
1113907	Man Arrested for Fake Vaccine Drive After TMC Leader Mimi Chakraborty Duped into	Link
1114077	Act of 'distorted mind', says Kolkata police chief on fake vaccination case	Link
1114167	Trinamul leaders deny links with organiser of fake jab camps	Link
1114245	Portrait Of An Ace Kolkata Conman Held For Fake Covid-19 Vaccination	Link
1114257	In Fake Vaccine Case, a Special Investigation Team Has Been Constituted Under Deputy ... - Latest Tweet by	Link
1114330	Kolkata fake vaccine camp: TMC MP clarifies as his photos with mastermind go viral	Link
1114332	BJP attacks TMC over fake Covid vaccination, demands probe by central agency	Link
1114433	Antibiotic jabbed instead of COVID-19 vaccine at fake centres in Kolkata	Link
1114447	Kolkata Police forms SIT to probe fake vaccination drive in city	Link

Table 45: Other Stories(continued)

ID	Title	Link
1114591	'Fake' Vaccine Drive: Kolkata Man Arrested, SIT Formed After TMC Leader Mimi Chakraborty Duped into Getting	Link
1114594	KMC dismantles plaque bearing name of fake IAS officer along with TMC leaders	Link
1114707	BJP wants CBI probe into fake vaccine scam	Link
1114753	TMC MP Mimi Chakraborty claims alleged fake Covid vaccination drive in Kolkata	Link
1114906	Fake Covid Vaccination Drive, How Were Hundreds Duped Without Authorities Knowing? I The Urban Debate	Link
1114950	Kolkata vaccine scam: Accused posed as IAS officer for years, KMC dismantles plaque bearing his name	Link
1115013	Central agencies must probe Kolkata vaccine fraud case, says BJP's Suvendu Adhikari; writes to Harsh Vardhan	Link
1115073	BJP, TMC trade charges over fake Covid-19 jab drive, police form SIT	Link
1115114	Kolkata vaccine fraud: BJP's Suvendu Adhikari demands immediate probe	Link
1115161	TMC MP Mimi Chakraborty falls ill, days after taking jab at 'fake' Covid-19 vaccine camp in Kolkata	Link
1115230	TMC MP Mimi Chakraborty falls sick days after taking 'fake' COVID-19 vaccine	Link
1115234	Kolkata Police Arrests UPSC Aspirant For Impersonating As IAS And Organising Fake Covid-19 Vaccine Camps	Link
1115237	Kolkata "Fake" Vaccine Drive Accused May Be Charged With Attempt To Murder	Link
1115257	Main Accused in Kolkata Fake Vaccine Drive Likely to be Charged With Attempt to Murder	Link
1115266	Kolkata Man, Accused Of Fake Vaccine Camps, Was Invited To A Police Event	Link
1115291	Mimi Chakraborty down with dehydration, low BP after taking fake COVID vaccine	Link
1115294	Days after taking fake COVID vaccine, TMC MP Mimi Chakraborty falls ill	Link
1115322	Trinamool MP Mimi Chakraborty, Who Got Fake Covid Vaccine, Falls Ill	Link
1115323	Mimi Chakraborty falls ill days after taking fake Covid jab	Link
1115330	Fake vaccination: Bengal BJP leader writes to Union health ministry, demands probe by central agencies	Link
1115331	Three more arrested in Kolkata vaccination scam; WB govt sets up expert committee	Link

Table 45: Other Stories(continued)

ID	Title	Link
1115360	BJP's Amit Malviya slams TMC over fake vaccine scam	Link
1115361	TMC MP Mimi Chakraborty falls ill days after taking fake COVID vaccine	Link
1115427	TMC MP Mimi Chakraborty falls ill days after taking fakeĆOVID-19 vaccine	Link
1115429	MP Mimi Chakraborty falls ill days after fake vaccination	Link
1115430	TMC MP Mimi Chakraborty Unwell with Dehydration, Low Blood Pressure After Fake Vaccine Shot	Link
1115499	Fake vaccination camps: Suvendu Adhikari writes to Union Health minister for central probe	Link
1115623	West Bengal: CM Mamata Banerjee demands strong action against organiser of fake vaccination camp	Link
1115726	Fake vaccine drive accused charged with attempt to murder; 3 others held	Link
1115759	TMC MP Mimi Chakraborty busts fake vaccination drive in Kolkata; police arrest one in connection	Link
1115809	Vaccine fraud: Three arrested, 'attempt to murder' charge added	Link
1115858	VAX LAX: BENGAL IN A TIZZY, CM STEPS IN	Link
1115868	Kolkata fake jab drive: Accused charged with attempt to murder	Link
1115869	Covid: Bengal govt issues guidelines for off-site vaccination camps	Link
1115900	Fake vaccines	Link
1115934	Kolkata cops send vaccine vials for testing after TMC MP busts fake inoculation drive	Link
1115962	Coronavirus News Updates Live: Kolkata fake vaccine scam's perpetrator to be charged with attempt to murder	Link
1115964	Fake vaccination: Suvendu Adhikari writes to Centre seeking probe	Link
1115967	Bengal: Suvendu Adhikari writes to Centre seeking CBI probe into fake COVID vaccination drive | Indiablooms - First Portal on Digital News Management	Link
1116014	COVID-19 Vaccination: How to save yourself from a fake inoculation drive? Read here	Link
1116197	States asked to probe fake vaccination camps, take strict action against those responsible: Centre tells SC	Link
1116205	Days after taking fake COVID vaccine, actor Mimi Chakraborty falls ill	Link
1116352	Vaccination camps: TMC leaders deny links with accused	Link

Table 45: Other Stories(continued)

ID	Title	Link
1116520	New vaccination SOP in place in Bengal after fraud unearthed	Link
1116585	The saga of a conman who spent his own money to run fake vaccination camps	Link
1116595	COVID-19 in West Bengal: Govt releases new SOPs for vaccination at private CVCs after Kolkata jab scam	Link
1116715	The Saga of a Conman: Debanjan Deb Spent His Own Money to Run Fake Vaccination Camps in Bengal	Link
1116735	Covid: Private hospitals seek SOP approval for off-site vaccination drive	Link
1116776	TMC running fake govt: Dilip Ghosh on illegal vaccine camps	Link
1116849	West Bengal: Pause on off-site vaccination camps; new rules to be discussed in meeting today	Link
1116940	Bengal fake vaccination racket: Accused says 'wrote to firm for vaccine', cops to verify claims	Link
1117053	Kolkata vaccine fraud: Accused organised two vaccination camps; sent mail to SII for doses	Link
1117096	Mimi Chakraborty fell ill few days after taking the fake Covid vaccine, now stable	Link
1117107	Kolkata vaccine fraud: Police raids accused Debanjan's residence	Link
1117113	Kolkata fake Covid-19 jab drive accused admitted to organising two camps: Police	Link
1117141	Days after Kolkata fake vaccination camps, panic attack remains main 'health worry'	Link
1117239	Mimi Chakraborty Falls Ill After Receiving FAKE Dose Of COVID-19 Vaccine, Doctors Say Her Condition Is Stable	Link
1117256	Covid-19 Vaccine Racket: Bengal Temporarily Suspends Private Vaccination Camps	Link
1117429	Bengal's fake vaccination drive has its roots in politics of patronage	Link
1117437	Kolkata: 'Family pressure and hunger for fame drove conman to hold fake vaccination drives'	Link
1117524	Bengal tightens rules for private firms organising vaccination camps	Link
1117572	Saga of a conman who spent his own money to run fake vaccination camps	Link
1117573	India News | The Saga of a Conman Who Spent His Own Money to Run Fake Vaccination Camps	Link
1117642	Fake COVID-19 vaccination camp: How West Bengal rea.. inoculation drives and why TMC and BJP are squabbling	Link

Table 45: Other Stories(continued)

ID	Title	Link
1117755	Kolkata fake jab scam: Off-site vaccination camps halted, SOP to be issued	Link
1117771	Actor-Turned-MP Mimi Chakraborty Falls Ill, Days After Taking Jab At 'Fake' Covid-19 Vaccine Camp -	Link
1117787	Left protests fake COVID vaccine camps	Link
1117840	Kolkata vaccine scam: Mamata Banerjee says TMC govt has no role, calls accused "more dreadful than terrorist"	Link
1117935	Ongoing off-site Covid vaccination camps by private hospitals to continue	Link
1118204	Fake vaccination camps: Suvendu Adhikari writes to Harsh Vardhan for CBI probe	Link
1118207	2 More Arrested in Dubious Covid Vaccine Camps Case in Kolkata	Link
1118301	Fake vaccine case: 2 more, including fake IAS officer's cousin, held in Kolkata	Link
1118302	2 more arrested in dubious COVID vaccine camps case in Kolkata	Link
1118307	Two more arrested in fake vaccination racket in Kolkata	Link
1118340	Two more arrested in fake Covid vaccine camps case in Kolkata	Link
1118379	Fake COVID-19 vaccination camp in Kolkata: Two more people arrested after raids on main accused	Link
1118495	Calcutta High Court Accepts PIL Demanding CBI Investigation into the Fake Vaccine Case. ... - Latest Tweet	Link
1118568	Impersonator posing as joint commissioner of Kolkata Municipal Corporation writes to Serum Institute for Covishield, held - 2021-06-29	Link
1118581	Fake Vaccine Scam: Mamata Calls Accused 'More Dreadful than a Terrorist'	Link
1118654	Vaccination lowest in Bengal, fake inoculation going on: J P Nadda	Link
1118807	Vaccination in Bengal at lowest, alleges Nadda	Link
1118953	Kolkata fake vaccine scam: Calcutta HC accepts PIL demanding CBI probe, hearing on June 30	Link
1118993	BJP chief Nadda claims Covid-19 vaccination lowest in Bengal; TMC hits back	Link
1119004	Vaccination scam: Accused's cousin, another staff held	Link
1119016	JP Nadda claims Covid-19 vaccination lowest in Bengal; TMC hits back	Link
1119096	Covid: Private hospitals defer vaccination camps for inspection	Link

Table 45: Other Stories(continued)

ID	Title	Link
1119153	Kolkata vaccination scam: Accused Debanjan Deb sent to police custody till July 5	Link
1119172	Fake IAS officer behind Kolkata Covid vaccine 'scam' under lens for fake raids, tenders too	Link
1119178	Fake vaccination camps: Kolkata Police's SIT finds man faking as Union Home Ministry official	Link
1119222	Fraudster chose amikacin since vials looked similar	Link
1119674	What is Amikacin, the fake 'Covid vaccine' used in Kolkata scam	Link
1119765	Centres Asks West Bengal Government To Probe Fake Covid-19 Vaccination Camps	Link
1119766	Centre seeks report from West Bengal government on fake COVID-19 vaccination camps	Link
1119774	Health Ministry takes note of Kolkata fake vaccination drive; seeks 'factual report' in two days	Link
1120014	Centre seeks report from Bengal govt over alleged fake covid-19 vaccination	Link
1120015	'This is a planted game': Mamata on criticism of Bengal govt over fake vaccine drives	Link
1120233	Fake COVID vaccine camps: HC directs West Bengal government to file report on probe progress	Link
1120278	Fake Covid vaccination camps in Bengal: Centre seeks report; Mamata hits back	Link
1120284	Centre seeks report from West Bengal govt on dubious Covid vaccination camps	Link
1120341	Centre directs Bengal to submit report on fake vaccine drive	Link
1120393	Kolkata vaccine fraud: Accused organised two Covid-19 vaccination camps	Link
1120431	Centre seeks report on fake vaccination racket busted in Bengal	Link
1120434	Fake jab camps: Centre asks Bengal for report	Link
1120623	HC questions Bengal govt on vaccine scam kingpin Debanjan Deb, seeks affidavit on steps taken	Link
1120882	Seventh man arrested in fake vaccination racket in Kolkata	Link
1121539	Trinamool alleges Governor link to Kolkata fake vaccine scam, questions his silence	Link
1121591	Video | Actor-MP Mimi Chakraborty Gets Covid Jab At "Fake" Drive, Man Arrested	Link
1121621	Bengal fake vaccination row: TMC ups the ante on Governor, says 'very bad if he has any relation with accused'	Link
1122092	TMC claims Governor Jagdeep Dhankhar involved in Kolkata fake vaccination drive	Link

Table 45: Other Stories(continued)

ID	Title	Link
1122432	Faux IAS, Fake Vax	Link
1122487	Security Guard Arrested In Fake COVID-19 Vaccine Camps Case: Police	Link
1122596	TMC releases Guv's photo with man held in connection with fake vaccine racket	Link
1122856	TMC suppressing charges against Kolkata vaccine scam accused, alleges BJP's Dilip Ghosh	Link
1122949	Kolkata fake vaccine scam: West Bengal Govt files affidavit before Calcutta High Court	Link
1122974	West Bengal: Fake vaccination scam's kingpin Debanjan Deb's security personnel nabbed by Kolkata Police	Link
1123014	Kolkata fake vaccine camp: Security guard arrested	Link
1123260	Debanjan Deb: Saga of conman who spent his money to run fake vaccination camps	Link
1123294	One Indrajit Shaw Has Been Arrested in Connection with Fake Vaccine Scam Case. The Accused ... - Latest	Link
1123485	Kolkata vaccination scam: Police records Mimi Chakraborty's statement, sends notice to Serum Institute	Link
1123633	Kolkata Police Apprehends Another Fake Vaccine Accomplice	Link
1123674	TMC leader allegedly administers Covid-19 vaccine, draws flak	Link
1123815	Fake vaccine scam case: Kolkata police arrests accused Debanjan Deb's employee Indrajit	Link
1123816	West Bengal: Controversy erupts after TMC leader Tabassum Ara administers COVID-19 vaccine at Asansol camp; watch video	Link
1123866	One more arrested in vaccination scam in Kolkata;samples of fluids in vials sent for examination	Link
1123911	TMC MP Mimi Chakraborty recovering now after falling prey to fake vaccine camp	Link
1123966	Fake Covid-19 vaccination camps emerging in India, South Asia News & Top Stories	Link
1123976	'Accomplice' of Debanjan Deb arrested in fake jab camp case	Link
1124007	Fake vax recipients don't show antibody	Link
1124081	BJP protests in Kol over fake vax camps	Link
1124500	BJP stir to expose nexus between TMC leaders and vaccine scam mastermind: Dilip Ghosh	Link
1124676	Kolkata Police denies BJP permission for protesting against fake vaccination scam	Link
1124807	Vax scam probe: Over 50 statements recorded	Link

Table 45: Other Stories(continued)

ID	Title	Link
1124816	Fake camp complaints from southern fringes	Link
1125352	BJP's Kolkata protest rally against fake vaccination racket may trigger clashes	Link
1125360	West Bengal	Link
1125374	The conman who spent his own money to run a fake vaccination camp	Link
1125425	Bengal: BJP workers stage protest over fake COVID vaccination drive; Dilip Ghosh says law & order ruined	Link
1125427	Fake vaccine racket: BJP workers clash with police during march to Kolkata municipal corporation	Link
1125504	Fake Vaccine Racket: BJP Workers Clash with Police During March to KMC Office	Link
1125644	BJP protests against fake vaccine racket in Kolkata	Link
1125932	BJP Workers Clash With Police During March Against Fake Vaccine In Kolkata	Link
1126220	Days after taking fake Covid vaccine, Trinamool MP Mimi Chakraborty falls ill	Link
1126265	Kolkata vaccine scam: Trinamool asks MLAs to check details before attending events	Link
1126326	BJP rally against fake vaccine camps chokes central Kolkata	Link
1126897	Kasba vaccine fraud: Suvendu Adhikari seeks probe by central investigating agencies	Link
1127150	Uddhav Thackeray calls COVID vaccine scam in Maha 'matter of concern'; assures action	Link
1127299	Kolkata fake vaccination racket: Accused may face attempt to murder charge, 3 aides held	Link
1127475	Fraudulent & illegitimate process of COVID-19 vaccination in West Bengal: BJP MP Locket Chatterjee	Link
1127537	Dubious vaccination camps: Centre asks state govt for report on fake jabs, Mamata calls it attempt to 'defame Bengal'	Link
1127623	TMC MP Mimi Chakraborty Unwell, Days After Taking 'Fake' Vaccine Shot in Kolkata	Link
1127969	Fake vaccines, fake camp, fake IAS officer — Kolkata 'scam' that didn't spare even Trinamool MP	Link
1128844	Fake vaccination camps:Suvendu Adhikari writes to Union Health minister for central probe	Link
1128910	Vaccine scam: Another fake govt official arrested in Kolkata	Link
1129478	Kolkata vaccine fraud: Accused organised two COVID vaccination camps	Link
1130357	Covid-19: Indian MP falls sick after getting fake vaccine	Link

Table 45: Other Stories(continued)

ID	Title	Link
1131119	ED to probe Kolkata's fake Covid vaccination camps for alleged money laundering	Link
1131137	No CBI probe needed in Kolkata fake vaccination scam, won't interfere in state matter: Calcutta High Court	Link
1131253	ED files case against Debanjan Deb, others in Kolkata fake Covid vaccination drive case	Link
1131372	Kolkata fake COVID vaccine scam: HC dismisses PILs seeking CBI probe, refuses intervention	Link
1131601	Calcutta HC turns down PIL seeking CBI probe in fake vaccination scam	Link
1131644	No CBI Probe, For Now: Calcutta High Court Refuses to Interfere in Fake Vaccine Case	Link
1131823	HC no to CBI probe into fake vaccination case	Link
1132291	debanjan deb: Fake IAS officer who pulled off a real vaccine scam	Link
1133537	Fake vaccination camp: Antibiotic vials, Covishield labels found at accused's home	Link
1133742	ED to probe fake Covid vaccination camps in Calcutta	Link
1136155	MP Mimi Chakraborty among hundreds duped as fake Kolkata vaccination camp busted	Link
1137095	Protests Against Fake Vaccine in Kolkata	Link
1137272	Bengal: BJP protests against fake vaccination drive	Link
1137601	Fake IAS officer case: Cops raid Debanjan Debs office	Link
1137958	Vaccination scam: CID searches office of fake IAS officer	Link
1138104	Kolkata vaccine scam: CBI searches office of fake IAS officer Debanjan Deb	Link
1138834	Kolkata fake vaccine scam: BJP stages massive protest against TMC's 'anti-people policies'	Link
1139760	ED registers case to probe fake vaccine camps in Kolkata	Link
1140774	Vaccine scam accused fake IAS officer quizzed in 2020 over job cheating complaint: Police	Link
1141436	State vaccinates 95 fake shot recipients	Link
1141484	The vaccine scamster of Kolkata	Link
1142381	Petitioner in 'Kolkata fake vaccine case' moves SC challenging HC's order refusing CBI probe	Link
1142984	Health Ministry seeks immediate report on 'fake' vaccination camps in Kolkata	Link
1143233	No need for CBI probe into fake vaccination racket: Calcutta High Court	Link
1143329	Fake Vaccination Camp Case: Plea In Supreme Court Filed Against Calcutta High Court Order Dismissing CBI... - Live Law	Link

Table 45: Other Stories(continued)

ID	Title	Link
1143598	Fake-vax victims double-check info before real jab	Link
1143867	Plea in Supreme Court on Kolkata fake vaccine drive	Link
1144707	Debanjan Deb, organiser of Kolkata's fake vaccine camps, posed as IAS officer for years, moved around in blue-beacon SUV	Link
1146348	Cuffs on two more of Debanjan's aides in vaccine scam	Link
1146630	Bengal sleuths use 3D scanner in fake vaccination racket probe	Link
1147179	Fake vaccination racket: Cousin of prime accused among 2 more arrested in Kolkata	Link
1148209	COVID-19 Vaccine Scam: Victims in India Await Gov't Aid, Fresh Doses	Link
1148529	Vaccination scam: Accuseds cousin, another staff held	Link
1148531	Kolkata fake COVID vaccine scam: Calcutta HC dismisses PILs seeking CBI probe	Link
1149981	Jabs fraud explodes: Fake vaccinations in Mumbai and Kolkata	Link
1150891	Enforcement Directorate to probe fake COVID vaccination camps in Kolkata	Link
1151659	Health Worker Arrested In West Bengal Over Fake COVID-19 Vaccine Camps	Link
1151999	Kolkata vaccination scam: Cops confirm TMC MP's claim of busting fake COVID camp	Link
1152075	How an impostor set up fake COVID vaccine camp, fooling Kolkata MP, MLA	Link
1153459	Kolkata: Vaccine coordinator steals vials from health facility, holds paid inoculation camps	Link
1153874	Kolkata fake jab drive: Accused charged with attempt to murder	Link
1158079	'Vials at fake vax centres not Covishield'	Link
1164297	Cases Of Fake IAS, IPS Officers Spurt In Bengal	Link
1166074	Bengal MLA seeks police probe into unauthorised vaccination camp at TMC office	Link
1193005	Police file charges against 8 in Kolkata fake vaccine racket	Link
1193194	Kolkata fake Covid vaccination case: Chargesheet filed against Debanjan Deb, 7 others	Link
1193477	Fake vaccines case chargesheet drawn up against Debanjan Deb	Link
1194078	Kolkata: Vaccine conman charged with attempt to murder | Kolkata News - Times of India	Link
1194079	Kolkata: Conman poses as IAS officer, arranges fake vaccination camps; charged with attempt to murder	Link
1194865	Fake vaccines case: Debanjan Deb produced in court	Link

Table 45: Other Stories(continued)

ID	Title	Link
1199795	News updates from HT: ED raids in Kolkata in connection with fake Covid vaccine racket and all the latest news	Link
1199933	Fake vaccine jabs, black marketing of remdesivir: ED conducts raids in Kolkata	Link
1200634	ED conducts raids across 10 locations in fake vaccine scam case in Kolkata	Link
1200635	Fake vaccine case: ED raids 10 locations in Kolkata	Link
1200636	ED raids 10 locations across Kolkata in connection with fake vaccine case	Link
1200746	Kolkata: ED conducts raids at 10 locations in connection with fake vaccine case	Link

Notes: [...] The vaccination camp was organised in the name of Kolkata Municipal Corporation (KMC) at its office in South Kolkata on Tuesday. Chakraborty took her first dose of the Covishield vaccine during the camp where she was also invited as a chief guest. The TMC MP was called in to encourage people from the transgender community and physically handicapped. Along with Chakraborty, 200-250 people were administered the Covishield vaccine on Tuesday. [...] According to sources, Ghosh discussed the matter with the Special Commissioner of KMC and found out that no such event was organised by the corporation in this area. After that, the police were informed. [...] Additional Information ID: 1112828 (https://www.hindustantimes.com/india-news/people-may-have-got-antibiotics-at-fake-jab-camp-in-kolkata-cops-101624561190596-amp.html): [...] People who went to take Covid-19 vaccine at the fake vaccination camp, organised by the man who was impersonating an IAS officer, in south Kolkata might have been injected with Amikacin, an antibiotic, police said on Thursday. Sleuths of the Kolkata Police's detective department, who raided accused Debanjan Deb's office in south Kolkata on Thursday, found a large number of Amikacin vials. Fake labels of Covishield were also recovered, police said. [...]

18 Venezuela: Casi 2.000 incautos cayeron con vacunas hechas con analgésicos y agua

Publication date 2021-06-28

Create date 2021-08-17

Score 105.89

Report id 1117847

Category Vaccine

Quality Falsified

Source Not applicable

Curation Manually curated

Incident or General Incident

Snippet: Venezuela: Casi 2.000 incautos cayeron con vacunas hechas con analgésicos y agua Portal Extra

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Table 46: Places for report 1117847

Region Name	Country	Location	Latitude	Longitude
Americas	Venezuela	Bolivarian Republic of Venezuela	8	-66
Americas	Venezuela	Barquisimeto	10.0647	-69.35703

Table 47: Drugs for report 1117847

Medicine Name	Medicine Class	Action	ATC Code
ampicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA01
ampicillin	Antibiotics	antiinfectives	S01AA19
			N02
amikacin	Other antibiotics for topical use	antibiotics for topical use	D06AX12
amikacin	Other aminoglycosides	aminoglycoside antibacterials	J01GB06
amikacin	Antibiotics	antiinfectives	S01AA21
			J07
	Antibiotics	intestinal antiinfectives	A07AA

Table 47: Drugs for report 1117847(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA

Notes: víctimas de un grupo de estafadores preparaba las supuestas fórmulas con una mezcla de agua hervida, antibióticos y analgésicos, entre otros componentes, para ocasionar reacciones en las personas [...] La Dirección de Inteligencia y Estrategias Preventivas (DIEP) de la policía del estado Lara desmanteló una banda dedicada a la comercialización de preparados falsos contra el covid-19. El grupo operaba en Barquisimeto [...] Las investigaciones apuntan a que casi 2.000 larenses pagaron entre 100 y 450 dólares por la aplicación de dos y hasta tres dosis de falsas vacunas que eran comercializadas como Sputnik V y Sinopharm [...]

19 Mumbai Society Residents Allege Vaccination Scam, Suspect They Received Fake COVID-19 Vaccine; Probe

Publication date	2021-06-16
Create date	2021-06-22
Score	97.45
Report id	1101158
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Mumbai Society Residents Allege Vaccination Scam, Suspect They Received Fake COVID-19 Vaccine; Probe LatestLY

Click here to see the Original Article

Table 48: Places for report 1101158

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Mumbai	19.07283	72.88261

Table 49: Other Stories

ID	Title	Link
1100549	Fraud vaccine dealer: Housing society in Kandivali which held COVID-19 vaccination camp for members suspects it was taken for ride	Link
1100623	Mumbai housing society residents raise doubts over Covid-19 vaccination camp	Link
1100800	Residents of Mumbai housing society allege 'vaccination scam', suspect they were given fake Covid shots	Link
1101084	Residents of Mumbai's Hiranandani Society of Kandivali claim they were given fake vaccination	Link
1101153	Vaccination scam in Mumbai's plush housing society?	Link
1101195	Residents of Mumbai society allege they were given fake Covid shots	Link
1101268	Vaccination scam: Residents of Mumbai housing society allege they were given fake Covid shots	Link

Table 49: Other Stories(continued)

ID	Title	Link
1101271	Frauds organise fake vaccination camp at Mumbai society, pocket Rs 5 lakh	Link
1101284	Residents of Mumbai's Hiranandani Society claim they were given fake vaccination	Link
1101317	390 People at Mumbai Society say that they were given "Fake Vaccine"	Link
1101370	'Vaccine could be spurious': Mumbai housing society residents raise doubts over COVID-19 vaccination camp	Link
1101378	Mumbai housing society residents allege vaccination scam, suspect they were given fake Covid jab	Link
1101379	Mumbai: Residents of Hiranandani Estate Society allege they were given fake 'Covishield' vaccine	Link
1101444	Mumbai housing society vaccine scam: 2 held as residents suspect 'fake' shots	Link
1101543	Housing Society In Mumbai's Kandivali Claims They Were Administered Fake Covid Vaccines	Link
1101585	'Taken for ride': Mumbai housing society residents allege vaccination scam	Link
1101598	Covid vaccination scam: 'Spurious' vaccine jabs given at 1,260 per dose in Mumbai's plush housing society	Link
1101665	Vaccination scam in Mumbai housing society; cops probe fake drive in Kokilaben Hospital's name	Link
1101854	Fake Covid-19 vaccination drive conducted in Mumbai	Link
1101859	India News | Mumbai Society Residents Allege Vaccination Scam, Suspect They Received Fake COVID-19 Vaccine	Link
1101958	Residents of Mumbai Housing Society allege 'vaccination scam'	Link
1102021	Mumbai Hospital employee behind Kandivali society vaccination scam, BMC orders probe	Link
1102097	3 detained in Mumbai fake vaccination racket; housing society, production house among targets | Details	Link
1102124	Mumbai Housing Society Alleges It Was Given Fake Shots As No One Got Side Effect After Vaccine	Link
1102229	Mumbai Police begins probe into alleged vaccination fraud in Kandivli	Link
1102269	BMC seeks probe into fears of 'fake' vaccination camp	Link
1102436	Mumbai: 390 Hiranandani Society residents allege receiving fake COVID-19 vaccines	Link
1103183	Vaccination 'fraud' in Mumbai: BMC orders probe, seeks report within 48 hours	Link
1103283	Mumbai: Three detained in COVID-19 vaccine fraud in Kandivali's Hiranandani Heritage	Link

Table 49: Other Stories(continued)

ID	Title	Link
1103347	Ramesh Taurani says Tips duped in Mumbai fake vaccine scam: Still waiting for certificate	Link
1103408	Mumbai Housing Society Says It Was Scammed Into A Fake Vaccine Drive	Link
1103409	Mumbai Film Crew, Housing Society Allege Vaccine Scam by Racket Disguising as Na	Link
1103526	COVID-19 vaccine fraud at Kandivali society: Organiser quizzed, no FIR yet	Link
1103530	Ramesh Taurani hit by the fake vaccination scam; Producer says, Mumbai Police is investigating the matter	Link
1103598	Mumbai housing society residents allege being given fake Covid vaccination shots	Link
1103600	356 employees of Tips industries duped in fake COVID-19 vaccination scam	Link
1103602	Residents of Hiranandani Society in Mumbai allege receiving fake Covid vaccination; 3 detained	Link
1103750	Covishield or Any Saline Water? Ramesh Taurani Says Tips Industries Duped by Fake COVID-19 Vaccination	Link
1103890	Mumbai housing society vaccination fraud? Police, BMC begin probe	Link
1103948	Mumbai vaccination scam: Maharashtra govt asks BMC to probe matter and file report within 15 days	Link
1104584	Now, Bollywood duped in fake vaccine scam	Link
1104652	Ramesh Taurani duped by fake COVID vaccination camp? Producer worried about employees vaccine jabs	Link
1104798	Mumbai police arrest four in fake COVID vaccination camp	Link
1104806	'Fake' Vaccination Drive Held in Mumbai's Kandivli, Allege Housing Society Residents; 4 Arrested	Link
1104810	Covid-19 vaccination fraud rocks Bollywood: THIS event management company conducted fake vaccination drive-...	Link
1104904	Mumbai COVID-19 Vaccination Scam: Police Nab Five People For Coronavirus Vaccine Fraud at Housing Society	Link
1104905	Mumbai vaccination scam: 4 arrested, 1 detained and 2 absconding	Link
1104978	Mumbai vaccination scam: None of the victim registered on CoWin app, says Mumbai police sources	Link
1104989	Fake COVID-19 vaccination racket busted in Mumbai, five arrested	Link
1105043	Mumbai Police Arrest 4, Detain 1 in Fake Covid-19 Vaccination Drive in Housing S	Link

Table 49: Other Stories(continued)

ID	Title	Link
1105052	Mumbai: 4 held in fake vaccination drive at Kandivali housing society	Link
1105053	Mumbai: Fraud in the name of COVID-19 vaccine in Hiranandani Estate Society	Link
1105130	4 Arrested In Mumbai 'Fake Vaccine Camp' Case. Producer Too Suspects Scam	Link
1105132	Mumbai Police lodges FIR in housing society Covid jab scam case	Link
1105298	Mumbai fake vaccine scam: Bollywood music producer Ramesh Taurani's 356 employees given 'saline water'?	Link
1105386	Mumbai Fake Vaccine Scam Case: All 4 Accused, Who Were Arrested, Have Been Sent to Police ... - Latest	Link
1105457	Mumbai fake vaccination racket: How can we stop vaccine scams?	Link
1105461	Mumbai Police lodges FIR in housing society Covid jab scam case, 4 people held	Link
1105511	How fraudsters duped Mumbai flat residents by holding fake vaccination camps	Link
1105559	DNA: Did you also get the dose of fake COVID-19 vaccine?	Link
1105928	Mumbai vaccine scam: 4 arrested for organizing fake COVID-19 vaccination camp at housing society	Link
1106189	Mumbai vaccination fraud: No permission was taken from BMC, jabs procured from unauthorised source, say police	Link
1106250	Mumbai: Cops looking for doctor fraudsters tied up with to source vaccines	Link
1106431	Mumbai COVID-19 Vaccination Scam: Aditya College in Borivali Complains of Fake Coronavirus Vaccine Drive	Link
1106432	India News | Mumbai: Aditya College in Borivali Complains of Fake COVID-19 Vaccine Drive	Link
1106499	Mumbai vaccine scam: 'Housing societies should take NOCs from BMC to ensure vaccination drive are...	Link
1106538	'Centre should make provision of life sentence': Rajasthan CM on fake vaccination racket	Link
1106879	BMC report doesn't say anything about genuineness of the vaccine which were given in Kandivali society	Link
1106882	BMC probe report: Vax drive in hsg society fake in Mumbai	Link
1106944	Fake vax racket: CM seeks life term for criminals	Link
1107167	Mumbai: Fake vaccinations camp were conducted without permission of BMC	Link
1107227	Second FIR in Mumbai vaccine scam, 150 employees of production house get fake jab and no certificate	Link

Table 49: Other Stories(continued)

ID	Title	Link
1107331	Mumbai police files second FIR in fake vaccination scam	Link
1107376	Mumbai police files second FIR in fake vaccination scam	Link
1107415	Mumbai: Four held for fraudulent Covid-19 vaccination camp at Kandivli housing society	Link
1107585	Vaccine scam: BMC asks Serum to verify batch of Covishield vials used in housing society	Link
1107642	Five men arrested in Kandivali for running unauthorised vaccination camp	Link
1107867	Mumbai: Kandivli doctor is key accused in Covid-19 vaccine scam	Link
1107931	'Concerned if vaccines were genuine or fake'	Link
1108216	Mumbai vaccine fraud: Second FIR accessed reveal more details	Link
1108381	Second FIR in vaccination scam; vials fake, bought from outside Mumbai?	Link
1108818	Bollywood Music Producer's Firm Goes To Cops Over "Fake Vaccine Camp"	Link
1108819	Mumbai's Fake Vaccine Fraud: Tanvi Shukla on slow pace of investigation | The Urban Debate	Link
1108856	Mumbai vaccine scam: Police look out for doctor who supplied vials for camp at housing society	Link
1108860	Covid vaccine fraud: Third FIR filed in Mumbai, accused booked for selling adulterated drugs	Link
1108878	Fake vaccine drive: Mumbai Police arrested five people	Link
1108879	Mumbai Police files second FIR in fake vaccination scam	Link
1108910	Mumbai Fake Vaccination Scam: Khar Police Register FIR Against 6 Accused; Know Details	Link
1108911	Six more booked for fake vaccination camp	Link
1108952	Mumbai: Cops to probe role of trainee nurses in fake COVID-19 vaccination drive	Link
1109238	Fake vaccine scam across Mumbai: Third FIR filed on complaint from Tips	Link
1109297	Third FIR in vaccination scam; Kandivli doctor may be kingpin, say police	Link
1109439	Fake Covid shots given at unauthorised vaccination camps in Mumbai: Police	Link
1109530	Covid-19: Bombay HC asks Maharashtra government to form policy against fake vaccination drives	Link
1109584	Fake vaccination drives unfortunate, says Bombay HC; asks BMC, Maharashtra govt to form policy	Link

Table 49: Other Stories(continued)

ID	Title	Link
1109644	FPJ Legal | Vaccination Fraud: HC expresses disgust, asks state and BMC to formulate policy urgently to prevent frauds	Link
1109658	Mumbai Jab fraud: Health Minister says, 'Not their job to find if the vaccines were fake'	Link
1109734	Coronavirus: Bombay HC asks Maharashtra government to frame policy against fake vaccination drives	Link
1109787	Humanity is suffering, yet people being defrauded: Bombay High Court asks State, BMC to take action against fake COVID-19 vaccination drives - Bar & Bench	Link
1109861	COVID-19 Vaccination Scam: Unearth Fake Coronavirus Vaccination Racket, Bombay HC to Maharashtra Govt	Link
1109904	[Exclusive] Fake vaccination scam: 'Some vaccines were genuine and some were fake', says Mumbai Police	Link
1109910	Mumbai: Doctor accused in Kandivali society fake vaccine drive seeks pre-arrest bail	Link
1110100	Mumbai Covid vax scam: Beneficiaries got fake Covid shots, say cops	Link
1110114	Filmmaker Ramesh Taurani's TIPS films and others get duped in fake vaccine scam	Link
1110178	Unearth fake COVID-19 vaccination racket: Bombay HC orders Maharashtra govt	Link
1110982	[Exclusive] Mumbai Police files 4th FIR in fake vaccination scam case	Link
1111012	4th fake camp in the Mumbai COVID vaccine fraud discovered & charged; 9 under scanner	Link
1111269	Mumbai: Doctor seeks pre-arrest bail in Kandivli's fake vax drive case	Link
1111355	'Fake' vaccination drive at college: Fourth FIR made in Borivali, arrest count goes to 6	Link
1111766	Mumbai: Fourth FIR in unauthorised vaccination drive case after camp in Borivali college	Link
1111939	Mumbai fake COVID-19 vaccine camp: Woman held for providing false certificates	Link
1112018	NESCO centre data entry official held for fake vaccination scam at Mumbai college	Link
1112145	Mumbai vaccination fraud: More than 2,000 people vaccinated in such fake camps, says Maha govt to HC	Link
1112146	Coronavirus India Live Updates: '2,053 people given fake vaccines, 4 FIRs registered,' Mumbai police tells Bombay HC	Link
1112198	Mumbai: Fourth FIR in vaccination scam at Borivali college, sixth accused arrested	Link

Table 49: Other Stories(continued)

ID	Title	Link
1112254	Coronavirus News LIVE Updates: Over 2,000 people given fake COVID-19 vaccines in Mumbai, Maharashtra govt...	Link
1112255	Over 2,000 people in Mumbai fell victim to fake COVID-19 vaccination drives: Maharashtra govt to Bombay HC	Link
1112256	FPJ Legal | Vaccination Fraud: Bombay HC voices concern for 2,053 citizens who received fake vaccines	Link
1112257	Vaccination Fraud: Podar Education Centre registers fifth FIR at Bhoiwada police station	Link
1112280	Fake vaccination scam: Mumbai Police files 5th FIR in the matter	Link
1112343	Do victims of Covid vaccine fraud in Mumbai have antibodies? Bombay HC asks BMC	Link
1112375	Fake Vaccine scam: 5th F.I.R linked to Mumbai's Podar Institute; More than 2000 jabs administered	Link
1112503	Over 2000 people administered fake vaccines, Mumbai Police tells High Court	Link
1112504	Over 2000 People Fell Victim for Fake COVID-19 Vaccine: Live India News 24 June 2021	Link
1112521	Mumbai fake vaccination scam: Staffer arrested for stealing Nesco's CoWIN ID password	Link
1112522	More Than 2,000 Fell Victim To Fake Vaccination Drives In Mumbai; 5 FIRs Registered	Link
1112623	Over 2,000 People in Mumbai Fell Victim to Fake Covid-19 Vaccination Drives: Mah	Link
1112647	Fake vaccination scam: Two more FIRs filed, Mumbai police lodges 8 FIRs so far	Link
1112700	Mumbai: SIT to probe fake vaccination racket suspected of using distilled water in vials	Link
1112780	Vaccination Fraud: Mumbai police register three more FIRs against 6 accused, doctor couple being questioned	Link
1112835	Mumbai vax scam: Seven FIRs registered; 6 who posed as doctors booked	Link
1112867	India: 2,000 people fall prey to fake COVID-19 vaccination drives in Mumbai	Link
1113139	Covid-19 vaccine scam in Mumbai: Victims given partial doses from leftover and expired shots	Link
1113148	Vaccination Fraud in Mumbai raises alarm; How did the fraudsters dupe hundreds? | The Urban Debate	Link
1113197	Over 2,000 in Mumbai duped in fake vaccine drives, says govt	Link
1113366	Mumbai fake vaccination scam: Founder-owner of Shivam hospital arrested	Link

Table 49: Other Stories(continued)

ID	Title	Link
1113374	Coronavirus news - live: Over 2,000 people get fake vaccines in Indian city as third wave looms	Link
1113604	Did you get saline water or vaccine? Here's what experts have to say about the recent fake jab busts	Link
1113699	COVID-19 Fake Vaccination Scam: Bombay HC Asks State, BMC to Probe, Track Scamsters	Link
1113806	Fake vaccination scam: Two more vaccination drives under police scanner now	Link
1114042	Over 2000 scammed in Mumbai's fake vaccination camps, 8 arrested	Link
1114151	Aapki Khabar Aapka Fayda: 2053 people received fake COVID-19 vaccine in Maharashtra - BMC	Link
1114258	Vaccination fraud | Mumbai police form special team to probe vaccination camp fraud	Link
1114344	Fake Covid vaccination drive busted in Mumbai	Link
1114423	Fake COVID-19 vaccine camp comes to light in Thane, several booked	Link
1114496	Shivam Hospital under scanner for unauthorised vaccination drives across Mumbai	Link
1114601	Fake Covid-19 vaccine camp comes to light in Thane, several booked	Link
1114706	2,000 Given Fake Vaccines In Mumbai, 10 People Arrested	Link
1114708	Find out the effects of fake vaccine on people: Bombay HC to BMC	Link
1114709	Beware of fake vaccine camp; thousands duped in Mumbai, ten arrested [details]	Link
1114711	Covid: Over 2,000 people get fake vaccines in Mumbai	Link
1114716	COVID-19 Live updates: Over 2,000 people in Mumbai fell victim to fake COVID-19 vaccination drives, HC told	Link
1114751	Mumbai: BMC may re-vaccinate victims of fraud if jabs are found bogus	Link
1114849	Mumbai vaccination camp fraud: SIT formed; doses had saline water	Link
1114856	Mumbai vaccination scam: SIT formed, stringent IPC sections added to nail culprits	Link
1115012	Mumbai doctor couple held for fake vax scam	Link
1115072	More than just vaccine scammers: Hospital was destroying proof, say Mumbai residents	Link
1115115	Doctor couple from Charkop arrested in vax camp fraud	Link
1115116	Mumbai fake vaccination drive: 10 arrested, police says saline may been administered to some	Link

Table 49: Other Stories(continued)

ID	Title	Link
1115238	3 more FIRs lodged into vaccination drives held in April & May; 2 arrested	Link
1115267	India arrests those involved in fake COVID-19 vaccine schemes	Link
1115363	Mumbai: Got jab in April but no certificate issued till today by Shivam Hospital, claims local resident	Link
1115507	Mumbai: Doctor couple who ran Shivam hospital arrested for vaccination fraud	Link
1115561	54 year old Khandivali resident fears she was injected with fake vaccine by Shivam hospital	Link
1115612	Five booked in connection with fake COVID vaccination camp held in Maharashtra's Thane	Link
1115670	Mumbai: Taking cognisance of fake vaccination drive, BMC directs private vaccine centres to provide unique identification, registration number	Link
1115671	54 year old Kandivali resident fears she was injected with fake vaccine by Shivam hospital	Link
1115672	Mumbai vaccination fraud: Bombay HC directs Maha govt & BMC to create policy on 'SOS' basis to avoid incidents	Link
1115761	Kandivali Vaccination Fraud: BMC Says Camp Held Illegally; Mumbai Police Arrest 4	Link
1115911	Mumbai: 'Travel agents got firm to trust fake vax providers'	Link
1115936	Mumbai: Role of two jobless travel agents emerges in fake vax drive	Link
1115963	Mumbai fake vaccination drive: Everything you need to know	Link
1116011	After Mumbai, fake COVID-19 vaccine camp found in neighbouring Thane; five booked	Link
1116012	Suvendu for CBI probe into Kasba vaccine fraud	Link
1116013	Five booked in connection with fake COVID vaccination camp held in Maharashtra	Link
1116054	Mumbai fake vaccination scam: Some targets received vaccination certificates on hospital letterheads	Link
1116101	Vaccination camp fraud: SIT formed; doses had saline water	Link
1116198	Mumbai Vaccine Fraud: Kandivali Case Accused Also Cheated Versova Man	Link
1116206	BMC expected to revise doorstep vax policy, finds multiple certificates in fake drive	Link
1116356	Vaccination scam in Mumbai: Here's all you need to know	Link
1116395	Mumbai: 'Fake' vaccination drive conducted in Kandivali	Link

Table 49: Other Stories(continued)

ID	Title	Link
1116437	[Exclusive] Fake vaccination scam: No authority probing the drive which was conducted in Thane	Link
1116481	Four held for fraudulent Covid-19 vaccination camp at Mumbai housing society	Link
1116777	Covid vaccination fraud: Is the government dragging its feet on the probe? | The Urban Debate	Link
1117106	Mumbai fake vaccination scam: 2 weeks into investigation, supplying sources of vials still unknown	Link
1117199	Duped At Fake COVID-19 Vaccination Camp, Alleges Mumbai Society	Link
1117412	Mumbai: Sessions court rejects pre-arrest bail plea by doctor in fake Covid jabs case	Link
1117490	Maha: Doctor couple arrested in connection with fake vaccination scam	Link
1117523	Mumbai court rejects pre-arrest bail of an accused in Kandivli fake vaccination case	Link
1117633	Mumbai fake vaccination drive: Everything you need to know - mid-day.com	Link
1117700	Mumbai Court Rejects Pre-arrest Bail of Accused Doctor in Kandivali Fake Vaccination Case	Link
1118020	Mumbai: Doc's pre-arrest bail rejected in fake vax case, to surrender	Link
1118081	Mumbai: No pre-arrest bail for dentist wanted in 9 illegal Covid vaccination drives	Link
1118107	Mumbai: College and private firm that organised vaccination drives also booked	Link
1118208	Mumbai fake vaccination case: Court rejects pre-arrest bail of an accused	Link
1118422	Mumbai fake COVID-19 vaccine camp case: Dr Manish Tripathi surrenders to Kandivali Police	Link
1118423	Don't spare 'big fish' in fake vaccination cases: HC to Mumbai police	Link
1118470	'Fake' Covid shots to 2,000 people: Check what they were given, vaccinate them, HC tells BMC	Link
1118496	Don't spare 'big fish' in fake vaccination cases: Bombay HC to Mumbai police	Link
1118520	Identify, dont spare big fish in fake vaccine scam, check on health of those who received jab: Bombay HC	Link
1118532	Don't Spare "Big Fish" In Fake Vaccination Cases: High Court To Mumbai Cops	Link
1118585	Doctor Linked To Fake Vaccine Drive At Mumbai Housing Society Surrenders	Link
1118634	Coronavirus: HC rejects bail plea of accused in alleged fake vaccination drive in Mumbai	Link

Table 49: Other Stories(continued)

ID	Title	Link
1118690	Mumbai Covid vaccine scam: Probe says victims given saline water, all to undergo antibody tests	Link
1118748	Fake vaccination cases: HC asks Mumbai police to identify big fish	Link
1118749	Mumbai fake vaccine scam: 2,040 people given saline water, all to undergo antibody tests, says Maharashtra minister Rajesh Tope	Link
1118750	Fake vaccination scam: Shivam Hospital, which is allegedly involved, doesn't have an occupancy certificate	Link
1119017	FPJ Legal: Arrest everyone involved in fake vaccination scam, Bombay HC orders Mumbai police	Link
1119044	Mumbai: Arrest everyone involved in fake vax drive, HC orders cops	Link
1119045	Mumbai court rejects pre-arrest bail of an accused in Kandivali fake vaccination case	Link
1119078	Mumbai: Dentist accused in nine 'bogus' Covid vaccination drives arrested	Link
1119175	Mumbai: Antibody test to be carried out in July for fake vax drive victims: Tope	Link
1119177	Mumbai: Doctor surrenders; 9th FIR likely in fake vax drive case	Link
1119475	[Exclusive] Fake vaccination scam: No FIR in Kwan vaccine drive, police cites no complainant as the reason	Link
1119578	[EXCLUSIVE] Mumbai vaccination scam: Maharashtra govt unclear on how to establish if vaccines were fake or not	Link
1119579	Coronavirus: Four arrested for fake vaccination camp in Mumbai apartment complex	Link
1119775	Four held for fraudulent COVID-19 vaccination camp at Mumbai housing society	Link
1119876	Fake vaccination scam: Another FIR in the scam, 618 people were given the unauthorised jab in Samta Nagar	Link
1119898	Mumbai fake vaccination scam: Mumbai Police receives one more complaint	Link
1120089	Fake vaccination scam: Two more drives under scanner, number of victims can reach 4,000 mark	Link
1120096	Maharashtra: Doctor surrenders; 9th FIR likely in fake vaccine drive case	Link
1120097	Mumbai Police Registers Tenth FIR in Connection with Fake Vaccine Cases in the City. - Latest Tweet by ANI	Link
1120164	Coronavirus News LIVE Updates: Mumbai Police registers 10th FIR in connection with fake vaccine cases	Link

Table 49: Other Stories(continued)

ID	Title	Link
1120214	Fake vaccination scam: Accused Dr Manish Tripathi sent to police custody till 4th July	Link
1120232	Mumbai vaccination scam: Police registers 9th FIR in Samta Nagar fake vaccine case	Link
1120312	Mumbai vaccination fraud: Borivali college emerges possible victim, files complaint	Link
1120336	Fake Vaccination Case: Mumbai court rejects pre-arrest bail of accused doctor	Link
1120349	Mumbai vaccination scam: 8th FIR registered, two doctors booked	Link
1120518	Mumbai: No pre-arrest bail as doctor played vital role in fraudulent vax drive scam, says Court	Link
1120569	Mumbai Vaccination Camp Fraud: Music-film Firm Approaches Cops in Khar	Link
1120642	Mumbai fake vaccination case: Ninth FIR filed	Link
1120883	Mumbai Fake vaccination: Mastermind arrested in Baramati; SIT probing 'vaccine' vials	Link
1120933	'Covishield' labels, cash payment, no photos — inside Mumbai's 'fake' vaccination camps	Link
1120934	An Accused in Mumbai Fake Vaccine Case Has Been Arrested from Baramati. This is the 12th ... - Latest Tweet	Link
1121059	COVID vaccination fraud: Distribution of fake vaccines and certificates exposed from Manipur	Link
1121060	Mumbai fake vaccination: Key accused arrested, two more firms fall prey to scam	Link
1121064	Two more FIRs filed in fake vaccine scam; Andheri trading unit submits complaint	Link
1121136	Mumbai: Former Kokilaben Hospital employee arrested in fake vaccination case	Link
1121196	Mumbai police arrest key accused Rajesh Pandey in fake vaccination scam	Link
1121280	Mumbai News LIVE Updates: 13 held so far in fake vaccination camp case	Link
1121392	'Fake' vaccines administered in all nine drives across Mumbai: Police	Link
1121431	Coronavirus News LIVE Updates: Maharashtra reports 9,195 cases; FIR registered against 13 people in Mumbai fak	Link
1121717	Mumbai vaccination scam: Ninth FIR registered; 218 from Andheri firm given saline	Link
1121773	Behind Mumbai fake vaccine scam: a medical association clerk, a hospital picked as centre	Link
1121774	Mumbai: BMC issues new guidelines for vaccination in housing societies, workplaces	Link

Table 49: Other Stories(continued)

ID	Title	Link
1121819	Mumbai	Link
1121870	Mumbai: Month after fake vax drive, municipal body yet to decide on re-vaccination	Link
1121871	Beneficiaries must insist on digital cert after dose in Mumbai: BMC	Link
1121877	Mumbai vaccination fraud: Two, including key accused Rajesh Pandey, arrested	Link
1121969	Mumbai fake vaccine case: FIR registered against 13 people with connection to scam	Link
1122200	Draft guidelines prepared to prevent fake vaccination drives: BMC tells HC	Link
1122598	Mumbai: Draft guidelines prepared to prevent fake vaccination drives	Link
1122748	Over 2000 people in Mumbai fell victim to fake COVID-19 vaccination drives: Maha to HC	Link
1122788	BMC cancels licence and seals Shivam Hospital over fake vaccination scam	Link
1122905	Mumbai vax scam: 10th FIR filed; 1,055 of Andheri firm given fake vaccine; 13 booked	Link
1122950	Pune police arrest suspect in connection with fake vaccination drive at Kandivali	Link
1122969	Mumbai: BMC to conduct health check-up for fake COVID-19 vaccination drive victims	Link
1123099	Four held for fake vaccination camps in Mumbai	Link
1123197	Bogus vaccine drives: BMC seals Shivam hospital, license revoked permanently	Link
1123262	Draft guidelines prepared to prevent fake vaccination drives: BMC tells Bombay high court	Link
1123264	BMC releases list of private vaccination centres administering Covishield in Mumbai today	Link
1123303	Mumbai: BMC seals Shivam Hospital in connection with fake vaccination scam	Link
1123337	Mumbai: First year dropout went around giving fake Covid-19 vaccine shots at camps	Link
1123659	Draft guidelines framed to prevent fake vaccination drives: BMC to HC	Link
1123662	Mumbai Fake COVID Vaccination: Police Arrest 6, Register FIR Against 8 As Another Dubious Drive Surfaces	Link
1123663	After Mumbai, case registered against Dr Manish Tripathi for conducting fake vaccination camp in Navi Mumbai's Nerul	Link
1123965	Fake vaccination camp: first case registered in Navi Mumbai	Link
1124023	Web posts offering shots can be bogus	Link

Table 49: Other Stories(continued)

ID	Title	Link
1124024	Mumbai fake vaccination scam: Day after court rejects pre-arrest bail, doctor surrenders before cops	Link
1124042	Mumbai: BMC draws plan for fresh shots for fake drive victims	Link
1124043	Mumbai: Citizen groups cautious in wake of fake vaccine camps	Link
1124176	Kandivli doctor named in 1st fake vaccination FIR filed in Navi Mumbai too	Link
1124220	Fake Vaccines May Have Been Given to Thousands in India, Police Say	Link
1124257	352 employees at Navi Mumbai office received fake vaccines	Link
1124291	Thousands of people in India may have been scammed into getting fake COVID-19 vaccines made of saltwater	Link
1124321	Thousands of people in India may have been scammed into getting fake Covid-19 vaccines made of saltwater	Link
1124609	Maharashtra vaccine scam: Key accused Dr. Manish Tripathi in jab fraud arrested by Mumbai police	Link
1124747	Mumbai jab scam	Link
1124776	Mumbai: No relief for wholesalers who sold fake Covid-19 medicine	Link
1124899	Vaccination scam in Mumbai housing society, residents claim fake vaccines given	Link
1124978	Mumbai: Hospital's lack of funds to buy shots led to fake vax scam	Link
1125161	Mumbai fake vaccination scam: Police lodges 11th FIR; first case filed in Navi Mumbai	Link
1125645	Mumbai fake vaccination scam: 11 FIRs filed so far, first in Navi Mumbai	Link
1126417	Vaccination scam feared in Mumbai apartment complex	Link
1127298	Don't Spare 'Big Fish' in Fake Vaccination Cases: HC to Mumbai Police	Link
1127474	Police form team to probe fake vaccination camps in Mumbai	Link
1127616	Mumbai: Police trace e-sale of fake Covid meds to Bihar, nab 6	Link
1127735	Mumbai Fake Vaccination Scam: People who were given fake jabs will be inoculated once again, said Uddhav...	Link
1127934	Maha Kumbh fake COVID-19 test scam: Action will be taken against private labs found guilty, says Uttarakhan...	Link
1128173	Mumbai Police busts illegal call centre in Bihar selling Remdesivir	Link

Table 49: Other Stories(continued)

ID	Title	Link
1128756	Residents of Mumbai's Hiranandani Estate Society Allege 'Vaccination Scam', 2 Arrested	Link
1128793	[Fake COVID-19 vaccination scams] Conduct meaningful investigation: Bombay High Court to State - Bar & Bench	Link
1129055	Don't spare 'big fish' in fake vaccination cases: Bombay High Court to Mumbai police	Link
1129475	Maharashtra govt to urge Centre to cancel vaccine certificates of fake jab scam victims	Link
1130358	Mumbai: Doctor Tripathi played vital role in fake vaccine drive: Court	Link
1130563	BMC orders inquiry into alleged fake vaccination drive at Mumbai's residential society	Link
1130941	Find and don't spare 'big fish' in fake vaccination scam: HC to Mumbai police	Link
1130985	Mumbai: Three more FIRs in a day in vaccination drive fraud; 514 had got jabs in Borivali	Link
1131824	Kandivali fake vaccine scam: Dr Manish Tripathi played vital role in fake vaccine drive, observes court	Link
1131898	Mumbai Vaccine Scam: Police arrests owner couple of Shivam Hospital	Link
1132108	Fake vaccination scam: Accused Dr Manish Tripathi said some shots were genuine but rest were saline water	Link
1133548	ALERT: Fake Vaccines Given To People In Mumbai's Hiranandani Society	Link
1133570	How vaccination scam unfolded in Mumbai	Link
1133783	Mumbai: 4 arrested, 1 detained in 'fraud' COVID-19 vaccination drive at Kandivali's Hiranandani Heritage	Link
1134424	Mumbai: Don't spare 'big fish' in fake COVID-19 vaccination cases, HC tells Mumbai police	Link
1134914	STF in Mumbai to probe fake drugs case	Link
1134974	Mumbai: Fake vaccine recipient tests +ve, hospitalized	Link
1135303	Mumbai: Recipient of Kandivli's Fake Vaccine Scam Tests Covid Positive	Link
1135723	Mumbai fake vaccination scam: BMC writes to Centre to cancel certificates of fake jab scam victims	Link
1135978	Watch: Fake vaccination drive in Navi Mumbai firm on April 23	Link
1136188	Mumbai: '+ve antibodies result if fake vax victims had got infected before'	Link
1136190	Mumbai: 'Doctor's wife was to get chunk of B'vli fake vax earnings'	Link
1138379	Maharashtra: Fake vaccine certificates not yet cancelled	Link

Table 49: Other Stories(continued)

ID	Title	Link
1138653	”No further adjournments”: Bombay HC warns Govt seeking its reply in fake vaccination scam	Link
1139515	Fake vaccination scam: Still no clarity on what was administered to the victims	Link
1139761	4 arrested in Hiranandani society fake vaccine scam, Tips Films, another production house were duped too: Reports	Link
1139857	Draft Guidelines Prepared Against Fake Vaccination Drives: Mumbai Civic Body Tells Court	Link
1141393	Mumbai: Police may file chargesheet in fake vax scam in two weeks	Link
1141783	Mumbai fake vax scam: Some received vaccination certs on hospital letterheads	Link
1142513	Mumbai vaccination scam: BMC confirms 4 suspects arrested in ’fake vaccine camp’	Link
1142537	Fake vaccination scam at Mumbai college: NESCO centre data entry official held	Link
1142645	Mumbai: First year dropout went around giving fake vaccine shots at camps	Link
1142807	’Fake’ vaccination drive in Mumbai: Two more FIRs lodged at Samta Nagar and Amboli police station	Link
1143859	Mumbai: Fake vaccination scam doctor tests positive for Covid-19	Link
1144626	Fake Vaccination Scam In Mumbai: Main Accused Doctor Tests Positive For COVID-19	Link
1145345	BMC and health officials meet over the fake vaccine in Mumbai	Link
1145787	[Exclusive] Mumbai fake vaccination scam: BMC to vaccinate victims in one week	Link
1146731	Mumbai vaccination camp fraud: Music-film firm approaches cops in Khar	Link
1147304	Mumbai Vaccination Scam: Police Asks BMC to Cancel Shivam Hospital’s License	Link
1150836	390 victims of Kandivli fake vaccination scam to be vaccinated on Saturday	Link
1151553	Mumbai fake vaccine drive: BMC to revaccinate 390 residents of Kandivali society	Link
1151662	Mumbai: 155 people duped at fake inoculation camp finally get Covid-19 vaccine jabs	Link
1151740	Mumbai vax scam: Seven FIRs registered; 6 who posed as doctors booked	Link
1151966	Mumbai fake vaccination scam: Relieved to get real jab, say Kandivli residents	Link
1157584	[Exclusive] Fake vaccination scam: Maharashtra govt still doesn’t have a concrete plan of action for victims	Link

Table 49: Other Stories(continued)

ID	Title	Link
1158442	COVID-19: HC asks Centre to approve BMC's plan to re-vaccinate victims of fake inoculation camps	Link
1158507	COVID-19: Bombay HC asks Centre to approve BMC's plan to re-vaccinate victims of fake inoculation camps	Link
1158508	Coronavirus News LIVE Updates: Bombay HC Asks Centre to Revaccinate Victims of Fake Shots Scam; AP's 10pm-6	Link
1158513	High Court asks Centre to approve BMC's plan to re-vaccinate victims of fake inoculation camps	Link
1158514	Bombay HC asks Centre to approve BMC's plan to re-vaccinate victims of fake inoculation camps	Link
1158558	Approve BMC's plan to re-vaccinate victims of fake inoculation: HC to Centre	Link
1159138	Decide on BMC proposal to enable genuine shots to those duped in fake vaccination camps: HC to Centre	Link
1159336	Fake Covid vax: HC gives Centre 1 week to decide in Mumbai	Link
1161081	COVID-19: Bombay HC Directs Centre To Permit CoWin Re-Registration of Fake Vaccination Scam Victims	Link
1164050	Fake Vaccines May Have Been Given to Thousands in India, Police Say	Link
1165559	Mumbai: BMC to inoculate 390 Kandivali residents who were administered fake COVID-19 vaccines	Link
1167627	Thousands in India injected with fake vaccine; at least 14 arrested in connection with scam	Link
1167846	Madhya Pradesh: Gang selling fake remdesivir injections in Jabalpur busted, 11 alleged accused identified	Link
1169678	'Covid-19 vaccine scam may have resulted in unused doses'	Link
1169809	Covid-19 vaccine scam may have resulted in unused doses: Civic sources	Link
1176701	Mumbai fake vaccination drive: Hospital owners among 11 chargesheeted	Link
1180552	BMC to vaccinate 390 citizens from Kandivali who were adminstered fake vaccines	Link
1183991	Mumbai: Statements of nursing students used as 'guinea pigs' form crux of chargesheet in fake vaccine drive case	Link
1185130	Mumbai: 2 doctors, 9 others chargesheeted in Kandivli society fake vaccine case	Link
1190443	Mumbai: Fake vax scam mastermind may have targeted Malad pharma company too	Link

Table 49: Other Stories(continued)

ID	Title	Link
1197931	Mumbai Fake vaccination drive: Nursing students lured with 150 marks	Link

Notes: Residents of a housing society in Mumbai suspect they were administered fake COVID-19 vaccines as part of an alleged "vaccination scam". The allegation has been made by residents of Hiranandani Estate Society in Kandivali. A COVID-19 vaccination camp was organised in the society on May 30 and around 390 people received their first dose of Covishield vaccine. [...]

20 Coronavirus.- Al menos 800 personas reciben vacunas contra la COVID-19 falsas en Uganda

Publication date	2021-06-30
Create date	2021-08-17
Score	87.85
Report id	1120116
Category	Vaccine
Quality	Substandard or Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Coronavirus.- Al menos 800 personas reciben vacunas contra la COVID-19 falsas en Uganda www.notimerica.com

Click here to see the Original Article

Table 50: Places for report 1120116

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5
Eastern Africa	Uganda	Kampala	0.31628	32.58219

Table 51: Drugs for report 1120116

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Al menos 800 personas recibieron vacunas contra la COVID-19 falsas entre el 15 de mayo y el 17 de junio en la zona metropolitana de Kampala, la capital de Uganda [...] Coronavirus.- Al menos 800 personas reciben vacunas contra la COVID-19 falsas en Uganda

entre los que se incluye un médico –actualmente huido– engañaron a las personas y les inocularon un fármaco falso. Algunos de los receptores han fallecido en el marco de la segunda ola de contagios de COVID-19 en el país africano[...]

21 Covid: Pharmacist held for vaccine fraud in Diamond Harbour

Publication date	2021-07-24
Create date	2021-07-27
Score	72.20
Report id	1151752
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Covid: Pharmacist held for vaccine fraud in Diamond Harbour Telegraph India

Click here to see the Original Article

Table 52: Places for report 1151752

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Sonārpur	22.44259	88.43044
Southern Asia	India	Diamond Harbour	22.19101	88.19047

Table 53: Drugs for report 1151752

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: A man who police said was a pharmacist attached with a primary health centre in Diamond Harbour has been arrested for allegedly procuring vaccines and organising small camps in people's homes in Sonarpur to administer the liquid he claimed was Covishield vaccine. [...] The police said two vials with "Covishield" labels were seized from him. "A sample will be sent for forensic examination to ascertain the composition of the liquid," said a senior officer of the Baruipur police district. [...]

22 Estafan con supuesta vacuna Covid-19

Publication date	2021-07-05
Create date	2021-08-17
Score	71.80
Report id	1126340
Category	Vaccine
Quality	Substandard or Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Estafan con supuesta vacuna Covid-19 El Diario de Chihuahua

Click here to see the Original Article

Table 54: Places for report 1126340

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 55: Drugs for report 1126340

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: En India al menos 2,500 personas fueron estafadas con campañas de vacunación falsas contra Covid-19.

El modus operandi de los estafadores era cobrar a sus victimas por una supuesta vacuna contra el Covid-19, sin embargo, les inyectaban solución salina. [...] Entre los detenidos se encuentran médicos y personal sanitario, quienes han declarado que con la estafa de la supuesta vacuna contra Covid-19 ganaban más de 500 mil pesos.

Además declararon utilizar la fachada de un hospital que producía los certificados, viales y jeringuillas falsas para la aplicación de la vacuna.

23 Venezuela's Thriving Black Market for COVID-19 Vaccines

Publication date	2021-06-30
Create date	2021-07-02
Score	70.75
Report id	1120499
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Venezuela's Thriving Black Market for COVID-19 Vaccines Insightcrime.org

Click here to see the Original Article

Table 56: Places for report 1120499

Region Name	Country	Location	Latitude	Longitude
Americas	Venezuela	Lara	10.16667	-69.83333

Table 57: Drugs for report 1120499

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: In the absence of an adequate COVID-19 vaccination plan, criminal networks in Venezuela have seized upon ongoing mismanagement to steal and resell doses or sell fake vaccines on the black market.

Authorities detained an employee of the health department in western Lara state on June 26 for allegedly filling vials with boiling water, painkillers and antibiotics only to later market them as COVID-19 vaccines. A total of four individuals are accused of scamming nearly 2,000 people, who paid between $50 and $150 per dose, El Pitazo reported. [...]

24 Detienen a presunto médico por aplicar vacunas falsas contra el COVID-19

Publication date	2021-07-25
Create date	2021-08-29
Score	70.03
Report id	1152693
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Detienen a presunto médico por aplicar vacunas falsas contra el COVID-19 Politico.mx

Click here to see the Original Article

Table 58: Places for report 1152693

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Estado de Chiapas	16.5	-92.5

Table 59: Drugs for report 1152693

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 60: Other Stories

ID	Title	Link
1152776	Detienen en Chiapas a sujeto que aplicaba falsas vacunas contra el Covid-19	Link
1152801	Detienen a falso médico que aplicaba suero como vacunas COVID-19 en Chiapas	Link
1153598	México Detienen a supuesto médico que vendía y aplicaba vacunas falsas anticovid en Chiapas	Link
1153862	Detienen a falso médico que aplicaba suero por vacunas Covid	Link
1155205	Detienen a hombre acusado de poner vacunas contra Covid falsas - Canal 44	Link

Table 60: Other Stories(continued)

ID	Title	Link
1155432	Detiene a supuesto médico que aplicaba suero por vacunas Covid-19 en Chiapas	Link
1155528	Alerta Coahuila por venta de medicamento falso anti covid	Link
1166438	Detienen en Chiapas a supuesto médico que aplicaba vacunas falsas antiCOVID	Link
1175918	Detienen a médico que aplicaba vacunas falsas contra COVID	Link
1190453	Médico de Chiapas inyectaba suero y decía que era vacuna COVID. Lo detienen	Link
1191044	Detienen a presunto médico que aplicaba vacunas falsas de COVID-19	Link

Notes: n supuesto médico fue detenido en Chiapas, acusado de haber aplicado vacunas falsas contra el COVID-19 en Tapachula [...] responsable de haber aplicado por lonlenos 300 vacunas falsas [...] el acusado citaba a las personas en un hotel de la ciudad para aplicarles la vacuna [...]

25 'Covid-19 vaccines and scheduled medicines now in the hands of looters'

Publication date 2021-07-15

Create date 2021-07-21

Score 68.44

Report id 1138581

Category Other, Vaccine

Quality Diverted/Unregistered

Source Other

Curation Manually curated

Incident or General Incident

Snippet: 'Covid-19 vaccines and scheduled medicines now in the hands of looters' IOL

Click here to see the Original Article

Table 61: Places for report 1138581

Region Name	Country	Location	Latitude	Longitude
Southern Africa	South Africa	Province of KwaZulu-Natal	-29	30
Southern Africa	South Africa	Gauteng	-26.08333	28.25

Table 62: Drugs for report 1138581

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 63: Other Stories

ID	Title	Link
1138656	#UnrestSA: Vaccines stolen and over 90 pharmacies destroyed as violence continues	Link
1142125	Public urged not to use COVID-19 vaccines looted from pharmacies	Link
1145715	Civil unrest: Warning against using, selling stolen medication	Link

Notes: The South African Pharmacy Council has slammed looting sprees that have targeted pharmacies, amongst other establishments, in KwaZulu-Natal and Gauteng, warning residents against buying medicine which could be stolen. [...] "Among the looted items are Covid-19 vaccines and scheduled medicines, which when used without proper pharmacist counselling on storage and dosage may result in harm to one's health," he said. [...]

26 Indignante: Médicos y enfermeras aplican falsas vacunas contra COVID-19 a cientos en Uganda - Radio Fórmula

Publication date	2021-07-22
Create date	2021-08-29
Score	65.15
Report id	1149348
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Indignante: Médicos y enfermeras aplican falsas vacunas contra COVID-19 a cientos en Uganda - Radio Fórmula Radio Fórmula

Click here to see the Original Article

Table 64: Places for report 1149348

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 65: Drugs for report 1149348

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Detalló que los estafadores cobraban un equivalente de entre 25 y 120 dólares por cada una de las ”vacunas” que, por fortuna, no contenían ningún producto peligroso y ”solo había agua en algunas de ellas” [...] En Nuevo León, 80 recibieron vacuna contra COVID falsa; cada una costó mil dólares:

27 2 million doses of J&J vaccine in South Africa possibly contaminated | Citypress

Publication date	2021-06-12
Create date	2021-06-17
Score	64.55
Report id	1097627
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: 2 million doses of J&J vaccine in South Africa possibly contaminated | Citypress News24

Click here to see the Original Article

Table 66: Places for report 1097627

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Baltimore	39.29038	-76.61219
Southern Africa	South Africa	Republic of South Africa	-29	24

Table 67: Drugs for report 1097627

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 68: Other Stories

ID	Title	Link
1089333	Africa's vaccine dumping challenge – about 1.5 million Covid-19 vaccine doses destroyed	Link
1097670	S. Africa pulls millions of doses of J&J vaccine due to contamination	Link
1097771	South Africa pulls two million doses of J&J vaccine	Link
1097860	Kubayi-Ngubane assures South Africans that contaminated COVID-19 vaccines will not be released	Link

Table 68: Other Stories(continued)

ID	Title	Link
1097866	South Africa pulls two million doses of Johnson & Johnson vaccine	Link
1097868	South Africa Pulls 2 Million Johnson & Johnson Covid Vaccine Doses	Link
1097872	Third wave surge: J&J vaccines mixed with contaminated substances won't be released, rules SAHPRA	Link
1097899	South Africa to Dispose of 2 Million Contaminated J&J Vaccines	Link
1097935	South African health inspectors will not release unsuitable J&J vaccines	Link
1098137	Cyril Ramaphosa says output of vaccines to be ramped up after loss of millions to contamination	Link
1098260	South Africa pulls 2 million doses of JJ vaccine after contamination concerns	Link
1098433	J&J vaccine contamination will cost us time and some lives - Prof Mosa Moshabela	Link
1098468	S.Africa pulls two million doses of J&J vaccine	Link
1098512	'Contaminated is not something you want to hear after vaccination' - SA reacts to J&J vaccine concerns	Link
1098614	'Destroying contaminated vaccines should give the public greater confidence'	Link
1098782	Contaminated J&J vaccines will not be released: Sahpra	Link
1098853	Aspen outlays plans post disposal of contaminated J&J vaccines	Link
1099053	Flash Briefing: SA destroys 2m 'contaminated' J&J Covid vaccines; Musk takes on Wierzycka after BizNews interview	Link
1099091	Western Cape to slow down vaccine rollout after contaminated J&J doses ditched	Link
1099229	Yet another vaccine setback hits South Africa	Link
1099910	J&J will deliver 2 million new jabs to SA within 2 weeks, says Aspen	Link
1100622	S. Africa inoculates 2 million J & J vaccines	Link
1101315	OPINION | Government should explain plans in wake of J&J setback	Link
1108640	South Africa pulls millions of doses of J&J vaccine	Link
1109699	South Africa: 2million doses of J&J vaccine reportedly contaminated	Link
1124813	COVID-19 vaccine | FDA orders J&J jabs be discarded - report	Link

Notes: Two million doses of the Johnson & Johnson (J&J) vaccine awaiting distribution from the Aspen Pharma plant in Gqeberha, Eastern Cape, will not be used due to suspicions that

a core component of the vaccine was contaminated in a US factory. Acting Health Minister Mmamoloko Kubayi-Ngubane confirmed yesterday that the vaccines would not be used. She was speaking during the first leg of her national tour at Chris Hani Baragwanath Academic Hospital in Soweto, Johannesburg. [...]

28 Médico del Área de la Bahía tras las rejas por vender vacunas y tarjetas de vacunación falsas

Publication date	2021-07-15
Create date	2021-08-28
Score	64.05
Report id	1139241
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Médico del Área de la Bahía tras las rejas por vender vacunas y tarjetas de vacunación falsas Telemundo Area de la Bahia

Click here to see the Original Article

Table 69: Places for report 1139241

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Napa	38.29714	-122.28553

Table 70: Drugs for report 1139241

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Una médico homeópata del Área de la Bahía es arrestada y enfrenta cargos federales por vender vacunas falsas de covid-19 y tarjetas de vacunación [...] residente de Napa fue acusada por fraude electrónico y declaraciones falsas relacionadas con asuntos de atención médica.[...]vendió información médica falsa y provocó escepticismo en un momento critico en el que funcionarios de salud le pedían a la población vacunarse contra el covid-19[...]vendió bolitas de inmunización afirmando que proporcionarían inmunidad de por vida contra el covid-19. Según ella, estas bolitas contenían pequeñas cantidades del virus y crearían una respuesta de anticuerpos, dijeron los fiscales.

29 Will inquire matter myself: Punjab Health Minister on allegations of vaccine diversion to private hospitals

Publication date	2021-06-04
Create date	2021-06-08
Score	63.34
Report id	1086967
Category	Vaccine
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Will inquire matter myself: Punjab Health Minister on allegations of vaccine diversion to private hospitals India Today

Click here to see the Original Article

Table 71: Places for report 1086967

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Punjab	30.91667	75.41667

Table 72: Drugs for report 1086967

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 73: Other Stories

ID	Title	Link
1087070	'Will order an inquiry': Punjab health minister on charges of vaccine diversion to private hospitals	Link
1087499	'Artificial shortage': SAD alleges vaccine scam in Punjab, alleges diversion to private hospitals at hefty margins	Link
1089281	AAP gheraoes Health Minister Balbir Sidhu's residence to protest against vaccine scam	Link
1089359	AAP gheraoes Punjab Health Minister's residence	Link

Table 73: Other Stories(continued)

ID	Title	Link
1089425	AAP holds protest against Punjab govt, accuses it of 'diverting' Covid vaccines to private hospitals	Link
1090809	Punjab: SAD holds sit-in near Health Minister Sidhu's residence, demands his removal from cabinet	Link

Notes: [...] Punjab's opposition party SAD on Thursday accused the state's Congress government of "diverting" Covid vaccines to private hospitals at "hefty margins". Shiromani Akali Dal chief Sukhbir Singh Badal, in a statement here, alleged that vaccine doses were not available in the state, but they were being sold to private institutions instead of being given free of cost to the common man. He claimed that a Covaxin dose costing Rs 400 to the state was being sold to private institutions at Rs 1,060. He said the private hospitals are further charging people Rs 1,560 for each dose.

Badal alleged that in Mohali alone, 35,000 doses were sold to private institutions to "earn a profit" of nearly Rs two crore in a single day. [...]

30 Así venderían ilegalmente vacunas de COVID-19 en Medellín

Publication date	2021-07-07
Create date	2021-08-28
Score	63.25
Report id	1128468
Category	Vaccine
Quality	Substandard or Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Así venderían ilegalmente vacunas de COVID-19 en Medellín Caracol Radio

Click here to see the Original Article

Table 74: Places for report 1128468

Region Name	Country	Location	Latitude	Longitude
Americas	Colombia	Medellín	6.25184	-75.56359

Table 75: Drugs for report 1128468

Medicine Name	Medicine Class	Action	ATC Code
silver	Silver compounds	antiseptics and disinfectants	D08AL30
			J07

Notes: vacuna Jansen

31 DCI probes facilities illegally giving Covid jabs at a fee

Publication date	2021-06-03
Create date	2021-06-07
Score	63.19
Report id	1086161
Category	Vaccine
Quality	Diverted/Unregistered
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: DCI probes facilities illegally giving Covid jabs at a fee The Star, Kenya

Click here to see the Original Article

Table 76: Places for report 1086161

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Kenya	Republic of Kenya	1	38

Table 77: Drugs for report 1086161

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: The Directorate of Criminal Investigations has moved in to investigate some facilities claimed to be illegally offering Covid-19 vaccines across the country.

This is after reports emerged that some facilities are now cashing in on Kenyans desperate for the vaccine to charge them for the dose, with some even advertising and claiming they offer Covid certificates for travel once vaccinated. [...]

32 Man held, former army officer booked on charges of 'illegal' Covid vaccination in Karachi

Publication date	2021-07-26
Create date	2021-08-02
Score	62.66
Report id	1153392
Category	Vaccine
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Man held, former army officer booked on charges of 'illegal' Covid vaccination in Karachi DAWN.com

Click here to see the Original Article

Table 78: Places for report 1153392

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Karachi	24.8608	67.0104

Table 79: Drugs for report 1153392

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 80: Other Stories

ID	Title	Link
1160442	Court seeks charge sheet in Pfizer vaccine theft case	Link
1160641	Court seeks charge sheet against suspects selling 'stolen Pfizer vaccine	Link

Notes: [...] According to the first information report (FIR), reviewed by Dawn.com, the complainant, provincial drug inspector for South district Ghulam Ali, said he had received information from "reliable sources" that certain persons had stolen Covid-19 vaccines from a vaccination

centre established by the Sindh government and were allegedly administering the jabs to residents at their homes in return for a payment. [...] The complainant said he, along with Covid-19 focal person Dr Sohail Raza Sher, Dr Dilawar Jiskani and a police party, reached the agreed spot where the suspect Mohammed Ali was taken into custody. The suspect possessed a box of syringes and also had two empty vaccination cards with inscription of Government of Sindh and the health department. The box also contained three used vials and 14 specimen collection swabs. [...]

33 Escroquerie aux faux vaccins en Inde: 2500 personnes vaccinées avec de l'eau saline

Publication date	2021-06-25
Create date	2021-06-30
Score	62.12
Report id	1114048
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Escroquerie aux faux vaccins en Inde: 2500 personnes vaccinées avec de l'eau saline RMC

Click here to see the Original Article

Table 81: Places for report 1114048

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
Southern Asia	India	Kolkata	22.56263	88.36304
Southern Asia	India	Mumbai	19.07283	72.88261

Table 82: Drugs for report 1114048

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 83: Other Stories

ID	Title	Link
1114054	Covid-19 - Des escrocs ont administré de faux vaccins en Inde	Link
1114148	C'est une dose d'eau distillée ? Mumbai et Kolkata frappés par de faux rackets de vaccins contre Covid ; plusieurs arrêtés – Marseille News	Link

Table 83: Other Stories(continued)

ID	Title	Link
1115126	Faux vaccin contre le Covid : ces 5 précautions de base peuvent vous sauver des fraudeurs de faux vaccins – Marseille News	Link
1115523	Coronavirus: plus de 2.000 personnes ont reçu un faux vaccin à Bombay	Link
1116535	Inde: plus de 2.000 personnes ont reçu un faux vaccin à Bombay	Link
1121360	Trinamool allègue que le gouverneur est lié à une arnaque au faux vaccin de Kolkata et remet en question son silence – Marseille News	Link
1124602	Un hôpital indien fermé à cause d'une arnaque au FAKE COVID VACCINE, car on craint que plus de 2 500 personnes n'aient reçu une solution saline et des antibiotiques à la place	Link
1127301	Inde: des milliers de personnes victimes d'une arnaque au faux vaccin	Link
1127926	Covid-19 : des milliers d'Indiens vaccinés avec un faux vaccin	Link
1128123	Faux vaccins en Inde : des milliers de personnes victimes de cette arnaque	Link
1128331	Inde : Plus de 2.000 personnes victimes d'une arnaque au faux vaccin contre le Covid-19	Link
1129669	En Inde, des milliers de personnes victimes d'un faux vaccin contre le Covid-19	Link
1130808	Des milliers de personnes vaccinées avec de l'eau salée par des médecins escrocs	Link
1134171	2 500 personnes victimes d'une arnaque au faux vaccin contre la Covid-19	Link

Notes: Au moins 2.500 personnes ont été victimes d'escroqueries aux faux vaccins contre le Covid-19 dans deux grandes villes indiennes, Bombay et Calcutta, a annoncé vendredi la police qui a procédé à plusieurs arrestations. Selon la police de Bombay, une dose de solution saline a été administrée à environ 2.000 personnes qui croyaient recevoir une injection de vaccin contre le coronavirus. Dix personnes ont été arrêtées, dont deux médecins d'un hôpital privé de Bombay, capitale financière de l'Inde, a expliqué la police vendredi lors d'une conférence de presse. [...]

34 Alertan por hallazgo de vacunas falsas contra Covid-19 en Ciudad Juárez

Publication date	2021-07-13
Create date	2021-08-28
Score	61.78
Report id	1157058
Category	Vaccine
Quality	Falsified
Source	Public and private outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Alertan por hallazgo de vacunas falsas contra Covid-19 en Ciudad Juárez Periódico Excélsior

Click here to see the Original Article

Table 84: Places for report 1157058

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Ciudad Juárez	31.73333	-106.48333

Table 85: Drugs for report 1157058

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 86: Other Stories

ID	Title	Link
1141073	Polémicas de Johnson & Johnson: Desde la vacuna COVID-19 que causa reacciones, hasta bloqueadores y talcos con cancerígenos	Link
1146461	Detectaron posible aplicación falsa de vacunas contra COVID-19 en Ciudad Juárez	Link
1164752	Cofepris emite alerta por venta de falsa vacuna contra COVID-19 en Chetumal	Link

Notes: la dependencia ubicó jeringas usadas y frascos vacíos que presumiblemente contenían el biológico, los cuales fueron asegurados en el lugar, y el local donde se aplicaban no reunía las condiciones para hacerlo, como la cadena de frío, almacenamiento, manejo, distribución y aplicación de la vacuna [...] evitar ser víctima de estafa, cualquier supuesta vacuna contra COVID-19 que esté a la venta a través de páginas de internet, redes sociales, vía telefónica, farmacias, hospitales y puntos de venta, constituye un fraude y un riesgo a la salud por ser de dudosa procedencia [...]

35 La députée de TMC Mimi Chakraborty se fait piquer dans un faux camp de vaccination contre le COVID-19 ; un homme se faisant passer pour un officier de l'IAS arrêté après le FIR – Marseille News

Publication date	2021-06-24
Create date	2021-06-28
Score	61.42
Report id	1112216
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: La députée de TMC Mimi Chakraborty se fait piquer dans un faux camp de vaccination contre le COVID-19 ; un homme se faisant passer pour un officier de l'IAS arrêté après le FIR – Marseille News Marseille News .net

Click here to see the Original Article

Table 87: Places for report 1112216

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kolkata	22.56263	88.36304

Table 88: Drugs for report 1112216

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: [...] La députée du Congrès de Trinamool, Mimi Chakraborty, a révélé un faux racket de vaccination contre le Covid-19 dirigé par un imitateur à Kolkata. Chakraborty a affirmé qu'elle avait été approchée par un homme qui s'était présenté comme un agent de l'IAS et l'avait informée que la Kolkata Municipal Corporation organisait une campagne spéciale pour les transgenres et les personnes handicapées. Le député de TMC a été invité à l'événement en tant qu'invité d'honneur. [...] La possibilité effrayante de faux vaccins donnés à des centaines de personnes a conduit à une enquête plus vaste de la police de Kolkata. L'affaire concernant la fausse campagne de vaccination contre le COVID a maintenant été transférée au département

des détectives de la police de Kolkata. [...]

36 Afrique du Sud: doutes sur deux millions de vaccins Johnson & Jo

Publication date	2021-06-12
Create date	2021-06-18
Score	60.81
Report id	1097186
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Afrique du Sud: doutes sur deux millions de vaccins Johnson & Jo M6info by MSN

Click here to see the Original Article

Table 89: Places for report 1097186

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	United States	Baltimore	39.29038	-76.61219
Southern Africa	South Africa	Republic of South Africa	-29	24

Table 90: Drugs for report 1097186

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 91: Other Stories

ID	Title	Link
1098019	L'Afrique du Sud retire deux millions de vaccins Johnson & Johnson pour un problème de "non-conformité"	Link
1098117	Coronavirus en direct - L'Afrique du Sud retire 2 millions de doses Johnson & Johnson	Link
1098575	L'Afrique retire 2 millions de vaccins Johnson & Johnson	Link

Table 91: Other Stories(continued)

ID	Title	Link
1107280	Afrique du Sud: doutes sur deux millions de vaccins Johnson & Johnson	Link
1119010	Afrique du Sud | Deux millions de vaccins Johnson & Johnson seraient contaminés	Link
1130918	Covid-19: la campagne de vaccination sud-africaine retardée après la contamination de 2 millions de doses du vaccin J&J	Link

Notes: L'Afrique du Sud doit mettre de côté 2 millions de doses du vaccin Johnson&Johnson. Plusieurs millions de doses de ce vaccin ont été contaminées par les composants d'autres vaccins dans une usine de Baltimore aux États-Unis. Au moins 60 millions de doses doivent être jetées, selon les autorités américaines. [...]

37 Police arrest man for administering fake Covid vaccine for 1,000 pesos

Publication date	2021-07-26
Create date	2021-08-02
Score	59.08
Report id	1153776
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Police arrest man for administering fake Covid vaccine for 1,000 pesos Mexico News Daily

Click here to see the Original Article

Table 92: Places for report 1153776

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Tapachula	14.90385	-92.25749

Table 93: Drugs for report 1153776

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 94: Other Stories

ID	Title	Link
1155073	Saline solution vaccines in Chiapas – The Yucatan Times	Link

Notes: A man posing as a doctor was arrested in Tapachula, Chiapas, on Saturday for selling fake shots of Covid-19 vaccines for 1,000 to 1,500 pesos.
Gerardo "N," 40, was found in a hotel — where he allegedly administered the vaccines — wearing a doctor's uniform with state Health Ministry logos and in possession of a plastic bag

with empty syringe cases, two empty bottles of sodium chloride, fake vaccination certificates and a list of people who had received the shots. [...]

38 Media report alleging vaccine wastage in Rajasthan 'false': State govt to Centre

Publication date	2021-06-01
Create date	2021-06-08
Score	59.00
Report id	1089276
Category	Vaccine
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Media report alleging vaccine wastage in Rajasthan 'false': State govt to Centre Hindustan Times

Click here to see the Original Article

Table 95: Places for report 1089276

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Rājasthān	26.58333	73.83333

Table 96: Drugs for report 1089276

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 97: Other Stories

ID	Title	Link
1103353	Media report alleging vaccine wastage in Raj false: State govt tells Centre	Link
1115871	Media report alleging vaccine wastage in Rajasthan 'false': State govt tells Centre	Link

Notes: [...] In the letter to Sharma on Monday, Union Health Minister Harsh Vardhan said a media report has highlighted that more than 500 vials of Covid-19 vaccines were found dumped

in the waste bins at 35 vaccination centres in the state, which is ”not acceptable” and must be investigated. [...]

39 Falsas vacunas eran comercializadas en redes sociales y vendidas a USD 25

Publication date	2021-06-15
Create date	2021-08-16
Score	57.32
Report id	1107242
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Falsas vacunas eran comercializadas en redes sociales y vendidas a USD 25 Teleamazonas

Click here to see the Original Article

Table 98: Places for report 1107242

Region Name	Country	Location	Latitude	Longitude
Americas	Ecuador	Portoviejo	-1.05458	-80.45445
Americas	Ecuador	Manta	-0.96212	-80.71271

Table 99: Drugs for report 1107242

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: vacunas adulteradas contra el covid-19, que contenían solución salina o agua de mar. [...]Según las primeras investigaciones, unas 400 personas habrían sido estafadas, entre ellas personal de algunas empresas de Portoviejo y Manta.

40 800 en Ouganda ont reçu de faux jabs COVID: Fonctionnaires

Publication date	2021-06-30
Create date	2021-07-08
Score	56.81
Report id	1120402
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: 800 en Ouganda ont reçu de faux jabs COVID: Fonctionnaires laminute.info

Click here to see the Original Article

Table 100: Places for report 1120402

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 101: Drugs for report 1120402

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 102: Other Stories

ID	Title	Link
1121259	Ouganda-Arrestation des infirmières pour usage de faux vaccins Covid-19	Link
1147918	Covid-19 : des centaines d'Ougandais ont reçu des injections de faux vaccins	Link
1147989	Ouganda : des centaines de personnes ont reçu de faux vaccins contre le Covid	Link
1148143	Fausse vaccination: au moins 800 personnes ont reçu de l'EAU après avoir acheté un vaccin Covid à des escrocs en Ouganda	Link

Table 102: Other Stories(continued)

ID	Title	Link
1148787	Covid: des centaines d'Ougandais ont reçu des injections de faux vaccins	Link
1148795	Coronavirus - BILAN MONDIAL: des médecins injectent des faux vaccins en Ouganda, le variant Delta toujours prédominant	Link
1149421	Covid-19: en Ouganda, des centaines de personnes victimes d'une escroquerie au faux vaccin	Link
1149596	Covid-19: des centaines d'Ougandais ont reçu des injections de faux vaccins	Link
1150101	Covid- 19 : des centaines d'Ougandais ont reçu des injections de faux vaccins	Link
1150392	Covid-19 : de faux vaccins administrés à des centaines d'Ougandais	Link
1150598	Coronavirus : des centaines d'Ougandais ont reçu des injections de faux vaccins	Link
1155098	Ouganda : plusieurs centaines de personnes ont reçu des doses de vaccins contrefaits	Link
1185420	Ouganda : De faux vaccins ont été injectés à des centaines de personnes	Link

Notes: Au moins 800 personnes en Ouganda ont reçu des vaccins contrefaits contre le COVID-19, ont révélé mercredi des responsables. La police, des responsables du ministère de la Santé et l'Unité de surveillance de la santé de la State House ont arrêté deux infirmières pour avoir injecté de faux vaccins à des personnes et délivré de faux certificats. Le médecin qui dirigeait l'opération est cependant en fuite. [...]

41 Detectan algunos lotes de Janssen contaminados en una sustancia activa

Publication date	2021-06-11
Create date	2021-07-22
Score	52.76
Report id	1095875
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Detectan algunos lotes de Janssen contaminados en una sustancia activa Diari Més

Click here to see the Original Article

Table 103: Places for report 1095875

Region Name	Country	Location	Latitude	Longitude
		Europe	48.69096	9.14062

Table 104: Drugs for report 1095875

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 105: Other Stories

ID	Title	Link
1096196	Rechazados en la UE lotes de vacunas de Janssen por posible contaminación	Link
1096441	EU solicita a Johnson & Johnson desechar 60 millones de vacunas contra COVID-19	Link
1096532	Contaminadas millones de vacunas Janssen por una sustancia activa	Link
1096579	Unión Europea rechaza lotes de vacunas de Johnson & Johnson por posible contaminación	Link
1097152	Rechazan millones de vacunas de Janssen en la UE por estar contaminadas con una sustancia activa	Link

Table 105: Other Stories(continued)

ID	Title	Link
1099528	La Unión Europea rechaza varios lotes de vacunas de Janssen por posible contaminación	Link
1106799	La UE rechaza lotes de Janssen por posible contaminación	Link
1133680	Rechazados en la UE lotes de vacunas de Janssen por posible contaminación	Link

Notes: La Agencia Europea de Medicamento (EMA, por sus siglas en inglés) recomienda evitar suministrar por precaución algunos lotes de la vacuna de Janssen contra la covid-19 después de que se haya detectado que un lote de la sustancia activa estaba contaminado por el material de otra vacuna fabricada en el mismo lugar.

El regulador europeo dice en un comunicado ser consciente de este hecho, pero apunta que ninguno de los lotes que han llegado a la Unión Europea tiene esta sustancia activa contaminada. Con todo, recomienda no suministrar los lotes de vacunas que se han hecho con una sustancia activa más o menos al mismo tiempo en que se estaba produciendo la contaminada.

42 Scandale à l'Hôpital de Batroun, un employé accusé d'avoir falsifié les vaccins Pfizer

Publication date	2021-07-13
Create date	2021-07-21
Score	47.29
Report id	1135850
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Scandale à l'Hôpital de Batroun, un employé accusé d'avoir falsifié les vaccins Pfizer Libnanews

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Table 106: Places for report 1135850

Region Name	Country	Location	Latitude	Longitude
Western Asia	Lebanon	Lebanon	33.83333	35.83333

Table 107: Drugs for report 1135850

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: La chaine de télévision MTV Lebanon indique qu'un employé de l'hôpital gouvernemental de Batroun aurait été renvoyé pour avoir donné de fausses doses de vaccins Pfizer. Pour l'heure, on ignore si son frère et sa mère, également employés au sein de l'établissement hospitalier seraient impliqués dans le même dossier.

Si l'information se révèle être exacte, il s'agira de déterminer le nombre de personnes ayant reçu un faux vaccins et procéder à une nouvelle campagne à leur bénéfice.

43 Vaccin Spoutnik V: l'OMS trouve des problèmes sur un site, le Kremlin dit que c'est réglé

Publication date	2021-06-23
Create date	2021-06-28
Score	40.93
Report id	1111772
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Vaccin Spoutnik V: l'OMS trouve des problèmes sur un site, le Kremlin dit que c'est réglé Sciences et Avenir

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Table 108: Places for report 1111772

Region Name	Country	Location	Latitude	Longitude
Western Asia	Russian Federation	Ufa	54.74306	55.96779

Table 109: Drugs for report 1111772

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 110: Other Stories

ID	Title	Link
1112841	Vaccin Spoutnik V : L'OMS trouve des problèmes sur un site, la Russie dit que c'est réglé	Link

Notes: Le Kremlin a assuré mercredi que des problèmes découverts sur un des sites de production du vaccin anti-Covid russe Spoutnik V par des inspecteurs de l'OMS ont depuis été résolus.
Le service de pré-qualification de l'Organisation mondiale de la santé a publié une note mercredi

qui fait la liste d'un certain nombre de problèmes découverts lors d'une inspection entre le 31 mai et le 4 juin sur un site de production de Pharmstandard - Ufa Vitamin dans la ville d'Oufa, au sud-ouest de la Russie. [...] Les inspecteurs avaient notamment constaté des problèmes dans les données de surveillance du processus de fabrication et de contrôle qualité. [...]

44 Website accepting cryptocurrency for selling fake coronavirus vaccines and certificates in Italy

Publication date	2021-07-03
Create date	2021-07-07
Score	36.11
Report id	1123690
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Website accepting cryptocurrency for selling fake coronavirus vaccines and certificates in Italy BOB fm

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Table 111: Places for report 1123690

Region Name	Country	Location	Latitude	Longitude
Europe	Italy	Repubblica Italiana	42.83333	12.83333
		Earth	0	0

Table 112: Drugs for report 1123690

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 113: Other Stories

ID	Title	Link
1124002	Italian police bust fake coronavirus passport network	Link
1125216	Italian police crack black market for corona-papers	Link
1125287	Italian police bust fake Covid certificate schemes using AI	Link
1126179	Italy Fights Crypto Trade in Fake Covid Passports	Link
1130188	Fake COVID vaccine certificates sold on dark web for 150	Link

Table 113: Other Stories(continued)

ID	Title	Link
1130449	VIDEO : Fake COVID vaccine certificates sold on dark web for 150	Link
1134508	Italy tackles crypto criminals selling fake Covid-19 passports	Link
1137094	Italy breaks up fake EU Covid vaccine pass schemes	Link

Notes: Italian police have broken up a network that was selling fake European vaccination certificates and vaccine vials online, where purchases and sales can be completed in cryptocurrency, Efe reported today. [...] The financial affairs and anti-fraud and cybercrime officers of the Public Prosecutor's Office of Milan (North) identified and blocked ten accounts and channels on "Telegram", referring users to anonymous "dark web" accounts, where they can be obtained. Fake testimonials and vaccines, local media reporting. [...] "Despite the exorbitant prices and extremely exorbitant health risks," the police notes, thousands of people registered on illegal channels in search of vaccines and certificates, attracted by the opportunity to purchase "all-in-one" packages, priced at between 110 and 130 euros, with the guarantee of anonymity , and track and trace the shipment. [...]

45 El mayor problema de Pfizer no es la vacuna sino la viagra falsificada

Publication date	2021-07-09
Create date	2021-08-28
Score	35.36
Report id	1131564
Category	Other
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: El mayor problema de Pfizer no es la vacuna sino la viagra falsificada El Confidencial

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Table 114: Places for report 1131564

Region Name	Country	Location	Latitude	Longitude
Europe	Spain	Kingdom of Spain	40	-4
		Earth	0	0

Table 115: Drugs for report 1131564

Medicine Name	Medicine Class	Action	ATC Code
sildenafil	Drugs used in erectile dysfunction	urologicals	G04BE03
			V

Table 116: Other Stories

ID	Title	Link
1170625	El mayor problema de Pfizer no es la vacuna sino la viagra falsificada	Link

Notes: Alrededor de 9 millones de productos farmacéuticos incautados, 277 personas detenidas

y 113.020 webs cerradas. Estas son las cifras de la Operación Pangea XIV, la última macro intervención mundial contra el tráfico de medicamentos y productos médicos falsificados coordinada en mayo por la Interpol, en colaboración con las autoridades policiales de 92 países, entre ellos España. Hurgando entre todo el material decomisado es fácil encontrar pastillas contra la disfunción eréctil o supuestos medicamentos contra el cáncer, un clásico en este tipo de intervenciones, aunque este año, con motivo de la pandemia, también se ha confiscado una gran cantidad de test falsos para detectar el covid y mascarillas de dudosa efectividad. [...] Además, decomisaron 313 tipos de anabolizantes, 13 productos adelgazantes y solo cinco tipos de otras sustancias, de acuerdo con los datos de la Memoria 2020 elaborada por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). [...] Más de 100 millones de dosis de Johnson & Johnson y al menos 70 millones de dosis de AstraZeneca quedaron en suspenso después de que Emergent descubriera en marzo que sus trabajadores habían contaminado un lote de vacuna de Johnson & Johnson con un ingrediente clave utilizado para producir la de AstraZeneca. Luego, los funcionarios federales ordenaron a la planta que detuviera la producción, despojaron a Emergent de su responsabilidad de producir la vacuna de AstraZeneca e instruyeron a Johnson & Johnson para que hiciera valer el control directo sobre la fabricación de su vacuna allí.

46 挨針卻無法抗病毒！無良醫「裝自來水」冒充新冠疫苗…800多人受害氣瘋

Publication date	2021-07-03
Create date	2021-07-19
Score	35.03
Report id	1123483
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 挨針卻無法抗病毒！無良醫「裝自來水」冒充新冠疫苗…800多人受害氣瘋 中天快點TV

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Table 117: Places for report 1123483

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 118: Other Stories

ID	Title	Link
1148587	非洲国家乌干达曝出假疫苗丑闻事件，800名接受疫苗注射者事后得知... - 2021-07-21	Link
1169587	800人接种假疫苗? - 2021-08-08	Link

Notes: 新冠疫情肆虐各地，當今唯有施打疫苗可讓百姓有抗體對抗病毒。怎料，在烏干達竟有無良醫護將自來水注入玻璃瓶中，冒充新冠疫苗，替民眾注射水疫苗，且有一間非法的製造工廠隱匿於鄉間，協助當地醫護人員製造、包裝假的疫苗瓶罐。消息曝光後，也讓百姓相當不滿和傻眼。

47 Mexico detects fake remdesivir at hospital, for sale on web Mexico detects fake remdesivir at hospital

Publication date	2021-07-20
Create date	2021-09-01
Score	32.18
Report id	1164000
Category	Antiviral others
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Mexico detects fake remdesivir at hospital, for sale on web Mexico detects fake remdesivir at hospital New York Post

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Table 119: Places for report 1164000

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Tampico	22.28519	-97.87777
Americas	Mexico	Mexico	23	-102

Table 120: Other Stories

ID	Title	Link
1145994	Mexico detects fake remdesivir at hospital, for sale on web	Link
1146001	Mexico detects fake remdesivir at hospital, for sale on web :: WRAL.com	Link
1146500	Mexico detects fake remdesivir at hospital, for sale on the web	Link

Notes: MEXICO CITY — Authorities in Mexico say they have found fake doses of the COVID-19 drug remdesivir offered for sale on the internet and at a private hospital near the US border. The federal medical safety commission said late Monday that the fake antiviral drug, which it called "a health risk," was found at a hospital in the Gulf coast city of Tampico, in the border state of Tamaulipas.

The commission said the doses had been purchased in an ”irregular manner” on the internet, but did not say whether the medication had been used there.

The drug’s manufacturer, Gilead Sciences, confirmed the falsification. The appearance and lot numbers on the packaging did not match the original.

In February, police in northern Mexico arrested six people in the border state of Nuevo León for allegedly trafficking in fake coronavirus vaccines, but did not say what kind of fake shots were involved. The suspects allegedly offered the vaccines for sale for the equivalent of around $2,000 per dose.

Analysts have long worried that criminal gangs in Mexico could seek to steal, hijack or counterfeit much-desired vaccines or medications during the pandemic. There have been hijackings or thefts of medicines and oxygen in Mexico.

Mexico is currently experiencing a third wave of coronavirus in which case numbers have now exceeded the first wave of 2020. The country has suffered about 236,000 test-confirmed deaths, but because so little testing is done, the real toll is closer to 360,000.

48 孟买数百居民怀疑自己接种假新冠疫苗,警方介入调查 - 2021-06-16

Publication date	2021-06-16
Create date	2021-06-30
Score	21.54
Report id	1101511
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 【环球网报道】据"今日印度"16日报道，印度孟买一住宅区的约390名居民表示他们中了一场精心策划的" 疫苗 骗局"，称自己被接种了假的新冠 疫苗 。目前，孟买警方已经介入调查。据报道，这些居民于5月30日接种了印度的"新冠盾牌" 疫苗 。

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Table 121: Places for report 1101511

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
Southern Asia	India	Mumbai	19.07283	72.88261

Table 122: Other Stories

ID	Title	Link
1101512	警方成立专案组,打掉生产销售假药犯罪团伙 - 2021-06-15	Link
1101567	孟买数百居民怀疑自己接种假新冠疫苗，警方介入调查	Link
1102076	孟买数百居民怀疑自己接种假新冠疫苗,警方介入调查 - 2021-06-15	Link
1102314	孟买数百居民怀疑自己接种假新冠疫苗警方介入调查	Link
1102943	印度孟买疫苗骗局:2 人因居民怀疑"假"注射而被拘留 - 2021-06-16	Link
1104152	花高价打个寂寞?孟买数百居民称遭遇假新冠疫苗,注射后毫无反应 - 2021-06-17	Link
1104201	花高价打个寂寞？孟买数百居民称遭遇假新冠疫苗，注射后毫无反应	Link

Table 122: Other Stories(continued)

ID	Title	Link
1104310	印度被曝10万份新冠检测造假,还有人接种了假疫苗! - 2021-06-16	Link
1106104	印度被曝10万份新冠检测造假,还有人接种了假疫苗! - 2021-06-17	Link
1106426	印媒:印度390名居民疑被接种"假疫苗" - 2021-06-19	Link
1106535	印度上百人打了假疫苗?|印度|疫苗_新浪新闻 - 2021-06-19	Link
1108434	"我们接种了假疫苗!"数百居民联合声讨,警方紧急介入调查 - 2021-06-21	Link
1108737	印媒:印度390名居民疑被接种"假疫苗" - 2021-06-21	Link
1109195	"我们接种了假疫苗!"数百居民联合声讨,警方紧急介入调查 - 2021-06-20	Link
1111735	"我们接种了假疫苗!"孟买数百居民声讨,警方紧急介入调查 - 2021-06-20	Link
1113359	印度孟买超2000人接种假疫苗法官和网友都怒了! - 2021-06-25	Link
1113875	印度孟买超2000人接种假疫苗,法官和印度人都怒了。 - 2021-06-25	Link
1114323	印度孟买超2000人接种假疫苗,法官和网友都怒了! - 2021-06-24	Link
1116837	印度孟买超2000人接种假疫苗,法官和印度人都怒了。 - 2021-06-27	Link
1117692	印度孟买超2000人接种假疫苗法官和网友都怒了! - 2021-06-24	Link
1126562	印度：生理盐水冒充疫苗警方已逮捕14人	Link
1127615	孟买医院用生理盐水冒充新冠疫苗,假疫苗事件冲撞印度"防疫盾牌" - 2021-07-06	Link
1127670	震惊!印度孟买现假疫苗事件　超2000人接种"盐水疫苗" - 2021-07-06	Link
1127726	震惊!假疫苗事件泛滥,印度超2600人接种"盐水疫苗" - 2021-07-04	Link
1129118	孟买医院用生理盐水冒充新冠疫苗,假疫苗事件冲撞印度"防疫盾牌" - 2021-07-07	Link
1131020	假疫苗谋财害命!孟买医院用生理盐水代替印度产阿斯利康疫苗 - 2021-07-09	Link
1131021	再曝"丑闻"!大批民众接种了假疫苗,印度警方展开紧急调查 - 2021-07-09	Link
1132952	假疫苗谋财害命!孟买医院用生理盐水代替印度产阿斯利康疫苗 - 2021-07-08	Link
1133023	震惊!印度孟买现假疫苗事件　超2000人接种"盐水疫苗" - 2021-07-07	Link
1135421	印度孟买现假疫苗事件,超2000人接种"盐水疫苗" - 2021-07-07	Link

Table 122: Other Stories(continued)

ID	Title	Link
1136501	孟买数千人打到假疫苗印度警捕14人	Link
1142013	不肖人士賺黑心財　孟買爆上千人打到食鹽水假疫苗｜TVBS新聞網	Link
1154266	印度抢接种孟买爆上千人打到食盐水假疫苗	Link
1165479	印度搶接種 孟買爆上千人打到食鹽水假疫苗	Link

Notes: 据"今日印度"16日报道，印度孟买一住宅区的约390名居民表示他们中了一场精心策划的"疫苗骗局"，称自己被接种了假的新冠疫苗。目前，孟买警方已经介入调查。

49 印度出现多个假新冠疫苗接种点 数百人被打不明物质 - 2021-06-24

Publication date	2021-06-24
Create date	2021-07-14
Score	19.45
Report id	1112555
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 海外网6月24日电据印度媒体报道，印度城市加尔各答的警方近期破获了一起假新冠 疫苗 接种点的案件，数百名民众在这些"接种点"被打了不明物质，包括一名印度议会议员。《印度时报》《印度教徒报》24日消息称，印度议会议员、知名演员米米...

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Table 123: Places for report 1112555

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kolkata	22.56263	88.36304
Southern Asia	India	Republic of India	22	79

Table 124: Other Stories

ID	Title	Link
1112610	印度出现多个假新冠疫苗接种点数百人被打不明物质	Link
1113042	印度出现多个假新冠疫苗接种点　数百人被打不明物质 - 2021-06-23	Link
1113173	印度出现多个假新冠疫苗接种点数百人上当受骗-中新网	Link
1113183	印度出现多个假新冠疫苗接种点　数百人上当受骗 - 2021-06-24	Link
1113245	印度出现假新冠疫苗接种点一议员被注射不明物质|欧盟|印第安|加拿大	Link
1113251	印度出现多个假新冠疫苗接种点,数百人被注射"不明物质" - 2021-06-24	Link
1113252	印度现假疫苗接种点　数百人被打不明物质 - 2021-06-24	Link

Table 124: Other Stories(continued)

ID	Title	Link
1113671	印度出现多个假新冠疫苗接种点？可以说真的很印度.....__中国医疗	Link
1113686	印度出现多个假新冠疫苗接种点数百人被打入不明物质原因待查明	Link
1113839	知名演员接种假疫苗？！|疫苗|新冠肺炎_新浪科技_新浪网	Link
1113876	印度超2000人注射假疫苗,法官要求做抗体测试,网友呼吁公开绞刑 - 2021-06-25	Link
1113877	印度出现多个新冠疫苗假接种点　数百人被注射不明物质 - 2021-06-25	Link
1114038	印度出现多个假新冠疫苗接种点　数百人上当受骗 - 2021-06-25	Link
1114136	知名演员接种假疫苗?! - 2021-06-25	Link
1114217	印度接种假疫苗事件频发:孟买2000多人、加尔各答500多人 - 2021-06-25	Link
1114304	两大城2500人接种假疫苗印度警方调查	Link
1114305	印度出现多个假新冠疫苗接种点数百人被打不明物质 国际新闻| 新西兰中文先驱网	Link
1114309	印度两千多人接种假新冠疫苗	Link
1114320	2名醫生也涉案！印度兩大城約2500人接種到「假疫苗」	聯合新聞網：最懂你的新聞網站	Link
1114399	印度超2000人注射假疫苗,法官要求做抗体测试,网友呼吁... - 2021-06-24	Link
1114400	印度出现多个假新冠疫苗接种点,数百人被注射"不明... - 2021-06-24	Link
1114633	印度兩城現假疫苗案醫師注射生理鹽水與抗生素	Link
1114936	印度两大城发生2000多人接种假疫苗事件	Link
1115001	印度假疫苗泛滥,数千人不幸中招,民众声讨莫迪:丢尽印度脸 - 2021-06-25	Link
1115002	印度两大城2500人接种假疫苗,嫌犯包括2名医生 - 2021-06-25	Link
1115054	印度出现多个假新冠疫苗接种点,数百人被注射"不明... - 2021-06-25	Link
1115152	印度两千多人接种到假新冠疫苗	Link
1115154	印度再曝"疫苗骗局"　孟买超2000人接种假疫苗- 2021-06-25	Link
1115194	印度约2500人上当:被接种假新冠疫苗- 2021-06-26	Link
1115220	印度两千多人接种假新冠疫苗警方逮捕多名涉案嫌疑人-中新网视频	Link
1115224	印度2000多人被接种假新冠疫苗警方逮捕多名涉案嫌疑人	Link
1115227	印度约2500人接种假新冠疫苗- 2021-06-25	Link
1115249	扯！新冠疫苗變尿道炎抗生素　印度2千多人遭施打假疫苗	Link

Table 124: Other Stories(continued)

ID	Title	Link
1115251	印度2000多人接种假疫苗,民众愤怒声讨莫迪:我们已沦为国际笑料 - 2021-06-26	Link
1115252	知名女演员接种假疫苗?!还有更可怕的... - 2021-06-26	Link
1115281	2500人打到假疫苗！亂打生理食鹽水詐財　印度2醫師涉案	Link
1115284	扯！新冠疫苗變尿道炎抗生素　印度2千多人遭施打假疫苗	TVBS新聞網	Link
1115288	2名医生也涉案!印度两大城约2500人接种到"假疫苗" - 2021-06-25	Link
1115315	印度2城2500人遭打假疫苗逮捕11人包括2医生	Link
1115319	印度2000多人接种假新冠疫苗！_国际_新闻	Link
1115418	印度超2000人注射假疫苗,法官要求做抗体测试,网友呼吁... - 2021-06-25	Link
1115544	2500人打到假疫苗！亂打生理食鹽水詐財　印度2醫師涉案	TVBS新聞網	Link
1115599	印度2000多人接种假新冠疫苗!	Link
1115668	印度2000多人接种假疫苗,民众愤怒声讨莫迪:我们已沦为国际笑料 - 2021-06-25	Link
1115919	印度接种假疫苗事件频发：孟买2000多人、加尔各答500多人_疫情	Link
1115930	印度假疫苗,2千多人中招,包括美女议员演员 - 2021-06-26	Link
1115951	女星打到假疫苗报警揭发数百人人受骗-　无忧资讯手机版	Link
1115955	印度女演员被打假疫苗报警后警方逮捕嫌疑人 - 2021-06-26	Link
1115956	[北京您早]记者连线:印度多地出现假疫苗骗局 - 2021-06-26	Link
1116008	密切关注!"德尔塔+"首现死亡病例!还有2500人打了假疫苗… - 2021-06-26	Link
1116038	連疫苗都有假的200人上當　印度女星誤接種盜版身體冒2異狀	Link
1116233	知名演员接种假疫苗?! - 2021-06-26	Link
1116292	新冠疫苗	印度女星受騙誤打假疫苗一個原因揭穿騙局逾200人中招- 晴報- 健康- 生活健康	Link
1116345	32歲女星接種假疫苗！幾天後驚傳病倒　已超過200人遭殃	Link
1116347	32歲女星接種假疫苗！幾天後驚傳病倒已超過200人遭殃-社會新聞	Link
1116435	假疫苗横行印度,知名女星接种后出现不适症状 - 2021-06-27	Link
1116619	32岁女星被打假疫苗,接种后出现不适症状住院,嫌犯已被逮捕 - 2021-06-26	Link

Table 124: Other Stories(continued)

ID	Title	Link
1116733	防不胜防!躲过"毒疫苗"还有假疫苗,印度超2500人接种不明物质 - 2021-06-27	Link
1116768	印度出现假新冠疫苗接种点,两千多人被打不明物质,民众... - 2021-06-27	Link
1116795	印度出现假新冠疫苗接种点,两千多人被打不明物质,民众愤怒质问 - 2021-06-27	Link
1116981	被注射假冠病疫苗印度女演员报警 - 2021-06-27	Link
1117045	印度女演员被打假疫苗报警后警方逮捕嫌疑人 - 2021-06-27	Link
1117409	变异病毒出现后,大量印度人被接种假疫苗- 2021-06-28	Link
1117625	印度知名女星打到假疫苗- 2021-06-28	Link
1117825	印度2500人打到假疫苗,2名医师涉案 - 2021-06-27	Link
1117919	印度阿三打"假疫苗"?民众施打治疗尿道炎的抗生素 - 2021-06-28	Link
1118005	数千人被注射不明物质,印度假疫苗点燃怒火,民众:脸面丢尽 - 2021-06-28	Link
1118056	视频丨印度出现假新冠疫苗接种点,数百人被打不明物质 - 2021-06-28	Link
1118247	印度女星獲邀打疫苗竟是「不明液體」！機靈找疑點報警，踢爆上千人受騙	Link
1118299	防不胜防!躲过"毒疫苗"还有假疫苗,印度超2500人接种不明物质 - 2021-06-26	Link
1118468	密切关注!"德尔塔+"首现死亡病例!还有2500人打了假疫苗… - 2021-06-28	Link
1118740	【医伴旅】印度出现多个假新冠疫苗接种点?可以说真的很印度…… - 2021-06-29	Link
1119072	印度被爆大规模假疫苗泛滥,印度美女女星议员也中招！ - 2021-06-29	Link
1119073	印度接种假疫苗事件频发:孟买2000多人、加尔各答500多人 - 2021-06-24	Link
1119474	印度又闹出大乌龙,"冒牌疫苗"在孟买炸锅,2000多人已接种 - 2021-06-29	Link
1119524	印度2000多人被打假疫苗!疫苗瓶里装的是生理盐水 - 2021-06-30	Link
1119525	印度2500多人接种假新冠疫苗警方已逮捕多名涉案嫌疑人	Link
1120611	印度出现假疫苗接种点 数百人被打不明物质	Link
1121176	女星为假疫苗助阵?大批印度人涌入接种点,接种的却是不明液体 - 2021-07-01	Link
1121767	印度2000多人接种假新冠疫苗！|加尔各答|新冠疫苗|孟买	Link

Table 124: Other Stories(continued)

ID	Title	Link
1121965	数千人被注射不明物质,印度假疫苗点燃怒火,民众:脸面... - 2021-06-28	Link
1122185	数千人被注射不明物质,印度假疫苗点燃怒火,民众:脸面丢尽 - 2021-06-29	Link
1122329	印度2000多人被接种假新冠疫苗警方逮捕多名涉案嫌疑人- IT 与健康	Link
1122336	"假疫苗"突然炸锅!2000多人已接种,我方明确表态 - 2021-07-01	Link
1122485	乱套了!印度假官员光明正大售卖假疫苗,还请到知名明星前来助阵 - 2021-07-02	Link
1122538	外媒:印度新冠疫苗接种速度缓慢,疫苗制假售假集团滋生 - 2021-07-02	Link
1122591	外媒：印度新冠疫苗接种速度缓慢，疫苗制假售假集团滋生|新冠疫苗|印度|德国之声	Link
1122723	印度新冠疫苗接种速度缓慢，疫苗制假售假集团滋生_国际_新闻	Link
1122770	外媒：印度新冠疫苗接种速度缓慢疫苗制假售假集团滋生	Link
1122774	"什么钱都敢挣"!印度乌干达新冠疫苗造假,生理盐水成救命水? - 2021-07-01	Link
1123221	外媒:印度新冠疫苗接种速度缓慢,疫苗制假售假集团滋生 - 2021-07-01	Link
1123452	外媒：印度疫苗制假售假集团滋生，有人伪装公务员给2000人接种| 国际新闻| 新西兰中文先驱网	Link
1123797	"假疫苗"突然炸锅!2000多人已接种,我方明确表态 - 2021-07-02	Link
1124041	印度约2500人上当:被接种假新冠疫苗- 2021-06-25	Link
1124136	比中美施打的都快?印度政府被当头一棒,2000民众被注射假疫苗- 2021-07-03	Link
1124242	印度出现多个假新冠疫苗接种点数百人上当受骗_新闻中心	Link
1124726	印度爆2500人接种假疫苗女星国会议员中招|光华网	Link
1125018	印度一医院涉嫌假疫苗案被查封:2000多人被注射生理盐水 - 2021-07-04	Link
1125019	印度一医院涉嫌假疫苗案被查封,2000多人被注射生理... - 2021-07-04	Link
1125072	震惊!假疫苗事件泛滥 印度超2600人接种"盐水疫苗" - 2021-07-05	Link
1125073	印度乱套了!假官员光明正大售卖假疫苗,还请到知名明星前来助阵 - 2021-07-04	Link
1125132	印度搶接種 孟買爆上千人打到食鹽水假疫苗	Link
1125143	印度新增近4萬宗確診 孟買懷疑數千人被注射假疫苗	Link
1125149	印度新增近4万宗确诊孟买怀疑数千人被注射假疫苗-RTHK	Link

Table 124: Other Stories(continued)

ID	Title	Link
1125150	印度新增近4萬宗確診孟買懷疑數千人被注射假疫苗- RTHK	Link
1125188	厂商拿生理食盐水冒充印度数千人打到假疫苗	Link
1125189	接種後沒收到證明…印度女星報警打到假疫苗	Link
1125210	印度抢接种　孟买爆上千人打到食盐水假疫苗- 2021-07-05	Link
1125265	印度一医院涉嫌假疫苗案被查封：2000多人被注射生理盐水	Link
1125282	女星打到假疫苗已200人上当|光华网	Link
1125285	印度又一地出现假疫苗,数千人受影响!政府此前要求扩大疫苗接种 - 2021-07-05	Link
1125347	果然是仿制药大国!印度出现大量假疫苗接种点,连议员都... - 2021-07-04	Link
1125488	【新冠肺炎】孟买数千人打到假疫苗印度警捕14人|国际	Link
1125493	大发国难财?2500人接种假疫苗后,印度一医院被吊销执照 - 2021-07-05	Link
1125495	震惊!假疫苗事件泛滥　印度超2600人接种"盐水疫苗" - 上游新闻... - 2021-07-04	Link
1125554	大发国难财？2500人接种假疫苗后，印度一医院被吊销执照	Link
1125693	印度搶接種孟買爆上千人打到食鹽水假疫苗| 聯合新聞網：最懂你的新聞網站	Link
1125721	震惊!假疫苗事件泛滥　印度超2600人接种"盐水疫苗"|... - 2021-07-04	Link
1125857	印度发生三件事,接种假疫苗超过2600人,现在还有人发国难财 - 2021-07-05	Link
1126320	印度发生三件事,接种假疫苗超过2600人,现在还有人发国... - 2021-07-04	Link
1126575	印度假官员,光明正大售卖假疫苗,居然还请知名明星来助阵。 - 2021-07-06	Link
1126616	印度奸商让数以千计民众注射假疫苗!疫苗瓶里装的竟然是... - 2021-07-06	Link
1126645	推廣疫苗接種 女星竟被注射「不明液體」：全身燥熱難耐	Link
1126724	2600人注射假疫苗!印度疫情诱发疫苗危机,医护人员铤而走险造假 - 2021-07-06	Link
1126859	假新冠检测后，部分印度人又打了假疫苗	Link
1126875	假新冠检测后,部分印度人又打了假疫苗- 2021-07-06	Link
1126932	印度疫苗被曝惊天造假:生理盐水灌注空瓶,从证书到注射器全是假的 - 2021-07-06	Link
1127248	2600人注射假疫苗!印度疫情诱发疫苗危机,医护人员铤而走险造假 - 2021-07-05	Link

Table 124: Other Stories(continued)

ID	Title	Link
1127359	印度发现至少12起假疫苗接种案件 - 2021-07-06	Link
1127403	印度发现至少12起假疫苗接种案件-中新网	Link
1127664	印度逾2千人疑被注射假疫苗 警拘14人包括醫護 - 國際 - 即時新聞 - 頭條日報 Headline Daily	Link
1127824	震惊!假疫苗事件泛滥 印度超2600人接种"盐水疫苗" - 2021-07-04	Link
1127963	印度疫苗被曝惊天造假:生理盐水灌注空瓶,从证书到注射器全做假 - 2021-07-06	Link
1128003	印度：生理盐水冒充疫苗警方已逮捕14人_国际_新闻频道	Link
1128356	印度现假的疫苗接种站,打盐水当疫苗,2600人受骗 - 2021-07-07	Link
1128423	"接种后没任何副作用!"印度民众刚炫耀,美媒:接种的是假疫苗- 2021-07-07	Link
1128585	印度2000多人接种假新冠疫苗！__中国医疗	Link
1128687	印度:盐水充数！ 数千人被骗接种假疫苗- 2021-07-07	Link
1128834	假疫苗屡禁不绝,学者怒斥这是草菅人命发国难财,印度防疫面临全... - 2021-07-07	Link
1129042	印度现假的疫苗接种站,打盐水当疫苗,2600人受骗 - 2021-07-06	Link
1129119	印度发现至少12起假疫苗接种案件 - 2021-07-07	Link
1129120	假新冠检测后,部分印度人又打了假疫苗- 2021-07-07	Link
1129122	印度假官员,光明正大售卖假疫苗,居然还请知名明星来助阵。 - 2021-07-07	Link
1129278	印度曝出假疫苗接种案 - 2021-07-08	Link
1129365	印度逾2千人疑被注射假疫苗警拘14人包括醫護	Link
1130164	推廣疫苗接種 女星竟被注射不明液體	Link
1130551	印度出现假疫苗里面是生理盐水 - 2021-07-07	Link
1130612	用生理盐水冒充!假疫苗事件冲撞印度"防疫盾牌" - 2021-07-06	Link
1131181	一波未平一波又起!印度假疫苗当道,大量民众被接种不明物质 - 2021-07-09	Link
1131240	印度新增近4萬宗確診孟買懷疑數千人被注射假疫苗	Link
1131300	印度搶接種孟買爆上千人打到食鹽水假疫苗	Link
1131478	假疫苗屡禁不绝,学者怒斥这是草菅人命发国难财,印度防疫面临全... - 2021-07-08	Link
1131537	一波未平一波又起!印度假疫苗当道,大量民众被接种不明物质 - 2021-07-08	Link
1132066	印媒爆料假疫苗乱象,超2600人打了"盐水疫苗" - 2021-07-10	Link

Table 124: Other Stories(continued)

ID	Title	Link
1132095	印度出现多个假新冠疫苗接种点数百人被打不明物质- 原创	Link
1132289	印度出现多个假新冠疫苗接种点数百人上当受骗	Link
1133603	印度数千人打"盐水假疫苗"医生涉案赚黑心钱 - 2021-07-11	Link
1134001	以为打了疫苗,其实没打!印度曝光"疫苗骗局",令人心惊 - 2021-07-11	Link
1134855	印度发现至少12起假疫苗接种案件_新闻中心_中国网	Link
1136431	印度数千人打"盐水假疫苗"医生涉案赚黑心钱 - 2021-07-12	Link
1137369	震惊!假疫苗事件泛滥 印度超2600人接种"盐水疫苗" - 2021-07-14	Link
1138554	印度一医院注射假疫苗被查封,2000多人被注射生理盐水 - 2021-07-15	Link
1142477	印媒爆料假疫苗乱象,超2600人打了"盐水疫苗" - 2021-07-09	Link
1145052	印度出现假疫苗诈骗事件,上千人接种"盐水"疫苗 - 2021-07-19	Link
1145127	在印度,有超过千人接种了"盐水"疫苗的假疫苗- 2021-07-19	Link
1147102	印度出现假疫苗诈骗事件,上千人接种"盐水"疫苗 - 2021-07-20	Link
1156059	印度2000多人被打假疫苗!疫苗瓶里装的是生理盐水 - 2021-07-27	Link
1161128	印度医院赚黑心钱!上千人注射假疫苗,网友:沾着人血的钱拿得安心吗? - 2021-07-08	Link
1166453	"盐水疫苗"冲撞印度"防疫盾牌" - 2021-07-12	Link

Notes: 据印度媒体报道，印度城市加尔各答的警方近期破获了一起假新冠疫苗接种点的案件，数百名民众在这些"接种点"被打了不明物质，包括一名印度议会议员。

Annexe D

D.2. Outils de diagnostic COVID-19

Medicine Quality Monitoring Globe

September 16, 2021

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Filters applied for this report

Search ("Thermometer" OR (("coronavirus kit" OR "RDT" OR "covid test" OR "lateral flow assay" OR "test kit" OR "LFA" OR "COVID kit" OR "Medical device for screening/diagnosis/monitoring" OR "rapid diagnostic test" OR "coronavirus test" OR "antigen test" OR "COVID-19 test" OR "test cassette" OR "In-vitro-diagnostic" OR "cassette test" OR "RT-PCR" OR "IVD" OR "testing kit" OR "qPCR" OR "antibody test" OR "COVID-19 kit" OR "PCR" OR "polymerase chain reaction" OR "ELISA") AND ("COVID-19" OR "COVID" OR "SARS-CoV-2" OR "Coronavirus" OR "CV19" OR "CV-19" OR "SARS" OR "CoV-2")))

Start date	2021-06-01
End date	2021-07-31
Language	en
Report type	incident
Curation status	validated

Number of Reports	13

1 FDA recalls unauthorized at-home coronavirus rapid test over false results concerns

Publication date	2021-06-02
Create date	2021-06-07
Score	89.42
Report id	1084734
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: FDA recalls unauthorized at-home coronavirus rapid test over false results concerns FOX 5 NY

Click here to see the Original Article

Table 1: Places for report 1084734

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 2: Other Stories

ID	Title	Link
1086258	Lepu recalls 8M COVID-19 tests due to risk for false results	Link
1172682	Lepu Medical Technology -Beijing- Co., Ltd. - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - Beijing Shi - 2021-07-29	Link

Notes: The Food and Drug Administration (FDA) has warned consumers to stop using an unauthorized COVID-19 at-home rapid test and antibody test over concerns that the kits may produce false results.

The kits, produced by Lepu Medical Technology, were distributed to pharmacies to be sold to consumers for at-home testing and made available through direct sales despite not having FDA authorization. [...]

2 USH Diagnostics, Inc./covidinstanttest.net - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - Missouri - 2021-07-09

Publication date	2021-07-09
Create date	2021-09-08
Score	84.61
Report id	1207459
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER USH Diagnostics, Inc./covidinstanttest.net MARCS-CMS 612084 — July 09, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Mr. Chris Ormiston USH Diagnostics, Inc./covidinstanttest.net 3456 E. 155th St. Kansas City , MO 64147 United States co@ushealthdiagnostics.com cormiston@ushealthdiagnostics.com support@covidinstanttest.net Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 9, 2021 TO: covidinstanttest.net 205 E. Osborn Rd. Phoenix, AZ 85012 support@ushealthdiagnostics.com support@americanmedicalsuppliers.com RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at the Internet addresses https://covidinstanttest.net and https://ushealthdiagnostics.com/ on March 30, 2021, and April 9, 2021. We also reviewed your social media websites at https://facebook.com/covid19instanttest, https://twitter.com/covidathometest, and https://www.instagram.com/covid19instanttest, where you direct consumers to your website, https://covidinstanttest.net, to purchase your products. The FDA has observed that your websites https://covidinstanttest.net and https://ushealthdiagnostics.com/ offer for sale a ”Rapid Dual Antibody Test” (which your website also refers to as the ”COVID-19 Instant Test,” ”Dual Antibody Rapid Test,” ”COVID-19 Dual Antibody Test,” ”Rapid 15 Minute Antibody,” ”Dual IgG/IgM Screening Test for COVID-19,” ”15-Minute COVID-19 Screening Test,” ”COVID-19 IgM/IgG Rapid Test Device,” ”COVID-19 Antibody Test Kit,” and ”Dual Antibody Test”) (hereafter referred to as the ”COVID-19 Antibody Test Kit”), a ”Rapid 10 Minute Antigen Test” (which your website also refers to as the ”Antigen Rapid Test,” ”COVID-19 Antigen Test Kit,” ”Access Bio COVID-19 Antigen Test,” and ”COVID-19 Instant Antigen Test”) (hereafter referred to as the ”COVID-19 Rapid Antigen Test”), and a ”Saliva Test Kit” (all hereafter referred to as ”COVID-19 Test Kits”) in the United States. Based on our review, the COVID-19 Test Kits are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, they are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the ”Act”), 21 U.S.C. § 321(h). The COVID-19 Test Kits are offered for sale in the United States to consumers for at-home testing without marketing approval,

clearance, or authorization from FDA. 2,3 Accordingly, your products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). Your products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 4 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. 5 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sell products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. We also note that different and potentially serious public health risks are presented with specimen collection and testing in the home versus using a test in a healthcare setting. Risks may include, but are not limited to, whether a lay person has the ability to collect their specimen, run the test, and interpret the test result accurately. Your websites, https://covidinstanttest.net and https://ushealthdiagnostics.com/, as well as social media websites, indicate that your firm's COVID-19 Test Kits may be purchased by consumers and are intended to be used for at-home testing for COVID-19, including: • "THE MOST RAPID COVID-19 TESTS ON THE INTERNET. PERIOD… The Fastest Home Tests on the Market Receive Your Test Next Day, Results Available in Minutes!" [https://covidinstanttest.net/] • "COVID-19 INSTANT ANTIGEN TEST This diagnostic test is used to get into sporting events, board flights, and meeting other mandatory testing requirements FDA EUA AUTHORIZED LOWER NASAL COVID 10 MIN RAPID TEST Coronavirus (COVID-19) Rapid Test with Telehealth Consultation. The test is administered over a video appointment from the comfort of your home with results in 10 minutes. [https://covidinstanttest.net/antigen] • "COVID-19 At Home Instant Test #COVID19…How does our Coronavirus (COVID-19) Rapid At Home Test work? Learn more: covidinstanttest.net #CoronaVirus #COVID #COVID19 #SARSCoV2 #COVIDInstantTest #COVIDRapidTest #COVIDAtHome #RapidTesting #InstantTest" [Pinned Tweet from November 24, 2020, at https://twitter.com/covidathometest] • "COVID-19 At Home Instant Test Our #COVID19 Rapid Tests have received an Emergency Use Authorization from the FDA. covidinstanttest.net" [https://www.instagram.com/covid19instanttest/] • "Saliva Test Kit FDA Submitted/EUA Approved Results in 24-48 hours Approved for In-Home Use! o 100% Accuracy with zero false negatives o ZERO false positives with 100% Overall Accuracy o Determines if the patient is currently infected." [https://ushealthdiagnostics.com] • "15-Minute COVID-19 Screening Test Self contained test can be administered at home or business under the supervision of a Telehealth professional with results in 15 minutes" [https://covidinstanttest.net/dual-antibody-test/] Your

products are also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), because your websites represent that the COVID-19 Test Kits are "FDA Submitted/EUA Approved," "FDA EUA Authorized," or "EUA/FDA Certified." These representations create a false impression that your products have been approved or authorized for emergency use by FDA and are misleading. As discussed above, your COVID-19 Test Kits have not been approved or authorized for emergency use by FDA. In addition, your website, https://ushealthdiagnostics.com, displays the FDA logo positioned near images of and information about the COVID-19 Antibody Test Kit and Saliva Test Kit. The FDA logo is for the official use of the FDA and not for use on private sector materials. 6 Such use may send a misleading message that the FDA favors or endorses your products. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices. In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 7 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

2 The "COVID-19 Antibody Test Kit" offered for sale on your website appears to be the RightSign COVID-19 IgG/IgM Rapid Test Cassette manufactured by Hangzhou Biotest Biotech Co., Ltd. On December 21, 2020, FDA reissued an Emergency Use Authorization (EUA) pursuant to section 564 of the Act, 21 U.S.C. § 360bbb-3, to permit emergency use of Hangzhou Biotest Biotech Co., Ltd.'s RightSign COVID-19 IgG/IgM Rapid Test Cassette. The test is indicated for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium heparin, potassium EDTA, and sodium citrate), serum, and plasma (sodium heparin, potassium EDTA, and sodium citrate), and, by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high, moderate, or waived complexity tests, for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in fingerstick whole blood specimens. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.The test is intended for use as an aid in identifying individuals with an adaptive immune response toSARS-CoV-2, indicating recent or prior infection. However, this EUA does not authorize the sale of the Hangzhou Biotest Biotech Co., Ltd., RightSign COVID-19 IgG/IgM Rapid Test Cassette to consumers for at-home testing. 3 The "COVID-19 Rapid Antigen Test" offered for sale on your website appears to be the CareStart COVID-19 Antigen test manufactured by Access Bio, Inc. On April 12, 2021, FDA reissued an EUA pursuant to section 564 of the Act, 21 U.S.C. § 360bbb-3, to permit emergency use of Access Bio, Inc.'s CareStart COVID-19 Antigen test. The test is indicated for for use by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high, moderate, or waived complexity tests and in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. However, this EUA does not authorize the sale of the Access Bio, Inc. CareStart COVID-19 Antigen test to consumers for at-home testing. 4 Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020 and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 5 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 6 FDA Logo Policy (available at: https://www.fda.gov/about-fda/website-policies/fda-logo-policy). 7 Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 3: Places for report 1207459

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Kansas City	39.09973	-94.57857

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at the Internet addresses https://covidinstanttest.net and https://ushealthdiagnostics.com/ on March 30, 2021, and April 9, 2021. We also reviewed your social media websites at https://facebook.com/covid19instanttest, https://twitter.com/covidathometest, and https://www.instagram.com/covid19instanttest, where you direct consumers to your website, https://covidinstanttest.net, to purchase your products. The FDA has observed that your websites https://covidinstanttest.net and https://ushealthdiagnostics.com/ offer for sale a "Rapid Dual Antibody Test" (which your website also refers to as the "COVID-19 Instant Test," "Dual Antibody Rapid Test," "COVID-19 Dual Antibody Test," "Rapid 15 Minute Antibody," "Dual IgG/IgM Screening Test for COVID-19," "15-Minute COVID-19 Screening Test," "COVID-19 IgM/IgG Rapid Test Device," "COVID-19 Antibody Test Kit," and "Dual Antibody Test") (hereafter referred to as the "COVID-19 Antibody Test Kit"), a "Rapid 10 Minute Antigen Test" (which your website also refers to as the "Antigen Rapid Test," "COVID-19 Antigen Test Kit," "Access Bio COVID-19 Antigen Test," and "COVID-19 Instant Antigen Test") (hereafter referred to as the "COVID-19 Rapid Antigen Test"), and a "Saliva Test Kit" (all hereafter referred to as "COVID-19 Test Kits") in the United States. [...] The COVID-19 Test Kits are offered for sale in the United States to consumers for at-home testing without marketing approval, clearance, or authorization from FDA. [...]

3 COVID-19: NAFDAC cautions importers, distributors others against Peruvian test kits

Publication date	2021-06-29
Create date	2021-07-02
Score	72.01
Report id	1119145
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19: NAFDAC cautions importers, distributors others against Peruvian test kits The Nation Newspaper

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Table 4: Places for report 1119145

Region Name	Country	Location	Latitude	Longitude
Americas	Peru	Republic of Peru	-10	-75.25
Western Africa	Nigeria	Federal Republic of Nigeria	10	8

Notes: The National Agency for Food and Drug Administration and Control (NAFDAC) has cautioned importers, distributors, healthcare professionals against the importation, distribution and sale of COVID-19 test kits from Peru.

The Director-General of the agency, Prof. Mojisola Adeyeye, gave the caution in a statement in Abuja on Tuesday.

Adeyeye said that the product was considered to be defective by the pharmacovigilance analysis of the agency.

The director-general stressed that the test kits did not meet the required IgG specificity and IgM sensitivity standards.

She said that the Peruvian Directorate of Medicines, Supplies and Drugs (DIGIMED), had ordered the recall of the defective COVID-19 Polymerase Chain Reaction (PCR) test kit. [...]

4 Quidel Recalls Lyra SARS-CoV-2 Assay (M120) Due to Risk of False Negative Results - 2021-07-07

Publication date	2021-07-07
Create date	2021-07-09
Score	67.89
Report id	1128626
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Quidel is recalling the Lyra SARS-CoV-2 Assay (M120) due to a significant risk of false negative results for patients with high virus amounts

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Table 5: Places for report 1128626

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: [...] Quidel is recalling the Lyra SARS-CoV-2 Assay (M120) due to a significant risk of false negative results for patients with relatively high amounts of SARS-CoV-2 virus potentially causing the PCR amplification to occur before a cycle-threshold (Ct) value 5 when using the following thermocyclers:

ThermoFisher QuantStudio 7 Pro, Applied Biosystems 7500 Fast Dx, Applied Biosystems 7500, Bio-Rad CFX96 Touch, Roche LightCycler 480, or Qiagen RotorGene MDx. [...]

5 Vivera Pharmaceuticals, Inc. - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-07-26

Publication date	2021-07-26
Create date	2021-08-19
Score	59.37
Report id	1172680
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Vivera Pharmaceuticals, Inc. MARCS-CMS 614412 — July 26, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Paul Edalat Recipient Title Chief Executive Officer Vivera Pharmaceuticals, Inc. 26021 Pala Drive - St A Mission Viejo , CA 92691 United States regulatory@viverapharma.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 26, 2021 RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) has reviewed your websites at the Internet addresses https://viveracovid19.com/covx-rda/ and https://viverapharmaceuticals.com/products/ on January 13, 2021, on March 3, 2021, and on April 1, 2021, and observed that your websites offered a "COVxRDA Saliva Antigen Test" and a "COVx-RDA Nasal Antigen Test" (herafter collectively referred to as "COVxRDA Antigen Test Kits") for sale in the United States. Based on our review, the COVxRDA Antigen Test Kits are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). The COVxRDA Antigen Test Kits were offered for sale in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxRDA Antigen Test Kits are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxRDA Antigen Test Kits are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There

is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sold products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate corrective action to prevent the sale of any unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 4 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to prevent future violations. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to prevent future violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to prevent future violations may result in legal action, including, without limitation, seizure, and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products . Once you have taken actions to prevent the sale of unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health

CC: sales@blackbirdgroupllc.org Blackbirdgroupllc 3121 Standard Street Bakersfield, California 93308 _____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaringnational-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 6: Places for report 1172680

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Mission Viejo	33.60002	-117.672

Notes: [...] The COVxRDA Antigen Test Kits were offered for sale in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxRDA Antigen Test Kits are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxRDA Antigen Test Kits are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. [...]

6 Innova Medical Group, Inc. - Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-06-10

Publication date	2021-06-10
Create date	2021-06-15
Score	54.69
Report id	1094616
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Innova Medical Group, Inc. MARCS-CMS 614819 — June 10, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA Electronic Mail Product: Medical Devices Recipient: Recipient Name Daniel J. Elliot Recipient Title Chief Executive Officer Innova Medical Group, Inc. 800 E. Colorado Blvd., Suite 288 Pasadena , CA 91101 United States Daniel.elliott@innovamedgroup.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER CMS # 614819 June 10, 2021 Dear Mr. Elliot: The United States Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations, Innova Medical Group, Inc., located at 800 E. Colorado Blvd., Suite 288, Pasadena, CA from March 15 through April 9, 2021. In addition, your other manufacturing facilities at 495 N. Berry Street, Brea, CA, and MPS Medical, Inc. at 785 Challenger Street, Brea, CA, were also inspected from March 15 through April 8, 2021. During these inspections, the FDA investigators determined that your firm is a medical device manufacturer and initial distributor/importer of the SARS-CoV-2 Antigen Rapid Qualitative Test (also distributed under the names INNOVA COVID-19 Self-Test Kit (3T Configuration), INNOVA SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and INNOVA SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration)). Based on our review, your SARS-CoV-2 Antigen Rapid Qualitative Test is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, it is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). Our inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test has been distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or

delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described herein, you have distributed a product that is intended for use in mitigation, prevention, treatment, diagnosis, or cure COVID-19 in people. We request that you take immediate action to cease the sale and distribution of such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 4 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. Our inspections also revealed that the 25T Configuration and 7T Configuration of the SARS-CoV-2 Antigen Rapid Qualitative Test are misbranded within the meaning of section 502(a) of the Act, 21 U.S.C. § 352(a), in that the devices' respective labeling was false or misleading. More specifically, the labeling distributed for your 25T Configuration devices included a "Clinical Performance" section, which claimed a Relative Sensitivity of 96% (88.75-99.17% CI); a Relative Specificity of 100% (98.34-100% CI); and an Accuracy of 98.98% (97.06-99.79% CI). This level of clinical performance for the 25T Configuration devices appears unsupported by any clinical data including both clinical performance data submitted to FDA in your Emergency Use Authorization (EUA) request for the SARS-CoV-2 Antigen Rapid Qualitative Test and in published reports of clinical studies of the SARS-CoV-2 Antigen Rapid Qualitative Test. 5 Similarly, the labeling distributed for your 7T Configuration devices included a "Performance of Prospective Clinical Study" section based on a prospective clinical study conducted by "third-party investigators in UK in September and October 2020" which claimed a Positive Percent Agreement of 81.4% (74.3-88.4% CI). This PPA for the 7T Configuration devices does not appear to align with the PPA observed in the phase 3b prospective clinical study conducted in the United Kingdom. 6 Accordingly, the clinical performance estimates reported in the labeling of the 25T Configuration and 7T Configurations devices are false or misleading as they do not accurately reflect the performance estimates observed during the clinical studies of your devices. Separate and apart from the foregoing issues, FDA further notes that the clinical study data you submitted in your EUA request for the SARS-CoV-2 Antigen Rapid Qualitative Test was identical to data previously provided by other manufacturers in their separate EUA requests. The data reliability and accuracy issues noted herein raise significant concerns that the performance of the SARS-CoV-2 Antigen Rapid Qualitative Test has not been adequately established, and that the products distributed by Innova without FDA approval, clearance, or authorization could present a serious risk to the public health. The inspections also revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test is adulterated with the meaning of sec-

tion 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, is manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received your response dated April 30, 2021, from Eric Grubel, Chief Operating Officer, and the following update dated May 28, 2021, from Janet L. Michener Whipple, Interim Vice President of Quality, which responded to the Form FDA 483, List of Inspectional Observations issued to your firm on April 9, 2021. We address your responses below. These violations include, but are not limited to, the following: 1. Failure to establish procedures for control and distribution of finished devices, as required by 21 CFR § 820.160(a). Specifically, your firm has not established and maintained procedures for the control and distribution of your SARS-CoV-2 Antigen Rapid Qualitative Test system to ensure only devices approved for release are distributed, and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. For example: Our investigators observed your firm has executed contractual agreements with at least (b)(4) distributors for the commercial promotion and sale of the SARS-CoV-2 Antigen Rapid Qualitative Tests in the United States and has distributed more than (b)(4) test kits to US customers. According to your firm, these Tests have been shipped to several customers to Indiana, New York, Vermont, and Oregon during January and February of 2021. No records were maintained to demonstrate that these devices were approved for release. We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge you have opened CAPA #2021-002 and created new standard operating procedures to address Purchase Management and Control and Distribution of your products, in addition to completing personnel training on the new procedures and processes. You did not provide evidence of implementation of your new SOPs, or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 2. Failure to establish procedures for acceptance activities, as required by 21 CFR § 820.80(a). Specifically, your firm has not established procedures for incoming product and finished device acceptance activities. There are no acceptance records of your SARS-CoV-2 Antigen Rapid Qualitative Test system to ensure that specified requirements for your devices are met and meets the acceptance criteria. For example, Your firm distributed SARS-CoV-2 Antigen Rapid Qualitative Tests. These test kits were not inspected, tested, or otherwise verified after receiving it from your contract manufacturer in China or prior to shipment to the end users. Consequently, the 7T and 3T boxes were shipped to customers with the incorrect Instructions for Use (IFU). We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge you opened CAPA #2021-003 and created a new acceptance activity work instruction for incoming and finished devices, and completed personnel training on the new procedures and work instructions. You did not provide evidence of implementation of your new work instruction and evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. We also acknowledge that your firm initiated a voluntary recall of certain lots of 3T and 7T test kits distributed for non-investigational use only. It is unclear how you plan to address incorrectly labeled products distributed for investigational use. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 3. Failure to establish procedures to control product that does not conform to specified requirements, as required by 21 CFR § 820.90(a). Specifically, your firm has not established and maintained procedures to ensure that nonconforming product is identified, documented, evaluated, segregated, and dispositioned. During the inspection, the investigators observed 13 cartons of SARS-CoV-2 Antigen Rapid Qualitative Tests co-mingled in a storage room with multiple cartons of returned nonconforming test kits, samples used for product evaluation, and

damaged controls, all of which was slated for destruction. The 13 cartons of test kits were not identified as nonconforming and no records were maintained to demonstrate if an investigation was needed or the disposition of nonconforming products. We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge that you opened CAPA #2021-004, and created an SOP 9.0, Control of Nonconformances, and completed personnel training on the new procedures. You did not provide adequate evidence of implementation of your new procedure or evidence demonstrating the CAPA is effective in preventing the noted violations from recurring. For example, in your May 28 response you provided the Nonconforming Incident Report, NCR #2021-002, for (b)(4) tests that were destroyed during the inspection. According to your incident report, an investigation to determine the root cause of the nonconforming product was not required because the "root cause is known as identified during FDA inspection" while your SOP 9.0 requires all product nonconformances to be investigated unless otherwise justified and documented. It is not clear how an FDA inspection justifies not investigating the root cause of the (b)(4) nonconforming tests. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 4. Failure to establish procedures for corrective and preventative action, as required by 21 CFR § 820.100(a). Specifically, Your firm has not established procedures for implementing and documenting corrective and preventive action, including requirements for: analyzing quality data sources; investigating the cause of nonconformities; identifying the action(s) needed to correct and prevent occurrence or recurrence of nonconformities; verifying or validating the CAPA to ensure the actions implemented are effective; documenting the changes in methods and procedures; disseminating information related to quality problems to appropriate individuals; and submitting relevant information on quality problems for management review. We reviewed your firm's response and conclude the adequacy cannot be determined at this time. We acknowledge your firm has created SOP 10.0, Corrective and Preventive Action, and opened CAPA #2021-001 in accordance with your new procedure, and completed training personnel on the new procedures. However, you did not provide evidence of the effectiveness of your new CAPA procedure as the corrective actions remain in progress, and therefore we are unable to fully assess the adequacy of your response. 5. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR § 820.198(a). Specifically, your firm has not established procedures for complaint handling to ensure that complaints are processed in a uniform and timely manner, oral complaints are documented upon receipt, and complaints are evaluated to determine if the reported event is required to be submitted to the FDA as a Medical Device Report. We reviewed your firm's response and conclude the adequacy cannot be determined at this time. We acknowledge that you opened CAPA #2021-006 and created SOP 14.0, Complaint Handling and Failure Investigation, and completed personnel training on the new procedures. However, your response does not indicate whether your firm will conduct a retrospective review of any complaints your firm previously received. While your response states your firm "has not received any complaints regarding its SARVS-CoV-2 Antigen Rapid Qualitative Test", our investigators noted your storage room was holding damaged product returned from your customers, which appears to fall under section 5.6 of your new complaint procedure. You did not provide evidence of implementation of your new procedure or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 6. Failure to establish procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR § 820.50. Specifically, your firm has not established procedures for the evaluation of suppliers, including the quality requirements that must be met by suppliers, to ensure that received products and services conform to specified requirements. You did not evaluate your

only contract manufacturer of the SARS-CoV-2 Antigen Rapid Qualitative Test system based on their ability to meet specified requirements, including quality requirements. We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge your firm opened CAPA #2021-005 and created new standard operating procedures for purchase management and supplier controls, and completed personnel training on the new procedures. You did not provide evidence of the implementation of your new SOPs, or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. Our inspection also revealed that your SARS-CoV-2 Antigen Rapid Qualitative Test is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 – Medical Device Reporting. Violation include, but is not limited to: 7. Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17. Specifically, your firm has not established procedures for timely and effective identification, communication, and evaluation of reportable events; a standardized review process for determining when an event meets reportability criteria; timely submission of MDRs to the FDA; or for compliance with the applicable documentation and recordkeeping requirements. We reviewed your firm's response and conclude that your firm's response dated April 30, 2021 is not adequate. In the response, your firm noted that it developed a written MDR procedure, scheduled staff training and planned to assess the effectiveness of corrective actions by July 1. Your response included a copy of your firm's MDR procedure titled "Medical Device Reporting (MDR and eMDR)", Document Number: 7.0, Revision 1.0, Effective Date: 4/29/2021. After reviewing your firm's MDR procedure, we noted that the procedure does not reference a process for identifying and evaluating events involving similar devices to those marketed in the United States (U.S.) as potentially reportable to FDA. Specifically, the procedure notes under the Scope section that it "applies to devices marketed in the United States". If an event involves a similar device to one legally marketed in the U.S., it may be reportable under the MDR regulation. By not considering events involving similar legally marketed devices, potentially reportable MDRs may not be identified and evaluated for MDR decision making and submission to FDA as required by 21 CFR 803.50 and 21 CFR 803.53. Additionally, your firm did not provide documentation or evidence of implementation of a systematic corrective action to include a retrospective review of its adverse events in accordance with its MDR procedure. Your firm should take prompt action to address the violations cited in this letter. Also, federal agencies may be advised of the issuance of Warning Letters about devices and may take your compliance with Act and its implementing regulations into account when considering the award of contracts. Additionally, should FDA determine that you have Quality System regulation violations that are reasonably related to premarket approval applications for Class III devices such devices will not be approved until the violations have been corrected. Also, should FDA determine that your devices do not meet the requirements of the Act, requests for Certificates to Foreign Governments (CFG) may not be granted. More information on processes for persons denied a CFG can be found at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices . Note, there are two response time frames specified. You should take immediate action to address the violations relating to your firm's sale or distribution of the SARS-CoV-2 Antigen Rapid Qualitative Test. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the prod-

ucts in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulentcoronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. Please also notify FDA in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted Quality Systems and MDR reporting violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter. This response should be sent to: US Food and Drug Administration, Division 3/West, Office of Medical Device and Radiological Health Operations at oradevices3firmresponse@fda.hhs.gov. Please identify your response with CMS Case #614819. If you have questions about the contents of this letter, please contact Compliance Officers, Charles J. Chacko at 214-253-4939, or via email at charles.chacko@fda.hhs.gov or Jamie M. Bumpas at 214-253-5336, or via email at Jamie.bumpas@fda.hhs.gov. Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, please provide us with your reasoning and any supporting information for our consideration. It is your firm's responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. Failure to adequately address any violations may result in legal action, including without limitation, seizure and injunction. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of any violations and take prompt actions to correct the violations and bring your products into compliance. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health /S/ Shari J. Shambaugh Program Division Director Office of Medical Device and Radiological Health Division 3 Cc: Mr. Eric E. Grubel, COO 800 E. Colorado Blvd., Suite 288 Pasadena, CA 91101 Eric.grubel@innovamedgroup.com _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public

Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 Accessible at https://www.fda.gov/media/135659/download . 5 See "Preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: Rapid evaluation of Lateral Flow Viral Antigen detection devices (LFDs) for mass community testing:" published November 8, 2020 available at https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20Unive 6 Id. Content current as of: 06/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 7: Places for report 1094616

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pasadena	34.14778	-118.14452

Table 8: Other Stories

ID	Title	Link
1094824	FDA accuses firm of distributing an unapproved Covid-19 test - STAT	Link
1094830	FDA accuses firm of distributing an unapproved Covid-19 test – Boston, Massachusetts	Link
1095770	Unapproved Covid Test Kits Recalled By FDA	Link
1095961	US FDA urges users to throw Innova rapid Covid test in trash, or return it to company	Link

Notes: [...]Our inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test has been distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. [...]

7 Biopolygen Corp. - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-07-09

Publication date	2021-07-09
Create date	2021-09-08
Score	42.74
Report id	1207458
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Biopolygen Corp. MARCS-CMS 613137 — July 09, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Brian Nguyen Biopolygen Corp. 2207 East Carson St Carson , CA 90810 United States customerservice@biopolygen.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 9, 2021 RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://www.biopolygen.com on January 7, 2021, February 26, 2021, and June 30, 2021. The FDA has observed that your website offers the "COVIGEN AG-1 Covid-19 Self Detection Kit," the "COVIDEX AB-1 Covid-19 Self Detection Kit," and the "COVID-19 Antigen and Antibody Combo Set" (hereafter referred to collectively as "COVID-19 Self Detection Test Kits") for sale in the United States. Based on our review, these products are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 [1] in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). The Covid-19 Self Detection Test Kits are offered for sale and distributed to consumers in the United States for self-testing without marketing approval, clearance, or authorization from FDA. Accordingly, the products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). Your products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2).

The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. [2] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. [3] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you offer for sale products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. We also note that different and potentially serious public health risks are presented with specimen collection and testing in the home versus a healthcare setting. Risks may include, but are not limited to, whether a lay person has the ability to collect their specimen, run the test, and interpret the test result accurately. Your website (noted above), includes statements indicating that the COVID-19 Self Detection Test Kits may be purchased directly by consumers and are intended to be used for self-testing for COVID-19, including: "ACCURACY BUT FAST, EFFICIENT; ANYTIME, ANYWHERE AT YOUR PRIVACY AND CONVENIENCE." [https://www.biopolygen.com/shop/-Covid-19-antigen/c-p778] "INSTANT AND EASY ACCESS TO SCREENING CAN BE LIFE OF[sic] DEATH. SCREENING FOR YOURSELF AND YOUR FAMILY TODAY AND REPEAT THE ROUTINE SCREENINGS TO PROTECT YOURSELF." [https://www.biopolygen.com/shop/-Covid-19-antigen/c-p778] A photograph of the "COVID-19 Antigen and Antibody Combo Set" includes the following language: "SELF-SCREENING METHOD FOR EALRY PREVENTION AND EARLY TREATMENT." [https://www.biopolygen.com/shop/-Covid-19-antigen-antibodycombination/c-p783] For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medicaldevices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" [4] provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-

fraud-scams/fraudulentcoronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health _____[1] As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). [2] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . [3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . [4] Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 9: Places for report 1207458

Region Name	Country	Location	Latitude	Longitude
Americas	United States	California	37.25022	-119.75126
Americas	United States	Carson	33.83141	-118.28202

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://www.biopolygen.com on January 7, 2021, February 26, 2021, and June 30, 2021. The FDA has observed that your website offers the "COVIGEN AG-1 Covid-19 Self Detection Kit," the "COVIDEX AB-1 Covid-19 Self Detection Kit," and the "COVID-19 Antigen and Antibody Combo Set" (hereafter referred to collectively as "COVID-19 Self Detection Test Kits") for sale in the United States. [...] The Covid-19 Self Detection Test Kits are offered for sale and distributed to consumers in the United States for self-testing without marketing approval, clearance, or authorization from FDA. [...]

8 Ome Care - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-07-26

Publication date	2021-07-26
Create date	2021-08-19
Score	39.59
Report id	1172681
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Ome Care MARCS-CMS 614382 — July 26, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Paul Edalat Recipient Title Chief Executive Officer Ome Care 26021 Pala Drive - St A Mission Viejo , CA 92691 United States regulatory@viverapharma.com customerservice@hometestbox.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 26, 2021 RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address hometestbox.com on March 3, 2021 and again on April 1, 2021. The FDA has observed that hometestbox.com offers for sale a VIVERA + OMECARE Home Specimen Collection Kit (also referred to as "COVx-HT" and "RT-PCR Test") (hereinafter referred to as "COVxHT Kit"), for sale in the United States directly to consumers. Based on our review, your COVxHT Kit is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, it is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). The COVxHT Kit is offered for sale directly to consumers in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxHT Kit is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxHT Kit is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2"

(SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described herein, you sell a product that is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 4 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health CC: michael.nova@omecare.com Michael Nova MD Ph.D. Chief Innovation Officer and Founder Ome Ventures Inc. 6777 Nancy Ridge Drive, San Diego, CA 92121 CC: sales@blackbirdgroupllc.org Blackbirdgroupllc 3121 Standard Street Bakersfield,

California 93308 _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020 and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx). 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 10: Places for report 1172681

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Mission Viejo	33.60002	-117.672

Notes: [...] The COVxHT Kit is offered for sale directly to consumers in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxHT Kit is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxHT Kit is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. [...]

9 Lup alleges illegal sale of RAT kits : 10th jul21

Publication date	2021-07-09
Create date	2021-07-14
Score	35.59
Report id	1134624
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Lup alleges illegal sale of RAT kits : 10th jul21 E-Pao.net

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Table 11: Places for report 1134624

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Imphal	24.80805	93.9442

Notes: While expressing concern over the fact that the number of Covid-19 deaths in the state has crossed 1241 and around 75,180 infected cases, All Club Organisation Association and Meira Paibi Lup (ACOAM-Lup) has accused pharmacies and stockists of illegally retailing 'Only For Professional and Health Care Users' kit also known as Standard Q Covid-19 AG Test Kit, which is not approved by ICMR for personal use, in the black market. [...]

10 Falsified medicines worth $23m seized in Interpol-led crackdown - 2021-06-08

Publication date 2021-06-08

Create date 2021-06-14

Score 26.58

Report id 1091825

Category Erectile dysfunction medicine, Medical device for screening/diagnosis/monitoring, Analgesic, Antidepressant, Medical devices for disease prevention, Other

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: $23m of illicit products were seized, up from $14m last year, with fake drugs and test kits for COVID-19 once again prominent.

Click here to see the Original Article

Table 12: Places for report 1091825

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	United Kingdom of Great Britain and Northern Ireland	54.75844	-2.69531
Europe	United Kingdom	Northern Ireland	54.5	-6.5
Europe	Italy	Repubblica Italiana	42.83333	12.83333

Table 13: Drugs for report 1091825

Medicine Name	Medicine Class	Action	ATC Code
		antidepressants	N06A
		anabolic steroids	A14A

Table 14: Other Stories

ID	Title	Link
1092436	Thousands of fake online pharmacies shut in global sting: Interpol	Link

Table 14: Other Stories(continued)

ID	Title	Link
1092602	Over 1 lakh web links removed in global crackdown on illegal medical trade	Link
1092778	£3m worth of illegally sold meds and devices seized in UK	Link
1093121	Consumers Face More Risk Than Ever Due to Fake Products	Link
1093206	Over £9m worth of illegal medicines and devices seized - Latest Pharmacy News | Business | Magazine	Link
1093310	Thousands of fake online pharmacies shut down	Link
1094010	A campaign manages to close thousands of fake online pharmacies – Explica .co	Link
1094165	Interpol Shutters Thousands Of Fake Online Pharmacies Amid Demand For COVID-Related Products	Link
1095588	Thousands of Fake Online Pharmacies Shut Down in Interpol Operation	Link
1097825	Interpol shuts down thousands of fake online pharmacies	Link
1098672	Millions Of Fake Covid Tests Seized	Link
1099398	Dozens of fake online pharmacies shut down - Here are the red flags	Link
1101527	Fake Online Pharmacies And Sales Of Illegal COVID Tests Boom During Pandemic	Link
1101588	Thousands of fake online pharmacies are closed worldwide: International Criminal Police Organization	Link
1102328	Falsified medicines worth $23m seized in Interpol-led crackdown	Link
1110025	Fake vaccines are undermining the world's fight against Covid-19	Link
1114752	'Global effort' needed to fight fake goods amid Covid-19 pandemic	Link
1156598	Thousands of illegal pharmacies shut down in international operation	Link

Notes: [...] Pangea XIV, which involved authorities from 92 countries and resulted in 277 arrests, also resulted in the takedown of 113,020 web links peddling fake medicines. [...] The UK was a focal point for the operation this year, with more than three million medicines and medical devices valued at over £9m (almost $13m) seized and seven people arrested in Northern Ireland.

Checks of some 710,000 packages led to the discovery of fake and illicit drugs hidden amongst legitimate products including clothes, jewellery, toys, food and baby products. Among the illegal medicines confiscated by enforcement officers were antidepressants, erectile dysfunction tablets, painkillers, anabolic steroids and slimming pills. More than half of all medical devices seized during the operation were fake and unauthorised COVID-19 tests. UK authorities also removed more than 3,100 advertising links for the illegal sale and supply of unlicensed medicines, and

shut down 43 websites.

Meanwhile, in Venezuela a man was arrested after he developed an e-commerce platform on WhatsApp to sell illicit medicines, while in Italy authorities recovered more than 500,000 fake surgical masks as well as 35 industrial machines used for production and packaging. [...]

11 COVID-19: Police investigate six people over sale of fake oximeters

Publication date	2021-07-10
Create date	2021-09-06
Score	18.13
Report id	1132521
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19: Police investigate six people over sale of fake oximeters

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Table 15: Places for report 1132521

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taipei	25.04776	121.53185
Eastern Asia	China	People's Republic of China	35	105

Notes: Taipei police said they are investigating six people in connection with the alleged sale of fake oximeters illegally imported from China.

The suspects allegedly imported the oximeters using forged paperwork, claiming that the devices were pedometers, and then sold more than 7,000 of them to a distributor that resold them to clinics and pharmacies, police said on Wednesday.

An investigator who initiated the case said they were alerted to the situation after reading a report that a member of the public had tested an oximeter purchased from a pharmacy on a doll, and it reportedly gave a reading.

Investigators lead by the Shilin District Prosecutors' Office on Tuesday raided nine sites in Taipei, Taoyuan and Kaohsiung, and confiscated 856 fake oximeters illegally imported from China, the office said. [...] [pulse oximeter]

12 Coronavirus: 600000 dodgy rapid tests seized in Cyprus

Publication date 2021-06-11

Create date 2021-06-15

Score 17.88

Report id 1095542

Category Erectile dysfunction medicine, Anaesthetic, Medical device for screening/diagnosis/monitoring, Antipsychotic

Quality Falsified

Source Unspecified outlet

Curation Manually curated

Incident or General Incident

Snippet: Coronavirus: 600000 dodgy rapid tests seized in Cyprus Cyprus Mail

Click here to see the Original Article

Table 16: Places for report 1095542

Region Name	Country	Location	Latitude	Longitude
Europe	Cyprus	Republic of Cyprus	35	33

Table 17: Drugs for report 1095542

Medicine Name	Medicine Class	Action	ATC Code
		antipsychotics	N05A

Notes: Police said on Friday they had confiscated 600,000 unauthorised or fake Covid rapid tests and suspended their use, as part of a worldwide Interpol-led operation targeting the sale of counterfeit and illicit medicines and medical products. [...] In Cyprus, some 700,000 counterfeit or unlicensed products were confiscated, with the majority being, apart from the rapid tests, local anaesthetics, antipsychotics, drugs for treating erectile dysfunction, police said. [...]

13 Karnataka's drugs control department identifies 595 low-grade items, including 89 sanitisers

Publication date	2021-06-13
Create date	2021-09-01
Score	6.94
Report id	1097480
Category	Antiseptic
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Karnataka's drugs control department identifies 595 low-grade items, including 89 sanitisers Times of India

Click here to see the Original Article

Table 18: Places for report 1097480

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Karnataka	14.66667	75.83333
Southern Asia	India	Republic of India	22	79

Notes: Since last year, Karnataka's drugs control department (DCD) has redflagged at least 595 substandard products, including 89 hand sanitisers, information accessed from the government shows. Officials confirmed the poor-quality sanitisers included those sold to government agencies, including hospitals and other establishments. [...] Bengaluru police, between March 2020 and May 6, 2021, seized 17,312 bottles of fake sanitisers, 18,750 fake masks and 270 fake thermometers

Annexe D

D.3. Equipement de Protection Individuelle

Medicine Quality Monitoring Globe

September 16, 2021

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Filters applied for this report

Search ((”Personal protective equipment” OR ”PPE” OR ”protective glasses” OR ”apron” OR ”n95” OR ”gowns” OR ”facemask” OR ”visor” OR ”gloves” OR ”goggles” OR ”respirator” OR ”KN95” OR ”face shield” OR ”mask”) OR ((”Medical devices for disease prevention”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”CV19” OR ”CV-19” OR ”SARS” OR ”CoV-2”)))

Start date	2021-06-01
End date	2021-07-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	16

1 Coronavirus: Substandard masks and gloves on sale in Cyprus

Publication date	2021-07-05
Create date	2021-07-08
Score	47.55
Report id	1125574
Category	Medical devices for disease prevention
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Coronavirus: Substandard masks and gloves on sale in Cyprus Cyprus Mail

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Notes: A large number of masks and gloves on sale in Cyprus have been found to be noncompliant with personal protective equipment standards, results of lab tests released on Monday showed.

The PPE monitoring exercise was part of a Europe wide project in which the ministry of labour partook and which was funded by the European Commission.

A hundred individual samples of masks and gloves were examined in total, with the tests being conducted by labs who specialise in testing such equipment.

Reasons for the non-compliance included lack of proper labelling, which would instruct the user on the proper usage and what certifications the product may have, as well as subpar protective qualities.

Nearly all KN95 masks, which are traditionally designed to prevent the exposure to large droplets and extremely small particles, did not meet the testing criteria.

Moreover, more than 50 per cent of the gloves tested were also found to be noncompliant with the designated criteria.

Authorities have moved to have the products withdrawn from sale.

2 Study suggests fraudulent masks are in US hospital stores - 2021-07-31

Publication date	2021-07-31
Create date	2021-08-06
Score	41.17
Report id	1160268
Category	Medical devices for disease prevention
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: A large number of KN95 models failed filtration testing and one unmarked mask was a potential health hazard.

Click here to see the Original Article

Table 1: Places for report 1160268

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 2: Other Stories

ID	Title	Link
1160870	Study suggests fraudulent masks are in US hospital stores	Link

Notes: Reports of counterfeit or substandard facemasks have been widespread during the pandemic, but a new study suggests US hospitals may still have fraudulent products in storage.

The study – published in the journal BMC Infectious Diseases – looked at samples from the 100 or so different makes and models of N95-type facemasks in the inventory of US hospitals during COVID-19 – approved for emergency use during the COVID-19 crisis. [...]

3 Zhejiang Xichen Medical Technology Co., Ltd. - Investigational Device Exemptions (IDE)/Premarket Approval Application (PMA) - Zhejiang Sheng - 2021-06-04

Publication date	2021-06-04
Create date	2021-09-08
Score	32.32
Report id	1207454
Category	Medical devices for disease prevention
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Zhejiang Xichen Medical Technology Co., Ltd. MARCS-CMS 612946 — June 04, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Yinlong Dong Zhejiang Xichen Medical Technology Co., Ltd. 2nd Floor, 3 Building, No. 6, Lvyuan Zhong Road Quzhou Shi Zhejiang Sheng , 324000 China xs2@xicengroup.com Xichen001@aliyun.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER DATE: June 4, 2021 Re: "FFP2 NR 5-Layer KN95 Face Mask," "Medical Face Mask," and "Sterile Surgical Mask" Dear Yinlong Dong: This is to advise you that the United States Food and Drug Administration (FDA) has reviewed your website at the internet address https://www.xichen-med.com/ on March 23, 2021. The FDA has observed that your website offers the "FFP2 NR 5-Layer KN95 Face Mask," "Medical Face Mask," and "Sterile Surgical Mask" for sale in the United States. Based on our review, these products are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). We also note that the FFP2 NR 5-Layer KN95 Face Mask is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people. FDA's review of your website revealed the following statements that establish that the products are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, including but not limited to: • Representing the FFP2 NR 5-Layer KN95 Face Mask as a "COVID-19 Respirator" with "effective antibacterial" properties for use to "prevent…bacteria, droplets and other harmful particles," "filter germs," and provide "protection for your family" [https://www.xichen-med.com/mask/ffp2-nr-5-layer-kn95-face-mask.html] • Representing the Medical Face Mask for use to "prevent infection," "protect patients and other persons from the transmission of pathogenic microorganisms, body fluids, particulate matter, etc., especially in the event of an epidemic or pandemic," and provide "protection for your family" as well as offering a "bacterial filtration efficiency [of] > 98%" and "microbial cleanliness [of] <30CFY/g" [https://www.xichen-med.com/mask/disposable-mask.html] • Representing the Sterile Surgical Mask as a "Medical Surgical Mask" that is "antibacterial" and provides a "BFE above 95%"

for use to "prevent the spread of body fluids and body splash content and isolate dust, particle [sic], alcohol, blood, bacteria, and virus invading." [https://www.xichen-med.com/mask/sterile-surgical-mask.html] The FFP2 NR 5-Layer KN95 Face Mask, Medical Face Mask, and Sterile Surgical Mask (each of which your website indicates is manufactured by Zhejiang Xichen Medical Technology Co. Ltd) are offered for sale in the United States without marketing approval, clearance, or authorization from the FDA. Accordingly, the products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). These products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). In addition, the FFP2 NR 5-Layer KN95 Face Mask is misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), because its labeling is false or misleading. FDA registration of a device establishment or assignment of a registration number does not denote FDA approval of the establishment or the device. Thus, references to a firm's establishment registration and registration number that create an impression of official FDA approval, clearance, authorization, certification, endorsement or other evaluation of the establishment or the devices are misleading and constitute misbranding. 21 CFR 807.39. Your website contains a number of false or misleading representations, including but not limited to: • Displaying a "FDA REGISTRATION CERTIFICATE" also referred to as the "kn95-FDA Certificate" issued by "J & F Technology Services LLC" (Certificate) under the "About Us" tab on your website. The Certificate certifies that "Zhejiang Xichen Medical Technology Co., Ltd…has completed the FDA Establishment Registration (as manufacturer, foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration." The Certificate has the look of an official government document, incorporating unauthorized use of the FDA logo 2 and an illustration of an eagle and a U.S. flag (or a similar flag). [https://www.xichen-med.com/our-certificate] • Displaying a screenshot titled "kn-95-Registration information is available on the FDA website" of what appears to be Zhejiang Xichen Medical Technology Co., Ltd.'s previous entry in FDA's Establishment Registration & Device Listing Database. [https://www.xichen-med.com/our-certificate] Taken together, display of the Certificate, bearing the FDA logo, and a screenshot from FDA's Establishment Registration & Device Listing Database positioned near images of and information about the FFP2 NR 5-Layer KN95 Face Mask are misleading because they imply FDA approval, clearance, authorization, certification, endorsement, or other evaluation of the product and/or establishment based on the representations that Zhejiang Xichen Medical Technology Co., Ltd. is or was registered with the FDA and that the firm is or was in possession of a registration number. Although the Certificate appears to be intended to function as a disclaimer, the small font size and overall placement of such language could be easily overlooked and does not limit or otherwise mitigate the misleading impression created by the use of the Certificate. We also note that you seem to reference the Certificate or some other certificate on the Sterile Surgical Mask's webpage [https://www.xichen-med.com/mask/sterilesurgical-mask.html], indicating the product has a "Certificate CE, FDA." These representations are especially concerning from a public health perspective because consumers rely on information provided by sellers to determine whether to purchase a device and your presentation conveys the misimpression that the products have been reviewed and approved by FDA. We remind you that FDA's Center for Devices and Radiological Health (CDRH) does not issue device registration certificates to medical device establishments, including to sellers and manufacturers. When an establishment registers and lists its devices, the resulting entry in FDA's Establishment Registration & Device

Listing Database merely denotes that the establishment has provided certain information to FDA. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID -19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 3 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. 4 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sell a product that is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of any adulterated and misbranded products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. This letter is not meant to be an all-inclusive list of violations that exist in connection with the products or your operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials to ensure that you do not make representations that misbrand the product(s) in violation of the Act. This letter notifies you of our concerns and provides you with an opportunity to address them. Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to address the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of any actions your firm has taken. If your firm's planned actions will occur over time, please include a timetable for implementation of those activities. Your firm's response should be comprehensive and address all violations included in this letter. If you believe that the products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be adulterated or misbranded may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States. Your firm's response should be sent via email to CDRHWarningLetterResponses@fda.hhs.gov or by mail to: Food and Drug Administration Center for Devices and Radiological Health Office of Regulatory Programs Division of Regulatory Programs 2: Establishment Support Regulatory Inspections and Audits Team White Oak Building 66 10903 New Hampshire Ave. Silver Spring, MD 20993 Refer to the Document number CMS Case# 612946 or CTS Number CPT2001023 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Assistant Director, Paola Barnett at 301-796-5462 or Paola.Barnett@fda.hhs.gov. Sincerely, / S/ Donna Engleman, MS, BSN Director Division of Market Intelligence Office of Regulatory Programs Office of Product Evaluation and Quality Center for Devices and Radiological Health Cc: US Agent: Fanny Zhao J & F Technology Services LLC 2424 Morris Ave 818 Union, New Jersey 07083 Email Address: info@jf-yiliao.com Contact: Yucai.qiu XICEN International Gmb Global Office Center, Beethovenstr. 5 DE-60325 Frankfurt/M,Germany Email Address: yucai.qiu@xicengroup.com XICEN International Corporation 245 E. Main Street, Suite 107 Alhambra, California, 91801 _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 The FDA logo is for official use by FDA and not for private use on labeling of FDA-regulated products. See FDA Logo Policy (available at: https://

www.fda.gov/about-fda/website-policies/fda-logo-policy). 3 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 4 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . Content current as of: 07/06/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 3: Places for report 1207454

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	quzhou shi	28.94273	118.87185
Americas	United States	United States	39.76	-98.5

Notes: This is to advise you that the United States Food and Drug Administration (FDA) has reviewed your website at the internet address https://www.xichen-med.com/ on March 23, 2021. The FDA has observed that your website offers the "FFP2 NR 5-Layer KN95 Face Mask," "Medical Face Mask," and "Sterile Surgical Mask" for sale in the United States. [...] The FFP2 NR 5-Layer KN95 Face Mask, Medical Face Mask, and Sterile Surgical Mask (each of which your website indicates is manufactured by Zhejiang Xichen Medical Technology Co. Ltd) are offered for sale in the United States without marketing approval, clearance, or authorization from the FDA. [...]

4 Foley & Lardner Slaps Manufacturer With Suit Over Reports of Counterfeit Nitrile Gloves Amid COVID-19 Pandemic | The Recorder

Publication date	2021-06-09
Create date	2021-06-14
Score	26.71
Report id	1093443
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Foley & Lardner Slaps Manufacturer With Suit Over Reports of Counterfeit Nitrile Gloves Amid COVID-19 Pandemic | The Recorder Law.com

Click here to see the Original Article

Table 4: Places for report 1093443

Region Name	Country	Location	Latitude	Longitude
Americas	United States	California	37.25022	-119.75126

Notes: (Need to subscribe) – Foley & Lardner filed a trademark lawsuit Wednesday in California Central District Court on behalf of Shijiazhuang Hongray Group over the alleged sale of counterfeit Hongray-brand Nitrile gloves amid the COVID-19 pandemic.

5 Non-profit Takes Amazon India To Court Over Fake Medical-grade Masks

Publication date	2021-06-03
Create date	2021-06-07
Score	19.96
Report id	1086265
Category	Medical devices for disease prevention
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Non-profit Takes Amazon India To Court Over Fake Medical-grade Masks tntribune.com

Click here to see the Original Article

Table 5: Places for report 1086265

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Mumbai	19.07283	72.88261

Table 6: Other Stories

ID	Title	Link
1112622	Decide NGO's plea on fake masks: Bombay HC to consumer rights body	Link

Notes: While India was dealing with mass destruction amid the deadly second wave of Covid-19, an Indian non-profit organization filed a petition in the country's financial center, Mumbai, against Amazon Retail India over the sale of fake medical-grade face masks. [...] The NGO had placed a bulk order of 400 masks for healthcare workers on Amazon in May. But the products were "shoddy and substandard in quality, were poorly packaged and nowhere close to what they were described as on the portal", the PIL states. [...]

6 Fake Remdesivir, Rs 10-Lakh Hospital Bed: How Covid Patients Were Fleeced

Publication date	2021-06-03
Create date	2021-06-07
Score	15.77
Report id	1086629
Category	Antiviral others, Medical devices for disease prevention
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Fake Remdesivir, Rs 10-Lakh Hospital Bed: How Covid Patients Were Fleeced NDTV

Click here to see the Original Article

Table 7: Places for report 1086629

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	New Delhi	28.63576	77.22445

Table 8: Other Stories

ID	Title	Link
1086797	How desperate covid patients in India were defrauded online by scamsters	Link
1087117	Fake medicines, recycled PPE: Scammers worsen India COVID misery	Link
1087429	Fake medicines, recovered personal protective equipment: crooks exacerbate the suffering of COVID in India | Coronavirus pandemic news	Link
1088174	Covid-19: India's scammers benefit from fake medicines, recycled PPEs during pandemic	Link
1089013	COVID vaccine, beds, oxygen, and other online scams in India	Link

Notes: [...] His Crime Branch teams have already arrested many scammers, including a gang that made and sold counterfeit doses of the antiviral drug Remdesivir for up to 40 times the

market price.

"These people were producing fake vials which cost them about 20 rupees and (they) sold it in the market for anything above 10,000 rupees," Singh said. [...] This week, six men were reportedly arrested on suspicion of washing, repackaging and selling several tonnes of used surgical gloves from hospitals. [...]

7 Fake hand sanitisers come under scanner again

Publication date	2021-07-08
Create date	2021-07-13
Score	15.32
Report id	1130689
Category	Antiseptic, Medical devices for disease prevention
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Fake hand sanitisers come under scanner again The New Indian Express

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Table 9: Places for report 1130689

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Ernakulam	10	76.5
Southern Asia	India	Thiruvananthapuram	8.4855	76.94924
Southern Asia	India	Malappuram	11.04199	76.08154
Southern Asia	India	Alappuzha	9.49004	76.3264
Southern Asia	India	Palakkad	10.77319	76.65366
Southern Asia	India	Thrissur	10.51667	76.21667

Table 10: Drugs for report 1130689

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: (Cannot access)

8 Captain's Cloth LLC - Investigational Device Exemptions (IDE)/Premarket Approval Application (PMA) - California - 2021-07-02

Publication date	2021-07-02
Create date	2021-09-08
Score	13.66
Report id	1207457
Category	Medical devices for disease prevention
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Captain's Cloth LLC MARCS-CMS 613965 — July 02, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Brian Eckert Captain's Cloth LLC 28871 El Apajo Laguna Niguel , CA 92677 United States Brian@eckertsales.com info@captainscloth.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER DATE: July 2, 2021 Re: "KN95 Face Mask" Dear Brian Eckert: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://captainscloth.com/ on June 10, 2021, where you offer the "KN95 Face Mask" for sale in the United States. We also reviewed your social media page at https://www.facebook.com/Captains-Cloth-140013110203384/ where you direct consumers to your website to purchase the KN95 Face Mask. Based on our review, these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). FDA's review of your website revealed the following statements that establish that the KN95 face masks are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, including but not limited to: Statements alongside an image of the KN95 Face Masks that they "filter out 95% of particles" and that your firm is "working primarily with medical distribution companies … to support those on the front lines" [https://captainscloth.com/products/kn95-face-masks-5-pack] Statements made on the KN95 Face Mask packaging that "This product can filter air particulates, dust, smoke, mist, microorganisms, block droplets, body fluids, secretions…" and "Prevent Virus" [https://captainscloth.com/products/kn95-face-masks-5-pack] The KN95 Face Mask, which your website represents is manufactured by "Lianyungang Manai Protective Equipment Co. Ltd." (Lianyungang) is offered for sale in the United States without marketing approval, clearance, or authorization from the FDA. Accordingly, this product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of

the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). This product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). In addition, the KN95 Face Mask is also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), because its labeling is false or misleading. Specifically, your websites contain false or misleading representations, including but not limited to: Representations that the KN95 Face Masks "have an active status with the FDA…" [https://captainscloth.com/products/kn95-face-masks-5-pack] Unauthorized display of what appears to be FDA's logo 1 on the front and back of the product's labeling [https://captainscloth.com/products/kn95-face-masks-5-pack] Display of the FDA logo on packaging and near images of and information about the respective products, combined with statements about having active status with the FDA, is misleading because such information implies FDA approval, clearance, authorization, certification, endorsement, or other evaluation of the products and/or establishments. Such representations are especially concerning from a public health perspective because consumers rely on information provided by sellers to determine whether to purchase a device and your presentation conveys the misimpression that the products have been reviewed and approved by FDA. This letter is not meant to be an all-inclusive list of violations that exist in connection with the products or your operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials to ensure that you do not make representations that misbrand the product(s) in violation of the Act. This letter notifies you of our concerns and provides you with an opportunity to address them. Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to address the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of any actions your firm has taken. If your firm's planned actions will occur over time, please include a timetable for implementation of those activities. Your firm's response should be comprehensive and address all violations included in letter. If you believe that the products are not in violation of the Act, include your reasoning and any supporting information for our consideration. Your firm's response should be sent via email to CDRHWarningLetterResponses@fda.hhs.gov or by mail to: Food and Drug Administration Center for Devices and Radiological Health Office of Regulatory Programs Division of Regulatory Programs 2: Establishment Support Regulatory Inspections and Audits Team White Oak Building 66 10903 New Hampshire Ave. Silver Spring, MD 20993 Refer to the Document number CMS Case# 611829 or CTS Number CPT2001007 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Assistant Director, Paola Barnett at 301-796-5462 or Paola.Barnett@fda.hhs.gov. Sincerely, /S/ Donna Engleman, MS, BSN Director Division of Market Intelligence Office of Regulatory Programs Office of Product Evaluation and Quality Center for Devices and Radiological Health Cc: Youbiao Wei Lianyungang Manai Protective Equipment Co., Ltd. Jinshan Town Industrial Park, Ganyu District Lianyangang, Jiangsu CN 222002 US Agent: Hong 38 South 18th Avenue, Suite A Brighton, CO 80601 Email: abmedservice@outlook.com Lianyungang Manai Protective Equipment Co., Ltd. No. 6 Building, 1-8 North Street, Sanyuanli Yaochi, Yuexiu District Guangzhou, Guangdong CN 510030 Official Correspondent: Shuo Wang Lianyungang Manai Protective Equipment Co., Ltd. Kuangquan Street Yaochi North Street Community Guangzhou, Guangdong CN 510030

_____1 The FDA logo is for official use by FDA and not for private use on labeling of FDA-regulated products. See FDA Logo Policy

(available at: https://www.fda.gov/about-fda/website-policies/fda-logo-policy). Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 11: Places for report 1207457

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Laguna Niguel	33.52253	-117.70755

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://captainscloth.com/ on June 10, 2021, where you offer the "KN95 Face Mask" for sale in the United States. [...] The KN95 Face Mask, which your website represents is manufactured by "Lianyungang Manai Protective Equipment Co. Ltd." (Lianyungang) is offered for sale in the United States without marketing approval, clearance, or authorization from the FDA. [...]

9 Falsified medicines worth $23m seized in Interpol-led crackdown - 2021-06-08

Publication date 2021-06-08

Create date 2021-06-14

Score 13.41

Report id 1091825

Category Erectile dysfunction medicine, Medical device for screening/diagnosis/monitoring, Analgesic, Antidepressant, Medical devices for disease prevention, Other

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: $23m of illicit products were seized, up from $14m last year, with fake drugs and test kits for COVID-19 once again prominent.

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Table 12: Places for report 1091825

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	United Kingdom of Great Britain and Northern Ireland	54.75844	-2.69531
Europe	United Kingdom	Northern Ireland	54.5	-6.5
Europe	Italy	Repubblica Italiana	42.83333	12.83333

Table 13: Drugs for report 1091825

Medicine Name	Medicine Class	Action	ATC Code
		antidepressants	N06A
		anabolic steroids	A14A

Table 14: Other Stories

ID	Title	Link
1092436	Thousands of fake online pharmacies shut in global sting: Interpol	Link

Table 14: Other Stories(continued)

ID	Title	Link
1092602	Over 1 lakh web links removed in global crackdown on illegal medical trade	Link
1092778	£3m worth of illegally sold meds and devices seized in UK	Link
1093121	Consumers Face More Risk Than Ever Due to Fake Products	Link
1093206	Over £9m worth of illegal medicines and devices seized - Latest Pharmacy News | Business | Magazine	Link
1093310	Thousands of fake online pharmacies shut down	Link
1094010	A campaign manages to close thousands of fake online pharmacies – Explica .co	Link
1094165	Interpol Shutters Thousands Of Fake Online Pharmacies Amid Demand For COVID-Related Products	Link
1095588	Thousands of Fake Online Pharmacies Shut Down in Interpol Operation	Link
1097825	Interpol shuts down thousands of fake online pharmacies	Link
1098672	Millions Of Fake Covid Tests Seized	Link
1099398	Dozens of fake online pharmacies shut down - Here are the red flags	Link
1101527	Fake Online Pharmacies And Sales Of Illegal COVID Tests Boom During Pandemic	Link
1101588	Thousands of fake online pharmacies are closed worldwide: International Criminal Police Organization	Link
1102328	Falsified medicines worth $23m seized in Interpol-led crackdown	Link
1110025	Fake vaccines are undermining the world's fight against Covid-19	Link
1114752	'Global effort' needed to fight fake goods amid Covid-19 pandemic	Link
1156598	Thousands of illegal pharmacies shut down in international operation	Link

Notes: [...] Pangea XIV, which involved authorities from 92 countries and resulted in 277 arrests, also resulted in the takedown of 113,020 web links peddling fake medicines. [...] The UK was a focal point for the operation this year, with more than three million medicines and medical devices valued at over £9m (almost $13m) seized and seven people arrested in Northern Ireland.

Checks of some 710,000 packages led to the discovery of fake and illicit drugs hidden amongst legitimate products including clothes, jewellery, toys, food and baby products. Among the illegal medicines confiscated by enforcement officers were antidepressants, erectile dysfunction tablets, painkillers, anabolic steroids and slimming pills. More than half of all medical devices seized during the operation were fake and unauthorised COVID-19 tests. UK authorities also removed more than 3,100 advertising links for the illegal sale and supply of unlicensed medicines, and

shut down 43 websites.

Meanwhile, in Venezuela a man was arrested after he developed an e-commerce platform on WhatsApp to sell illicit medicines, while in Italy authorities recovered more than 500,000 fake surgical masks as well as 35 industrial machines used for production and packaging. [...]

10 Houston paid $1.7M in counterfeit N95 masks, according to court records

Publication date	2021-06-22
Create date	2021-06-25
Score	12.46
Report id	1110592
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Houston paid $1.7M in counterfeit N95 masks, according to court records KPRC Click2Houston

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Table 15: Places for report 1110592

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Houston	29.76328	-95.36327

Table 16: Other Stories

ID	Title	Link
1110225	Houston paid $1.7M for counterfeit N95 masks earlier this year	Link

Notes: The city of Houston spent more than a million dollars on counterfeit masks, according to court documents.

The court records said the city paid a company called Med-Tech Resource roughly $1.7 million for around 900,000 3M-N95 masks. The masks were intended for frontline employees.

After the masks were delivered, 3M and the city determined they were counterfeit, the documents said. [...]

11 Fake medical equipment manufacturing factory busted in Agra, 1 arrested

Publication date	2021-07-01
Create date	2021-07-07
Score	11.75
Report id	1121782
Category	Medical devices for disease prevention, Other
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake medical equipment manufacturing factory busted in Agra, 1 arrested India Today

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Table 17: Places for report 1121782

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Agra	27.18333	78.01667

Notes: Afake medical equipment manufacturing factory was busted in Agra on Thursday, police said.

A number of medical devices, syringes, gloves, sanitary pads, and other surgical equipment were seized during the raid. [...] "The team has confiscated 1 lakh gloves, 26,000 sanitary napkins, 2,000 urine catheters, 1,000 Nebulizer masks, 50,000 surgical masks, syringes, and a large quantity of raw material worth Rs 2 crores," he said. [...]

12 Marshals raid Lexington company for one million counterfeit 3M masks - ABC 36 News

Publication date	2021-06-10
Create date	2021-06-15
Score	9.81
Report id	1094690
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Marshals raid Lexington company for one million counterfeit 3M masks - ABC 36 News WTVQ

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Table 18: Places for report 1094690

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Lexington	37.98869	-84.47772

Table 19: Other Stories

ID	Title	Link
1094831	Company accuses Lexington's Old World Timber of selling fake N95 masks	Link
1095138	3M Helps Thwart Sale of 1M Suspected Fake Respirators from Kentucky Warehouse	Link
1095363	3M and U.S. marshals confiscate more than 1M counterfeit N95 masks	Link
1114657	Injunction sought to stop Minnesota man, business from selling counterfeit N95 masks	Link
1128647	1 Million Fake 3M N95 Masks Seized From Kentucky Company	Link
1130112	3M accuses Lexington company of selling fake N95 respirators	Link

Notes: [...] The U.S. District Court for the Eastern District of Kentucky granted 3M a temporary restraining order stopping defendant Old World Timber, located on Versailles Road in Lexington, from selling counterfeit products. 3M then worked with the U.S. Marshals Service to seize more than one million respirators from the company, according to 3M and federal court records. [...]

13 Counterfeit face masks worth over RM60,000 seized in JB

Publication date	2021-07-25
Create date	2021-07-28
Score	5.62
Report id	1152233
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Counterfeit face masks worth over RM60,000 seized in JB Daily Express

Click here to see the Original Article

Table 20: Places for report 1152233

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Malaysia	Taman Sentosa	5.3598	100.29845
South-Eastern Asia	Malaysia	Johor Bahru	1.4655	103.7578
South-Eastern Asia	Malaysia	Kampung Kangkar Teberau	1.532	103.7549

Table 21: Other Stories

ID	Title	Link
1160329	Ministry officials seize over 100000 face masks, knock-offs of known brand	Link
1168113	KPDNHEP seizes counterfeit face masks worth over RM60,000 in JB	Link
1168781	Domestic Trade Ministry seizes counterfeit face masks worth over RM60,000 in Johor Baru	Link

Notes: The Johor Domestic Trade and Consumer Affairs Ministry (KPDNHEP) has seized 112,350 units of suspected counterfeit face masks worth RM60,669 around Taman Sentosa and Tebrau here, Saturday. Its director Mohd Hairul Anuar Bohro said the fake Neutrovis masks were confiscated in a special operation on three premises selling various types of face masks,

following complaints from the trademark owner. [...]

14 HSA busts Vision Empire illegal mask manufacturing facility

Publication date	2021-06-10
Create date	2021-06-15
Score	5.60
Report id	1095146
Category	Medical devices for disease prevention
Quality	Substandard
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: HSA busts Vision Empire illegal mask manufacturing facility Yahoo News

Click here to see the Original Article

Table 22: Places for report 1095146

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Singapore	Republic of Singapore	1.36667	103.8

Table 23: Other Stories

ID	Title	Link
1095147	S'pore firm being investigated for illegal mask manufacturing, repackaging	Link
1095853	Singapore's HSA finds illegal mask-making, repackaging facility in Ubi; more than 80,000 masks seized	Link
1098916	Singapore HSA finds illegal mask-making, repackaging facility in Ubi; more than 80,000 masks seized	Link
1102039	HSA finds illegal mask-making, repackaging facility in Ubi; more than 80000 masks seized	Link

Notes: [...] The masks sold by Vision Empire International and branded under Vision Empire Healthcare were observed by enforcement officers to be manufactured in an unhygienic and makeshift environment and placed in carton boxes left out in the open, said HSA in a press release on Friday (11 June).

A total of 82,500 masks in 33 cartons were seized. [...]

15 2 expats arrested with huge quantities of counterfeit detergents and masks

Publication date	2021-06-26
Create date	2021-06-30
Score	5.47
Report id	1115857
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 2 expats arrested with huge quantities of counterfeit detergents and masks Saudi Gazette

Click here to see the Original Article

Table 24: Places for report 1115857

Region Name	Country	Location	Latitude	Longitude
Western Asia	Saudi Arabia	Riyadh	24.68773	46.72185

Table 25: Other Stories

ID	Title	Link
1117479	2 expats arrested with huge quantities of counterfeit detergents and masks in Saudi Arabia	Link

Notes: Inspection teams from the Ministry of Commerce and police arrested two foreign nationals after seizing huge quantities of counterfeit detergents and low-quality masks. The seized items include more than 2,000,000 packages of adulterated detergents and 4,430,000 masks.

The ministry had closed the warehouse, which was run by a Syrian and an Egyptian national for stocking their counterfeit products. [...]

16 Karnataka's drugs control department identifies 595 low-grade items, including 89 sanitisers

Publication date	2021-06-13
Create date	2021-09-01
Score	3.32
Report id	1097480
Category	Antiseptic
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Karnataka's drugs control department identifies 595 low-grade items, including 89 sanitisers Times of India

Click here to see the Original Article

Table 26: Places for report 1097480

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Karnataka	14.66667	75.83333
Southern Asia	India	Republic of India	22	79

Notes: Since last year, Karnataka's drugs control department (DCD) has redflagged at least 595 substandard products, including 89 hand sanitisers, information accessed from the government shows. Officials confirmed the poor-quality sanitisers included those sold to government agencies, including hospitals and other establishments. [...] Bengaluru police, between March 2020 and May 6, 2021, seized 17,312 bottles of fake sanitisers, 18,750 fake masks and 270 fake thermometers

Annexe D

D.4. Désinfectants

Medicine Quality Monitoring Globe

September 24, 2021

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Filters applied for this report

Search ("wipes" OR "disinfectant" OR "sanitizer" OR "sanitizing" OR "iodoform" OR "sanitiser")

Start date	2021-06-01
End date	2021-07-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	13

1 DMM Vission, S.A. de C.V. - Finished Pharmaceuticals/ Unapproved New Drug/Misbranded/Adulterated - Estado de México - 2021-06-03

Publication date	2021-06-03
Create date	2021-06-10
Score	15.84
Report id	1091500
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER DMM Vission, S.A. de C.V. MARCS-CMS 609797 — June 03, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA UPS Product: Drugs Recipient: Recipient Name Ma. de la Luz Escorza Recipient Title CEO DMM Vission, S.A. de C.V. Calle Lago Guija 234 Col. Agua Azul 57500 Ciudad Nezahualcoyotl , Méx. Mexico Issuing Office: Center for Drug Evaluation and Research United States Warning Letter 320-21-48 June 03, 2021 Dear Ms. Escorza: Your firm was registered as a human drug manufacturer. The U.S. Food and Drug Administration (FDA) conducted testing of consumer antiseptic hand rub drug products (also referred to as consumer hand sanitizers) labeled as SYP HEALTH HAND SANITIZER ALCOHOL GEL and Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel. SYP HEALTH HAND SANITIZER ALCOHOL GEL was labeled as manufactured at your facility, and Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel was declared to be manufactured at your facility, DMM Vission, S.A. de C.V., FEI 3016833130, at Calle Lago Guija 234, Col. Agua Azul, Cuidad Nezahualcoyotl, Mexico. Following an attempt to import DMM Hand Sanitizer drug products into the United States, these products were detained and refused admission at the border. The results of FDA laboratory testing of batches of these drug products detained at the border demonstrate that these drug products, labeled or declared to be manufactured at your facility, are adulterated within the meaning of section 501(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(d)(2), in that a substance was substituted wholly or in part therefor. In addition, these products are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), in that the substitution demonstrates that the quality assurance within your facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements. In addition, your Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL drug products are unapproved new drugs in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and are misbranded under sections 502(j), (a), (e), (f)(2), (x) and (ee) of the FD&C Act, 21 U.S.C. 352 (j), (a), (e), (f)(2), (x) and (ee). Lastly, SYP HEALTH HAND SANITIZER is also misbranded under 502 (i) of the FD&C Act, 21 U.S.C 352(i). Introduction or delivery for introduction of such products into interstate

commerce is prohibited under sections 301(d) and (a) of the FD&C Act, 21 U.S.C. 331(d) and (a). Adulteration Violations SYP HEALTH HAND SANITIZER ALCOHOL GEL, labeled as manufactured at your facility, is labeled to contain 70% of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of SYP HEALTH HAND SANITIZER ALCOHOL GEL product detained at the border found that the product contained an average of 31% ethanol and an average of 2.3% methanol volume/volume (v/v). Additionally, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel, declared to be manufactured at your facility, is labeled to contain 70% v/v of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel product detained at the border found that the product contained an average of 22% ethanol and an average of 10% methanol v/v. Therefore, these hand sanitizer drug products are adulterated under section 501(d)(2) of the FD&C Act in that the active ingredient of ethanol was substituted wholly or in part with methanol, a dangerous chemical when in contact with human skin or ingested. Methanol is not an acceptable ingredient for hand sanitizers and should not be used due to its toxic effects. Skin exposure to methanol can cause dermatitis, as well as transdermal absorption with systemic toxicity. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system, or death. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute are most at risk for methanol poisoning. On August 21, 2020, FDA held a teleconference with you and Registrar Corp, your registered U.S. agent. We recommended you consider removing all of your firm's hand sanitizer drug products currently in distribution from the U.S. market. On August 21, 2020, FDA notified the public of methanol contamination of your hand sanitizer at the following website: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use . On September 8, 2020, you announced a voluntary nationwide recall for five lots of Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel 500ml and 1200ml bottles due to potential presence of undeclared methanol (Wood Alcohol), as noted on the following FDA webpage: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dmm-vission-sa-de-cv-issues-voluntary-nationwide-recall-cleaner-hand-sanitizer-500-ml-and-1200-ml?utm_medium=
. Additionally, the FDA contacted your firm's consignees to recall. On September 24, 2020, one of your firm's consignees, AA Products Inc., recalled one lot of SYP HEALTH HAND SANITIZER ALCOHOL GEL 500ml bottles. In response to this letter, provide the following: • A detailed investigation into how the drug products described above, which were declared or labeled as manufactured at your facility, and which were labeled as containing ethanol, were substituted in part or in whole with methanol. • A list of all raw materials used to manufacture all of your hand sanitizer drug products, including the suppliers' names, addresses, and contact information. • A list of all batches of any hand sanitizer drug products shipped to the United States by your firm, and a full reconciliation of all material you distributed. • Copies of the complete batch records for all batches distributed to the U.S. The substitution and methanol contamination in a drug product declared or labeled as manufactured in your facility demonstrates that the quality assurance within your facility is not functioning in accordance with CGMP requirements under section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). 1 Unapproved New Drug and Misbranding Violations Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically,

Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are intended for use as consumer topical antiseptics. Examples of claims observed on the Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL labeling that provide evidence of the intended use (as defined in 21 CFR 201.128) of the products include, but may not be limited to, the following: Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel: " Drug Facts . . . Purpose . . . Antimicrobial Use : To help reduce bacteria on the skin. . . Directions: Wet hands thoroughly with product, gently rub into skin and allow to dry without wiping. SYP HEALTH HAND SANITIZER ALCOHOL GEL: DRUG FACTS: . . . USES: hand sanitizer to help decrease bacteria on the skin. . . DIRECTIONS: pump as needed into your palms thoroughly spread on both hands, rub into skin until dry. These topical antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL drug products are GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). We note that over-the-counter (OTC) topical antiseptic products had been the subject of rulemaking under FDA's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified in Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer rub. Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements. However, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL do not conform to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rubs Proposed Rue, nor any other TFM, proposed rule, or final rule, and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing

without an approved application under section 505. According to the product labels, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL purportedly contain the active ingredient ethyl alcohol (ethanol) 70%. However, as previously discussed, FDA laboratory analyses of batches of these products detained at the border demonstrated that Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL contain ethyl alcohol (ethanol) in a concentration that is less than the 70% stated on its product labels and less than the amount of ethyl alcohol (ethanol) described in the 1994 TFM. 2 Such products do not conform with the TFM or applicable requirements nor are they consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. 3 FDA laboratory analyses also demonstrated that batches of Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL contain significant concentrations of the undeclared ingredient methyl alcohol (methanol). Use of methanol as an active ingredient is not in conformance with the 1994 TFM, nor is methanol included in the formulations described in FDA's Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry. Furthermore, methanol is not acceptable as an inactive ingredient in hand sanitizers. As previously discussed, methanol has significant and sometimes fatal toxic effects and, therefore, does not meet the requirements under 21 CFR 330.1(e) that its inactive ingredients be safe and suitable. 4 Additionally, these methanol-containing drug products, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL, are misbranded under sections 502(j), (a), (e), (f)(2), (x) and (ee) of the FD&C Act, 21 U.S.C. 352(j), (a), (e), (x) and (ee). SYP HEALTH HAND SANITIZER ALCOHOL GEL is also misbranded under section 502(i) of the FD&C Act, 21 U.S.C 352(i). These products are misbranded under section 502(j) of the FD&C Act, 21 U.S.C. 352(j), because they are dangerous to health when used according to their labeling as hand sanitizers. As previously stated, skin exposure to methanol could lead to systemic absorption, and substantial methanol exposure can potentially result in, among other things, blindness, permanent nervous system damage, and even death. These hand sanitizers are misbranded under section 502(a) of the FD&C Act, 21 U.S.C 352(a), because their labeling is false or misleading. As noted above, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are labeled to contain ethyl alcohol (ethanol) 70%. However, FDA laboratory analyses of batches of these products demonstrate that the products contain a concentration of ethyl alcohol (ethanol) that is less than what is stated on the product labels and contain a significant concentration of methyl alcohol (methanol), an ingredient that is not declared on the product labels. Section 201(n) of the FD&C Act, 21 U.S.C. 321(n), provides that "in determining whether the labeling or advertising is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result. . .." Thus, the misleading representation of the concentration of the active ingredient ethyl alcohol (ethanol), and the failure of the product labels to disclose the presence of methyl alcohol (methanol) in the products, causes these products to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). The failure of these products to list methyl alcohol (methanol) as an ingredient on their labels causes them to be misbranded under section 502(e)(1)(A) of the FD&C Act, 21 U.S.C. 352(e)(1)(A). Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER GEL are also misbranded under section 502(f)(2) of the FD&C Act, 21 U.S.C. 352(f)(2) because the product labels do not include all of the applicable warnings as required under 21 CFR 330.1(g). Specifically,

the labels do not include the warning statement that reads, "If swallowed, get medical help or contact a Poison Control Center right away." Furthermore, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x) because the product labels fail to disclose a complete domestic address or domestic telephone number through which the responsible person may receive a report of a serious adverse event with such drug. In addition, SYP HEALTH HAND SANITIZER ALCOHOL GEL is packaged in a container that resembles a drinking water bottle customarily purchased by U.S. consumers. Section 502(i)(1) of the FD&C Act, 21 U.S.C. 352(i)(1), provides that a drug is misbranded if "its container is so made, formed, or filled as to be misleading …"As such, your clear, colorless hand sanitizer that fills a 33.8 fl oz container resembling a plastic water bottle ordinarily used to package drinking water is misbranded under section 502(i)(1) of the FD&C Act, 21 U.S.C. 352(i)(1). Lastly, these products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee) because Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a). CGMP Consultant Recommended Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant qualified as set forth in 21 CFR 211.34 to evaluate your operations and to assist your firm in meeting CGMP requirements if your firm intends to resume manufacturing drugs for the U.S. market. We also recommend that the qualified consultant perform a comprehensive audit of your entire operation for CGMP compliance and that the consultant evaluates the completion and efficacy of your corrective actions and preventive actions before you pursue resolution of your firm's compliance status with FDA. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance. Conclusion The violations cited in this letter are not intended to be an all-inclusive list of violations associated with your drug products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. Note that FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-78 on September 02, 2020, as the methods used in and controls used for the manufacture, processing, packing, or holding of these products do not appear to conform to current good manufacturing practices within the meaning of section 501(a)(2)(B) of the FD&C Act. Drugs and drug products that appear to be adulterated or misbranded may be detained or refused admission without physical examination. All drugs and drug products manufactured by your firm may remain listed on this import alert, until there is evidence establishing that the conditions that gave rise to the appearance of the violation have been resolved, and the Agency has confidence that future entries will be in compliance with the FD&C Act. This may include an inspection prior to the agency considering the appearance of adulteration to be addressed. If you decide you want to manufacture drugs for the United States in the future, request a Regulatory Meeting to discuss corrective actions. This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot do so within 15 working days, state your reasons for delay and your schedule for com-

pletion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov Identify your response with FEI 3016833130 and ATTN: Towanda Terrell. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research CC: Registered US Agent: Registrar Corp David Lennarz 144 Research Drive Hampton, VA 23666 Firm's External Attorney: Teresa Arellano Tere_Arellano8@hotmail.com _____1 Due to an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, FDA published the Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) on March 19, 2020, and subsequently updated the guidance several times, most recently on February 10, 2021. This guidance communicates the Agency's temporary policy that we do not intend to take action against firms for CGMP violations under section 501(a)(2)(B) of the FD&C Act if such firms prepare alcohol-based hand sanitizers for consumer use (or for use as health care personnel hand rubs) during the public health emergency, provided certain circumstances described in the guidance are present. These circumstances include preparation of hand sanitizer products using only the ingredients and formulas set forth in the guidance. In addition to the violative sample results detailed above that demonstrate the substitution of hand sanitizer products declared or labeled as manufactured at your facility, a review of the purported formulations on the drug products' labeling further indicates that these products are not prepared consistent with FDA's temporary policy set forth in the guidance. Therefore, these products do not fall within the Agency's temporary policy not to take action against firms manufacturing hand sanitizer products for violations of section 501(a)(2)(B) of the FD&C Act. 2 The 1994 TFM, which does not distinguish between antiseptic hand washes and rubs, proposed for antiseptic handwashes and healthcare personnel handwashes an alcohol concentration of 60 to 95% by volume in an aqueous solution: 59 FR at 31442. Later amendments to the 1994 TFM distinguished between antiseptic hand washes and rubs, and between consumer and healthcare personnel antiseptics, but did not change the alcohol concentration originally proposed in 1994. 3 See, e.g., Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) . Because Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. 4 An inactive ingredient used in over-the-counter (OTC) monograph drugs must meet the requirements of 21 CFR 330.1(e), which requires, among other things, that inactive ingredients must be safe in the amount administered. Content current as of: 06/08/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 1: Places for report 1091500

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	Mexico	Ciudad Nezahualcoyotl	19.40061	-99.01483

Table 2: Drugs for report 1091500

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: [...] SYP HEALTH HAND SANITIZER ALCOHOL GEL, labeled as manufactured at your facility, is labeled to contain 70% of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of SYP HEALTH HAND SANITIZER ALCOHOL GEL product detained at the border found that the product contained an average of 31% ethanol and an average of 2.3% methanol volume/volume (v/v). [...]

2 Sck Zeta Dis Ticaret, Pazarlama Ltd. - 610432 - 07/15/2021 - 2021-07-27

Publication date	2021-07-27
Create date	2021-08-02
Score	15.68
Report id	1154811
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Finished Pharmaceuticals/Unapproved New Drug/Misbranded/Adulterated

Click here to see the Original Article

Table 3: Places for report 1154811

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Western Asia	Turkey	İstanbul	41.01384	28.94966

Table 4: Drugs for report 1154811

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: [...] NEUTREVO Instant Hand Sanitizer, declared as being manufactured at your facility, is labeled to contain 70% volume/volume (v/v) of the active ingredient alcohol (ethanol). However, FDA laboratory testing of a batch of this product detained at the border found that the drug product contained on average 63% v/v ethanol and an average of 6% methanol v/v. Therefore, this hand sanitizer drug product is adulterated under section 501(d)(2) of the FD&C Act in that the active ingredient, ethanol, was substituted wholly or in part with methanol, a

dangerous chemical when in contact with human skin or ingested. [...]

3 Health Canada recalls nearly 20 more hand sanitzers

Publication date	2021-06-23
Create date	2021-06-25
Score	13.91
Report id	1111814
Category	Antiseptic
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Health Canada recalls nearly 20 more hand sanitzers insauga.com

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Table 5: Places for report 1111814

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Brampton	43.68341	-79.76633
Americas	Canada	Mississauga	43.5789	-79.6583

Table 6: Drugs for report 1111814

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: Hand saniters have become a necessity for residents of Mississauga and Brampton during the COVID-19 pandemic, but Health Canada has recalled another 18 disinfectants due to health risks. The federal agency on Wednesday listed a number of reasons for taking the products off of the market. Those include containing (or possibly containing) ingredients that are not permitted by Health Canada; defective or faulty packaging; undeclared impurities; improper labelling; a lack of sufficient product testing; being unauthorized for sale in Canada; and, being counterfeit. [...]

4 Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil - 614402 - 07/08/2021 - 2021-07-20

Publication date 2021-07-20

Create date 2021-09-01

Score 13.70

Report id 1146050

Category Antiseptic

Quality Diverted/Unregistered

Source Land point of entry

Curation Manually curated

Incident or General Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

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Table 7: Places for report 1146050

Region Name	Country	Location	Latitude	Longitude
Western Asia	Turkey	İstanbul	41.01384	28.94966

Table 8: Drugs for report 1146050

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: Your firm is registered as a human drug manufacturer. The U.S. Food and Drug Administration (FDA) conducted testing of a consumer antiseptic hand rub drug product (also referred to as a consumer hand sanitizer), labeled as (b)(4). This drug product was listed to be manufactured at your facility, Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil, FEI 3010166780, at N.12 Istanbul Endustri Ve Ticaret Serbest, Bolgesi Aydinli Sb Mahallesi, 6. Sokak, Tuzla, Istanbul. Following an attempt to import (b)(4) into the United States, it was detained and

refused admission at the border.

The results of the FDA laboratory testing of a batch of this product detained at the border demonstrate that this drug product listed to be manufactured at your facility is adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), 21 U.S.C. 351(c), in that its strength, purity, or quality falls below that which it purports or is represented to possess. In addition, this product is adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), in that the subpotency demonstrates that the quality assurance within your facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements.

Adulteration Violations

(b)(4), listed to be manufactured at your facility, is labeled to contain (b)(4)% volume/volume (v/v) of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of this product detained at the border found that the drug product contained an average of only 59% v/v ethanol. This hand sanitizer drug product is adulterated under section 501(c) of the FD&C Act in that the active ingredient of ethanol is present at levels in the product lower than that which is declared on its labeling.

5 FDA Finds More Faulty Hand Sanitizers - HAPPI

Publication date	2021-06-11
Create date	2021-06-15
Score	13.42
Report id	1095799
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA Finds More Faulty Hand Sanitizers - HAPPI happi.com

Click here to see the Original Article

Table 9: Places for report 1095799

Region Name	Country	Location	Latitude	Longitude
Americas	United States	California	37.25022	-119.75126

Notes: [...] On June 2, the CEO of PurePurge Inc., Rancho Dominguez, CA, was sent a letter related to its Medpure Hand Sanitizer product line after the agency reviewed its website on Feb. 11, 2021. Based on FDA's review, Medpure Hand Sanitizer are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). [...]

6 Hand Sanitizer Recalled Due to Microbial Contamination Concerns

Publication date	2021-06-09
Create date	2021-06-14
Score	12.84
Report id	1093504
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Hand Sanitizer Recalled Due to Microbial Contamination Concerns WebWire

Click here to see the Original Article

Table 10: Places for report 1093504

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Florida	28.75054	-82.5001

Notes: A company based in Florida recently announced the voluntary recall of 26 lots of antimicrobial hand sanitizers manufactured from February through June of last year. The product was packaged in multiple sizes and distributed to select retailers nationwide. The recall is due to microbial contamination concerns caused by Burkholderia cepacia complex and Ralstonia pickettii. [...]

7 Fake hand sanitisers come under scanner again

Publication date	2021-07-08
Create date	2021-07-13
Score	12.34
Report id	1130689
Category	Antiseptic, Medical devices for disease prevention
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake hand sanitisers come under scanner again The New Indian Express

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Table 11: Places for report 1130689

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Thiruvananthapuram	8.4855	76.94924
Southern Asia	India	Palakkad	10.77319	76.65366
Southern Asia	India	Ernakulam	10	76.5
Southern Asia	India	Thrissur	10.51667	76.21667
Southern Asia	India	Malappuram	11.04199	76.08154
Southern Asia	India	Alappuzha	9.49004	76.3264

Table 12: Drugs for report 1130689

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: (Cannot access)

8 37 caught for black marketing in essentials

Publication date 2021-06-03

Create date 2021-06-07

Score 11.90

Report id 1086685

Category Antiseptic, Medical device for screening/diagnosis/monitoring, Antiviral others, Medical device used for cure/mitigation/treatment

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: 37 caught for black marketing in essentials The Kathmandu Post

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Table 13: Places for report 1086685

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Nepal	Federal Democratic Republic of Nepal	28	84

Table 14: Drugs for report 1086685

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01
			J07
oxygen	Medical gases	all other therapeutic products	V03AN01

Notes: [...] In the last six weeks, a total of 37 persons were arrested from across the country for their alleged involvement in black marketing of oxygen, remedevisir, and oximeters, and producing fake hand sanitisers, according to the Nepal Police. [...]

9 Karnataka's drugs control department identifies 595 low-grade items, including 89 sanitisers

Publication date	2021-06-13
Create date	2021-06-17
Score	8.06
Report id	1097480
Category	Antiseptic
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Karnataka's drugs control department identifies 595 low-grade items, including 89 sanitisers Times of India

Click here to see the Original Article

Table 15: Places for report 1097480

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	India	22	79
Southern Asia	India	State of Karnataka	14.66667	75.83333

Notes: Since last year, Karnataka's drugs control department (DCD) has redflagged at least 595 substandard products, including 89 hand sanitisers, information accessed from the government shows. Officials confirmed the poor-quality sanitisers included those sold to government agencies, including hospitals and other establishments. [...]

10 Mum FDA lab finds 6 Rem samples in Maha spurious

Publication date	2021-07-28
Create date	2021-08-05
Score	8.06
Report id	1156719
Category	Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Mum FDA lab finds 6 Rem samples in Maha spurious Times of India

Click here to see the Original Article

Table 16: Places for report 1156719

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Nagpur	21.14631	79.08491
Southern Asia	India	Delhi	28.65195	77.23149

Table 17: Other Stories

ID	Title	Link
1159097	Samples of four Remdesivir brands fail in analytical test	Link

Notes: Even as the country prepares to face the projected third wave of Covid-19 pandemic, a government laboratory in Mumbai finding half a dozen samples of Remdesivir, used to treat critically ill Covid patients, spurious or substandard has sent the authorities in a tizzy. Not only the much sought after Remdesivir, but several samples of hand sanitizers, anti-bacterial hand rubs and other medicines used to treat Covid-19 patients have also been found spurious and substandard during sample testing this month. [...]

11 Covid: Arrest over manufacturing sanitiser without valid papers

Publication date	2021-06-15
Create date	2021-06-21
Score	7.37
Report id	1100774
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Covid: Arrest over manufacturing sanitiser without valid papers Telegraph India

Click here to see the Original Article

Table 18: Places for report 1100774

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	North 24 Parganas	22.71	88.7108

Notes: The manager of a Rajarhat unit that manufactures chemicals was arrested and 500 litres of liquid seized in a raid on Monday.

The Bidhannagar commissionerate raided the unit based on information that the factory was producing ”hand sanitiser” without valid papers. [...]

12 Fake sanitisers flood city

Publication date	2021-07-27
Create date	2021-08-02
Score	7.35
Report id	1155514
Category	Antiseptic
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake sanitisers flood city Pune Mirror

Click here to see the Original Article

Table 19: Places for report 1155514

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Pune	18.51957	73.85535

Notes: [...] Acting on a tip-off and complaint, Dinesh Khivansara, assistant commissioner of FDA (drug) and his team had conducted the raid at the premises of Atma Agencies in Chandan Nagar. Agency owner Prakash Atmaram Gurnani was found to be involved in manufacturing and marketing of various sanitisers — but upon detailed investigation it was found they are manufacturing sanitisers in the name of other companies by affixing labels he printed and selling spurious products under other brand names. Allegedly, Gurnani has been selling such products for the last five months in areas like Chandan Nagar, Vadgaonsheri, Kharadi, Hadapsar, Viman Nagar, Wagholi, Yerwada and more. [...]

13 CDSCO flags 22 drugs as not of standard quality - 2021-06-06

Publication date	2021-06-06
Create date	2021-06-04
Score	4.92
Report id	1083074
Category	Antiseptic, Antidiabetic, Antiepileptic, Analgesic, Other, Antipyretic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: New Delhi: In its latest drug safety alert, the apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) has flagged 22 samples including drugs and a medical device as Not of Standard Quality for failing to qualify for a random sample test for the month of April-2021.These drugs samples which are declared Not of Standard Quality include Aksum's PANTOWEL-40, Synokem's L-CETAM 500, Unimark Healthcare's MISOPROSTOL Tablets I.P. 200 mcg, Bharat Parenteral's OLANZAPINE Tablets I.P. 5 mg. In addition, other popular drug samples that are declared Not of Standard Quality include Paracetamol Tablets IP 650 manufactured by Sotac Pharmaceuticals, GLUCORID (Metformin Hydrochloride Sustained-Release Tablets I.P. 500 mg) manufactured by Ridley Life Science, ZINC SULPHATE DISPERSIBLE TABLETS IP 20 mg manufactured by Hindustan Laboratories and others.Apart from drugs, a medical device manufactured by Ramaraju Surgical Cotton Mills, an instant sterile mopping pad (Absorbent Gauze-BP Type 13 with X-Ray Detectable Thread) has been declared non-standard quality.Also Read: Drug Alert: CDSCO Flags 19 formulations As Not Of Standard QualityThis came after analysis and tests were conducted by the CDSCO, Drugs Control Departments on 931 samples. Out of this, 908 samples were found of standard quality while 22 (legal) +1 (survey) of them were declared as Not of Standard Quality (NSQ).A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of the Vitamin D3 assay, failure of Serratiopeptidase assay.The samples collected were tested in four laboratories, namely CDL Kolkata, CDTL Mumbai, RDTL Chandigarh and RDTL Guwahati.List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of April -2021 Total number of samples tested 931 Total number of samples declared as of Standard Quality 908 Total number of samples declared as Not of Standard Quality 22(Legal)+01(Survey) Total number of samples declared as Spurious 0 Total number of samples declared as Misbranded 0 S.No. Name of Drugs/medical device/cosmetic s Batch No./Date of Manufacture/Date of Expiry/Manufactured By Reason for failure Drawn By From 1. INSTANT STERILE MOPPING PAD (Absorbent Gauze- BP Type 13 with X-Ray Detectable Thread) B. No.:1017/20 Mfg dt: 03/2020 Exp dt: 02/2023 Mfd by: M/s.The Ramaraju Surgical Cotton Mills Ltd., 2/318 - 2/321, Sankarankovil Road, Perumalpatti - 627 753 Tamil Nadu. Threads per stated length CDSCO, South Zone, Chennai CDL, Kolkata 2. RUTIN (RutosideTrihydra te 95%)

(as per F.M) B. No.:20181126 (as per F.M) Mfg dt: 11/2018 (as per F.M) Exp dt: 11/2021 (as per F.M) Mfd by: M/s.Ningbo Hi- Tech Biochemicals Co., Ltd, China (as per F.M). Water, Related Substances and Assay CDSCO, Sub Zone Baddi CDL, Kolkata 3. REALHIM-10 (Tadalafil Tablets I.P. 10 mg) B. No.:LC9L225 Mfg dt: 12/2019 Exp dt: 11/2021 Mfd by: M/s.LifecareNeuro Products Limited, 70/1, Dharampur, Nr. EPIP Phase-II, Baddi-173 205, Himachal Pradesh. Dissolution CDSCO, East Zone, Kolkata CDL, Kolkata 4. SPINOBAK-10 (Baclofen Tablets I.P. 10 mg) B. No.:K3ALT001 Mfg dt: 06/2020 Exp dt: 05/2022 Mfd by: M/s. Sirmour Remedies (P) Ltd., Village - Layarda, P.O. Assay CDSCO, East Zone, Kolkata CDL, Kolkata Missarwala, Paonta Sahib, Distt . Sirmour (HP) -173 205. 5. PANTOWEL - 40 (Pantoprazole Sodium Tablets B. No.:OBYA01 Mfg dt: 02/2020 Exp dt: 07/2022 Mfd by: M/s. Akums Drugs & Pharmaceuticals Ltd., 19, 20, 21 Sector-6A, I.I.E, SIDCUL, Ranipur, Haridwar-249403 Uttarakhand. Dissolution CDSCO East Zone Kolkata CDL, Kolkata I.P. 40 mg) 6. L-CETAM 500 (Levetiracetam Tablets I.P. 500 mg) B. No.:20S1GTA508 Mfg dt: 11/2020 Exp dt: 10/2022 Mfd by: M/s.Synokem Pharmaceuticals Ltd., Plot No: 35-36, Sector-6A, I.I.E. (SIDCUL). Ranipur (BHEL), Haridwar -249403 Uttarakhand. Dissolution CDSCO East Zone Kolkata CDL, Kolkata 7. MISOPROSTOL Tablets I.P. 200 mcg B....

Click here to see the Original Article

Table 20: Drugs for report 1083074

Medicine Name	Medicine Class	Action	ATC Code
olanzapine	Diazepines, oxazepines, thiazepines and oxepines	antipsychotics	N05AH03
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02
	Zinc	other mineral supplements	A12CB
	Antiseptics	throat preparations	R02AA
levetiracetam	Other antiepileptics	antiepileptics	N03AX14
pantoprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC02
misoprostol	Prostaglandins	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BB01
misoprostol	Prostaglandins	uterotonics	G02AD06
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 21: Other Stories

ID	Title	Link
1084554	CDSCO flags 22 drugs as not of standard quality	Link

Table 21: Other Stories(continued)

ID	Title	Link
1124284	22 drug samples including Sun Pharma Rosuvas fail to qualify CDSCO test - 2021-07-04	Link

Notes: In its latest drug safety alert, the apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) has flagged 22 samples including drugs and a medical device as Not of Standard Quality for failing to qualify for a random sample test for the month of April-2021. [...]

Annexe D

D.5. Médicaments COVID-19

Medicine Quality Monitoring Globe

September 16, 2021

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Filters applied for this report

Search ((”tranilast” OR ”interleukin-2” OR ”INC424” OR ”TNKase” OR ”nitazoxanide” OR ”LY3832479” OR ”baloxavir” OR ”interleukin-7” OR ”Kineret” OR ”ritonavir” OR ”Crizanlizumab” OR ”Apixaban” OR ”cyclosporin” OR ”losartan” OR ”ATI-450” OR ”nitrogen monoxide” OR ”tirofiban” OR ”Ebselen” OR ”corbistadine” OR ”atorvastatin” OR ”Eicosapentaenoic” OR ”nitrite” OR ”Riamilovir” OR ”black cumin” OR ”NK-1R” OR ”Pemziviptadil” OR ”colchicine” OR ”Lithium” OR ”Vancomycin” OR ”Broncho-Vaxom” OR ”ramipril” OR ”Teicoplanin” OR ”tofacitinib” OR ”budesonide” OR ”Paracetamol” OR ”dipyridamole” OR ”levamisole” OR ”atovaquone” OR ”Senicapoc” OR ”covid drug” OR ”enoxaparin” OR ”Brequinar” OR ”povidone-iodine” OR ”levilimab” OR ”degarelix” OR ”LY3819253” OR ”Sofusbovir” OR ”masitinib” OR ”Omega-3” OR ”INM005” OR ”RBT-9” OR ”deferoxamine” OR ”canakinumab” OR ”Ramelteon” OR ”chlorpromazine” OR ”selinexor” OR ”Piclidenoson” OR ”DAS181” OR ”M5049” OR ”Ibudilast” OR ”CM4620-IE” OR ”GNS561” OR ”zanubrutinib” OR ”Cenicriviroc” OR ”sofosbovir” OR ”Trimethoprim” OR ”vadadustat” OR ”AVM0703” OR ”Rabeprazole” OR ”Moxifloxacin” OR ”cobicistat” OR ”BAT2020” OR ”ABX464” OR ”XAV-19” OR ”thalidomide” OR ”bamlanivimab” OR ”GX-19” OR ”corticosteroid”

OR "Tradipitant" OR "cotrimoxazole" OR "HuMax-Inflam" OR "Apilimod" OR "DUR-928" OR "escin" OR "PF-06650833" OR "octagam" OR "Antroquinonol" OR "pacritinib" OR "Imatinib" OR "ribavirin" OR "ambrisentan" OR "baricitinib" OR "imatinib" OR "CD24Fc" OR "Sulodexide" OR "AlloStim" OR "DFV890" OR "Emapalumab" OR "sitagliptin" OR "Metformin" OR "prednisone" OR "ulinastatin" OR "naltrexone" OR "abidor" OR "niclosamide" OR "BIO101" OR "GS-441524" OR "argatroban" OR "Leukine" OR "xiyanping" OR "peginterferon" OR "pembrolizumab" OR "HuMax" OR "Lambda" OR "dornase" OR "Itraconazole" OR "telemedicine" OR "Adenosine" OR "Curosurf" OR "clarithromycin" OR "bromhexine" OR "Xpovio" OR "ebastine" OR "amoxicillin/clavulanate" OR "PD-1 mAb" OR "EPA" OR "oseltamivir" OR "Betamethasone" OR "favipiravir" OR "mefloquine" OR "bismuth" OR "CM4620" OR "ifenprodil" OR "Levofloxacin" OR "REGN10987" OR "Candesartan" OR "secukinumab" OR "Trihexyphenidyl" OR "Daclatasvir" OR "pinavir" OR "tocilizumab" OR "co-amoxiclav" OR "EG-HPCP-03a" OR "hydroxychloroquine" OR "Polyoxidonium" OR "STI-5656" OR "Artesunate" OR "triazavirine" OR "Disulfiram" OR "cholecalciferol" OR "INO-4800" OR "PG1" OR "zinc" OR "oxytocin" OR "gimsilumab" OR "suramin" OR "rhG-CSF" OR "desferoxamine" OR "TD-0903" OR "OM-85" OR "Bucillamine" OR "pirfenidone" OR "Acetaminophen" OR "adamumab" OR "sulfamethoxazole" OR "BI 764198" OR "RPH-104" OR "COVID-19 drug" OR "alpha lipoic" OR "almitrine" OR "melphalan" OR "dapagliflozin" OR "NBT-NM108" OR "TMJ2" OR "Icosapent" OR "Ceftriaxone" OR "isoprinosine" OR "IMU-838" OR "tridecactide" OR "chloroquine" OR "CSL324" OR "Lian Hua Qing Weng" OR "Kevzara" OR "valsartan" OR "meplazumab" OR "Namilumab" OR "Prednisolone" OR "sargramostim" OR "estradiol" OR "cyclosporine" OR "Aprepitant" OR "silymarin" OR "linagliptin" OR "Noscapine" OR "Gemtuzumab" OR "methylprednisolone" OR "fluvoxamine" OR "Coroquard" OR "mavrilimumab" OR "anakinra" OR "ozanimod" OR "mepolizumab" OR "acetylsalicylic" OR "darunavir" OR "novaferon" OR "YinHu QingWen" OR "OM85" OR "camrelizumab" OR "Cosentyx" OR "estrogen" OR "dexmedetomidine" OR "LL-37" OR "Dantonic" OR "rivaroxaban" OR "adalimumab" OR "apremilast" OR "polyinosinic-polycytidylic" OR "farpiravir" OR "montelukast" OR "Ibuprofen" OR "IFX-1" OR "Iodine" OR "Molnupiravir" OR "Pioglitazone" OR "verapamil" OR "Rapamycin" OR "Brexanolone" OR "Eltrombopag" OR "ravulizumab" OR "hydrocortisone" OR "auxora" OR "tinzaparin" OR "Vascepa" OR "omalizumab" OR "Tybost" OR "Actemra" OR "dociparastat" OR "NA-831" OR "ascorbic acid" OR "MAS825" OR "C21" OR "RoActemra" OR "eculizumab" OR "Bivalirudin" OR "povidon-iodine" OR "ivermectin" OR "Pamrevlumab" OR "danoprevir" OR "Neurokinin" OR "sirolimus" OR "Fostamatinib" OR "resveratrol" OR "Icatibant" OR "bromelain" OR "dexamethasone" OR "TJ003234" OR "iloprost" OR "tacrolimus" OR "astegolimab" OR "interferon" OR "plitidepsin" OR "metenkefalin" OR "azoximer" OR "lopinavir" OR "Tazobactam" OR "carrimycin" OR "CM-4620" OR "CYT107" OR "Heparin" OR "Pyronaridine-Artesunate" OR "Itolizumab" OR "zilucoplan" OR "oxpentifylline" OR "AT-001" OR "Abivertinib" OR "doxycycline" OR "Nigella Sativa" OR "AZD1222" OR "leronlimab" OR "Enalapril" OR "nangibotide" OR "Piperacillin" OR "bevacizumab" OR "lactoferrin" OR "UTTR1147A" OR "Caesalpinia spinosa" OR "mometasone" OR "hydroxychloroquin" OR "Febuxostat" OR "lanadelumab" OR "Thymalfasin" OR "huaier extract" OR "Levoflozacin" OR "Pentoxifylline" OR "tozumab" OR "NP-120" OR "Alvelestat" OR "captopril" OR "merimepodib" OR "Iota-Carrageenan" OR "Lianhua Qingwen" OR "GLS-1200" OR "aescinate" OR "tranexamic" OR "Ledipasvir" OR "ISIS 721744" OR "procalcitonin" OR "SNDX-6352" OR "sirukumab" OR "Enzalutamide" OR "carriomycin" OR "amphotericin" OR "bemiparin" OR "T89" OR "Spironolactone" OR "fin-

golimod" OR "aspirin" OR "Remdesivir" OR "TJM2" OR "pyridostigmine" OR "Prolastin" OR "EC-18" OR "poractant" OR "isotretinoin" OR "telmisartan" OR "lenzilumab" OR "avdoralimab" OR "duvelisib" OR "BIO 300" OR "bicalutamide" OR "Ilaris" OR "atlizumab" OR "desferrioxamine" OR "LB1148" OR "vitamin D3" OR "Clopidogrel" OR "CD24" OR "tetrandrine" OR "Lansoprazole" OR "Ruconest" OR "amoxicillin" OR "Trifluoperazine" OR "Ganovo" OR "nitric Oxide" OR "chlorine dioxide" OR "olokizumab" OR "lucinactant" OR "galidesivir" OR "TXA127" OR "Maraviroc" OR "conestat" OR "CA S001" OR "vazegepant" OR "REGN10933" OR "Propranolol" OR "Viagra" OR "Fisetin" OR "Previfenon" OR "omega 3" OR "thymosin" OR "Prasugrel" OR "retinoic acid" OR "Ceftaroline" OR "sevoflurane" OR "amoxicillin/clavulanic acid" OR "oestrogen" OR "leflunomide" OR "virazole" OR "PLN-74809" OR "ATYR1923" OR "Olumiant" OR "dalargin" OR "Alinia" OR "methotrexate" OR "dapansutrile" OR "artemisinin" OR "ibrutinib" OR "aescin" OR "CERC-002" OR "fludase" OR "isoflurane" OR "XPro1595" OR "LY-CoV555" OR "CAS0001" OR "immunoglobulin" OR "nafamostat" OR "Crocetinate" OR "Diphenhydramine" OR "BIO 101" OR "AZD1656" OR "PTC299" OR "amodiaquine" OR "casirivimab" OR "BGB-DXP593" OR "opaganib" OR "melatonin" OR "huaier granule" OR "HuMax-IL8" OR "famotidine" OR "GLS-1027" OR "Trimodulin" OR "tenofovir" OR "Primaquine" OR "AMY-101" OR "covid medicine" OR "umifenovir" OR "EDP1815" OR "Vitamin B12" OR "Gamunex-C" OR "Bardoxolone" OR "AstroStem-V" OR "LAU-7b" OR "Vitamin E" OR "Vitamin B" OR "RTB101" OR "COVID-19 medicine" OR "curcumin" OR "fondaparinux" OR "Edoxaban" OR "L-Citrulline" OR "ciclesonide" OR "azithromycin" OR "remdesivir" OR "Diltiazem" OR "Methylene blue" OR "clazakizumab" OR "BCX4430" OR "Pyronaridine" OR "Quercetin" OR "Toremifene" OR "COVI-AMG" OR "etoposide" OR "DWJ1248" OR "defibrotide" OR "AT-527" OR "prazosin" OR "triazavirin" OR "BIO300" OR "Ensifentrine" OR "coronavirus medicine" OR "Anti-IL-8" OR "dihydroartemisinin" OR "vitamin c" OR "25-hydroxyvitamin D3" OR "coronavirus drug" OR "formoterol" OR "indomethacin" OR "Rayaldee" OR "ciclosporin" OR "naproxen" OR "fluoxetine" OR "Infliximab" OR "Tenecteplase" OR "ruxolitinib" OR "Molgramostim" OR "vitamin D" OR "simvastatin" OR "alteplase" OR "sildenafil" OR "isoquercetin" OR "GC4419" OR "ketamine" OR "Razuprotafib" OR "camostat" OR "Arbidol" OR "Montmorrillonite" OR "acalabrutinib" OR "nivolumab" OR "aviptadil" OR "PUL-042" OR "diammonium" OR "Clevudine" OR "nitrogen oxide" OR "BMS-986253" OR "siltuximab" OR "interleukin 2" OR "jakotinib" OR "nintedanib" OR "Axatilimab" OR "garadacimab" OR "Treamid" OR "ASC09" OR "emtricitabine" OR "LY-CoV016" OR "Pulmozyme" OR "Prostaglandin" OR "ciclosporine" OR "hydrogen peroxide" OR "sarilumab" OR "Losmapimod" OR "azvudine" OR "BLD-2660" OR "EIDD-2801" OR "MSTT1041A" OR "Desidustat" OR "abidole" OR "omeprazole" OR "progesterone" OR "Decitabine" OR "tocopherol" OR "berberine" OR "APL-9" OR "colomycin" OR "XC221" OR "amiodarone" OR "lenalidomide" OR "imdevimab" OR "ixekizumab" OR "VentaProst" OR "acetylcysteine" OR "LY3127804" OR "Atazanavir" OR "TL-895" OR "dalteparin" OR "Thimerosal" OR "Xue-Bi-Jing" OR "GC376" OR "Angiotensin" OR "gs-441542" OR "Risankizumab" OR "co-trimoxazole") OR (("Medicine" OR "Plasma" OR "Treatment" OR "Medication" OR "Monoclonal antibodies" OR "Antibody therapy" OR "Antibody cocktail") AND ("COVID-19" OR "COVID" OR "SARS-CoV-2" OR "Coronavirus" OR "CV19" OR "CV-19" OR "SARS" OR "CoV-2")))

Start date	2021-06-01
End date	2021-07-31

Language	en
Report type	incident
Curation status	validated
Number of Reports	60

1 Rising problem: Viagra and other ED drugs disguised as vitamin C, bromelain supplements to enter South Korea

Publication date	2021-07-27
Create date	2021-08-02
Score	50.97
Report id	1155471
Category	Vaccine, Nutritional supplement
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Rising problem: Viagra and other ED drugs disguised as vitamin C, bromelain supplements to enter South Korea FoodNavigator-Asia.com

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Table 1: Drugs for report 1155471

Medicine Name	Medicine Class	Action	ATC Code
ascorbic acid	Organic acids	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AD03
ascorbic acid	Other ophthalmologicals	other ophthalmologicals	S01XA15

Notes: [...] Out of the 2,133 products inspected, 31.9 per cent of them (681 products which were equivalent to 1,860 bottles/units) were found to contain pharmaceutical ingredients or other substances illegal for use in dietary supplements. [...] In one particular case, the product Kamagra oral jelly was reported as vitamin C when test results showed that it contained sildenafil, a drug for ED treatment, and dapoxetin, a medicine for premature ejaculation. [...]

2 Innova Medical Group, Inc. - Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-06-10

Publication date	2021-06-10
Create date	2021-06-15
Score	46.21
Report id	1094616
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Innova Medical Group, Inc. MARCS-CMS 614819 — June 10, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA Electronic Mail Product: Medical Devices Recipient: Recipient Name Daniel J. Elliot Recipient Title Chief Executive Officer Innova Medical Group, Inc. 800 E. Colorado Blvd., Suite 288 Pasadena , CA 91101 United States Daniel.elliott@innovamedgroup.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER CMS # 614819 June 10, 2021 Dear Mr. Elliot: The United States Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations, Innova Medical Group, Inc., located at 800 E. Colorado Blvd., Suite 288, Pasadena, CA from March 15 through April 9, 2021. In addition, your other manufacturing facilities at 495 N. Berry Street, Brea, CA, and MPS Medical, Inc. at 785 Challenger Street, Brea, CA, were also inspected from March 15 through April 8, 2021. During these inspections, the FDA investigators determined that your firm is a medical device manufacturer and initial distributor/importer of the SARS-CoV-2 Antigen Rapid Qualitative Test (also distributed under the names INNOVA COVID-19 Self-Test Kit (3T Configuration), INNOVA SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and INNOVA SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration)). Based on our review, your SARS-CoV-2 Antigen Rapid Qualitative Test is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, it is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). Our inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test has been distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or

delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described herein, you have distributed a product that is intended for use in mitigation, prevention, treatment, diagnosis, or cure COVID-19 in people. We request that you take immediate action to cease the sale and distribution of such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 4 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. Our inspections also revealed that the 25T Configuration and 7T Configuration of the SARS-CoV-2 Antigen Rapid Qualitative Test are misbranded within the meaning of section 502(a) of the Act, 21 U.S.C. § 352(a), in that the devices' respective labeling was false or misleading. More specifically, the labeling distributed for your 25T Configuration devices included a "Clinical Performance" section, which claimed a Relative Sensitivity of 96% (88.75-99.17% CI); a Relative Specificity of 100% (98.34-100% CI); and an Accuracy of 98.98% (97.06-99.79% CI). This level of clinical performance for the 25T Configuration devices appears unsupported by any clinical data including both clinical performance data submitted to FDA in your Emergency Use Authorization (EUA) request for the SARS-CoV-2 Antigen Rapid Qualitative Test and in published reports of clinical studies of the SARS-CoV-2 Antigen Rapid Qualitative Test. 5 Similarly, the labeling distributed for your 7T Configuration devices included a "Performance of Prospective Clinical Study" section based on a prospective clinical study conducted by "third-party investigators in UK in September and October 2020" which claimed a Positive Percent Agreement of 81.4% (74.3-88.4% CI). This PPA for the 7T Configuration devices does not appear to align with the PPA observed in the phase 3b prospective clinical study conducted in the United Kingdom. 6 Accordingly, the clinical performance estimates reported in the labeling of the 25T Configuration and 7T Configurations devices are false or misleading as they do not accurately reflect the performance estimates observed during the clinical studies of your devices. Separate and apart from the foregoing issues, FDA further notes that the clinical study data you submitted in your EUA request for the SARS-CoV-2 Antigen Rapid Qualitative Test was identical to data previously provided by other manufacturers in their separate EUA requests. The data reliability and accuracy issues noted herein raise significant concerns that the performance of the SARS-CoV-2 Antigen Rapid Qualitative Test has not been adequately established, and that the products distributed by Innova without FDA approval, clearance, or authorization could present a serious risk to the public health. The inspections also revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test is adulterated with the meaning of sec-

tion 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, is manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received your response dated April 30, 2021, from Eric Grubel, Chief Operating Officer, and the following update dated May 28, 2021, from Janet L. Michener Whipple, Interim Vice President of Quality, which responded to the Form FDA 483, List of Inspectional Observations issued to your firm on April 9, 2021. We address your responses below. These violations include, but are not limited to, the following: 1. Failure to establish procedures for control and distribution of finished devices, as required by 21 CFR § 820.160(a). Specifically, your firm has not established and maintained procedures for the control and distribution of your SARS-CoV-2 Antigen Rapid Qualitative Test system to ensure only devices approved for release are distributed, and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. For example: Our investigators observed your firm has executed contractual agreements with at least (b)(4) distributors for the commercial promotion and sale of the SARS-CoV-2 Antigen Rapid Qualitative Tests in the United States and has distributed more than (b)(4) test kits to US customers. According to your firm, these Tests have been shipped to several customers to Indiana, New York, Vermont, and Oregon during January and February of 2021. No records were maintained to demonstrate that these devices were approved for release. We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge you have opened CAPA #2021-002 and created new standard operating procedures to address Purchase Management and Control and Distribution of your products, in addition to completing personnel training on the new procedures and processes. You did not provide evidence of implementation of your new SOPs, or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 2. Failure to establish procedures for acceptance activities, as required by 21 CFR § 820.80(a). Specifically, your firm has not established procedures for incoming product and finished device acceptance activities. There are no acceptance records of your SARS-CoV-2 Antigen Rapid Qualitative Test system to ensure that specified requirements for your devices are met and meets the acceptance criteria. For example, Your firm distributed SARS-CoV-2 Antigen Rapid Qualitative Tests. These test kits were not inspected, tested, or otherwise verified after receiving it from your contract manufacturer in China or prior to shipment to the end users. Consequently, the 7T and 3T boxes were shipped to customers with the incorrect Instructions for Use (IFU). We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge you opened CAPA #2021-003 and created a new acceptance activity work instruction for incoming and finished devices, and completed personnel training on the new procedures and work instructions. You did not provide evidence of implementation of your new work instruction and evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. We also acknowledge that your firm initiated a voluntary recall of certain lots of 3T and 7T test kits distributed for non-investigational use only. It is unclear how you plan to address incorrectly labeled products distributed for investigational use. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 3. Failure to establish procedures to control product that does not conform to specified requirements, as required by 21 CFR § 820.90(a). Specifically, your firm has not established and maintained procedures to ensure that nonconforming product is identified, documented, evaluated, segregated, and dispositioned. During the inspection, the investigators observed 13 cartons of SARS-CoV-2 Antigen Rapid Qualitative Tests co-mingled in a storage room with multiple cartons of returned nonconforming test kits, samples used for product evaluation, and

damaged controls, all of which was slated for destruction. The 13 cartons of test kits were not identified as nonconforming and no records were maintained to demonstrate if an investigation was needed or the disposition of nonconforming products. We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge that you opened CAPA #2021-004, and created an SOP 9.0, Control of Nonconformances, and completed personnel training on the new procedures. You did not provide adequate evidence of implementation of your new procedure or evidence demonstrating the CAPA is effective in preventing the noted violations from recurring. For example, in your May 28 response you provided the Nonconforming Incident Report, NCR #2021-002, for (b)(4) tests that were destroyed during the inspection. According to your incident report, an investigation to determine the root cause of the nonconforming product was not required because the "root cause is known as identified during FDA inspection" while your SOP 9.0 requires all product nonconformances to be investigated unless otherwise justified and documented. It is not clear how an FDA inspection justifies not investigating the root cause of the (b)(4) nonconforming tests. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 4. Failure to establish procedures for corrective and preventative action, as required by 21 CFR § 820.100(a). Specifically, Your firm has not established procedures for implementing and documenting corrective and preventive action, including requirements for: analyzing quality data sources; investigating the cause of nonconformities; identifying the action(s) needed to correct and prevent occurrence or recurrence of nonconformities; verifying or validating the CAPA to ensure the actions implemented are effective; documenting the changes in methods and procedures; disseminating information related to quality problems to appropriate individuals; and submitting relevant information on quality problems for management review. We reviewed your firm's response and conclude the adequacy cannot be determined at this time. We acknowledge your firm has created SOP 10.0, Corrective and Preventive Action, and opened CAPA #2021-001 in accordance with your new procedure, and completed training personnel on the new procedures. However, you did not provide evidence of the effectiveness of your new CAPA procedure as the corrective actions remain in progress, and therefore we are unable to fully assess the adequacy of your response. 5. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR § 820.198(a). Specifically, your firm has not established procedures for complaint handling to ensure that complaints are processed in a uniform and timely manner, oral complaints are documented upon receipt, and complaints are evaluated to determine if the reported event is required to be submitted to the FDA as a Medical Device Report. We reviewed your firm's response and conclude the adequacy cannot be determined at this time. We acknowledge that you opened CAPA #2021-006 and created SOP 14.0, Complaint Handling and Failure Investigation, and completed personnel training on the new procedures. However, your response does not indicate whether your firm will conduct a retrospective review of any complaints your firm previously received. While your response states your firm "has not received any complaints regarding its SARVS-CoV-2 Antigen Rapid Qualitative Test", our investigators noted your storage room was holding damaged product returned from your customers, which appears to fall under section 5.6 of your new complaint procedure. You did not provide evidence of implementation of your new procedure or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. 6. Failure to establish procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR § 820.50. Specifically, your firm has not established procedures for the evaluation of suppliers, including the quality requirements that must be met by suppliers, to ensure that received products and services conform to specified requirements. You did not evaluate your

only contract manufacturer of the SARS-CoV-2 Antigen Rapid Qualitative Test system based on their ability to meet specified requirements, including quality requirements. We reviewed your firm's response and conclude that the adequacy cannot be determined at this time. We acknowledge your firm opened CAPA #2021-005 and created new standard operating procedures for purchase management and supplier controls, and completed personnel training on the new procedures. You did not provide evidence of the implementation of your new SOPs, or evidence demonstrating that your CAPA is effective in preventing noted violations from recurring. As your corrective actions remain in progress, we are unable to fully assess the adequacy of your response. Our inspection also revealed that your SARS-CoV-2 Antigen Rapid Qualitative Test is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 – Medical Device Reporting. Violation include, but is not limited to: 7. Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17. Specifically, your firm has not established procedures for timely and effective identification, communication, and evaluation of reportable events; a standardized review process for determining when an event meets reportability criteria; timely submission of MDRs to the FDA; or for compliance with the applicable documentation and recordkeeping requirements. We reviewed your firm's response and conclude that your firm's response dated April 30, 2021 is not adequate. In the response, your firm noted that it developed a written MDR procedure, scheduled staff training and planned to assess the effectiveness of corrective actions by July 1. Your response included a copy of your firm's MDR procedure titled "Medical Device Reporting (MDR and eMDR)", Document Number: 7.0, Revision 1.0, Effective Date: 4/29/2021. After reviewing your firm's MDR procedure, we noted that the procedure does not reference a process for identifying and evaluating events involving similar devices to those marketed in the United States (U.S.) as potentially reportable to FDA. Specifically, the procedure notes under the Scope section that it "applies to devices marketed in the United States". If an event involves a similar device to one legally marketed in the U.S., it may be reportable under the MDR regulation. By not considering events involving similar legally marketed devices, potentially reportable MDRs may not be identified and evaluated for MDR decision making and submission to FDA as required by 21 CFR 803.50 and 21 CFR 803.53. Additionally, your firm did not provide documentation or evidence of implementation of a systematic corrective action to include a retrospective review of its adverse events in accordance with its MDR procedure. Your firm should take prompt action to address the violations cited in this letter. Also, federal agencies may be advised of the issuance of Warning Letters about devices and may take your compliance with Act and its implementing regulations into account when considering the award of contracts. Additionally, should FDA determine that you have Quality System regulation violations that are reasonably related to premarket approval applications for Class III devices such devices will not be approved until the violations have been corrected. Also, should FDA determine that your devices do not meet the requirements of the Act, requests for Certificates to Foreign Governments (CFG) may not be granted. More information on processes for persons denied a CFG can be found at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices . Note, there are two response time frames specified. You should take immediate action to address the violations relating to your firm's sale or distribution of the SARS-CoV-2 Antigen Rapid Qualitative Test. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the prod-

ucts in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulentcoronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. Please also notify FDA in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted Quality Systems and MDR reporting violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter. This response should be sent to: US Food and Drug Administration, Division 3/West, Office of Medical Device and Radiological Health Operations at oradevices3firmresponse@fda.hhs.gov. Please identify your response with CMS Case #614819. If you have questions about the contents of this letter, please contact Compliance Officers, Charles J. Chacko at 214-253-4939, or via email at charles.chacko@fda.hhs.gov or Jamie M. Bumpas at 214-253-5336, or via email at Jamie.bumpas@fda.hhs.gov. Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, please provide us with your reasoning and any supporting information for our consideration. It is your firm's responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. Failure to adequately address any violations may result in legal action, including without limitation, seizure and injunction. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of any violations and take prompt actions to correct the violations and bring your products into compliance. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health /S/ Shari J. Shambaugh Program Division Director Office of Medical Device and Radiological Health Division 3 Cc: Mr. Eric E. Grubel, COO 800 E. Colorado Blvd., Suite 288 Pasadena, CA 91101 Eric.grubel@innovamedgroup.com _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public

Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 Accessible at https://www.fda.gov/media/135659/download . 5 See "Preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: Rapid evaluation of Lateral Flow Viral Antigen detection devices (LFDs) for mass community testing:" published November 8, 2020 available at https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20Unive 6 Id. Content current as of: 06/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 2: Places for report 1094616

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pasadena	34.14778	-118.14452

Table 3: Other Stories

ID	Title	Link
1094824	FDA accuses firm of distributing an unapproved Covid-19 test - STAT	Link
1094830	FDA accuses firm of distributing an unapproved Covid-19 test – Boston, Massachusetts	Link
1095770	Unapproved Covid Test Kits Recalled By FDA	Link
1095961	US FDA urges users to throw Innova rapid Covid test in trash, or return it to company	Link

Notes: [...]Our inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test has been distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the product is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The product is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. [...]

3 USH Diagnostics, Inc./covidinstanttest.net - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - Missouri - 2021-07-09

Publication date	2021-07-09
Create date	2021-09-08
Score	37.05
Report id	1207459
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER USH Diagnostics, Inc./covidinstanttest.net MARCS-CMS 612084 — July 09, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Mr. Chris Ormiston USH Diagnostics, Inc./covidinstanttest.net 3456 E. 155th St. Kansas City , MO 64147 United States co@ushealthdiagnostics.com cormiston@ushealthdiagnostics.com support@covidinstanttest.net Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 9, 2021 TO: covidinstanttest.net 205 E. Osborn Rd. Phoenix, AZ 85012 support@ushealthdiagnostics.com support@americanmedicalsuppliers.com RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at the Internet addresses https://covidinstanttest.net and https://ushealthdiagnostics.com/ on March 30, 2021, and April 9, 2021. We also reviewed your social media websites at https://facebook.com/covid19instanttest, https://twitter.com/covidathometest, and https://www.instagram.com/covid19instanttest, where you direct consumers to your website, https://covidinstanttest.net, to purchase your products. The FDA has observed that your websites https://covidinstanttest.net and https://ushealthdiagnostics.com/ offer for sale a ”Rapid Dual Antibody Test” (which your website also refers to as the ”COVID-19 Instant Test,” ”Dual Antibody Rapid Test,” ”COVID-19 Dual Antibody Test,” ”Rapid 15 Minute Antibody,” ”Dual IgG/IgM Screening Test for COVID-19,” ”15-Minute COVID-19 Screening Test,” ”COVID-19 IgM/IgG Rapid Test Device,” ”COVID-19 Antibody Test Kit,” and ”Dual Antibody Test”) (hereafter referred to as the ”COVID-19 Antibody Test Kit”), a ”Rapid 10 Minute Antigen Test” (which your website also refers to as the ”Antigen Rapid Test,” ”COVID-19 Antigen Test Kit,” ”Access Bio COVID-19 Antigen Test,” and ”COVID-19 Instant Antigen Test”) (hereafter referred to as the ”COVID-19 Rapid Antigen Test”), and a ”Saliva Test Kit” (all hereafter referred to as ”COVID-19 Test Kits”) in the United States. Based on our review, the COVID-19 Test Kits are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, they are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the ”Act”), 21 U.S.C. § 321(h). The COVID-19 Test Kits are offered for sale in the United States to consumers for at-home testing without marketing approval,

clearance, or authorization from FDA. 2,3 Accordingly, your products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). Your products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 4 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. 5 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sell products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. We also note that different and potentially serious public health risks are presented with specimen collection and testing in the home versus using a test in a healthcare setting. Risks may include, but are not limited to, whether a lay person has the ability to collect their specimen, run the test, and interpret the test result accurately. Your websites, https://covidinstanttest.net and https://ushealthdiagnostics.com/, as well as social media websites, indicate that your firm's COVID-19 Test Kits may be purchased by consumers and are intended to be used for at-home testing for COVID-19, including: • "THE MOST RAPID COVID-19 TESTS ON THE INTERNET. PERIOD… The Fastest Home Tests on the Market Receive Your Test Next Day, Results Available in Minutes!" [https://covidinstanttest.net/] • "COVID-19 INSTANT ANTIGEN TEST This diagnostic test is used to get into sporting events, board flights, and meeting other mandatory testing requirements FDA EUA AUTHORIZED LOWER NASAL COVID 10 MIN RAPID TEST Coronavirus (COVID-19) Rapid Test with Telehealth Consultation. The test is administered over a video appointment from the comfort of your home with results in 10 minutes. [https://covidinstanttest.net/antigen] • "COVID-19 At Home Instant Test #COVID19…How does our Coronavirus (COVID-19) Rapid At Home Test work? Learn more: covidinstanttest.net #CoronaVirus #COVID #COVID19 #SARSCoV2 #COVIDInstantTest #COVIDRapidTest #COVIDAtHome #RapidTesting #InstantTest" [Pinned Tweet from November 24, 2020, at https://twitter.com/covidathometest] • "COVID-19 At Home Instant Test Our #COVID19 Rapid Tests have received an Emergency Use Authorization from the FDA. covidinstanttest.net" [https://www.instagram.com/covid19instanttest/] • "Saliva Test Kit FDA Submitted/EUA Approved Results in 24-48 hours Approved for In-Home Use! o 100% Accuracy with zero false negatives o ZERO false positives with 100% Overall Accuracy o Determines if the patient is currently infected." [https://ushealthdiagnostics.com] • "15-Minute COVID-19 Screening Test Self contained test can be administered at home or business under the supervision of a Telehealth professional with results in 15 minutes" [https://covidinstanttest.net/dual-antibody-test/] Your

products are also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), because your websites represent that the COVID-19 Test Kits are "FDA Submitted/EUA Approved," "FDA EUA Authorized," or "EUA/FDA Certified." These representations create a false impression that your products have been approved or authorized for emergency use by FDA and are misleading. As discussed above, your COVID-19 Test Kits have not been approved or authorized for emergency use by FDA. In addition, your website, https://ushealthdiagnostics.com, displays the FDA logo positioned near images of and information about the COVID-19 Antibody Test Kit and Saliva Test Kit. The FDA logo is for the official use of the FDA and not for use on private sector materials. 6 Such use may send a misleading message that the FDA favors or endorses your products. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices. In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 7 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

2 The "COVID-19 Antibody Test Kit" offered for sale on your website appears to be the RightSign COVID-19 IgG/IgM Rapid Test Cassette manufactured by Hangzhou Biotest Biotech Co., Ltd. On December 21, 2020, FDA reissued an Emergency Use Authorization (EUA) pursuant to section 564 of the Act, 21 U.S.C. § 360bbb-3, to permit emergency use of Hangzhou Biotest Biotech Co., Ltd.'s RightSign COVID-19 IgG/IgM Rapid Test Cassette. The test is indicated for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium heparin, potassium EDTA, and sodium citrate), serum, and plasma (sodium heparin, potassium EDTA, and sodium citrate), and, by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high, moderate, or waived complexity tests, for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in fingerstick whole blood specimens. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.The test is intended for use as an aid in identifying individuals with an adaptive immune response toSARS-CoV-2, indicating recent or prior infection. However, this EUA does not authorize the sale of the Hangzhou Biotest Biotech Co., Ltd., RightSign COVID-19 IgG/IgM Rapid Test Cassette to consumers for at-home testing. 3 The "COVID-19 Rapid Antigen Test" offered for sale on your website appears to be the CareStart COVID-19 Antigen test manufactured by Access Bio, Inc. On April 12, 2021, FDA reissued an EUA pursuant to section 564 of the Act, 21 U.S.C. § 360bbb-3, to permit emergency use of Access Bio, Inc.'s CareStart COVID-19 Antigen test. The test is indicated for for use by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high, moderate, or waived complexity tests and in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. However, this EUA does not authorize the sale of the Access Bio, Inc. CareStart COVID-19 Antigen test to consumers for at-home testing. 4 Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020 and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 5 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 6 FDA Logo Policy (available at: https://www.fda.gov/about-fda/website-policies/fda-logo-policy). 7 Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 4: Places for report 1207459

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Kansas City	39.09973	-94.57857

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at the Internet addresses https://covidinstanttest.net and https://ushealthdiagnostics.com/ on March 30, 2021, and April 9, 2021. We also reviewed your social media websites at https://facebook.com/covid19instanttest, https://twitter.com/covidathometest, and https://www.instagram.com/covid19instanttest, where you direct consumers to your website, https://covidinstanttest.net, to purchase your products. The FDA has observed that your websites https://covidinstanttest.net and https://ushealthdiagnostics.com/ offer for sale a "Rapid Dual Antibody Test" (which your website also refers to as the "COVID-19 Instant Test," "Dual Antibody Rapid Test," "COVID-19 Dual Antibody Test," "Rapid 15 Minute Antibody," "Dual IgG/IgM Screening Test for COVID-19," "15-Minute COVID-19 Screening Test," "COVID-19 IgM/IgG Rapid Test Device," "COVID-19 Antibody Test Kit," and "Dual Antibody Test") (hereafter referred to as the "COVID-19 Antibody Test Kit"), a "Rapid 10 Minute Antigen Test" (which your website also refers to as the "Antigen Rapid Test," "COVID-19 Antigen Test Kit," "Access Bio COVID-19 Antigen Test," and "COVID-19 Instant Antigen Test") (hereafter referred to as the "COVID-19 Rapid Antigen Test"), and a "Saliva Test Kit" (all hereafter referred to as "COVID-19 Test Kits") in the United States. [...] The COVID-19 Test Kits are offered for sale in the United States to consumers for at-home testing without marketing approval, clearance, or authorization from FDA. [...]

4 CDSCO flags 39 drug samples including Aspirin, Remdesivir as not of standard quality - 2021-07-31

Publication date	2021-07-31
Create date	2021-08-06
Score	35.41
Report id	1159752
Category	Veterinary medicines, Antibiotic, Antipyretic, Antiviral others, Antacid, Vitamin, Anti-inflammatory medicine, Antifungal, Other, Medicine for allergy
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: New Delhi: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO) has flagged 39 medicine batches as 'Not of Standard Quality' after the samples failed to qualify a random drug sample test for the month of June, 2021.These drug samples which have been declared as not of standard quality include Skymap Pharmaceutical's Omeprazole Gastro-Resistant Capsules, Bharat Parenteral's Folic acid tablets, and Jackson Laboratorie's Aspirin tablets.In addition to this , the list also includes some popular medicines such as Diclofenac Sodium manufactured by Hindustan Antibiotics, Goodvit (Folic Acid Tablets I.P) manufactured by Overseas Health Care, Amikef-500-2 ml (Amikacin Sulphate Injection I.P.) manufactured by Lupin, lverpil-12 (lvermectin Dispersible Tablets 12 mg manufactured by Psychotropics India Ltd., Coldbest- PC SYRUP (Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Syrup, 60 ml) manufactured by Digital Vision.Remdesivir for Injection 100 mg/vial (COVIPRI INJECTION), a popular covid medication manufactured by Pristine Life Sciences, is also on the list of 'Not of Standard Quality' drugs..Further, two veterinary medications, Cypermethrin Dip Concentrate Liquid IP Vet. manufactured by Saibliss Drugs & Pharmaceuticals and Amitraz Dip Concentrate Liquid manufactured by Ambrosia Pharma, are on the list of 'Not of Standard Quality.'This came after analysis and testing were conducted by the CDSCO, Drugs Control Department, on 681 drug samples. Out of these, 642 samples were found to be of standard quality while 39 of them were declared as Not of Standard Quality (NSQ).A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of the Vitamin D3 assay, failure of Phenylephrine Hydrochloride assay, and the Assay of Methylcobalamine & Dissolution of Pregabalin.The samples collected were tested in four laboratories, namely CDL Kolkata, CDTL Mumbai, RDTL Chandigarh, and RDTL Guwahati.List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded , for the Month of June - 2021 Total number of samples tested 681 Total number of samples declared as of Standard Quality 642 Total number of samples declared as Not of Standard Quality 39 Total number of samples declared as Spurious Nil Total number of samples declared as Misbranded Nil S. No Name of Drugs/medical devices/cosmetics Batch No./Date of Manufacture/Date of Expiry/Manufactured by Reason for failure Drawn By From 1 SESTIL –AD (Loperamide

Hydrochloride Dispersible Tablets) B. No: CST-75 Mfg dt: 07/2020 Exp dt: 06/2023 Mfd by: M/s Coastal Medicare Pvt Ltd. RS No. 9/2,5,Ramachandrapuram, Surampalli, Krisha Dist, Andhra Pradesh Assay CDSCO Hyderabad CDL, Kolkata 2 Alusil (Aliuminium, Magnesium and Simethicone Chewable Tablet I.P.) B. No.: AC80 Mfg dt: 08/2020 Exp dt: 07/2022 Mfd by: Mls. Unicure India Ltd., C-21, 22 & 23,Sector-3, Noida - 201 301, Distt. Gautam Budh Nagar, Uttar Pradesh. Assay of Polydimethylsiloxane (Simethicone) CDSCO Hyderabad CDL, Kolkata 3 Belitra - 200 (Itraconazole Capsules 200 mg) B. No.. AC20084 Mfg dt: 08/2020 Exp dt. 07/2022 Mfd by: Mls. Cian Healthcare Ltd., Khasra No. 248 Vill Sisona, Bhagwan pur, Roorkee, Uttarakhand Dissolution CDSCO Hyderabad CDL, Kolkata 4 Dicloenac Sodium lnj. I.P. 75 mg / 3ml B. No.. DSIX-109 Mfg dt: 12/2020 Exp dt: 11/2022 Mfd by Mls. Hindustan Antibiotics Ltd., At: 11, W.E.A. F aridabad -121001 Haryana. Particulate Matter CDSCO South Zone CDL, Kolkata 5 Bupivacaine Hydrochloride in Dextrose lnjection USP 4 ml. GB No : TBD-2003 Mfg dt: 07/2020 Exp dt: 06/2022 Mfd by: Mls. Systochem Laboratories Ltd., B-75, Roop Nagar, Indl. Area Loni 201102, Uttar Pradesh. pH CDSCO South Zone CDL, Kolkata 6 FEN PIL – 120 (Fexofenadine Hydrochloride Tablets I.P 120 mg B. No.: AWX29002 Mfg dt: 10/2019 Exp dt: 09/2021 Mfd by: Mls. Psychotropics India Limited, Plot No. 46 & 49, Sector - 6A, I IE, SIDC UL, Ranipur, Haridwar - 249 403 Uttarakhand. Dissolution CDSCO East Zone Kolkata CDL, Kolkata 7 Asonac-100 (Aceclofenac Tablets I.P.) ...

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Table 5: Drugs for report 1159752

Medicine Name	Medicine Class	Action	ATC Code
chlorphenamine	Substituted alkylamines	antihistamines for systemic use	R06AB04
amikacin	Other antibiotics for topical use	antibiotics for topical use	D06AX12
amikacin	Other aminoglycosides	aminoglycoside antibacterials	J01GB06
amikacin	Antibiotics	antiinfectives	S01AA21
folic acid	Folic acid and derivatives	vitamin b12 and folic acid	B03BB01
cypermethrin	Pyrethrines	insecticides and repellents	P03BA02
diclofenac	Other dermatologicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic products, non-steroids	M01AB05
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03

Table 5: Drugs for report 1159752(continued)

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
ivermectin	Other dermatologicals	other dermatological preparations	D11AX22
ivermectin	Avermectines	antinematodal agents	P02CF01
phenylephrine	Adrenergic and dopaminergic agents	cardiac stimulants excl. cardiac glycosides	C01CA06
phenylephrine	Sympathomimetics, plain	decongestants and other nasal preparations for topical use	R01AA04
phenylephrine	Sympathomimetics, combinations excl. corticosteroids	decongestants and other nasal preparations for topical use	R01AB01
phenylephrine	Sympathomimetics	nasal decongestants for systemic use	R01BA03
phenylephrine	Sympathomimetics excl. antiglaucoma preparations	mydriatics and cycloplegics	S01FB01
phenylephrine	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA05
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01

Notes: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO) has flagged 39 medicine batches as 'Not of Standard Quality' after the samples failed to qualify a random drug sample test for the month of June, 2021. [...]

5 Mexico detects fake remdesivir at hospital, for sale on web Mexico detects fake remdesivir at hospital

Publication date	2021-07-20
Create date	2021-09-01
Score	30.05
Report id	1164000
Category	Antiviral others
Quality	Falsified
Source	Hospital pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Mexico detects fake remdesivir at hospital, for sale on web Mexico detects fake remdesivir at hospital New York Post

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Table 6: Places for report 1164000

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102
Americas	Mexico	Tampico	22.28519	-97.87777

Table 7: Other Stories

ID	Title	Link
1145994	Mexico detects fake remdesivir at hospital, for sale on web	Link
1146001	Mexico detects fake remdesivir at hospital, for sale on web :: WRAL.com	Link
1146500	Mexico detects fake remdesivir at hospital, for sale on the web	Link

Notes: MEXICO CITY — Authorities in Mexico say they have found fake doses of the COVID-19 drug remdesivir offered for sale on the internet and at a private hospital near the US border. The federal medical safety commission said late Monday that the fake antiviral drug, which it called "a health risk," was found at a hospital in the Gulf coast city of Tampico, in the border state of Tamaulipas.

The commission said the doses had been purchased in an ”irregular manner” on the internet, but did not say whether the medication had been used there.

The drug’s manufacturer, Gilead Sciences, confirmed the falsification. The appearance and lot numbers on the packaging did not match the original.

In February, police in northern Mexico arrested six people in the border state of Nuevo León for allegedly trafficking in fake coronavirus vaccines, but did not say what kind of fake shots were involved. The suspects allegedly offered the vaccines for sale for the equivalent of around $2,000 per dose.

Analysts have long worried that criminal gangs in Mexico could seek to steal, hijack or counterfeit much-desired vaccines or medications during the pandemic. There have been hijackings or thefts of medicines and oxygen in Mexico.

Mexico is currently experiencing a third wave of coronavirus in which case numbers have now exceeded the first wave of 2020. The country has suffered about 236,000 test-confirmed deaths, but because so little testing is done, the real toll is closer to 360,000.

6 Kangra-based pharma unit shut for making medicines without approval

Publication date	2021-06-18
Create date	2021-06-23
Score	29.19
Report id	1104799
Category	Antiviral others, Anti-inflammatory medicine
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Kangra-based pharma unit shut for making medicines without approval Hindustan Times

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Table 8: Places for report 1104799

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kangra	32.16667	76.25

Table 9: Drugs for report 1104799

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
ibuprofen	Other cardiac preparations	other cardiac preparations	C01EB16
ibuprofen	Antiinflammatory products for vaginal administration	other gynecologicals	G02CC01
ibuprofen	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE01
ibuprofen	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA13

Table 9: Drugs for report 1104799(continued)

Medicine Name	Medicine Class	Action	ATC Code
ibuprofen	Other throat preparations	throat preparations	R02AX02

Notes: The state health safety and regulation authorities raided a pharmaceutical company at Surajpur in Indora sub-division of Kangra district for manufacturing and selling medicines without approval from the drug regulator, police said on Friday. Nurpur drug inspector Piar Chand led the raid and seized 1.71 lakh tablets of an anti-inflammatory medicine that had been made illegally. The company is already facing probe for manufacturing fake Remdesivir injections and selling it in black. [...] "The medicine is a combination of ibuprofen and paracetamol used as a painkiller," said Chand, adding the medicine was in demand during the spike in Covid-19 cases recently. [...]

7 Gujarat: Anything from salt to steroids used to 'make' antiviral drugs

Publication date	2021-06-15
Create date	2021-06-22
Score	26.14
Report id	1100945
Category	Immunosuppressant, Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Gujarat: Anything from salt to steroids used to 'make' antiviral drugs Times of India

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Table 10: Places for report 1100945

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Gujarāt	23	71.75

Table 11: Drugs for report 1100945

Medicine Name	Medicine Class	Action	ATC Code
tocilizumab	Interleukin inhibitors	immunosuppressants	L04AC07

Table 12: Other Stories

ID	Title	Link
1139986	Gujarat: Anything from salt to steroids used to 'make' antiviral drugs	Link

Notes: What did the spurious injection vials of tocilizumab and remdesivir contain which were sold for thousands of rupees to desperate kin of Covid patients at the peak of the pandemic in April and May in Gujarat ? State police investigators and forensic sciences experts say the drugs contained anything from steroids to salt - giving no respite to the patients and posing a

grave health hazard. [...]

8 Ome Care - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-07-26

Publication date	2021-07-26
Create date	2021-08-19
Score	25.42
Report id	1172681
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Ome Care MARCS-CMS 614382 — July 26, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Paul Edalat Recipient Title Chief Executive Officer Ome Care 26021 Pala Drive - St A Mission Viejo , CA 92691 United States regulatory@viverapharma.com customerservice@hometestbox.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 26, 2021 RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address hometestbox.com on March 3, 2021 and again on April 1, 2021. The FDA has observed that hometestbox.com offers for sale a VIVERA + OMECARE Home Specimen Collection Kit (also referred to as "COVx-HT" and "RT-PCR Test") (hereinafter referred to as "COVxHT Kit"), for sale in the United States directly to consumers. Based on our review, your COVxHT Kit is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, it is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). The COVxHT Kit is offered for sale directly to consumers in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxHT Kit is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxHT Kit is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2"

(SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described herein, you sell a product that is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 4 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health CC: michael.nova@omecare.com Michael Nova MD Ph.D. Chief Innovation Officer and Founder Ome Ventures Inc. 6777 Nancy Ridge Drive, San Diego, CA 92121 CC: sales@blackbirdgroupllc.org Blackbirdgroupllc 3121 Standard Street Bakersfield,

California 93308 _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020 and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx). 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 13: Places for report 1172681

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Mission Viejo	33.60002	-117.672

Notes: [...] The COVxHT Kit is offered for sale directly to consumers in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxHT Kit is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxHT Kit is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. [...]

9 Vivera Pharmaceuticals, Inc. - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-07-26

Publication date	2021-07-26
Create date	2021-08-19
Score	25.42
Report id	1172680
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Vivera Pharmaceuticals, Inc. MARCS-CMS 614412 — July 26, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Paul Edalat Recipient Title Chief Executive Officer Vivera Pharmaceuticals, Inc. 26021 Pala Drive - St A Mission Viejo , CA 92691 United States regulatory@viverapharma.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 26, 2021 RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) has reviewed your websites at the Internet addresses https://viveracovid19.com/covx-rda/ and https://viverapharmaceuticals.com/products/ on January 13, 2021, on March 3, 2021, and on April 1, 2021, and observed that your websites offered a "COVxRDA Saliva Antigen Test" and a "COVx-RDA Nasal Antigen Test" (herafter collectively referred to as "COVxRDA Antigen Test Kits") for sale in the United States. Based on our review, the COVxRDA Antigen Test Kits are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). The COVxRDA Antigen Test Kits were offered for sale in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxRDA Antigen Test Kits are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxRDA Antigen Test Kits are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There

is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sold products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate corrective action to prevent the sale of any unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" 4 provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to prevent future violations. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to prevent future violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to prevent future violations may result in legal action, including, without limitation, seizure, and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products . Once you have taken actions to prevent the sale of unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health

CC: sales@blackbirdgroupllc.org Blackbirdgroupllc 3121 Standard Street Bakersfield, California 93308 _____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaringnational-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 14: Places for report 1172680

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Mission Viejo	33.60002	-117.672

Notes: [...] The COVxRDA Antigen Test Kits were offered for sale in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, the COVxRDA Antigen Test Kits are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The COVxRDA Antigen Test Kits are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. [...]

10 Seizure of contraband and unauthorized items at Dorchester Penitentiary - Medium-security unit 19 June

Publication date	2021-06-18
Create date	2021-06-23
Score	25.15
Report id	1105576
Category	Medical device used for cure/mitigation/treatment, Vitamin, Opioid
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Seizure of contraband and unauthorized items at Dorchester Penitentiary - Medium-security unit 19 June Mirage News

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Table 15: Places for report 1105576

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	New Brunswick/ Nouveau-Brunswick	46.5001	-65.99878

Table 16: Drugs for report 1105576

Medicine Name	Medicine Class	Action	ATC Code
ascorbic acid	Organic acids	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AD03
ascorbic acid	Other ophthalmologicals	other ophthalmologicals	S01XA15

Notes: [...] The contraband and unauthorized items seized included 10 bales of tobacco, 10 packages of rolling papers, 4 hypodermic syringe kits, 10 ascorbic acid sachets, and 60 counterfeit Dilaudid pills that contained the presence of Protonitazene. The total estimated institutional value of this seizure is $15,000. [...]

11 Biopolygen Corp. - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - California - 2021-07-09

Publication date	2021-07-09
Create date	2021-09-08
Score	25.15
Report id	1207458
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Biopolygen Corp. MARCS-CMS 613137 — July 09, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Brian Nguyen Biopolygen Corp. 2207 East Carson St Carson , CA 90810 United States customerservice@biopolygen.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER Date: July 9, 2021 RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https:// www.biopolygen.com on January 7, 2021, February 26, 2021, and June 30, 2021. The FDA has observed that your website offers the "COVIGEN AG-1 Covid-19 Self Detection Kit," the "COVIDEX AB-1 Covid-19 Self Detection Kit," and the "COVID-19 Antigen and Antibody Combo Set" (hereafter referred to collectively as "COVID-19 Self Detection Test Kits") for sale in the United States. Based on our review, these products are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 [1] in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). The Covid-19 Self Detection Test Kits are offered for sale and distributed to consumers in the United States for self-testing without marketing approval, clearance, or authorization from FDA. Accordingly, the products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). Your products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2).

The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. [2] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. [3] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you offer for sale products that are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. We also note that different and potentially serious public health risks are presented with specimen collection and testing in the home versus a healthcare setting. Risks may include, but are not limited to, whether a lay person has the ability to collect their specimen, run the test, and interpret the test result accurately. Your website (noted above), includes statements indicating that the COVID-19 Self Detection Test Kits may be purchased directly by consumers and are intended to be used for self-testing for COVID-19, including: "ACCURACY BUT FAST, EFFICIENT; ANYTIME, ANYWHERE AT YOUR PRIVACY AND CONVENIENCE." [https://www.biopolygen.com/shop/-Covid-19-antigen/c-p778] "INSTANT AND EASY ACCESS TO SCREENING CAN BE LIFE OF[sic] DEATH. SCREENING FOR YOURSELF AND YOUR FAMILY TODAY AND REPEAT THE ROUTINE SCREENINGS TO PROTECT YOURSELF." [https://www.biopolygen.com/shop/-Covid-19-antigen/c-p778] A photograph of the "COVID-19 Antigen and Antibody Combo Set" includes the following language: "SELF-SCREENING METHOD FOR EALRY PREVENTION AND EARLY TREATMENT." [https://www.biopolygen.com/shop/-Covid-19-antigen-antibodycombination/c-p783] For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medicaldevices/coronavirus-covid-19-and-medical-devices . In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)" [4] provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that are not in compliance with FDA requirements and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the Act. This list can be found at https://www.fda.gov/consumers/health-

fraud-scams/fraudulentcoronavirus-disease-2019-covid-19-products . Once you have taken actions to address the sale of your unapproved, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov. Sincerely, /S/ Timothy T. Stenzel, M.D., Ph.D. Director OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality Center for Devices and Radiological Health _____[1] As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). [2] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . [3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . [4] Accessible at https://www.fda.gov/media/135659/download . Content current as of: 08/10/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 17: Places for report 1207458

Region Name	Country	Location	Latitude	Longitude
Americas	United States	California	37.25022	-119.75126
Americas	United States	Carson	33.83141	-118.28202

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://www.biopolygen.com on January 7, 2021, February 26, 2021, and June 30, 2021. The FDA has observed that your website offers the "COVIGEN AG-1 Covid-19 Self Detection Kit," the "COVIDEX AB-1 Covid-19 Self Detection Kit," and the "COVID-19 Antigen and Antibody Combo Set" (hereafter referred to collectively as "COVID-19 Self Detection Test Kits") for sale in the United States. [...] The Covid-19 Self Detection Test Kits are offered for sale and distributed to consumers in the United States for self-testing without marketing approval, clearance, or authorization from FDA. [...]

12 Fungus drug: Cops swoop down on black marketers

Publication date	2021-06-01
Create date	2021-06-04
Score	24.21
Report id	1083769
Category	Antiviral others, Antifungal
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Fungus drug: Cops swoop down on black marketers Deccan Chronicle

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Table 18: Places for report 1083769

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Hyderabad	17.38405	78.45636

Table 19: Drugs for report 1083769

Medicine Name	Medicine Class	Action	ATC Code
amphotericin B	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB04
amphotericin B	Antibiotics	intestinal antiinfectives	A07AA07
amphotericin B	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA03
amphotericin B	Antibiotics	antimycotics for systemic use	J02AA01

Notes: Special Operations Team (SOT) of the Rachakonda police cracked around eight cases of illegally selling amphotericin B injection vials and around 50 cases of remdesivir. [...]

13 CDSCO flags 22 drugs as not of standard quality - 2021-06-06

Publication date	2021-06-06
Create date	2021-06-04
Score	22.98
Report id	1083074
Category	Antipyretic, Analgesic, Antiepileptic, Antidiabetic, Other
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: New Delhi: In its latest drug safety alert, the apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) has flagged 22 samples including drugs and a medical device as Not of Standard Quality for failing to qualify for a random sample test for the month of April-2021.These drugs samples which are declared Not of Standard Quality include Aksum's PANTOWEL-40, Synokem's L-CETAM 500, Unimark Healthcare's MISOPROSTOL Tablets I.P. 200 mcg, Bharat Parenteral's OLANZAPINE Tablets I.P. 5 mg. In addition, other popular drug samples that are declared Not of Standard Quality include Paracetamol Tablets IP 650 manufactured by Sotac Pharmaceuticals, GLUCORID (Metformin Hydrochloride Sustained-Release Tablets I.P. 500 mg) manufactured by Ridley Life Science, ZINC SULPHATE DISPERSIBLE TABLETS IP 20 mg manufactured by Hindustan Laboratories and others.Apart from drugs, a medical device manufactured by Ramaraju Surgical Cotton Mills, an instant sterile mopping pad (Absorbent Gauze-BP Type 13 with X-Ray Detectable Thread) has been declared non-standard quality.Also Read: Drug Alert: CDSCO Flags 19 formulations As Not Of Standard QualityThis came after analysis and tests were conducted by the CDSCO, Drugs Control Departments on 931 samples. Out of this, 908 samples were found of standard quality while 22 (legal) +1 (survey) of them were declared as Not of Standard Quality (NSQ).A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of the Vitamin D3 assay, failure of Serratiopeptidase assay.The samples collected were tested in four laboratories, namely CDL Kolkata, CDTL Mumbai, RDTL Chandigarh and RDTL Guwahati.List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of April -2021 Total number of samples tested 931 Total number of samples declared as of Standard Quality 908 Total number of samples declared as Not of Standard Quality 22(Legal)+01(Survey) Total number of samples declared as Spurious 0 Total number of samples declared as Misbranded 0 S.No. Name of Drugs/medical device/cosmetic s Batch No./Date of Manufacture/Date of Expiry/Manufactured By Reason for failure Drawn By From 1. INSTANT STERILE MOPPING PAD (Absorbent Gauze- BP Type 13 with X-Ray Detectable Thread) B. No.:1017/20 Mfg dt: 03/2020 Exp dt: 02/2023 Mfd by: M/s.The Ramaraju Surgical Cotton Mills Ltd., 2/318 - 2/321, Sankarankovil Road, Perumalpatti - 627 753 Tamil Nadu. Threads per stated length CDSCO, South Zone, Chennai CDL, Kolkata 2. RUTIN (RutosideTrihydra te 95%)

(as per F.M) B. No.:20181126 (as per F.M) Mfg dt: 11/2018 (as per F.M) Exp dt: 11/2021 (as per F.M) Mfd by: M/s.Ningbo Hi- Tech Biochemicals Co., Ltd, China (as per F.M). Water, Related Substances and Assay CDSCO, Sub Zone Baddi CDL, Kolkata 3. REALHIM-10 (Tadalafil Tablets I.P. 10 mg) B. No.:LC9L225 Mfg dt: 12/2019 Exp dt: 11/2021 Mfd by: M/s.LifecareNeuro Products Limited, 70/1, Dharampur, Nr. EPIP Phase-II, Baddi-173 205, Himachal Pradesh. Dissolution CDSCO, East Zone, Kolkata CDL, Kolkata 4. SPINOBAK-10 (Baclofen Tablets I.P. 10 mg) B. No.:K3ALT001 Mfg dt: 06/2020 Exp dt: 05/2022 Mfd by: M/s. Sirmour Remedies (P) Ltd., Village - Layarda, P.O. Assay CDSCO, East Zone, Kolkata CDL, Kolkata Missarwala, Paonta Sahib, Distt . Sirmour (HP) -173 205. 5. PANTOWEL - 40 (Pantoprazole Sodium Tablets B. No.:OBYA01 Mfg dt: 02/2020 Exp dt: 07/2022 Mfd by: M/s. Akums Drugs & Pharmaceuticals Ltd., 19, 20, 21 Sector-6A, I.I.E, SIDCUL, Ranipur, Haridwar-249403 Uttarakhand. Dissolution CDSCO East Zone Kolkata CDL, Kolkata I.P. 40 mg) 6. L-CETAM 500 (Levetiracetam Tablets I.P. 500 mg) B. No.:20S1GTA508 Mfg dt: 11/2020 Exp dt: 10/2022 Mfd by: M/s.Synokem Pharmaceuticals Ltd., Plot No: 35-36, Sector-6A, I.I.E. (SIDCUL). Ranipur (BHEL), Haridwar -249403 Uttarakhand. Dissolution CDSCO East Zone Kolkata CDL, Kolkata 7. MISOPROSTOL Tablets I.P. 200 mcg B....

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Table 20: Drugs for report 1083074

Medicine Name	Medicine Class	Action	ATC Code
pantoprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC02
olanzapine	Diazepines, oxazepines, thiazepines and oxepines	antipsychotics	N05AH03
misoprostol	Prostaglandins	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BB01
misoprostol	Prostaglandins	uterotonics	G02AD06
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
	Zinc	other mineral supplements	A12CB
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02
levetiracetam	Other antiepileptics	antiepileptics	N03AX14

Table 21: Other Stories

ID	Title	Link
1084554	CDSCO flags 22 drugs as not of standard quality	Link

Table 21: Other Stories(continued)

ID	Title	Link
1124284	22 drug samples including Sun Pharma Rosuvas fail to qualify CDSCO test - 2021-07-04	Link

Notes: In its latest drug safety alert, the apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) has flagged 22 samples including drugs and a medical device as Not of Standard Quality for failing to qualify for a random sample test for the month of April-2021. [...]

14 Steroids found in Tocilizumab sold by Surat black marketers

Publication date 2021-06-03

Create date 2021-06-07

Score 22.40

Report id 1086529

Category Immunosuppressant, Antiviral others, Medical device used for cure/mitigation/ treatment

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Steroids found in Tocilizumab sold by Surat black marketers Ahmedabad Mirror

Click here to see the Original Article

Table 22: Places for report 1086529

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Sūrat	21.19594	72.83023

Table 23: Drugs for report 1086529

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01
tocilizumab	Interleukin inhibitors	immunosuppressants	L04AC07

Notes: The corona pandemic has been an eye-opener of sorts. Though it has been painful for most, there have been those who have cashed in on the situation to make some quick bucks even at the cost of someone else's health. Eight people, including a doctor, were arrested last month in a black-marketing case of Tocilizumab injection by Surat's Umra police on a tip-off. According to Surat police sources, two of the injections seized from the accused were sent for laboratory tests at FSL Gandhinagar, investigations of which found that the injections contained a deadly steroid. So, now the Surat police are toying with the possibility of adding more sections to the case. [...]

15 Case filed in Haridwar over sale of fake favipiravir medicine

Publication date	2021-06-15
Create date	2021-06-21
Score	22.37
Report id	1100164
Category	Antiviral others
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Case filed in Haridwar over sale of fake favipiravir medicine Hindustan Times

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Table 24: Places for report 1100164

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Haridwar	29.94791	78.16025

Notes: [...] Police in Haridwar have registered a case against unnamed people for the alleged sale of fake antiviral drug favipiravir, which is used to treat Covid-19 patients.
Ads by
Life Max Cancer Laboratories owner Ashwini Garg has filed a complaint in this regard saying fake favipiravir was being sold under the company's logo and brand name. [...]

16 Authorities seize unauthorized COVID-19 treatments bound for Mexico | TheHill

Publication date	2021-06-23
Create date	2021-06-25
Score	22.32
Report id	1111214
Category	Antiviral others
Quality	Falsified
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: Authorities seize unauthorized COVID-19 treatments bound for Mexico | TheHill The Hill

Click here to see the Original Article

Table 25: Places for report 1111214

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102
Americas	United States	United States	39.76	-98.5
Southern Asia	Bangladesh	Bangladesh	24	90
Southern Asia	India	Republic of India	22	79

Table 26: Other Stories

ID	Title	Link
1110905	Illicit Covid-19 Drugs Bound for Mexico Seized by U.S. Authorities	Link
1111338	Customs Officers Seize Illicit Remdesivir Treatments Bound for Mexico	Link
1111400	US officials reportedly seize illegal COVID-19 drugs en route to Mexico	Link
1111416	Feds seize illegal COVID-19 drugs en route to Mexico: report – The Madison Leader Gazette	Link
1111461	Feds seize illegal COVID-19 drugs en route to Mexico: report	Link

Table 26: Other Stories(continued)

ID	Title	Link
1112698	Covid-19 manufacturing roundup: Smuggled remdesivir seized en route to Mexico; As Sputnik awaits WHO approval, a Russian plant raises concerns	Link
1114043	Illegal remdesivir seized in US en route to Mexico	Link
1114122	Illegal remdesivir seized in US en route to Mexico - 2021-06-25	Link
1117095	Illicit covid-19 drugs bound for Mexico seized by US authorities	Link
1128640	U.S. Authorities Seize Shipments of Illicit Covid-19 Drugs Smuggled Into Mexico	Link

Notes: Federal authorities have reportedly seized more than a hundred shipments of unauthorized versions of the COVID-19 treatment remdesivir bound for Mexico in recent months.

The Wall Street Journal reported Wednesday that people familiar with the investigation said the shipments were seized by Customs and Border Protection (CBP) officers at various U.S. airports after they arrived by plane from Bangladesh and India. [...]

17 BJP to mount pressure over Covid drug scam

Publication date	2021-06-06
Create date	2021-06-08
Score	22.23
Report id	1089047
Category	Immunosuppressant
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: BJP to mount pressure over Covid drug scam The Statesman

Click here to see the Original Article

Table 27: Places for report 1089047

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kolkata	22.56263	88.36304

Table 28: Drugs for report 1089047

Medicine Name	Medicine Class	Action	ATC Code
tocilizumab	Interleukin inhibitors	immunosuppressants	L04AC07

Notes: Bengal BJP vice-president Jay Prakash Majumdar on Saturday said that his party will organise a bigger movement demanding exemplary punishment to accused TMC MLA of Uluberia Dr Nirmal Majhi in an alleged scam of missing 26 vials of Tocilizumab from the Medical College Hospital in Kolkata. [...] Around 26 vials of Tocilizumab were stolen through some fake prescription from Medical College and Hospital. In a cell phone conversation that went viral, a female doctor is asking a nurse to give her 26 vials of the injection through some forged prescription. [...]

18 UP: Fake medicines used in Covid cure seized in large quantity from illegal manufacturing unit

Publication date	2021-06-08
Create date	2021-06-10
Score	21.92
Report id	1091779
Category	Antibiotic, Antiviral others
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: UP: Fake medicines used in Covid cure seized in large quantity from illegal manufacturing unit Outlook India

Click here to see the Original Article

Table 29: Places for report 1091779

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Greater Noida	28.49615	77.53601

Table 30: Drugs for report 1091779

Medicine Name	Medicine Class	Action	ATC Code
azithromycin	Macrolides	macrolides, lincosamides and streptogramins	J01FA10
azithromycin	Antibiotics	antiinfectives	S01AA26

Table 31: Other Stories

ID	Title	Link
1092544	Fake medicines used in Covid treatment seized in Greater Noida	Link
1093016	Noida Factory Of Fake COVID Treatment Drugs With Links To Racket In Mumbai & Meerut, Busted	Link
1096654	Fake Covid medicines recovered in Noida: FIR against firm owner	Link

Notes: Counterfeit Azithromycin and Favipiravir medicines, which are used in treatment of Covid patients, with a face value worth Rs 25 lakh were seized from an illegal drug-manufacturing unit in Uttar Pradesh"s Greater Noida on Tuesday, officials said. [...]

19 Maharashtra FDA seizes stock of spurious Favimax worth Rs 1.54 cr

Publication date 2021-06-04

Create date 2021-09-03

Score 21.54

Report id 1086758

Category Antibiotic, Antiviral others

Quality Falsified

Source Website(s)

Curation Manually curated

Incident or General Incident

Snippet: Maharashtra FDA seizes stock of spurious Favimax worth Rs 1.54 cr The Hitavada

Click here to see the Original Article

Table 32: Places for report 1086758

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Aurangabad	19.87757	75.34226
Southern Asia	India	State of Karnataka	14.66667	75.83333
Southern Asia	India	State of Mahārāshtra	19.5	76
Southern Asia	India	State of Gujarāt	23	71.75
Southern Asia	India	Mumbai	19.07283	72.88261

Table 33: Drugs for report 1086758

Medicine Name	Medicine Class	Action	ATC Code
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Table 34: Other Stories

ID	Title	Link
1132839	Mumbai: 'Pharma unit owner' held in second case of fake meds	Link

Notes: Maharashtra FDA seized a stock of Rs 1.54 crore of spurious Favimax 400 and 200

mg from the stock points. Meanwhile, the analytical report of samples of Hydroxychloroquine Sulphate tablets (M HCQ 200) manufactured by Max Relief Healthcare too has confirmed it as spurious. D R Gahane, Joint Commissioner, FDA Maharashtra (HQ Mumbai) told 'The Hitavada', "The Mumbai Police had arrested the alleged kingpin identified as Sudip Mukherji who ran Max Relief Healthcare. FDA found the name of company fake and no licence was issued by the Drug Controller in the name of Max Relief Healthcare on its address mentioned on the label as 'Max Relief Healthcare, Village Anji, Solan, Himachal Pradesh." "Both the drugs Favipiravir and Hydroxychloroquine Sulphate tablets were marketed by Covalent Healthcare, Kolkata.

FDA officials led by Ganesh Rokade, Assistant Commissioner (Intelligence Branch FDA) seized the medicines from three premises named Shivsrushti Surgimed, Mumbai-63; Nirav Trade Link, Mumbai-20 and Meditab Worldwide, Kandivali east, Mumbai, suspected to be spurious. These firms were operating from Mumbai and pushing fake drugs through a website for on-line sales," he added. "These firms had distributed the drugs to all major cities in Maharashtra, Karnataka, Gujarat. Thousands of strips of Favimax have been sold from major stockists in Aurangabad city in Maharashtra as well as district. Though FDA had issued an order to stop sale of these fake brands to all its divisions, thousands of persons had already consumed the medicine during COVID treatment. These persons may have lost their lives due to the consumption of Favimax," expressed a drug activist. When asked about the same, Gahane said, "It may be possible. Now, Sudip Mukherji is in police custody.

FDA officials are trying to unearth the number of strips being sold in the State. All divisions have issued the orders to stop sale and recall the unsold stock. Each strip of 10 tablets costs Rs 1,290 and on the basis of this value, FDA seized a stock of Rs 1.54 crore. The fake anti-viral drug were sold as Favimax-400 and Favimax-200, and M Hcq 200. FDA officials are now concerned if these tablets have already made their way to patients." "Mukherji's firm was shown to be fictitiously registered in Solan, Himachal Pradesh. He even claimed that he marketed his fake anti-viral concoction through a Kolkata-based firm, Covalent Healthcare. We found this marketing firm to be fake," he added.

20 Zhejiang Xichen Medical Technology Co., Ltd. - Investigational Device Exemptions (IDE)/Premarket Approval Application (PMA) - Zhejiang Sheng - 2021-06-04

Publication date	2021-06-04
Create date	2021-09-08
Score	19.23
Report id	1207454
Category	Medical devices for disease prevention
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Zhejiang Xichen Medical Technology Co., Ltd. MARCS-CMS 612946 — June 04, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Yinlong Dong Zhejiang Xichen Medical Technology Co., Ltd. 2nd Floor, 3 Building, No. 6, Lvyuan Zhong Road Quzhou Shi Zhejiang Sheng , 324000 China xs2@xicengroup.com Xichen001@aliyun.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER DATE: June 4, 2021 Re: "FFP2 NR 5-Layer KN95 Face Mask," "Medical Face Mask," and "Sterile Surgical Mask" Dear Yinlong Dong: This is to advise you that the United States Food and Drug Administration (FDA) has reviewed your website at the internet address https://www.xichen-med.com/ on March 23, 2021. The FDA has observed that your website offers the "FFP2 NR 5-Layer KN95 Face Mask," "Medical Face Mask," and "Sterile Surgical Mask" for sale in the United States. Based on our review, these products are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h). We also note that the FFP2 NR 5-Layer KN95 Face Mask is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 1 in people. FDA's review of your website revealed the following statements that establish that the products are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, including but not limited to: • Representing the FFP2 NR 5-Layer KN95 Face Mask as a "COVID-19 Respirator" with "effective antibacterial" properties for use to "prevent…bacteria, droplets and other harmful particles," "filter germs," and provide "protection for your family" [https://www.xichen-med.com/mask/ffp2-nr-5-layer-kn95-face-mask.html] • Representing the Medical Face Mask for use to "prevent infection," "protect patients and other persons from the transmission of pathogenic microorganisms, body fluids, particulate matter, etc., especially in the event of an epidemic or pandemic," and provide "protection for your family" as well as offering a "bacterial filtration efficiency [of] > 98%" and "microbial cleanliness [of] <30CFY/g" [https://www.xichen-med.com/mask/disposable-mask.html] • Representing the Sterile Surgical Mask as a "Medical Surgical Mask" that is "antibacterial" and provides a "BFE above 95%"

for use to "prevent the spread of body fluids and body splash content and isolate dust, particle [sic], alcohol, blood, bacteria, and virus invading." [https://www.xichen-med.com/mask/sterile-surgical-mask.html] The FFP2 NR 5-Layer KN95 Face Mask, Medical Face Mask, and Sterile Surgical Mask (each of which your website indicates is manufactured by Zhejiang Xichen Medical Technology Co. Ltd) are offered for sale in the United States without marketing approval, clearance, or authorization from the FDA. Accordingly, the products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). These products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). In addition, the FFP2 NR 5-Layer KN95 Face Mask is misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), because its labeling is false or misleading. FDA registration of a device establishment or assignment of a registration number does not denote FDA approval of the establishment or the device. Thus, references to a firm's establishment registration and registration number that create an impression of official FDA approval, clearance, authorization, certification, endorsement or other evaluation of the establishment or the devices are misleading and constitute misbranding. 21 CFR 807.39. Your website contains a number of false or misleading representations, including but not limited to: • Displaying a "FDA REGISTRATION CERTIFICATE" also referred to as the "kn95-FDA Certificate" issued by "J & F Technology Services LLC" (Certificate) under the "About Us" tab on your website. The Certificate certifies that "Zhejiang Xichen Medical Technology Co., Ltd…has completed the FDA Establishment Registration (as manufacturer, foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration." The Certificate has the look of an official government document, incorporating unauthorized use of the FDA logo 2 and an illustration of an eagle and a U.S. flag (or a similar flag). [https://www.xichen-med.com/our-certificate] • Displaying a screenshot titled "kn-95-Registration information is available on the FDA website" of what appears to be Zhejiang Xichen Medical Technology Co., Ltd.'s previous entry in FDA's Establishment Registration & Device Listing Database. [https://www.xichen-med.com/our-certificate] Taken together, display of the Certificate, bearing the FDA logo, and a screenshot from FDA's Establishment Registration & Device Listing Database positioned near images of and information about the FFP2 NR 5-Layer KN95 Face Mask are misleading because they imply FDA approval, clearance, authorization, certification, endorsement, or other evaluation of the product and/or establishment based on the representations that Zhejiang Xichen Medical Technology Co., Ltd. is or was registered with the FDA and that the firm is or was in possession of a registration number. Although the Certificate appears to be intended to function as a disclaimer, the small font size and overall placement of such language could be easily overlooked and does not limit or otherwise mitigate the misleading impression created by the use of the Certificate. We also note that you seem to reference the Certificate or some other certificate on the Sterile Surgical Mask's webpage [https://www.xichen-med.com/mask/sterilesurgical-mask.html], indicating the product has a "Certificate CE, FDA." These representations are especially concerning from a public health perspective because consumers rely on information provided by sellers to determine whether to purchase a device and your presentation conveys the misimpression that the products have been reviewed and approved by FDA. We remind you that FDA's Center for Devices and Radiological Health (CDRH) does not issue device registration certificates to medical device establishments, including to sellers and manufacturers. When an establishment registers and lists its devices, the resulting entry in FDA's Establishment Registration & Device

Listing Database merely denotes that the establishment has provided certain information to FDA. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID -19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 3 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. 4 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval, clearance, or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described above, you sell a product that is intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people. We request that you take immediate action to cease the sale of any adulterated and misbranded products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. This letter is not meant to be an all-inclusive list of violations that exist in connection with the products or your operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials to ensure that you do not make representations that misbrand the product(s) in violation of the Act. This letter notifies you of our concerns and provides you with an opportunity to address them. Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to address the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of any actions your firm has taken. If your firm's planned actions will occur over time, please include a timetable for implementation of those activities. Your firm's response should be comprehensive and address all violations included in this letter. If you believe that the products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be adulterated or misbranded may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States. Your firm's response should be sent via email to CDRHWarningLetterResponses@fda.hhs.gov or by mail to: Food and Drug Administration Center for Devices and Radiological Health Office of Regulatory Programs Division of Regulatory Programs 2: Establishment Support Regulatory Inspections and Audits Team White Oak Building 66 10903 New Hampshire Ave. Silver Spring, MD 20993 Refer to the Document number CMS Case# 612946 or CTS Number CPT2001023 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Assistant Director, Paola Barnett at 301-796-5462 or Paola.Barnett@fda.hhs.gov. Sincerely, / S/ Donna Engleman, MS, BSN Director Division of Market Intelligence Office of Regulatory Programs Office of Product Evaluation and Quality Center for Devices and Radiological Health Cc: US Agent: Fanny Zhao J & F Technology Services LLC 2424 Morris Ave 818 Union, New Jersey 07083 Email Address: info@jf-yiliao.com Contact: Yucai.qiu XICEN International Gmb Global Office Center, Beethovenstr. 5 DE-60325 Frankfurt/M,Germany Email Address: yucai.qiu@xicengroup.com XICEN International Corporation 245 E. Main Street, Suite 107 Alhambra, California, 91801 _____1 As explained below, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 The FDA logo is for official use by FDA and not for private use on labeling of FDA-regulated products. See FDA Logo Policy (available at: https://

www.fda.gov/about-fda/website-policies/fda-logo-policy). 3 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 4 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . Content current as of: 07/06/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 35: Places for report 1207454

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	quzhou shi	28.94273	118.87185
Americas	United States	United States	39.76	-98.5

Notes: This is to advise you that the United States Food and Drug Administration (FDA) has reviewed your website at the internet address https://www.xichen-med.com/ on March 23, 2021. The FDA has observed that your website offers the ”FFP2 NR 5-Layer KN95 Face Mask,” ”Medical Face Mask,” and ”Sterile Surgical Mask” for sale in the United States. [...] The FFP2 NR 5-Layer KN95 Face Mask, Medical Face Mask, and Sterile Surgical Mask (each of which your website indicates is manufactured by Zhejiang Xichen Medical Technology Co. Ltd) are offered for sale in the United States without marketing approval, clearance, or authorization from the FDA. [...]

21 Some batches of high blood pressure medicine were recalled i...

Publication date	2021-07-20
Create date	2021-07-23
Score	18.84
Report id	1145242
Category	Cardiovascular medicine
Quality	Substandard
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Some batches of high blood pressure medicine were recalled i... MENAFN.COM

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Table 36: Drugs for report 1145242

Medicine Name	Medicine Class	Action	ATC Code
losartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA01
irbesartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA04
valsartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA03

Notes: A drug importer notified the Health Inspectorate of Aruba that some batches of the drugs Losartankalium, Valsartan, and Irbesartan were recalled. These batches were recalled from the pharmacies in Aruba because of contamination with the AZBT. One of the local importers in Aruba confirmed the import of the contaminated batch. This importer took the necessary action of informing all pharmacies. Consequently, the pharmacies removed these batches and are contacting the patients that received these medicines. [...]

22 UP factory owner arrested by Mumbai police for manufacturing ‘fake’ drugs

Publication date	2021-06-06
Create date	2021-06-09
Score	17.86
Report id	1089601
Category	Antiviral others
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: UP factory owner arrested by Mumbai police for manufacturing ‘fake’ drugs Times of India

Click here to see the Original Article

Table 37: Places for report 1089601

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Meerut	28.98002	77.70636

Table 38: Other Stories

ID	Title	Link
1090478	Man arrested for making fake Covid drugs in Meerut lab	Link
1090672	Pharma wholesalers in Mumbai suburbs raided, fake Covid drug scam busted	Link
1090969	Mumbai: Man manufactures fake COVID drug ’Favipiravir’ in private lab in Meerut, arrested	Link
1091076	Mumbai: Man held for making fake Covid drugs at private lab in UP’s Meerut	Link
1091138	Mumbai: Fake Favipiravir racket busted, two including ’healthcare company’ owner arrested	Link
1092395	Greater Noida: Illegal factory manufacturing and selling fake COVID medicines busted, no arrest yet	Link

Notes: [...] The Mumbai team led by inspector Appa Sahib Sampat Rai Sirsath probing the case had earlier arrested Sudeep Mukherjee, a resident of Ghaziabad, who was caught sending fake medicines. An FIR under relevant sections was registered at Samtanagar police station in Mumbai. [...] "Additional information report ID: 1090478 (https://indianexpress.com/article/cities/mumbai/man-arrested-for-making-fake-covid-drugs-in-meerut-lab-7348474/): A man has been arrested for allegedly manufacturing fake Favipiravir tablets, used in Covid-19 treatment, at a private lab in Meerut. The police are now interrogating the accused, Sandeep Mishra, to find out for how long he has been making the fake drugs. [...]

23 Letters and medicine recalls sent to healthcare professionals in June 2021

Publication date 2021-07-07

Create date 2021-07-13

Score 17.84

Report id 1131318

Category Cardiovascular medicine, Analgesic

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: Letters and medicine recalls sent to healthcare professionals in June 2021 GOV.UK

Click here to see the Original Article

Table 39: Places for report 1131318

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	United Kingdom of Great Britain and Northern Ireland	54.75844	-2.69531

Table 40: Drugs for report 1131318

Medicine Name	Medicine Class	Action	ATC Code
losartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA01
irbesartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA04
codeine and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ06

Table 41: Other Stories

ID	Title	Link
1132103	Blood pressure pills recalled over cancer risk	Link
1170461	Health chiefs recall another 25 batches of blood pressure pills over cancer fears	Link
1170462	Common blood pressure drug may contain cancer-causing chemical - batches recalled	Link
1186840	Batches of high blood pressure drug recalled due to 'contamination'	Link
1188991	MHRA recalls contaminated Irbesartan- batches as precautionary measure	Link
1205708	25 batches of blood pressure pills recalled by health chiefs 'because they contain an impurity that may cause cancer'	Link

Notes: [...] A batch of Noidecs T20/C4 Indica Cannabis Flower, and a batch of sativa cannabis flower are being recalled due to potential contamination with mould. [...] A batch of Co-codamol 30/500 Effervescent Tablets is being recalled due to varying levels of active ingredients present in the tablets. [...] Batches of the following medicines are being recalled by multiple manufacturers: irbesartan 75mg, 150mg and 300mg film coated tablets; losartan potassium 50mg and 100mg film coated tablets; irbesartan/hydrochlorothiazide 150mg/12.5mg, 300mg/12.5mg and 300mg/25mg film coated tablets. [...]

24 Spurious COVID-19 Drugs Seized From Cuttack Chemist Shop

Publication date	2021-06-11
Create date	2021-06-15
Score	15.53
Report id	1095707
Category	Antifungal
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Spurious COVID-19 Drugs Seized From Cuttack Chemist Shop Pragativadi

Click here to see the Original Article

Table 42: Places for report 1095707

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Cuttack	20.46497	85.87927

Table 43: Other Stories

ID	Title	Link
1095708	Spurious Favipiravir Tablets Seized In Cuttack; Uttar Pradesh Link Under Scanner	Link
1095984	Fake Favipiravir now in Cuttack	Link
1096028	17000 Fake Tablets Of Covid-19 Drug Seized In Cuttack	Link
1096356	Fake Covid medicine worth Rs 69 lakh seized in Odisha's Cuttack	Link
1096474	Fake Favipiravir tablets seized from Cuttack	Link
1096657	Spurious COVID-19 drugs seized in Odisha	Link
1096765	Odisha Govt Orders Probe Into Fake Anti-Covid Drugs 'Favipiravir' Trade In Cuttack	Link
1097112	Odisha govt orders probe into "fake" COVID-19 medicine circulation	Link
1097259	Odisha govt orders probe into 'fake' COVID-19 medicine circulation	Link

Table 43: Other Stories(continued)

ID	Title	Link
1097292	Spurious Medicines Seized During Raid In Rourkela	Link
1097394	Odisha government orders probe against 'fake' COVID-19 medicine circulation	Link
1097525	Fake testing racket busted, one arrested	Link
1097528	Odisha government orders probe as fake Covid drugs seized from more districts	Link
1097638	Unscrupulous Traders Selling Fake Covid Drugs To Face Strict Action: Health Minister	Link
1097736	Raids across Odisha on spurious Favipiravir	Link
1097789	Spurious Drugs Scare: Authorities Raid Pharmaceuticals In Bolangir	Link
1098339	Fake COVID testing racket busted in Bhubaneswar, one arrested	Link
1121400	PIL Filed At Orissa HC Demanding CBI Probe Over Fake Medicine Racket	Link
1126486	17,000 fake Favipiravir tablets seized in Odisha's Cuttack	Link
1152000	Odisha Police arrest drug company MD for selling fake, overpriced Covid medicine	Link

Notes: In a huge haul, officials of the Drug Control Squad seized at least 170 boxes containing 17,000 spurious Favipiravir tablets from a chemist shop in Cuttack's Kanika square on Friday. [...]

25 Fake remdesivir case: Gang sold 900 vials in city

Publication date	2021-06-17
Create date	2021-06-22
Score	15.44
Report id	1104076
Category	Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Fake remdesivir case: Gang sold 900 vials in city Times of India

Click here to see the Original Article

Table 44: Places for report 1104076

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Jaipur	26.91962	75.78781

Notes: A day after a lab report revealed that remdesivirs seized from a gang were spurious; the police suspect that at least 900 such drugs were sold by the racketeers in the city. Deputy Commissioner of Police (North), Paris Deshmukh said that teams have been sent to Uttar Pradesh, Bihar, and other cities to track down manufacturers and suppliers of fake remdesivirs. [...]

26 Black Fungus: 3,293 vials of fake Amphotericin-B injections found at Delhi doctor's house; 7 arrested

Publication date	2021-06-20
Create date	2021-06-23
Score	15.12
Report id	1107417
Category	Antifungal
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Black Fungus: 3,293 vials of fake Amphotericin-B injections found at Delhi doctor's house; 7 arrested Free Press Journal

Click here to see the Original Article

Table 45: Places for report 1107417

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Delhi	28.65195	77.23149

Table 46: Drugs for report 1107417

Medicine Name	Medicine Class	Action	ATC Code
amphotericin B	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB04
amphotericin B	Antibiotics	intestinal antiinfectives	A07AA07
amphotericin B	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA03
amphotericin B	Antibiotics	antimycotics for systemic use	J02AA01

Table 47: Other Stories

ID	Title	Link
1107449	Gang selling fake Black Fungus medication busted in Delhi, 3500 injections recovered	Link
1107487	Over 3,000 vials of fake COVID injections recovered in big crackdown by Delhi Police; 2 doctors arrested	Link
1107531	Unit manufacturing fake drugs meant for Covid, black fungus patients busted, 2 doctors among 10 held	Link
1107574	Delhi: 2 doctors among 10 held for manufacture, sale of fake amphotericin-B injections	Link
1107616	Delhi Police Arrests 2 Doctors for Black-marketing Fake Drugs Meant for Covid, B	Link
1107651	Unit manufacturing fake drugs meant for Covid, black fungus patients busted in Delhi, 2 doctors among 10	Link
1107696	Fake Covid, Black Fungus Drugs Manufacturing Unit Busted in Delhi, 2 Doctors Among 10 Held	Link
1107697	Ten, including 2 doctors, held for manufacturing, black marketing Covid, black fungus injections	Link
1107698	Delhi Police recovers 3,000 fake Amphotericin-B injections used for treating black fungus, arrests 10	Link
1107741	Crime Branch busts unit manufacturing fake drugs	Link
1107799	Fake drug unit busted in Delhi	Link
1108102	10, including two doctors, arrested for selling fake Covid-19 and mucormycosis medicines	Link
1108687	Delhi police bust fake COVID drug-making racket, 10 arrested	Link
1108762	Delhi Police bust racket involved in black-marketing of fake injections of COVID	Link
1114424	Delhi: Unit manufacturing fake COVID-19 drugs busted, 2 doctors among 10 held	Link
1116987	Two Doctors, 8 Others Held In Delhi For Manufacturing Fake Drugs Meant For Covid, Black Fungus Patients	Link
1117968	Delhi: Two doctors held for making, selling fake mucormycosis drug	Link
1122546	Delhi Police Recovers Over 3000 Fake Amphotericin-B Injections Used For Treating Black Fungus; 10 Arrested	Link

Notes: Delhi Police Crime Branch on Sunday arrested 7 persons, including 2 doctors, for manufacturing and selling fake Liposomal Amphotericin-B injections, used in the treatment of Black Fungus.

3,293 vials of fake injections have also been recovered from the house of one of the doctors, Dr Altamas Hussain, in southeast Delhi's Nizamuddin area.

Delhi Police Commissioner S. N. Shrivastava took to Twitter and wrote: "Delhi Police Crime Branch arrested 7 persons including 2 doctors for manufacturing and selling fake Black Fungus

Liposomal Amphotericin-B injections and recovered." "3293 vials of fake 'Injections' etc from residence of Dr. Altamas Hussain in Nizamuddin," he added. [...]

27 3 pharmacists arrested for illegal sale of mucor drug

Publication date	2021-06-21
Create date	2021-06-24
Score	15.10
Report id	1109134
Category	Antifungal
Quality	Diverted/Unregistered
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: 3 pharmacists arrested for illegal sale of mucor drug Times of India

Click here to see the Original Article

Table 48: Places for report 1109134

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Hyderabad	17.38405	78.45636

Table 49: Drugs for report 1109134

Medicine Name	Medicine Class	Action	ATC Code
amphotericin B	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB04
amphotericin B	Antibiotics	intestinal antiinfectives	A07AA07
amphotericin B	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA03
amphotericin B	Antibiotics	antimycotics for systemic use	J02AA01

Notes: Task force police arrested three pharmacists for indulging in illegal sale of Amphotericin-B injection used to treat mucormycosis and seized 35 vials from them. Acting on specific information, central zone team of task force laid a trap to nab three members of the gang at Necklace Road. [...]

28 Man arrested for ‘selling’ 42 fake vials of mucormycosis drug

Publication date	2021-06-09
Create date	2021-06-14
Score	14.91
Report id	1093374
Category	Antifungal
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Man arrested for ‘selling’ 42 fake vials of mucormycosis drug The Indian Express

Click here to see the Original Article

Table 50: Places for report 1093374

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Surendranagar	22.72706	71.64856

Table 51: Drugs for report 1093374

Medicine Name	Medicine Class	Action	ATC Code
amphotericin B	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB04
amphotericin B	Antibiotics	intestinal antiinfectives	A07AA07
amphotericin B	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA03
amphotericin B	Antibiotics	antimycotics for systemic use	J02AA01

Table 52: Other Stories

ID	Title	Link
1131819	Man arrested for 'selling' 42 fake vials of mucormycosis drug	Link

Notes: A 24-year-old man from Surendranagar was arrested on Wednesday for allegedly selling 42 fake vials of amphotericin B injections, needed for treatment of mucormycosis, to a patient. [...]

29 Punjab Police Bust Fake Remdesivir Manufacturing Racket | India | indiawest.com

Publication date	2021-06-18
Create date	2021-06-23
Score	14.83
Report id	1105491
Category	Antifungal
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Punjab Police Bust Fake Remdesivir Manufacturing Racket | India | indiawest.com India West

Click here to see the Original Article

Table 53: Places for report 1105491

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Punjab	30.91667	75.41667

Table 54: Other Stories

ID	Title	Link
1105619	Punjab Police bust fake remdesivir manufacturing racket	Link
1106022	6 arrested in fake Remdesivir racket	Link
1112084	Punjab: Six arrested in fake Remdesivir racket in Ropar district	Link

Notes: Punjab Police June 18 cracked a multi-crore rupee interstate fake Remdesivir manufacturing racket with the arrest of six people, including the kingpin, who used to black market fake replicas of the life-saving anti-viral drug used to treat critical Covid-19 patients. [...]

30 40,000 fake favipiravir shipped from Cuttack to Gwalior

Publication date	2021-06-12
Create date	2021-06-17
Score	14.57
Report id	1096845
Category	Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 40,000 fake favipiravir shipped from Cuttack to Gwalior Times of India

Click here to see the Original Article

Table 55: Places for report 1096845

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Gwalior	26.22983	78.17337
Southern Asia	India	Cuttack	20.46497	85.87927

Table 56: Other Stories

ID	Title	Link
1099973	Naveen directs CB to probe fake drugs case	Link
1103010	Spurious Favimax tablets used in COVID treatment seized in MP - 2021-06-17	Link
1103030	Spurious Favimax tablets used in COVID treatment seized in MP	Link
1105809	40,000 fake Favipiravir tablets sent from Cuttack to Gwalior	Link
1107457	Gwalior: 'Fake' Favimax tablets seized from wholesaler, thousands may be in circulation, says official	Link
1109299	MP: "Fake" Favimax tablets seized from Gwalior wholesaler; thousands may be in circulation, says official	Link

Notes: Around 40,600 spurious Covid drug favipiravir tablets were shipped from Odisha to Gwalior in Madhya Pradesh after these were brought from Noida in Uttar Pradesh to Cuttack

, authorities here said on Saturday. [...]

31 Delhi court denies bail to ex-GTB hospital employee accused of selling fake Remdesivir injections

Publication date	2021-06-14
Create date	2021-06-17
Score	14.53
Report id	1098779
Category	Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Delhi court denies bail to ex-GTB hospital employee accused of selling fake Remdesivir injections Devdiscourse

Click here to see the Original Article

Table 57: Places for report 1098779

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Delhi	28.65195	77.23149

Notes: [...] During a police raid on April 30, accused Amit was found to be in possession of two injections of low-cost antibiotic Monocef over which he had allegedly pasted stickers of 'Remdesivir'. He has been in judicial custody since May 1. Rejecting his bail plea, Additional Sessions Judge Sanjeev Kumar Malhotra said, allegations against the accused are grave. [...]

32 Fake Remdesivir, Rs 10-Lakh Hospital Bed: How Covid Patients Were Fleeced

Publication date	2021-06-03
Create date	2021-06-07
Score	13.84
Report id	1086629
Category	Antiviral others, Medical devices for disease prevention
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Fake Remdesivir, Rs 10-Lakh Hospital Bed: How Covid Patients Were Fleeced NDTV

Click here to see the Original Article

Table 58: Places for report 1086629

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	New Delhi	28.63576	77.22445

Table 59: Other Stories

ID	Title	Link
1086797	How desperate covid patients in India were defrauded online by scamsters	Link
1087117	Fake medicines, recycled PPE: Scammers worsen India COVID misery	Link
1087429	Fake medicines, recovered personal protective equipment: crooks exacerbate the suffering of COVID in India | Coronavirus pandemic news	Link
1088174	Covid-19: India's scammers benefit from fake medicines, recycled PPEs during pandemic	Link
1089013	COVID vaccine, beds, oxygen, and other online scams in India	Link

Notes: [...] His Crime Branch teams have already arrested many scammers, including a gang that made and sold counterfeit doses of the antiviral drug Remdesivir for up to 40 times the

market price.

"These people were producing fake vials which cost them about 20 rupees and (they) sold it in the market for anything above 10,000 rupees," Singh said. [...] This week, six men were reportedly arrested on suspicion of washing, repackaging and selling several tonnes of used surgical gloves from hospitals. [...]

33 Fake Medicines Seized From Medical Agency In Jharsuguda's Sarbahal

Publication date	2021-06-13
Create date	2021-06-17
Score	13.68
Report id	1097696
Category	Antiviral others
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Fake Medicines Seized From Medical Agency In Jharsuguda's Sarbahal Pragativadi

Click here to see the Original Article

Table 60: Places for report 1097696

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Jharsuguda	21.85531	84.00698

Table 61: Other Stories

ID	Title	Link
1097773	2 brands of fake medicines seized in Jharsuguda of Odisha	Link

Notes: Jharsuguda Drug Inspector Jyoti Ranjan Panda today informed that fake COVID-19 medicine has seized from Amit Medical Agency in Sarbahal area.

The Department of Drugs Control took up an investigation after fake medicines were seized from a Cuttack-based medical warehouse.

After learning that the spurious drug had come to Amit Medical Agency here, the Jharsuguda Drug Inspector raided the Medical Agency and seized three types of drugs. The drug samples have been reportedly sent to Bhubaneswar for laboratory tests.

34 Fake versions of herbal drug flood market

Publication date	2021-06-19
Create date	2021-06-23
Score	13.35
Report id	1106884
Category	Herbal medicine
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake versions of herbal drug flood market Times of India

Click here to see the Original Article

Table 62: Places for report 1106884

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Andhra Pradesh	15.83333	79.75

Table 63: Other Stories

ID	Title	Link
1110973	Andhra Pradesh: One held for selling fake 'Krishnapatnam medicine'	Link

Notes: With rising demand for Bonigi Anandaiah's herbal concoction that purportedly cures Covid-19, some miscreants are trying to capitalise on the situation by selling fake versions across the state. [...] Police have already busted eight such centres in the state. On May 28, police arrested a Yedavalli Venkatesh, a resident of Varakavipudi village of Nellore district, for selling a homemade concoction in the name of 'Krishnapatnam medicine'. On June 13, police arrested another person in Guntur district's Tadikonda for selling 'Anandaiah's Covid medicine' and seized 150 packets of the said medicine along with Rs 1.5 lakh cash. Investigation revealed that the accused, A Kantha Rao, had sold 750 packets of the concoction for Rs 200 each. [...]

35 37 caught for black marketing in essentials

Publication date 2021-06-03

Create date 2021-09-06

Score 13.06

Report id 1086685

Category Medical device for screening/diagnosis/monitoring, Antiviral others, Antiseptic, Medical device used for cure/mitigation/treatment

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: 37 caught for black marketing in essentials The Kathmandu Post

Click here to see the Original Article

Table 64: Places for report 1086685

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Nepal	Federal Democratic Republic of Nepal	28	84

Table 65: Drugs for report 1086685

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01
			J07
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: [...] In the last six weeks, a total of 37 persons were arrested from across the country for their alleged involvement in black marketing of oxygen, remedevisir, and oximeters, and producing fake hand sanitisers, according to the Nepal Police. [...] In the course of raids, police confiscated 13,756 litres of sanitiser, 25,000 litre of fake sanitiser, 55 oximeters, 765

fake oximeters, 6 vials of remdesivir injection, 1 vial of fake remdesivir injection, 2,000 litre methanol, 3,600 liters of ethanol, 2 fake receipt pads and 46 boxes of several medicines. [...] [pulse oximeters]

36 Mum FDA lab finds 6 Rem samples in Maha spurious

Publication date	2021-07-28
Create date	2021-08-05
Score	12.66
Report id	1156719
Category	Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Mum FDA lab finds 6 Rem samples in Maha spurious Times of India

Click here to see the Original Article

Table 66: Places for report 1156719

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Delhi	28.65195	77.23149
Southern Asia	India	Nagpur	21.14631	79.08491

Table 67: Other Stories

ID	Title	Link
1159097	Samples of four Remdesivir brands fail in analytical test	Link

Notes: Even as the country prepares to face the projected third wave of Covid-19 pandemic, a government laboratory in Mumbai finding half a dozen samples of Remdesivir, used to treat critically ill Covid patients, spurious or substandard has sent the authorities in a tizzy. Not only the much sought after Remdesivir, but several samples of hand sanitizers, anti-bacterial hand rubs and other medicines used to treat Covid-19 patients have also been found spurious and substandard during sample testing this month. [...]

37 CBP seizes sildenafil tablets worth more than $700000

Publication date	2021-07-31
Create date	2021-08-06
Score	12.16
Report id	1160270
Category	Erectile dysfunction medicine
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: CBP seizes sildenafil tablets worth more than $700000 SecuringIndustry.com

Click here to see the Original Article

Table 68: Places for report 1160270

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Cincinnati	39.12711	-84.51439
Southern Asia	India	Republic of India	22	79

Table 69: Drugs for report 1160270

Medicine Name	Medicine Class	Action	ATC Code
sildenafil	Drugs used in erectile dysfunction	urologicals	G04BE03

Table 70: Other Stories

ID	Title	Link
1160292	CBP seizes sildenafil tablets worth more than $700,000 - 2021-07-31	Link
1162291	Customs and Border Protection Seizes 44 Pounds of Sildenafil Pills Worth $712,756	Link

Notes: US Customs and Border Protection (CBP) officers in Cincinnati have seized almost

24,000 pills of sildenafil citrate, the active ingredient in the prescription erectile dysfunction drug Viagra. [...]

38 Advisory - Be informed: know the potential risks of buying health products online

Publication date	2021-06-08
Create date	2021-06-10
Score	11.75
Report id	1091721
Category	Erectile dysfunction medicine, Antibiotic, Analgesic, Nutritional supplement
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Advisory - Be informed: know the potential risks of buying health products online Canada NewsWire

Click here to see the Original Article

Table 71: Places for report 1091721

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Ottawa	45.41117	-75.69812

Notes: [...] During Operation Pangea XIV's week of action, which took place May 18 to 25, 2021, Health Canada inspected 2,076 packages, refused 867 packages from entering the country, and seized 228 packages at the border containing suspected counterfeit or unauthorized health products. The majority of products seized (238 of 244, or 97.5%) were sexual enhancement products (primarily erectile dysfunction medications). Other products included antibiotics, painkillers, and bodybuilding supplements. Although Health Canada did not seize products related to COVID-19 during this week of action, the Department remains alert to the heightened risk, takes action when illegal products related to COVID-19 are identified, and continues to remind Canadians to be vigilant. [...]

39 Fake drugs racket busted: Meds made in M'ngr, packed in Baghpat

Publication date	2021-06-28
Create date	2021-07-02
Score	11.66
Report id	1117967
Category	Antibiotic, Analgesic
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake drugs racket busted: Meds made in M'ngr, packed in Baghpat Times of India

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Table 72: Places for report 1117967

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Baghpat	28.95	77.2167

Table 73: Drugs for report 1117967

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA

Table 74: Other Stories

ID	Title	Link
1118473	Fake medicine factory busted in UP	Link
1118814	Fake medicine factory busted in Uttar Pradesh	Link
1119166	Racket which made fake painkillers & antibiotics with chalk busted, machines worth Rs 50L seized	Link

Notes: A joint team of Baghpat police and officials of the food safety and drug administration department (FSDA) busted a huge racket of manufacturing and packaging of fake drugs, mostly painkillers and antibiotics of branded companies, during a late night raid in Baghpat's Singhawali Aheer region. The team seized packaging machines, printed wrappers and a small consignment of fake drugs. [...] "Gaffar is one such associate of Balraj who had started this 'business' on a trial basis during the peak of the second wave of the Covid-19 pandemic. We recovered 300 tablets of a painkiller and a few antibiotics which have been sent for testing to an Agra lab." [...]

40 8 held for illegal e-sales of pregnancy termination kits

Publication date	2021-06-12
Create date	2021-06-17
Score	11.44
Report id	1097183
Category	Other
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: 8 held for illegal e-sales of pregnancy termination kits Times of India

Click here to see the Original Article

Table 75: Places for report 1097183

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Gujarāt	23	71.75

Table 76: Drugs for report 1097183

Medicine Name	Medicine Class	Action	ATC Code
oxytocin	Oxytocin and analogues	posterior pituitary lobe hormones	H01BB02

Notes: [...] On Saturday, Gujarat Food and Drugs Control Administration (FDCA) booked eight persons who had allegedly been selling pregnancy termination kits and psychotropic drugs online for the past two years. A police case has been registered against three in Deesa town for selling psychotropic drugs. The state FDCA seized 24,366 kits worth Rs 1.5 crore and 800 oxytocin injections worth Rs 3 lakh. [...]

41 Dr Reddy's recalls 2,980 bottles of cholesterol lowering drug in US

Publication date	2021-06-07
Create date	2021-06-09
Score	11.38
Report id	1090519
Category	Cardiovascular medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Dr Reddy's recalls 2,980 bottles of cholesterol lowering drug in US Kashmir Reader

Click here to see the Original Article

Table 77: Places for report 1090519

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Southern Asia	India	Telangana	17.83333	79.08333
Southern Asia	India	Republic of India	22	79

Table 78: Drugs for report 1090519

Medicine Name	Medicine Class	Action	ATC Code
atorvastatin	HMG CoA reductase inhibitors	lipid modifying agents, plain	C10AA05

Table 79: Other Stories

ID	Title	Link
1093318	Dr Reddy's recalls 2,980 bottles of cholesterol lowering drug in US	Link
1115908	Dr Reddyś recalls 2,980 cholesterol lowering drug bottles in US	Link

Notes: Drug major Dr Reddy's Laboratories is recalling 2,980 bottles of Atorvastatin Calcium tablets in the US due to quality issues. Atorvastatin is indicated to lower cholesterol in the blood for adults and children over ten years of age. [...]

42 Erectile dysfunction meds and sedatives among 1.6m illegal medicines seized last year

Publication date	2021-06-08
Create date	2021-06-10
Score	11.25
Report id	1091505
Category	Erectile dysfunction medicine, Analgesic, Other
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Erectile dysfunction meds and sedatives among 1.6m illegal medicines seized last year Irish Examiner

Click here to see the Original Article

Table 80: Places for report 1091505

Region Name	Country	Location	Latitude	Longitude
Europe	Ireland	Dublin	53.33306	-6.24889

Table 81: Drugs for report 1091505

Medicine Name	Medicine Class	Action	ATC Code
			N02
		anabolic steroids	A14A

Table 82: Other Stories

ID	Title	Link
1091663	Sedatives and erectile dysfunction pills: One million doses of illegal medicines seized last year	Link
1091983	Seizure of illegal medicines up 58% in past year, says regulator	Link
1092043	Ireland 'well above' EU average for sale of counterfeit goods	Link

Notes: More than 1.6m units of illegal medicines like sedatives and erectile dysfunction medications were detained in 2020, a sharp increase on previous figures, which the State said is ”very concerning”. [...] Some 583,805 units of sedative medication and 484,846 doses of erectile dysfunction drugs were seized, with 370,000 tablets of the latter detained in one seizure alone, the HPRA said.

Other examples of illegal medications seized included anabolic steroids, analgesic medicines, and 56,876 doses of Covid-19 medicines. [...]

43 Sex shop fined for selling herbal viagra

Publication date	2021-06-11
Create date	2021-06-15
Score	11.25
Report id	1096390
Category	Nutritional supplement
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Sex shop fined for selling herbal viagra Connacht Tribune Group

Click here to see the Original Article

Table 83: Places for report 1096390

Region Name	Country	Location	Latitude	Longitude
Europe	Ireland	Galway City	53.2877	-9.05004

Notes: The owners of a city centre sex shop were left with a stiff fine of 3,000 at Galway District Court for selling 'herbal Viagra' containing prescription-only drugs. [...] The charges included supplying a medicine without prescription, supplying a medicine without marketing authorisation and supplying a falsified medicine. The medicine in question contained prescription-only medicinal substances, Sildenafil (commonly known as Viagra) and Tadalafil (otherwise known as Cialis), which are both used to treat erectile dysfunction. [...]

44 Doctors call for crackdown on Ivermectin black market

Publication date	2021-06-26
Create date	2021-07-23
Score	11.09
Report id	1146006
Category	Veterinary medicines, Antiparasitic
Quality	Diverted/Unregistered
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Doctors call for crackdown on Ivermectin black market Free Malaysia Today

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Table 84: Drugs for report 1146006

Medicine Name	Medicine Class	Action	ATC Code
ivermectin	Other dermatologicals	other dermatological preparations	D11AX22
ivermectin	Avermectines	antinematodal agents	P02CF01

Notes: A coalition of doctors and medical professional groups has urged Putrajaya to crack down on the illegal sale of anti-parasitic drug Ivermectin in the wake of what the coalition said was an active black market for the drug.

The Malaysian Health Coalition said Ivermectin was sold at very high prices from veterinary supplies and other ”unknown” sources, adding that false or misleading claims online had led to demand for the drug. [...]

45 'Covid-19 vaccines and scheduled medicines now in the hands of looters'

Publication date	2021-07-15
Create date	2021-07-21
Score	10.94
Report id	1138581
Category	Vaccine, Other
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: 'Covid-19 vaccines and scheduled medicines now in the hands of looters' IOL

Click here to see the Original Article

Table 85: Places for report 1138581

Region Name	Country	Location	Latitude	Longitude
Southern Africa	South Africa	Province of KwaZulu-Natal	-29	30
Southern Africa	South Africa	Gauteng	-26.08333	28.25

Table 86: Drugs for report 1138581

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 87: Other Stories

ID	Title	Link
1138656	#UnrestSA: Vaccines stolen and over 90 pharmacies destroyed as violence continues	Link
1142125	Public urged not to use COVID-19 vaccines looted from pharmacies	Link
1145715	Civil unrest: Warning against using, selling stolen medication	Link

Notes: The South African Pharmacy Council has slammed looting sprees that have targeted pharmacies, amongst other establishments, in KwaZulu-Natal and Gauteng, warning residents against buying medicine which could be stolen. [...] "Among the looted items are Covid-19 vaccines and scheduled medicines, which when used without proper pharmacist counselling on storage and dosage may result in harm to one's health," he said. [...]

46 Public Notification: Premier maxxzen Platinum 12000 contains hidden drug ingredients - 2021-06-15

Publication date	2021-06-15
Create date	2021-06-21
Score	10.03
Report id	1100458
Category	Nutritional supplement
Quality	Substandard
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: The Food and Drug Administration is advising consumers not to purchase or Premier maxxzen Platinum 12000, a product promoted and sold for sexual enhancement on various websites, including eBay.com, and possibly in some retail stores.

Click here to see the Original Article

Table 88: Places for report 1100458

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: [...] FDA laboratory analysis confirmed that Premier maxxzen Platinum 12000 purchased from eBay.com contains sildenafil and tadalafil, the active ingredients in the FDA-approved prescription drugs Viagra and Cialis, respectively, used to treat erectile dysfunction. FDA approvals of Viagra and Cialis are restricted to use under the supervision of a licensed health care professional. These undeclared ingredients may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. [...]

47 Public Notification: Poseidon Platinum 3500 contains hidden drug ingredients - 2021-06-15

Publication date	2021-06-15
Create date	2021-06-21
Score	10.03
Report id	1100588
Category	Nutritional supplement
Quality	Substandard
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: The Food and Drug Administration is advising consumers not to purchase or use Poseidon Platinum 3500, a product promoted and sold for sexual enhancement on various websites, including eBay.com, and possibly in some retail stores.

Click here to see the Original Article

Table 89: Places for report 1100588

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 90: Other Stories

ID	Title	Link
1100589	Public Notification: Poseidon Platinum 10000 contains hidden drug ingredient - 2021-06-15	Link

Notes: [...] FDA laboratory analysis confirmed that Poseidon Platinum 3500 purchased from eBay.com contains sildenafil and tadalafil, the active ingredients in the FDA-approved prescription drugs Viagra and Cialis, respectively, used to treat erectile dysfunction. FDA approvals of Viagra and Cialis are restricted to use under the supervision of a licensed health care professional. These undeclared ingredients may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. [...]

48 Counterfeit medicines worth millions seized

Publication date	2021-07-14
Create date	2021-07-21
Score	9.49
Report id	1137809
Category	Antibiotic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Counterfeit medicines worth millions seized Pakistan Observer

Click here to see the Original Article

Table 91: Places for report 1137809

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Multan	30.19679	71.47824
Southern Asia	Pakistan	Islamic Republic of Pakistan	30	70

Table 92: Other Stories

ID	Title	Link
1137973	Fake medicines worth millions of rupees seized	Link

Notes: The Multan District Administration and Health Department, in a joint operation recovered counterfeit medicines worth millions of rupees on Wednesday. The raid was carried out on a private house in Double Phatak area following a tip-off. [...] The recovered counterfeit medicines included fake antibiotic injection" Tanzon" used for treatment of Covid-19 patients. [...]

49 Cadila Healthcare arm recalls 21,240 bottles of diabetes drug in US

Publication date	2021-07-04
Create date	2021-07-13
Score	7.76
Report id	1131542
Category	Antidiabetic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Cadila Healthcare arm recalls 21,240 bottles of diabetes drug in US ETHealthworld.com

Click here to see the Original Article

Table 93: Places for report 1131542

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 94: Drugs for report 1131542

Medicine Name	Medicine Class	Action	ATC Code
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02

Notes: [...] Viona Pharmaceuticals Inc is recalling 21,240 bottles of metformin hydrochloride extended-release tablets, USP 750 mg, on account of "CGMP Deviations: FDA analysis detected n-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit", the report by the US health regulator said. [...]

50 Black fungus spreading in coronavirus patients through substandard oxygen cylinders: health expert

Publication date	2021-06-03
Create date	2021-06-07
Score	7.46
Report id	1085977
Category	Medical device used for cure/mitigation/treatment
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Black fungus spreading in coronavirus patients through substandard oxygen cylinders: health expert Geo News

Click here to see the Original Article

Table 95: Places for report 1085977

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Peshawar	34.008	71.57849

Table 96: Drugs for report 1085977

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Table 97: Other Stories

ID	Title	Link
1086088	Medic warns of black fungus spread among COVID-19 patients via substandard oxygen cylinders	Link
1087073	Doctor warns of black fungus inside poorly cleaned oxygen cylinders	Link
1087793	Doctor warns of black fungus inside oxygen cylinders	Link

Notes: Khyber Teaching Hospital's ENT chief Dr Arif Raza has said mucormycosis, also known as "black fungus", is spreading among several coronavirus patients as they were using substandard and used old oxygen cylinders. [...] The letter said the fungus was found at the bottom of the oxygen cylinders due to lack of cleanliness. [...]

51 Fake viagra sent to Clare were bound for Lithuanian sex shop

Publication date	2021-07-29
Create date	2021-08-06
Score	7.10
Report id	1158348
Category	Erectile dysfunction medicine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Fake viagra sent to Clare were bound for Lithuanian sex shop Clare Champion

Click here to see the Original Article

Table 98: Places for report 1158348

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	People's Republic of China	35	105
Europe	Ireland	Shannon	52.70389	-8.86417

Notes: COUNTERFEIT viagra tablets estimated to be worth 65,000, posted to an address in Ennistymon were ultimately destined for a sex shop in Lithuania, a court has heard. Ennis District Court heard that 13,160 tablets, falsely branded Pfizer viagra, were intercepted by customs officers at the DHL facility in Shannon on April 17, 2018. [...] A report by Pfizer also found that the illegal tablets contained the falsified medical product, Sildnafil, which made the counterfeit viagra, the court heard, "twice as strong" as certain legal viagra products. [...]

52 Coronavirus: 600000 dodgy rapid tests seized in Cyprus

Publication date 2021-06-11

Create date 2021-06-15

Score 6.92

Report id 1095542

Category Erectile dysfunction medicine, Anaesthetic, Medical device for screening/diagnosis/monitoring, Antipsychotic

Quality Falsified

Source Unspecified outlet

Curation Manually curated

Incident or General Incident

Snippet: Coronavirus: 600000 dodgy rapid tests seized in Cyprus Cyprus Mail

Click here to see the Original Article

Table 99: Places for report 1095542

Region Name	Country	Location	Latitude	Longitude
Europe	Cyprus	Republic of Cyprus	35	33

Table 100: Drugs for report 1095542

Medicine Name	Medicine Class	Action	ATC Code
		antipsychotics	N05A

Notes: Police said on Friday they had confiscated 600,000 unauthorised or fake Covid rapid tests and suspended their use, as part of a worldwide Interpol-led operation targeting the sale of counterfeit and illicit medicines and medical products. [...] In Cyprus, some 700,000 counterfeit or unlicensed products were confiscated, with the majority being, apart from the rapid tests, local anaesthetics, antipsychotics, drugs for treating erectile dysfunction, police said. [...]

53 Falsified medicines worth $23m seized in Interpol-led crackdown - 2021-06-08

Publication date 2021-06-08

Create date 2021-06-14

Score 6.88

Report id 1091825

Category Erectile dysfunction medicine, Medical device for screening/diagnosis/monitoring, Analgesic, Antidepressant, Medical devices for disease prevention, Other

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: $23m of illicit products were seized, up from $14m last year, with fake drugs and test kits for COVID-19 once again prominent.

Click here to see the Original Article

Table 101: Places for report 1091825

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	United Kingdom of Great Britain and Northern Ireland	54.75844	-2.69531
Europe	United Kingdom	Northern Ireland	54.5	-6.5
Europe	Italy	Repubblica Italiana	42.83333	12.83333

Table 102: Drugs for report 1091825

Medicine Name	Medicine Class	Action	ATC Code
		antidepressants	N06A
		anabolic steroids	A14A

Table 103: Other Stories

ID	Title	Link
1092436	Thousands of fake online pharmacies shut in global sting: Interpol	Link

Table 103: Other Stories(continued)

ID	Title	Link
1092602	Over 1 lakh web links removed in global crackdown on illegal medical trade	Link
1092778	£3m worth of illegally sold meds and devices seized in UK	Link
1093121	Consumers Face More Risk Than Ever Due to Fake Products	Link
1093206	Over £9m worth of illegal medicines and devices seized - Latest Pharmacy News | Business | Magazine	Link
1093310	Thousands of fake online pharmacies shut down	Link
1094010	A campaign manages to close thousands of fake online pharmacies – Explica .co	Link
1094165	Interpol Shutters Thousands Of Fake Online Pharmacies Amid Demand For COVID-Related Products	Link
1095588	Thousands of Fake Online Pharmacies Shut Down in Interpol Operation	Link
1097825	Interpol shuts down thousands of fake online pharmacies	Link
1098672	Millions Of Fake Covid Tests Seized	Link
1099398	Dozens of fake online pharmacies shut down - Here are the red flags	Link
1101527	Fake Online Pharmacies And Sales Of Illegal COVID Tests Boom During Pandemic	Link
1101588	Thousands of fake online pharmacies are closed worldwide: International Criminal Police Organization	Link
1102328	Falsified medicines worth $23m seized in Interpol-led crackdown	Link
1110025	Fake vaccines are undermining the world's fight against Covid-19	Link
1114752	'Global effort' needed to fight fake goods amid Covid-19 pandemic	Link
1156598	Thousands of illegal pharmacies shut down in international operation	Link

Notes: [...] Pangea XIV, which involved authorities from 92 countries and resulted in 277 arrests, also resulted in the takedown of 113,020 web links peddling fake medicines. [...] The UK was a focal point for the operation this year, with more than three million medicines and medical devices valued at over £9m (almost $13m) seized and seven people arrested in Northern Ireland.

Checks of some 710,000 packages led to the discovery of fake and illicit drugs hidden amongst legitimate products including clothes, jewellery, toys, food and baby products. Among the illegal medicines confiscated by enforcement officers were antidepressants, erectile dysfunction tablets, painkillers, anabolic steroids and slimming pills. More than half of all medical devices seized during the operation were fake and unauthorised COVID-19 tests. UK authorities also removed more than 3,100 advertising links for the illegal sale and supply of unlicensed medicines, and

shut down 43 websites.

Meanwhile, in Venezuela a man was arrested after he developed an e-commerce platform on WhatsApp to sell illicit medicines, while in Italy authorities recovered more than 500,000 fake surgical masks as well as 35 industrial machines used for production and packaging. [...]

54 Woman dies of possible Fentanyl overdose potentially caused by fake pills flooding region

Publication date	2021-07-27
Create date	2021-08-24
Score	6.02
Report id	1181572
Category	Opioid
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Woman dies of possible Fentanyl overdose potentially caused by fake pills flooding region Valley News Live

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Table 104: Places for report 1181572

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Florida	28.75054	-82.5001

Table 105: Drugs for report 1181572

Medicine Name	Medicine Class	Action	ATC Code
oxycodone and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ17

Notes: [...] Piatkoff was later arrested along with 43-year-old Laschon Metcalf of Crookston. Both are currently facing pending charges.

Authorities say about 16 M30 pills, which are considered to be fake Percocet, were recovered. It is suspected these pills were laced with Fentanyl. [...]

55 DR Congo study shows 'strong' signal for fake malaria drugs - 2021-07-19

Publication date	2021-07-19
Create date	2021-07-22
Score	5.99
Report id	1144323
Category	Anti-malarial
Quality	Falsified
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: A third of quinine sulfate samples had no active pharmaceutical ingredient (API) at all, while 8 per cent had a different API.

Click here to see the Original Article

Table 106: Places for report 1144323

Region Name	Country	Location	Latitude	Longitude
Central Africa	Democratic Republic of the Congo	Bukavu	-2.49077	28.84281

Table 107: Drugs for report 1144323

Medicine Name	Medicine Class	Action	ATC Code
quinine	Methanolquinolines	antimalarials	P01BC01
		antimalarials	P01B
artemether	Artemisinin and derivatives, plain	antimalarials	P01BE02

Table 108: Other Stories

ID	Title	Link
1144693	DR Congo study shows 'strong' signal for fake malaria drugs	Link

Notes: The study was carried out in Bukavu, one of the larger cities in DRC over a five months period in 2019, and involved samples of quinine sulfate (QS) and artemether/lumefantrine(AL) products obtained from community pharmacies and street vendors. [...] While most (93 per cent) of AL samples met quality standards, a third of the QS tablets contained no active ingredient at all suggesting they were falsified rather than simply substandard. Another 8 per cent had a different active ingredient, which also points to falsification. [...]

56 Man Convicted of Conspiracy to Import and Distribute Fentanyl

Publication date	2021-07-09
Create date	2021-07-13
Score	5.78
Report id	1131752
Category	Opioid
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Man Convicted of Conspiracy to Import and Distribute Fentanyl Department of Justice

Click here to see the Original Article

Table 109: Places for report 1131752

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 110: Drugs for report 1131752

Medicine Name	Medicine Class	Action	ATC Code
oxycodone and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ17

Table 111: Other Stories

ID	Title	Link
1139495	Rhode Island Man Indicted for Producing Counterfeit Percocet Pills -	Link

Notes: [...] According to court documents and evidence presented at trial, Steven Barros Pinto, 40, of Pawtucket, conspired to import kilogram-quantities of fentanyl from China and use the fentanyl to manufacture counterfeit Percocet pills. Pinto personally distributed tens

of thousands of the fentanyl-laced pills. Pinto acquired the fentanyl with the assistance of co-conspirators Daniel Vivas Ceron, of Colombia, who pleaded guilty in July 2019, and Anthony Gomes, of Rhode Island, who pleaded guilty in April 2018. Pinto also engaged in a series of obstructive acts intended to silence witnesses and tamper with evidence. [...]

57 FDA to Amazon: Stop shipping products that contain undisclosed drugs

Publication date	2021-07-29
Create date	2021-08-05
Score	4.08
Report id	1158023
Category	Nutritional supplement
Quality	Substandard or Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: FDA to Amazon: Stop shipping products that contain undisclosed drugs Regulatory Focus

Click here to see the Original Article

Table 112: Places for report 1158023

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 113: Other Stories

ID	Title	Link
1158187	FDA: Amazon selling nearly 30 weight loss, sexual enhancement products with harmful ingredients	Link
1158223	FDA to Amazon: Stop shipping products that contain undisclosed drugs	Link

Notes: [...] FDA purchased samples of 26 sexual enhancement products through the company's website between December 2019 and February 2020 and confirmed through laboratory analyses that all products sampled contained one of more of the active pharmaceutical drug ingredients sildenafil, tadalafil or vardenafil, yet none of these ingredients were declared on the product's labeling. [...] In March 2021, FDA yet again purchased samples of two additional sexual enhancement products and one weight loss product through the Amazon website. FDA confirmed through laboratory analyses that the sexual enhancement products it purchased and sampled in this time frame contained tadalafil. The weight loss product contained sibutramine, a weight

loss drug that has been withdrawn from the market in the US and many other countries over safety concerns, including an increased risk of cardiovascular events. None of these drug ingredients were declared in the products' labeling, observed FDA. [...]

58 DMM Vission, S.A. de C.V. - Finished Pharmaceuticals/ Unapproved New Drug/Misbranded/Adulterated - Estado de México - 2021-06-03

Publication date	2021-06-03
Create date	2021-06-10
Score	3.48
Report id	1091500
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER DMM Vission, S.A. de C.V. MARCS-CMS 609797 — June 03, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA UPS Product: Drugs Recipient: Recipient Name Ma. de la Luz Escorza Recipient Title CEO DMM Vission, S.A. de C.V. Calle Lago Guija 234 Col. Agua Azul 57500 Ciudad Nezahualcoyotl , Méx. Mexico Issuing Office: Center for Drug Evaluation and Research United States Warning Letter 320-21-48 June 03, 2021 Dear Ms. Escorza: Your firm was registered as a human drug manufacturer. The U.S. Food and Drug Administration (FDA) conducted testing of consumer antiseptic hand rub drug products (also referred to as consumer hand sanitizers) labeled as SYP HEALTH HAND SANITIZER ALCOHOL GEL and Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel. SYP HEALTH HAND SANITIZER ALCOHOL GEL was labeled as manufactured at your facility, and Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel was declared to be manufactured at your facility, DMM Vission, S.A. de C.V., FEI 3016833130, at Calle Lago Guija 234, Col. Agua Azul, Cuidad Nezahualcoyotl, Mexico. Following an attempt to import DMM Hand Sanitizer drug products into the United States, these products were detained and refused admission at the border. The results of FDA laboratory testing of batches of these drug products detained at the border demonstrate that these drug products, labeled or declared to be manufactured at your facility, are adulterated within the meaning of section 501(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(d)(2), in that a substance was substituted wholly or in part therefor. In addition, these products are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), in that the substitution demonstrates that the quality assurance within your facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements. In addition, your Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL drug products are unapproved new drugs in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and are misbranded under sections 502(j), (a), (e), (f)(2), (x) and (ee) of the FD&C Act, 21 U.S.C. 352 (j), (a), (e), (f)(2), (x) and (ee). Lastly, SYP HEALTH HAND SANITIZER is also misbranded under 502 (i) of the FD&C Act, 21 U.S.C 352(i). Introduction or delivery for introduction of such products into interstate

commerce is prohibited under sections 301(d) and (a) of the FD&C Act, 21 U.S.C. 331(d) and (a). Adulteration Violations SYP HEALTH HAND SANITIZER ALCOHOL GEL, labeled as manufactured at your facility, is labeled to contain 70% of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of SYP HEALTH HAND SANITIZER ALCOHOL GEL product detained at the border found that the product contained an average of 31% ethanol and an average of 2.3% methanol volume/volume (v/v). Additionally, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel, declared to be manufactured at your facility, is labeled to contain 70% v/v of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel product detained at the border found that the product contained an average of 22% ethanol and an average of 10% methanol v/v. Therefore, these hand sanitizer drug products are adulterated under section 501(d)(2) of the FD&C Act in that the active ingredient of ethanol was substituted wholly or in part with methanol, a dangerous chemical when in contact with human skin or ingested. Methanol is not an acceptable ingredient for hand sanitizers and should not be used due to its toxic effects. Skin exposure to methanol can cause dermatitis, as well as transdermal absorption with systemic toxicity. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system, or death. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute are most at risk for methanol poisoning. On August 21, 2020, FDA held a teleconference with you and Registrar Corp, your registered U.S. agent. We recommended you consider removing all of your firm's hand sanitizer drug products currently in distribution from the U.S. market. On August 21, 2020, FDA notified the public of methanol contamination of your hand sanitizer at the following website: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use . On September 8, 2020, you announced a voluntary nationwide recall for five lots of Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel 500ml and 1200ml bottles due to potential presence of undeclared methanol (Wood Alcohol), as noted on the following FDA webpage: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dmm-vission-sa-de-cv-issues-voluntary-nationwide-recall-cleaner-hand-sanitizer-500-ml-and-1200-ml?utm_medium=
. Additionally, the FDA contacted your firm's consignees to recall. On September 24, 2020, one of your firm's consignees, AA Products Inc., recalled one lot of SYP HEALTH HAND SANITIZER ALCOHOL GEL 500ml bottles. In response to this letter, provide the following: • A detailed investigation into how the drug products described above, which were declared or labeled as manufactured at your facility, and which were labeled as containing ethanol, were substituted in part or in whole with methanol. • A list of all raw materials used to manufacture all of your hand sanitizer drug products, including the suppliers' names, addresses, and contact information. • A list of all batches of any hand sanitizer drug products shipped to the United States by your firm, and a full reconciliation of all material you distributed. • Copies of the complete batch records for all batches distributed to the U.S. The substitution and methanol contamination in a drug product declared or labeled as manufactured in your facility demonstrates that the quality assurance within your facility is not functioning in accordance with CGMP requirements under section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). 1 Unapproved New Drug and Misbranding Violations Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically,

Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are intended for use as consumer topical antiseptics. Examples of claims observed on the Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL labeling that provide evidence of the intended use (as defined in 21 CFR 201.128) of the products include, but may not be limited to, the following: Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel: " Drug Facts . . . Purpose . . . Antimicrobial Use : To help reduce bacteria on the skin. . . Directions: Wet hands thoroughly with product, gently rub into skin and allow to dry without wiping. SYP HEALTH HAND SANITIZER ALCOHOL GEL: DRUG FACTS: . . . USES: hand sanitizer to help decrease bacteria on the skin. . . DIRECTIONS: pump as needed into your palms thoroughly spread on both hands, rub into skin until dry. These topical antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL drug products are GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). We note that over-the-counter (OTC) topical antiseptic products had been the subject of rulemaking under FDA's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified in Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer rub. Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements. However, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL do not conform to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rubs Proposed Rue, nor any other TFM, proposed rule, or final rule, and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing

without an approved application under section 505. According to the product labels, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL purportedly contain the active ingredient ethyl alcohol (ethanol) 70%. However, as previously discussed, FDA laboratory analyses of batches of these products detained at the border demonstrated that Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL contain ethyl alcohol (ethanol) in a concentration that is less than the 70% stated on its product labels and less than the amount of ethyl alcohol (ethanol) described in the 1994 TFM. 2 Such products do not conform with the TFM or applicable requirements nor are they consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. 3 FDA laboratory analyses also demonstrated that batches of Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL contain significant concentrations of the undeclared ingredient methyl alcohol (methanol). Use of methanol as an active ingredient is not in conformance with the 1994 TFM, nor is methanol included in the formulations described in FDA's Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry. Furthermore, methanol is not acceptable as an inactive ingredient in hand sanitizers. As previously discussed, methanol has significant and sometimes fatal toxic effects and, therefore, does not meet the requirements under 21 CFR 330.1(e) that its inactive ingredients be safe and suitable. 4 Additionally, these methanol-containing drug products, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL, are misbranded under sections 502(j), (a), (e), (f)(2), (x) and (ee) of the FD&C Act, 21 U.S.C. 352(j), (a), (e), (x) and (ee). SYP HEALTH HAND SANITIZER ALCOHOL GEL is also misbranded under section 502(i) of the FD&C Act, 21 U.S.C 352(i). These products are misbranded under section 502(j) of the FD&C Act, 21 U.S.C. 352(j), because they are dangerous to health when used according to their labeling as hand sanitizers. As previously stated, skin exposure to methanol could lead to systemic absorption, and substantial methanol exposure can potentially result in, among other things, blindness, permanent nervous system damage, and even death. These hand sanitizers are misbranded under section 502(a) of the FD&C Act, 21 U.S.C 352(a), because their labeling is false or misleading. As noted above, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are labeled to contain ethyl alcohol (ethanol) 70%. However, FDA laboratory analyses of batches of these products demonstrate that the products contain a concentration of ethyl alcohol (ethanol) that is less than what is stated on the product labels and contain a significant concentration of methyl alcohol (methanol), an ingredient that is not declared on the product labels. Section 201(n) of the FD&C Act, 21 U.S.C. 321(n), provides that "in determining whether the labeling or advertising is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result. . .." Thus, the misleading representation of the concentration of the active ingredient ethyl alcohol (ethanol), and the failure of the product labels to disclose the presence of methyl alcohol (methanol) in the products, causes these products to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). The failure of these products to list methyl alcohol (methanol) as an ingredient on their labels causes them to be misbranded under section 502(e)(1)(A) of the FD&C Act, 21 U.S.C. 352(e)(1)(A). Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER GEL are also misbranded under section 502(f)(2) of the FD&C Act, 21 U.S.C. 352(f)(2) because the product labels do not include all of the applicable warnings as required under 21 CFR 330.1(g). Specifically,

the labels do not include the warning statement that reads, "If swallowed, get medical help or contact a Poison Control Center right away." Furthermore, Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x) because the product labels fail to disclose a complete domestic address or domestic telephone number through which the responsible person may receive a report of a serious adverse event with such drug. In addition, SYP HEALTH HAND SANITIZER ALCOHOL GEL is packaged in a container that resembles a drinking water bottle customarily purchased by U.S. consumers. Section 502(i)(1) of the FD&C Act, 21 U.S.C. 352(i)(1), provides that a drug is misbranded if "its container is so made, formed, or filled as to be misleading …"As such, your clear, colorless hand sanitizer that fills a 33.8 fl oz container resembling a plastic water bottle ordinarily used to package drinking water is misbranded under section 502(i)(1) of the FD&C Act, 21 U.S.C. 352(i)(1). Lastly, these products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee) because Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a). CGMP Consultant Recommended Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant qualified as set forth in 21 CFR 211.34 to evaluate your operations and to assist your firm in meeting CGMP requirements if your firm intends to resume manufacturing drugs for the U.S. market. We also recommend that the qualified consultant perform a comprehensive audit of your entire operation for CGMP compliance and that the consultant evaluates the completion and efficacy of your corrective actions and preventive actions before you pursue resolution of your firm's compliance status with FDA. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance. Conclusion The violations cited in this letter are not intended to be an all-inclusive list of violations associated with your drug products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. Note that FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-78 on September 02, 2020, as the methods used in and controls used for the manufacture, processing, packing, or holding of these products do not appear to conform to current good manufacturing practices within the meaning of section 501(a)(2)(B) of the FD&C Act. Drugs and drug products that appear to be adulterated or misbranded may be detained or refused admission without physical examination. All drugs and drug products manufactured by your firm may remain listed on this import alert, until there is evidence establishing that the conditions that gave rise to the appearance of the violation have been resolved, and the Agency has confidence that future entries will be in compliance with the FD&C Act. This may include an inspection prior to the agency considering the appearance of adulteration to be addressed. If you decide you want to manufacture drugs for the United States in the future, request a Regulatory Meeting to discuss corrective actions. This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot do so within 15 working days, state your reasons for delay and your schedule for com-

pletion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov Identify your response with FEI 3016833130 and ATTN: Towanda Terrell. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research CC: Registered US Agent: Registrar Corp David Lennarz 144 Research Drive Hampton, VA 23666 Firm's External Attorney: Teresa Arellano Tere_Arellano8@hotmail.com _____1 Due to an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, FDA published the Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) on March 19, 2020, and subsequently updated the guidance several times, most recently on February 10, 2021. This guidance communicates the Agency's temporary policy that we do not intend to take action against firms for CGMP violations under section 501(a)(2)(B) of the FD&C Act if such firms prepare alcohol-based hand sanitizers for consumer use (or for use as health care personnel hand rubs) during the public health emergency, provided certain circumstances described in the guidance are present. These circumstances include preparation of hand sanitizer products using only the ingredients and formulas set forth in the guidance. In addition to the violative sample results detailed above that demonstrate the substitution of hand sanitizer products declared or labeled as manufactured at your facility, a review of the purported formulations on the drug products' labeling further indicates that these products are not prepared consistent with FDA's temporary policy set forth in the guidance. Therefore, these products do not fall within the Agency's temporary policy not to take action against firms manufacturing hand sanitizer products for violations of section 501(a)(2)(B) of the FD&C Act. 2 The 1994 TFM, which does not distinguish between antiseptic hand washes and rubs, proposed for antiseptic handwashes and healthcare personnel handwashes an alcohol concentration of 60 to 95% by volume in an aqueous solution: 59 FR at 31442. Later amendments to the 1994 TFM distinguished between antiseptic hand washes and rubs, and between consumer and healthcare personnel antiseptics, but did not change the alcohol concentration originally proposed in 1994. 3 See, e.g., Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) . Because Cleaner BY CRYSTALWARE HAND SANITIZER alcohol gel and SYP HEALTH HAND SANITIZER ALCOHOL GEL are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. 4 An inactive ingredient used in over-the-counter (OTC) monograph drugs must meet the requirements of 21 CFR 330.1(e), which requires, among other things, that inactive ingredients must be safe in the amount administered. Content current as of: 06/08/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 114: Places for report 1091500

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	Mexico	Ciudad Nezahualcoyotl	19.40061	-99.01483

Table 115: Drugs for report 1091500

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: [...] SYP HEALTH HAND SANITIZER ALCOHOL GEL, labeled as manufactured at your facility, is labeled to contain 70% of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of SYP HEALTH HAND SANITIZER ALCOHOL GEL product detained at the border found that the product contained an average of 31% ethanol and an average of 2.3% methanol volume/volume (v/v). [...]

59 Advisory - Unauthorized drugs seized from Tokyo Beauty in Burnaby, BC, may pose serious health risks

Publication date 2021-07-07

Create date 2021-07-09

Score 3.37

Report id 1128429

Category Ophthalmic medicines, Antibiotic, Dermatological medicine

Quality Substandard

Source Distributor/Wholesaler

Curation Manually curated

Incident or General Incident

Snippet: Advisory - Unauthorized drugs seized from Tokyo Beauty in Burnaby, BC, may pose serious health risks Canada NewsWire

Click here to see the Original Article

Table 116: Places for report 1128429

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Tokyo	35.6895	139.69171
Americas	Canada	Burnaby	49.26636	-122.95263

Table 117: Drugs for report 1128429

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB

Table 117: Drugs for report 1128429(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA

Table 118: Other Stories

ID	Title	Link
1128487	Advisory - Unauthorized drugs seized from Tokyo Beauty in Burnaby, B.C., may pose serious health risks	Link

Notes: Health Canada has seized several health products—including an acne gel, an antibiotic cream, eye drops and eyewashes—from Tokyo Beauty in the Metropolis at Metrotown mall, Burnaby, B.C., because they are unauthorized drugs and may pose serious health risks. [...]

60 DRAP recovers huge quantity of medicines stolen from NICVD, CHK

Publication date	2021-06-28
Create date	2021-07-07
Score	2.87
Report id	1118072
Category	Anaesthetic, Antibiotic, Other
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: DRAP recovers huge quantity of medicines stolen from NICVD, CHK The News International

Click here to see the Original Article

Table 119: Places for report 1118072

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Karachi	24.8608	67.0104

Table 120: Drugs for report 1118072

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB

Table 120: Drugs for report 1118072(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	antiinfectives	S01AA

Table 121: Other Stories

ID	Title	Link
1118117	Costly medicines stolen from NICVD, CHK recovered in raids	Link

Notes: A huge quantity of medicines stolen from the National Institute of Cardiovascular Diseases (NICVD) and Dr Ruth KM Pfao Civil Hospital were seized when the National Task Force against Spurious Drugs raided various shops and a warehouse in the Katchi Gali and Hussainabad areas of Karachi on Monday. [...] DRAP officials disclosed that they had recovered medicines stolen from the NICVD and CHK, which included costly injections to give anesthesia to patients, as well as antibiotics, steroids and other categories of medicines. They added that drugs stolen from other healthcare facilities were also stolen during the raids. [...]

Annexe D

D.6. Equipements et consommables de ventilation et d’oxygénation

Medicine Quality Monitoring Globe

September 16, 2021

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Filters applied for this report

Search	("Continuous Positive Airway Pressure" OR "Oxygen" OR "nasal catheter " OR "CPAP" OR "oximeter" OR "positive end-expiratory pressure" OR "PEEP" OR "positive end expiratory pressure" OR "bag-valve-mask" OR "self-inflating bag" OR "oropharyngeal catheter" OR "BMV" OR "nebulizer" OR "tracheostomy tube" OR "tracheal tube" OR "ambu bag" OR "ventilator" OR "bag valve" OR "nasal cannula" OR "manual resuscitator" OR "HEPA filter" OR "endotracheal tube" OR "air purifier" OR "intubation kit")
Start date	2021-06-01
End date	2021-07-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	9

1 CPAP machines and ventilators recalled over potentially dangerous foam

Publication date	2021-06-25
Create date	2021-09-08
Score	47.66
Report id	1120503
Category	Medical device used for cure/mitigation/treatment
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CPAP machines and ventilators recalled over potentially dangerous foam KGET 17

Click here to see the Original Article

Table 1: Places for report 1120503

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	Canada	Canada	60.10867	-113.64258
		Earth	0	0

Table 2: Other Stories

ID	Title	Link
1124396	Recall on Philips CPAP Devices - LVHN News	Link
1125649	Safety concerns about your Philips Ventilator, CPAP and BiPAP devices? - What you need to know	Link
1126801	TGA Therapeutic Goods Administration : Philips recall action for CPAP, Bi-Level PAP devices and mechanical ventilators	Link
1159253	Wrestling With a Recall	Link
1159598	Company recalls CPAP, BiLevel PAP machines and ventilators due to possible health risks	Link
1162597	Sleep apnoea machine recall leads to uncertainty for vulnerable consumers	Link
1175291	Certain Philips Respironics ventilators, BiPAP, CPAP machines recalled due to potential health risks	Link

Table 2: Other Stories(continued)

ID	Title	Link
1201228	Recall: Philips Respironics CPAP, BiPAP, and Ventilators	Link
1206696	Tamil Nadu govt asks company to rectify or replace 600 ventilators	Link
1211856	JPML to Hear Arguments on Philips CPAP MDL End of September	Link

Notes: Philips Respironics has issued a recall on thousands of ventilators and CPAP machines. The recall only affects units sold in the United States. The units affected include specific Philips Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilators. The issue stems from potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices. [...] Additional Information: ID 1159598 (https://winnipeg.ctvnews.ca/company-recalls-cpap-bilevel-pap-machines-and-ventilators-due-to-possible-health-risks-1.5529874): Health Canada announced the recall on Friday, saying that Philips Respironics is recalling these devices due to reports of the sound-reducing foam breaking down. This poses potential health risks as the foam can break down into particles, which could be inhaled or swallowed, or release volatile organic compounds. [...] Additional Information: ID 1162597 (https://www.miragenews.com/sleep-apnoea-machine-recall-leads-to-606695/): Philips recently issued a world-wide recall for a range of their sleep apnoea machines after finding the polyurethane foam within the machine had the potential to degrade and cause the consumer to inhale and ingest its particles, which is feared may cause cancer. [...]

2 37 caught for black marketing in essentials

Publication date 2021-06-03

Create date 2021-09-06

Score 18.82

Report id 1086685

Category Medical device for screening/diagnosis/monitoring, Antiviral others, Antiseptic, Medical device used for cure/mitigation/treatment

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: 37 caught for black marketing in essentials The Kathmandu Post

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Table 3: Places for report 1086685

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Nepal	Federal Democratic Republic of Nepal	28	84

Table 4: Drugs for report 1086685

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01
			J07
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: [...] In the last six weeks, a total of 37 persons were arrested from across the country for their alleged involvement in black marketing of oxygen, remedevisir, and oximeters, and producing fake hand sanitisers, according to the Nepal Police. [...] In the course of raids, police confiscated 13,756 litres of sanitiser, 25,000 litre of fake sanitiser, 55 oximeters, 765

fake oximeters, 6 vials of remdesivir injection, 1 vial of fake remdesivir injection, 2,000 litre methanol, 3,600 liters of ethanol, 2 fake receipt pads and 46 boxes of several medicines. [...] [pulse oximeters]

3 COVID-19: Police investigate six people over sale of fake oximeters

Publication date	2021-07-10
Create date	2021-09-06
Score	12.15
Report id	1132521
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19: Police investigate six people over sale of fake oximeters

Click here to see the Original Article

Table 5: Places for report 1132521

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taipei	25.04776	121.53185
Eastern Asia	China	People's Republic of China	35	105

Notes: Taipei police said they are investigating six people in connection with the alleged sale of fake oximeters illegally imported from China.

The suspects allegedly imported the oximeters using forged paperwork, claiming that the devices were pedometers, and then sold more than 7,000 of them to a distributor that resold them to clinics and pharmacies, police said on Wednesday.

An investigator who initiated the case said they were alerted to the situation after reading a report that a member of the public had tested an oximeter purchased from a pharmacy on a doll, and it reportedly gave a reading.

Investigators lead by the Shilin District Prosecutors' Office on Tuesday raided nine sites in Taipei, Taoyuan and Kaohsiung, and confiscated 856 fake oximeters illegally imported from China, the office said. [...] [pulse oximeter]

4 Sale of fake oxygen cylinders deplorable: Jakarta governor

Publication date	2021-07-27
Create date	2021-08-02
Score	9.30
Report id	1154953
Category	Other
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Sale of fake oxygen cylinders deplorable: Jakarta governor ANTARA English

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Table 6: Places for report 1154953

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Indonesia	Jakarta	-6.21462	106.84513

Table 7: Drugs for report 1154953

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Notes: Jakarta Governor Anies Baswedan on Tuesday described the sale of fake oxygen cylinders by certain elements to profit from scarcity of oxygen in local markets as a ”deplorable act”. [...] Earlier, Central Jakarta regional police uncovered the smuggling of imported oxygen cylinders and confiscated 166 one-meter cubic sized cylinders with falsified goods. After they were examined by the Health Ministry, around 138 oxygen cylinders were found to be in a usable condition. [...]

5 Black fungus spreading in coronavirus patients through substandard oxygen cylinders: health expert

Publication date	2021-06-03
Create date	2021-06-07
Score	8.93
Report id	1085977
Category	Medical device used for cure/mitigation/treatment
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Black fungus spreading in coronavirus patients through substandard oxygen cylinders: health expert Geo News

Click here to see the Original Article

Table 8: Places for report 1085977

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Peshawar	34.008	71.57849

Table 9: Drugs for report 1085977

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Table 10: Other Stories

ID	Title	Link
1086088	Medic warns of black fungus spread among COVID-19 patients via substandard oxygen cylinders	Link
1087073	Doctor warns of black fungus inside poorly cleaned oxygen cylinders	Link
1087793	Doctor warns of black fungus inside oxygen cylinders	Link

Notes: Khyber Teaching Hospital's ENT chief Dr Arif Raza has said mucormycosis, also known as "black fungus", is spreading among several coronavirus patients as they were using substandard and used old oxygen cylinders. [...] The letter said the fungus was found at the bottom of the oxygen cylinders due to lack of cleanliness. [...]

6 Fake medical equipment manufacturing factory busted in Agra, 1 arrested

Publication date	2021-07-01
Create date	2021-07-07
Score	8.93
Report id	1121782
Category	Medical devices for disease prevention, Other
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake medical equipment manufacturing factory busted in Agra, 1 arrested India Today

Click here to see the Original Article

Table 11: Places for report 1121782

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Agra	27.18333	78.01667

Notes: Afake medical equipment manufacturing factory was busted in Agra on Thursday, police said.

A number of medical devices, syringes, gloves, sanitary pads, and other surgical equipment were seized during the raid. [...] "The team has confiscated 1 lakh gloves, 26,000 sanitary napkins, 2,000 urine catheters, 1,000 Nebulizer masks, 50,000 surgical masks, syringes, and a large quantity of raw material worth Rs 2 crores," he said. [...]

7 3 dead after ingesting poison disguised as Covid cure pills in Erode; 2 arrested

Publication date	2021-06-28
Create date	2021-07-02
Score	7.22
Report id	1117058
Category	Not applicable
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 3 dead after ingesting poison disguised as Covid cure pills in Erode; 2 arrested India Today

Click here to see the Original Article

Table 12: Places for report 1117058

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Tamil Nādu	11	78.33333

Table 13: Other Stories

ID	Title	Link
1117181	Erode: Three die of 'Covid drug' turn out to be murder	Link
1117197	Three members of a family poisoned to death by administering fake Covid-19 pills	Link

Notes: In a shocking incident, three members of a family died in Tamil Nadu's Erode after they were given poison in the guise of Covid-19 cure pills. Police have arrested two people in connection with the case. [...] Armed with the accoutrements of a healthcare worker, including a temperature gun and pulse oximeter, Sabari visited Karuppanakounder's house on June 26. He enquired whether Karuppanakounder and his family had fever or cough, then gave them some pills by saying they would boost immunity against Covid-19. [...]

8 Steroids found in Tocilizumab sold by Surat black marketers

Publication date 2021-06-03

Create date 2021-06-07

Score 5.53

Report id 1086529

Category Immunosuppressant, Antiviral others, Medical device used for cure/mitigation/ treatment

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Steroids found in Tocilizumab sold by Surat black marketers Ahmedabad Mirror

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Table 14: Places for report 1086529

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Sūrat	21.19594	72.83023

Table 15: Drugs for report 1086529

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01
tocilizumab	Interleukin inhibitors	immunosuppressants	L04AC07

Notes: The corona pandemic has been an eye-opener of sorts. Though it has been painful for most, there have been those who have cashed in on the situation to make some quick bucks even at the cost of someone else's health. Eight people, including a doctor, were arrested last month in a black-marketing case of Tocilizumab injection by Surat's Umra police on a tip-off. According to Surat police sources, two of the injections seized from the accused were sent for laboratory tests at FSL Gandhinagar, investigations of which found that the injections contained a deadly steroid. So, now the Surat police are toying with the possibility of adding more sections to the case. [...]

9 Mexico detects fake remdesivir at hospital, for sale on web Mexico detects fake remdesivir at hospital

Publication date	2021-07-20
Create date	2021-09-01
Score	4.21
Report id	1164000
Category	Antiviral others
Quality	Falsified
Source	Hospital pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Mexico detects fake remdesivir at hospital, for sale on web Mexico detects fake remdesivir at hospital New York Post

Click here to see the Original Article

Table 16: Places for report 1164000

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102
Americas	Mexico	Tampico	22.28519	-97.87777

Table 17: Other Stories

ID	Title	Link
1145994	Mexico detects fake remdesivir at hospital, for sale on web	Link
1146001	Mexico detects fake remdesivir at hospital, for sale on web :: WRAL.com	Link
1146500	Mexico detects fake remdesivir at hospital, for sale on the web	Link

Notes: MEXICO CITY — Authorities in Mexico say they have found fake doses of the COVID-19 drug remdesivir offered for sale on the internet and at a private hospital near the US border. The federal medical safety commission said late Monday that the fake antiviral drug, which it called "a health risk," was found at a hospital in the Gulf coast city of Tampico, in the border state of Tamaulipas.

The commission said the doses had been purchased in an ”irregular manner” on the internet, but did not say whether the medication had been used there.

The drug’s manufacturer, Gilead Sciences, confirmed the falsification. The appearance and lot numbers on the packaging did not match the original.

In February, police in northern Mexico arrested six people in the border state of Nuevo León for allegedly trafficking in fake coronavirus vaccines, but did not say what kind of fake shots were involved. The suspects allegedly offered the vaccines for sale for the equivalent of around $2,000 per dose.

Analysts have long worried that criminal gangs in Mexico could seek to steal, hijack or counterfeit much-desired vaccines or medications during the pandemic. There have been hijackings or thefts of medicines and oxygen in Mexico.

Mexico is currently experiencing a third wave of coronavirus in which case numbers have now exceeded the first wave of 2020. The country has suffered about 236,000 test-confirmed deaths, but because so little testing is done, the real toll is closer to 360,000.