Table of Contents

Medical Quality Product Report - COVID-19 issues

Issue 13. Data from August & September 2021

ANNEX C: Report ID information and source articles

The document has been produced by the Medicine Quality Research Group, Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford

Annex C. Report ID information and source articles

Annex D is part of the 'Medical Product Quality Report – COVID-19 Issues. Issue 13, August & September 2021'. Please consult the Medical Product Quality Report page on the IDDO or MORU webpage to access the main text of the report.

This annex contains the reports generated by the Medicine Quality Monitoring Globe (MQM Globe) using pre-defined search terms for each of the six product categories. At the beginning of each MQM Globe-report the pre-defined search terms used to generate the report are displayed.

Only the relevant articles in the MQM Globe-reports were selected for the current COVID-19 report. For each of the report IDs (six or seven digit code) discussed in the sections on 'Articles of incidents in the lay literature', additional information (including the source article) can be found in the MQM Globe reports in this annex or they are available on the online MQM Globe[1], when introducing "reportID:XXXXXXX" in the search box.

Annex C.1. Vaccines

Annex C.2. COVID-19 diagnostics

Annex C.3. Personal Protective Equipment

Annex C.4 Sanitisers & disinfectants

Annex C.5 COVID-19 medicines

Annex C.6 Ventilation & oxygenation equipment and consumables

[1]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed January 24, 2022. https://www.iddo.org/medicine-quality-monitoring-globe

Annex C

C.1. Vaccines

Medicine Quality Monitoring Globe

November 18, 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.

Translation Disclaimer:

THIS REPORT MAY CONTAIN TRANSLATIONS POWERED BY GOOGLE. GOOGLE DISCLAIMS ALL WARRANTIES RELATED TO THE TRANSLATIONS, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF ACCURACY, RELIABILITY, AND ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

This Medicine Quality Monitoring Globe report is issued by IDDO, University of Oxford, and some sections, indicated in blue, may have been translated for your convenience using translation software powered by Google Translate. Reasonable efforts have been made to provide an accurate translation, however, no automated translation is perfect nor is it intended to replace human translators. Translations are provided as a service to users of the Medicine Quality Monitoring Globe, and are provided "as is." No warranty of any kind, either expressed or implied, is made as to the accuracy, reliability, or correctness of any translations made from the source language (Chinese, French, Spanish, or Vietnamese) into English.

The official text is the version in the source language (Chinese, French, Spanish, or Vietnamese). Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the information contained in the translated text, refer to the text in the source language (Chinese, French, Spanish, or Vietnamese) which is the official version.

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	2021-08-01
End date	2021-09-30
Language	
Report type	incident
Curation status	validated

Number of Reports	39

1 10,000 doses of fake COVID-19 vaccines destroyed by ZAMRA

Publication date	2021-09-01
Create date	2021-09-02
Score	200.04
Report id	1199738
Category	Vaccine
Quality	Diverted/Unregistered
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: 10,000 doses of fake COVID-19 vaccines destroyed by ZAMRA mwebantu.com

Click here to see the Original Article

Table 1: Places for report 1199738

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Zambia	Lusaka	-15.40669	28.28713

Table 2: Drugs for report 1199738

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 3: Other Stories

ID	Title	Link
1199667	The fake Covid vaccine scandal: How Findlay's company imported 10,000 doses without permit, license – Zambia	Link
1201176	MoH distances itself from Findlay's fake Covid Vaccine – Zambia	Link
1201354	Get to root of fake vaccines – Zambia Daily Mail	Link

Notes: THE Zambia Medicines Regulatory Authority (ZAMRA) has intercepted and destroyed 10,000 doses of a suspected COVID-19 vaccine imported into the country without authorisation. On July, 2 this year, the vaccine labelled as Hayat Vax [SARS-COV-2 Vaccine] (Vero

Cell) inactivated, with batch number HV0025, was brought into the country by an importer named Chrismar Earthmoving Equipment. In a media statement, ZAMRA said it seized the consignment which was worth USD150, 000 was seized at Kenneth Kaunda International Airport in conjunction with the Zambia Revenue Authority. The authority said the named vaccine is unauthorised for use on the Zambian market as it is not registered by ZAMRA. "In addition, the vaccine is not under the World Health Organization Emergency Use Listing.The WHO EUL procedure is one of the regulatory reliance mechanisms which ZAMRA utilizes, like other national regulatory authorities in other jurisdictions, to consider COVID 19 vaccines for national use. According to the documentation (Invoice) which was furnished to ZAMRA, the purported manufacturer of Hayat Vax vaccine is Gulf Pharmaceutical Industries while the selling entity is G42 Medications Trading LLC of the United Arab Emirates," reads the statement. [...]

2 8,900 May Have Received Fake COVID-19 Vaccines, Injected With Saline Instead

Publication date	2021-08-10
Create date	2021-08-18
Score	199.76
Report id	1172699
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: 8,900 May Have Received Fake COVID-19 Vaccines, Injected With Saline Instead International Business Times

Click here to see the Original Article

Table 4: Places for report 1172699

Region Name	Country	Location	Latitude	Longitude
Europe	Germany	Federal Republic of Germany	51.5	10.5

Table 5: Drugs for report 1172699

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 6: Other Stories

ID	Title	Link
1173343	Anti-vax nurse injects 8,600 with saline instead of COVID vaccine: police	Link
1173494	German nurse accused of switching vaccines with saline; thousand to be injected again | TheHill	Link
1173697	Anti-vaccine nurse injected 8,600 people with false COVID-19 vaccine | TheHill	Link
1173766	Nurse In Germany Allegedly Gave People Saline Instead Of COVID-19 Vaccine	Link

Table 6: Other Stories(continued)

ID	Title	Link
1173774	Nurse in Germany may have injected thousands with fake COVID vaccine	Link
1173921	Anti-vax nurse 'injected 8,600 people with saline solution instead of vaccine'	Link
1174052	Did an anti-vax nurse fake vaccine to thousands of Germans?	Link
1174309	Suspected anti-vax nurse accused of delivering thousands of fake jabs	Link
1174418	Anti-Vax Nurse Allegedly Injects 8,600 People With Salt Water Instead of Covid-19 Vaccine	Link
1175063	Anti-Vax German Nurse May Have Given 8,000 Fake Coronavirus Shots	Link
1175158	Thousands in Germany may have received fake COVID vaccines, health officials say	Link
1175659	Anti-vax nurse suspected of injecting over 8,500 with salt water instead of vaccine	Link
1176255	'Anti-vax' nurse denies injecting 8,600 patients with fake COVID vaccine	Link
1176257	'Anti-vax' nurse denies injecting patients with fake vaccine	Link
1176464	'Anti-vaxx' nurse suspected of injecting thousands with saline instead of Covid vaccine	Link
1177222	German Anti-Vaxxer Nurse Allegedly Injects 8,600 Fake Jabs; Saline Solution Not Harmful but Has Side Effects	Link
1177679	German nurses may have injected fake COVID vaccines into thousands of people	Link
1178024	Anti-vaxxer nurse 'swapped more than 8,000 vaccines for saline water'	Link
1178204	German Nurse Allegedly Switched Covid Vaccine With Saline Solution	Link
1180914	Nearly 9,000 people in Germany have to be vaccinated again after a nurse swapped vaccines for salt water	Link
1184841	Nurse Administers Saline Instead of COVID-19 Vaccine to Patients	Link
1186972	Nurse in Germany may have injected thousands with fake COVID vaccine - KTAB	Link
1187141	Thousands in Germany may have received saline shot instead of COVID vaccine, health officials say	Link
1193598	Nurse in Germany may have injected thousands with fake COVID vaccine - KLAS	Link
1193813	'Anti-vax' nurse accused of giving fake jabs	Link
1198529	A German nurse injected patients with saline instead of coronavirus vaccines, sparking fury	Link

Table 6: Other Stories(continued)

ID	Title	Link
1203091	Saline instead of COVID vaccine: German nurse speaks out about scandal	Link
1207671	German Nurse Suspected of Giving Thousands Saline Solution Instead of COVID Vaccine	Link
1211783	Covid: Germany fears thousands got saline, not vaccine from nurse	Link

Notes: Nearly 9,000 people in Germany may need to be vaccinated again after a nurse swapped out COVID-19 vaccines for a saline solution.

The German nurse is currently being investigated after she admitted to replacing doses of the Pfizer-BioNTech coronavirus vaccine for a saltwater solution to cover up dropping a vial. [...]

3 Japan's Moderna vaccine woes widen

Publication date	2021-08-30
Create date	2021-09-13
Score	137.49
Report id	1197034
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Japan's Moderna vaccine woes widen The West Australian

Click here to see the Original Article

Table 7: Places for report 1197034

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309

Table 8: Drugs for report 1197034

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 9: Other Stories

ID	Title	Link
1197035	Auckland stays in lockdown, officials report Pfizer-linked death, Moderna woes in Japan widen	Link
1197145	Japan's Moderna vaccine contamination woes widen as 1 million more shots suspended	Link
1197172	Japan's Moderna vaccine contamination woes widen	Link
1197175	Japan's Moderna vaccine contamination woes widen as 1 million more shots withdrawn	Link
1197185	Japan Suspends Moderna COVID Vaccine After Another Million Doses Found Contaminated	Link
1197331	Moderna Withdraws Additional COVID-19 Shots In Japan: What You Need To Know	Link

Table 9: Other Stories(continued)

ID	Title	Link
1197809	Japan's Moderna vaccine woes widen | Magnet | Eden, NSW	Link
1197882	Japan's Moderna vaccine contamination woes widen as regions ...	Link
1197999	Moderna Slips after Another Contaminated COVID-19 Vaccine Batch By TipRanks	Link
1200298	Japan finds another contaminated Moderna vial	Link
1200459	Japan's Moderna vaccine contamination woes widen as 1 mln more shots suspended	Link
1200863	Japan's Moderna vaccine contamination woes widen as 1mln more shots withdrawn	Link
1201870	Japan's Moderna vaccine contamination woes widen as 1 million more shots suspended | Saltwire	Link
1203873	Another 1M Moderna coronavirus vaccine doses halted in Japan as officials probe 2 deaths	Link

Notes: Moderna's COVID-19 vaccine contamination woes in Japan have widened with another million doses temporarily suspended after foreign substances were found in more batches and two people died following shots from affected lots.

The suspension of Moderna supplies, affecting more than 2.6 million doses in total, comes as Japan battles its worst wave of COVID-19 yet, driven by the contagious Delta variant, with new daily infections exceeding 25,000 this month for the first time amid a slow vaccine rollout. [...]

4 Au Japon, des particules noires découvertes dans le vaccin Moderna

[Google translate: In Japan, black particles discovered in Moderna vaccine]

Publication date	2021-09-01
Create date	2021-09-17
Score	129.67
Report id	1200712
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Au Japon, des particules noires découvertes dans le vaccin Moderna Ulyces [Google translate: In Japan, black particles discovered in Moderna Ulyces vaccine]

Click here to see the Original Article

Table 10: Places for report 1200712

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309
Eastern Asia	Japan	Kanagawa	35.41667	139.33333

Table 11: Drugs for report 1200712

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Le Japon a mis en attente un lot du vaccin Covid-19 de Moderna après qu'un pharmacien de la préfecture japonaise de Kanagawa a découvert des particules noires dans un flacon du vaccin, rapporte la BBC ce 1er septembre. En vérifiant un flacon de vaccin Moderna contre le Covid-19, un pharmacien japonais y a découvert des particules noires. Selon les médias locaux, quelque 3 790 personnes avaient déjà reçu des vaccins de ce lot mais pour l'heure, on ne sait pas si le vaccin potentiellement contaminé présente des risques pour la santé. Le distributeur national du vaccin a récupéré le flacon suspecté d'être contaminé et le reste du lot a été mis en attente . [...]

[Google translate: Japan has put a batch of Moderna's Covid-19 vaccine on hold after a pharmacist in the Japanese prefecture of Kanagawa discovered "black particles" in a vial of the vaccine, the BBC reported on September 1. While checking a vial of Moderna vaccine against Covid-19, a Japanese pharmacist discovered black particles in it. According to local media reports, some 3,790 people had already received vaccines from this batch, but at this time, it is not known whether the potentially contaminated vaccine poses a health risk. The national vaccine distributor recovered the suspected contaminated vial and the rest of the batch was "put on hold." [...]]

5 Contaminants found in more Moderna COVID vaccine in Japan

Publication date	2021-08-29
Create date	2021-09-13
Score	128.60
Report id	1196215
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Contaminants found in more Moderna COVID vaccine in Japan Kyodo News Plus

Click here to see the Original Article

Table 12: Places for report 1196215

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Gunma-ken	36.50747	138.98235

Table 13: Drugs for report 1196215

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 14: Other Stories

ID	Title	Link
1196323	Contaminants found in more Moderna COVID vaccine in Japan - The Mainichi	Link
1196750	Japanese prefecture reports contaminated Moderna Covid jab | Free Malaysia Today	Link
1196906	Japan's Moderna vaccine contamination woes widen as 1 million more shots withdrawn	Link
1196951	Japan's Moderna vaccine contamination woes widen as 1 mln more shots withdrawn	Link
1196958	Explainer: What we know about Japan's contaminated Moderna COVID-19 vaccine supplies	Link

Table 14: Other Stories(continued)

ID	Title	Link
1197021	Explainer-What we know about Japan's contaminated Moderna COVID-19 vaccine supplies	Link
1197022	Japan's Moderna vaccine contamination woes widen as 1 million more shots suspended	Link
1197031	What we know about Japan's contaminated Moderna COVID-19 vaccine supplies	Link
1197134	EXPLAINER: Japan's contaminated Moderna COVID-19 vaccine	Link
1197944	Explainer-What we know about Japan's contaminated Moderna COVID-19 vaccine supplies | Saltwire	Link
1198105	EXPLAINER-What we know about Japan's contaminated Moderna COVID-19 vaccines	Link
1198156	Explainer-What we know about Japan's contaminated Moderna COVID-19 vaccines	Link
1198814	Japan's Moderna vaccine contamination woes widen as regions put holds on shots	Link
1199136	Japan's Moderna vaccine contamination woes widen as regions put holds on more shots	Link
1200247	Japan's Moderna vaccine contamination problems widen as regions put holds on more shots	Link
1201547	Gunma latest prefecture to find contaminants in Moderna vaccine	Link
1202452	Japan's Moderna vaccine contamination woes widen as regions put holds on more shots | Saltwire	Link
1212114	A look at what we know about Japan's contaminated Moderna Covid-19 vaccines	Link
1212694	Moderna to recall COVID-19 doses in Japan after stainless steel contaminants found	Link
1213569	Japan's contaminated Moderna vaccines: what we know	Link
1214143	Japan's Moderna vaccine contamination woes widen as regions put holds on more shots	Link

Notes: The Gunma prefectural government said Sunday that foreign substances were discovered in Moderna Inc.'s COVID-19 vaccine, the latest in a series of contaminants in the company's product reported in Japan over the past several days. Blackish foreign matter, less than 0.5 millimeters in size, was spotted during pre-inoculation inspections in a vial that has a different lot number from those of the three lots suspended Thursday for use and another found Saturday in Okinawa containing black and pink substances. About 4,500 people received shots in Gunma under the lot number over the three days through Sunday but no cases of ill health have been reported, the local government said. [...] Additional Information: ID 1196958 (https://www.reuters.com/business/healthcare-pharmaceuticals/what-we-know-about-japans-contaminated-moderna-covid-19-vaccine-supplies-2021-08-30/): A vaccine centre in Gunma prefecture near Tokyo found a tiny, black substance in a vial from lot

3005236. [...]

6 Suspension de nouveaux lots du vaccin Moderna au Japon à cause d'une anomalie [Google translate: New lots of Moderna vaccine suspended in Japan due to anomaly]

Publication date	2021-08-29
Create date	2021-09-17
Score	127.56
Report id	1195952
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Suspension de nouveaux lots du vaccin Moderna au Japon à cause d'une anomalie Ouest-France Covid-19 : le Japon suspend l'utilisation de lots du vaccin de Moderna potentiellement contaminés par des impu franceinfo Lots contaminés de vaccins Moderna: le Japon enquête sur deux décès La Croix Japon : deux trentenaires décèdent après une injection de Moderna contaminée par des particules RT en français Vaccins : plus d'un million de doses contenaient une anomalie Closer France Voir la couverture complète sur Google Actualités [Google translate: Suspension of new batches of Moderna vaccine in Japan due to a West-France Covid-19 anomaly: Japan suspends the use of batches of Moderna vaccine potentially contaminated by impu franceinfo Contaminated batches of Moderna vaccines: Japan is investigating two deaths La Croix Japan: two in their thirties die after an injection of Moderna contaminated by RT particles in French Vaccines: more than a million doses contained an anomaly Closer France See full coverage on Google News]

Click here to see the Original Article

Table 15: Places for report 1195952

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Gunma-ken	36.50747	138.98235
Eastern Asia	Japan	Japan	35.68536	139.75309
Eastern Asia	Japan	Okinawa	26.5	127.93333

Table 16: Drugs for report 1195952

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 17: Other Stories

ID	Title	Link
1211851	Des lots contaminés du vaccin Moderna suspendus au Japon	Link
1212470	Impuretés dans des vaccins Moderna au Japon : enquête ouverte après deux morts, de nouveaux lots retirés	Link
1217121	Vaccin Moderna: le Japon découvre (et suspend) de nouveaux lots contaminés	Link

Notes: Les régions d'Okinawa et de Gunma au Japon ont suspendu dimanche des injections du vaccin Moderna contre le Covid-19 après la découverte de nouveaux lots contaminés, ont annoncé les autorités locales. [...] "Nous suspendons l'utilisation des vaccins Moderna contre le Covid-19 car des substances étrangères ont été repérées" dans certains lots, selon un communiqué.

Les lots concernés par cette contamination, détectée samedi à Okinawa, sont différents de ceux suspendus après la découverte d'impuretés dans certaines fioles de ce produit, selon les médias locaux.

La préfecture de Gunma, située au nord de Tokyo, a également indiqué avoir suspendu l'utilisation de lots contaminés. "Nous continuons d'utiliser les lots Moderna qui ne sont pas affectés par l'incident", a précisé un responsable. [...]

[Google translate: The regions of Okinawa and Gunma in Japan on Sunday suspended injections of the Moderna vaccine against Covid-19 after the discovery of new contaminated batches, local authorities announced. [...] "We are suspending the use of Moderna vaccines against Covid-19 because foreign substances have been spotted" in certain batches, according to a press release.

The lots affected by this contamination, detected on Saturday in Okinawa, are different from those suspended after the discovery of impurities in some vials of this product, according to local media.

Gunma prefecture, located north of Tokyo, also said it had suspended the use of contaminated lots. "We continue to use Moderna batches which are not affected by the incident," said an official. [...]]

7 Moderna probes reports of COVID-19 vaccine contamination in Japan

Publication date	2021-08-25
Create date	2021-09-15
Score	126.81
Report id	1191874
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Moderna probes reports of COVID-19 vaccine contamination in Japan FiercePharma

Click here to see the Original Article

Table 18: Places for report 1191874

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Aichi-ken	35.18017	136.90656
Eastern Asia	Japan	Japan	35.68536	139.75309
Eastern Asia	Japan	Gifu	35.78333	137.05
Europe	Spain	Kingdom of Spain	40	-4
Eastern Asia	Japan	Tokyo	35.6895	139.69171
Eastern Asia	Japan	Ibaraki	36.3	140.31667
Eastern Asia	Japan	Saitama	35.90807	139.65657

Table 19: Drugs for report 1191874

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 20: Other Stories

ID	Title	Link
1191710	Coronavirus latest: 1.6m Moderna doses withdrawn in Japan over contamination	Link
1191890	Moderna doses contaminated: Japan	Link

Table 20: Other Stories(continued)

ID	Title	Link
1191930	Moderna withholds 1.63 mln COVID-19 vaccine doses in Japan due to contamination	Link
1191934	Japan halts use of 1.63 mil. Moderna vaccine doses over contamination - The Mainichi	Link
1192065	Moderna suspends shipments of vaccine to Japan after reports of contamination	Link
1192078	Japan halts use of 1.63 mil. Moderna vaccine doses over contamination	Link
1192292	1.6 million jabs halted after tainted Moderna doses discovered | The Asahi Shimbun: Breaking News, Japan News and Analysis	Link
1192302	Japan suspends 1.6 mln doses of Moderna shot days after contamination reports	Link
1192407	Japan suspends 1.63 million Moderna doses beyond pollution	Link
1192411	Japan halts use of 1.6m doses of Moderna jab after contaminated vials found	Link
1192551	Japan pulls 1.6M COVID vaccine doses over contamination fear as COVID's spread causes heartache, Paralympic anxiety	Link
1192552	Japan stops use of 1.63 million Moderna vaccine doses over contamination	Link
1192613	Covid-19 roundup: Biden now plans boosters after 6 months as Pfizer submits sBLA; 1.6M Moderna doses contaminated in Japan — reports	Link
1192748	Japan suspends 1.6m doses of Moderna vaccine days after contamination reports	Link
1193136	Covid-19 Live Updates: Japan Suspends 1.6 Million Moderna Doses Over Contamination Fears	Link
1193408	Japan suspends 1.6M doses of Moderna shot after contamination reports	Link
1193471	Moderna's contaminated vaccine only shipped to Japan: Spanish maker	Link
1193525	COVID live updates: Moderna puts 1.6 million vials on hold in Japan	Link
1193642	UPDATE 6-Japan suspends 1.6 mln doses of Moderna shot after contamination reports	Link
1194281	Japan Pulls 1.6 Million Doses of 'Contaminated' Moderna Vax	Link
1194354	Moderna vaccine production continues in EU amid contamination probe	Link
1195244	Amid contamination probe, Moderna COVID vaccine production goes on in EU - 2021-08-28	Link
1195527	Japan suspends 1.6 million Moderna Covid vaccine doses over contamination concerns	Link

Table 20: Other Stories(continued)

ID	Title	Link
1195784	Contaminant in Moderna COVID-19 vaccine vials found in Japan was metallic particles: report	Link
1195949	Japan probes deaths of men jabbed with suspended Moderna doses	Link
1195988	Moderna jabs in PH not contaminated; procurement continuous	Link
1197345	What We're Reading: Japan Reports Vaccine Contamination Risk; Biogen Offers Aduhelm for Free; Hospitalization Risk With Delta Variant	Link
1198975	Moderna's contaminated jab only shipped to Japan: Spanish maker	Link
1199250	No contaminated Moderna vaccine in Korea, officials say	Link
1199816	Explainer: What we know about Japan's contaminated Moderna COVID-19 vaccines	Link
1199869	Contaminated vaccine shocks Japan; Kiss frontman has Covid	Link
1200163	Covid: Universal credit top-up phasing out and vaccine contamination fears	Link
1200164	Japan: Foreign material in Covid vax vials puts shots on hold	Link
1200390	3 lots of Moderna Covid vaccine doses to be recalled by Japanese distributor over stainless steel contamination – worldnewshere.net	Link
1200432	Modana says the contaminated COVID vaccine sent to Japan contains steel	Link
1200433	Contaminated COVID-19 jabs sent to Japan contained steel: Moderna | Daily Sabah	Link
1200441	Moderna says tainted COVID vaccines sent to Japan contained steel	Link
1200499	In Japan, Two Die After Receiving Possibly Contaminated COVID-19 Vaccines	Link
1200590	Japan Begins Recall of Tainted Moderna COVID-19 Vaccine	Link
1200696	Moderna vaccine contaminated in Japan: Stainless steel particles found in vials	Link
1201229	Japan's Moderna Covid vaccine rollout hit by recall and contamination scares	Link
1201233	Moderna (MRNA) Japan Jabs Resume Amid Safety Risk Per Reports	Link
1202406	EU investigating Moderna vaccine contamination incident – latest updates	Link
1202603	Moderna jabs safe, not part of contaminated batch in Japan — FDA	Link

Table 20: Other Stories(continued)

ID	Title	Link
1202604	Japan has paused the use of 1.63 million Moderna vaccine doses over contamination claims	Link
1203090	WATCH | Japan finds another contaminated Moderna vial	Link
1205419	EDITORIAL| Probe Moderna Contamination to Ease Public Anxiety Over Vaccine Safety	Link
1207279	After Moderna contamination mess, Takeda strikes deal with Japan to supply Novavax COVID-19 vaccines	Link
1207887	Japan Suspends 1.63 Million Doses Of Moderna's COVID-19 Vaccine Over Contamination	Link
1208088	EU investigating Moderna vaccine contamination incident	Link
1212449	Japan withdraws 1.6 mln Moderna COVID-19 vaccine doses over contamination - Nikkei	Link
1216393	Japan halted use of 1.63 million Moderna doses over claims particles were found floating in vials	Link
1217056	Japan has not approved ivermectin as a COVID treatment, and it's still using the Moderna vaccine – Poynter	Link
1219641	Spain's Rovi says possible Moderna vaccine contamination under investigation	Link
1228406	The Latest: Moderna, Japan partner recall 1.6 million doses	Link
1228808	Japan suspends 1.63M doses of Moderna over contamination	Link
1236420	Japan halts Moderna doses due to CDMO contamination fears - BioProcess Insider	Link
1236731	Japan: 1.6m Moderna vaccines recalled; Novavax replacement deal signed	Link
1237555	Takeda of Japan says "human error" caused contamination of the Moderna vaccine	Link
1238145	Floating material found in Pfizer COVID-19 vaccine vials in Japan, but company says it's not contamination	Link
1238148	Moderna Says Covid-19 Vaccine Contaminant in Japan Was Stainless Steel, Sees No Safety Issue	Link
1238680	'Human Error' Caused Contamination Of 1.63M Moderna COVID Vaccine Doses In Japan	Link
1239103	Takeda Says 'Human Error' Reason Behind Contaminated Moderna COVID-19 Vaccines	Link
1243609	Japan unable to link deaths to withdrawn batches of Moderna vaccine	Link
1252157	Japan's Takeda says 'human error' caused contamination of Moderna vaccines	Link

Table 20: Other Stories(continued)

ID	Title	Link
1254546	'Human Error' Caused Contamination Of Moderna Vaccines In Japan, Distributor Takeda Says	Link
1254610	Moderna says contaminated vaccines posed no 'undue' health risk	Link
1254679	Moderna Vaccine Recall Over Stainless Steel Contamination Caused by 'Human Error'	Link
1254828	Moderna report says 'human error' to blame for contamination found in 3 vaccine lots from Rovi plant	Link

Notes: It's been a relatively smooth ride for Moderna's global COVID-19 vaccine roll out. But on Wednesday, the company said it's investigating the possible contamination of one batch sent to Japan. [...] The complaints came from "one product lot" which was distributed in Japan, the representative added. Kyodo News reported that Moderna's vaccine partner in Japan, Takeda, has suspended the use of 1.63 million doses. Moderna said it believes an issue affecting a production line at a contract manufacturing facility in Spain is responsible. [...] Additional information: ID 1191930 (https://www.reuters.com/world/asia-pacific/japan-withdraws-16-mln-moderna-covid-19-vaccine-doses-over-contamination-nikkei-2021-08-25/): [...] Japan's defence ministry, which operates a mass vaccination site in Osaka, said shots from the lot in question, which contains 565,400 doses, had been used in the western prefecture between Aug. 6 and Aug. 20, but it did not say how many people were affected. Japanese carrier ANA (9202.T) said about 4,700 shots of the halted Moderna lot had been used and it would stop all vaccinations planned on Thursday. [...] Additional information: ID 1191934 (https://mainichi.jp/english/articles/20210826/p2g/00m/0na/002000c): [...] The 1.63 million doses, which have been distributed to 863 vaccination centers, were manufactured on the same production line at the same time in Spain, and fall under three lot numbers – 3004667, 3004734 and 3004956, the Health, Labor and Welfare Ministry said. The Tokyo metropolitan government said around 9,100 people may have received contaminated shots at two of the vaccination sites it runs. Among other prefectures, Osaka counted about 50,000 such shots, Hyogo 41,500 and Aichi 28,000. [...] The foreign substances have been confirmed since Aug. 16 at eight vaccination sites in five prefectures – Ibaraki, Saitama, Tokyo, Gifu and Aichi. They were found in a total of 39 vials. [...] Additional information: ID 1195784 (https://www.fiercepharma.com/pharma/contaminant-moderna-covid-19-vaccine-vials-found-japan-was-metallic-particles-report): [...] The contaminant is believed to be a metallic particle, said Japanese public broadcasting outlet NHK, citing health ministry sources. [...]

8 Contrefaçon de vaccins et d'antiviraux contre la c... [Google translate: Counterfeit vaccines and antivirals against c ...]

Publication date	2021-09-12
Create date	2021-09-14
Score	125.70
Report id	1214113
Category	Vaccine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Contrefaçon de vaccins et d'antiviraux contre la c... MesVaccins.net
[Google translate: Counterfeit vaccines and antivirals against c ... MesVaccins.net]

Click here to see the Original Article

Table 21: Places for report 1214113

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Iran	Islamic Republic of Iran	32	53

Table 22: Drugs for report 1214113

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: [...] En juillet 2021, en Iran, le ministère iranien du Renseignement (VAJA) a arrêté plusieurs personnes lors d'une opération de saisie d'une importante cargaison de vaccins anti-covid contrefaits et passés en contrebande. L'agence de presse officielle IRNA a déclaré, en citant un communiqué du VAJA, que les réseaux étaient actifs dans le trafic et la contrefaçon de vaccins très demandés en Iran. Le communiqué précise que les forces de la VAJA ont été informées par le public et ont utilisé des renseignements détaillés pour démanteler ces réseaux. Selon le rapport, les vaccins confisqués comprenaient de grandes marques étrangères comme le chinois Sinopharm ou le suédo-britannique AstraZeneca, ainsi que le produit américain de BioNTech-Pfizer, qui est interdit en Iran. Le rapport ne précise toutefois pas la proportion de vaccins contrefaits. [...]

[Google translate: [...] In July 2021, in Iran, the Iranian Ministry of Intelligence (VAJA) arrested several people during an operation to seize a large shipment of counterfeit and smuggled anti-covid vaccines. The official IRNA news agency said, citing a statement from the VAJA, that the networks were active in trafficking and counterfeiting vaccines in high demand in Iran. The statement said VAJA forces were briefed by the public and used detailed intelligence to dismantle these networks. According to the report, the confiscated vaccines included big foreign brands like Chinese Sinopharm or Swedish-British AstraZeneca, as well as the US product from BioNTech-Pfizer, which is banned in Iran. However, the report does not specify the proportion of counterfeit vaccines. [...]]

9 Japón suspende aplicación de Moderna contra Covid-19 por lote contaminado [Google translate: Japan suspends application of Moderna against Covid-19 due to contaminated batch]

Publication date	2021-08-25
Create date	2021-09-16
Score	123.89
Report id	1192098
Category	Vaccine
Quality	Degraded
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Japón suspende aplicación de Moderna contra Covid-19 por lote contaminado La Lista

[Google translate: Japan suspends application of Moderna against Covid-19 due to contaminated batch The List]

Click here to see the Original Article

Table 23: Places for report 1192098

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309

Table 24: Drugs for report 1192098

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01
			V
			J07

Table 25: Other Stories

ID	Title	Link
1193427	Contaminante en vacunas de Moderna podría ser partícula metálica: NHK	Link
1193441	Japón suspende el uso de más de 1.5 millones de vacunas Moderna, ¿por qué lo hizo?	Link
1193538	Partícula metálica habría contaminado más de 1.6 millones da dosis de la vacuna Moderna	Link
1193715	Japón detecta 'partículas metálicas' en el lote contaminado de Moderna-Rovi	Link
1193835	Coronavirus.- Japón no registra problemas vinculados a las vacunas de los lotes contaminados de Moderna	Link
1194491	Hallan 'partícula metálica' en vacuna contaminada de Moderna	Link
1194605	Suspenden más de 1 millón de dosis de Moderna por tener 'partículas metálicas' - Diario El Heraldo	Link
1194613	Vacunas de Moderna contra la Covid-19 que recibió Japón podrían tener partículas metálicas	Link
1194644	Japón suspende más de 1 millón de dosis de Moderna por tener 'partículas metálicas' - Diario El Heraldo	Link
1195094	Dos personas mueren en Japón tras recibir la vacuna del lote contaminado de Moderna	Link
1195141	Japón investiga la relación entre dos muertes y la vacuna del lote contaminado de Moderna	Link
1195319	Coronavirus.- Japón investiga dos muertes presuntamente relacionadas con un lote contaminado de la vacuna Moderna	Link
1195323	Japón investiga dos muertes presuntamente relacionadas con un lote contaminado de la vacuna Moderna	Link
1195326	Japón investiga la muerte de dos vacunados con un lote contaminado de Moderna procedente de España	Link
1195349	Japón investiga la muerte de 2 vacunados con un lote contaminado de Moderna procedente de España	Link
1195448	Japón investiga 2 muertes de vacunados contra el COVID con los lotes fabricados en Madrid	Link
1195605	Mueren dos personas en Japón tras recibir vacunas de Moderna contra Covid-19	Link
1195715	Fallecen dos hombres en Japón tras recibir vacuna anticovid de Moderna contaminada	Link
1196264	Japón reporta dos muertes en vacunados con los lotes procedentes de España: se investiga causa de los decesos	Link
1196662	Japón encuentra más vacunas Moderna contaminadas	Link
1197042	Okinawa de Japón suspende vacunación tras descubrir otro lote de Moderna contaminado	Link

Table 25: Other Stories(continued)

ID	Title	Link
1197103	Los problemas de contaminación con la vacuna japonesa Moderna se expanden, con un millón de dosis adicionales suspendidas	Link
1197501	Japón investiga dos muertes relacionadas con lote contaminado de Moderna - HOY DIARIO DEL MAGDALENA	Link
1197502	Japón investiga caso de vacunas contaminadas de Moderna	Link
1197503	Coronavirus.- Japón investiga la muerte de dos vacunados con un lote contaminado de Moderna procedente de España	Link
1197565	Japón detiene 2,6 millones de dosis de Moderna mientras los funcionarios dicen que dos muertes posiblemente estén relacionadas con la vacuna	Link
1197629	Lote contaminado de Moderna	Link
1197776	Dos personas murieron en Japón días después de recibir vacunas Moderna: Lote habría estado contaminado	Link
1198941	Lo que sabemos sobre las vacunas de Moderna contaminadas en Japón	Link
1199281	Detectan otro lote de Moderna contaminado en Japón, suman más de 4 millones de dosis desechadas	Link
1200338	Japón suspende la vacunación al descubrir nuevos lotes contaminados de Moderna	Link
1200404	Suspenden vacunación contra la Covid-19 en región de Japón tras hallar nuevas impurezas en dosis de Moderna	Link
1200462	Moderna confirma que las vacunas Covid-19 enviadas a Japón contenían partículas de acero	Link
1200463	Moderna dice que vacunas anticovid enviadas a Japón contenían acero	Link
1200464	Moderna admite que lote de vacunas anticovid enviado a Japón contenía acero inoxidable	Link
1200472	Vacunas contaminadas de Moderna en Japón contenían acero inoxidable	Link
1200547	Japón detecta otro caso de vacuna de Moderna contra Covid-19 contaminada	Link
1200548	Las vacunas que Moderna envió a Japón tenían ”partículas de acero”, informó el laboratorio	Link
1200549	Moderna afirma que las dosis con ”partículas de acero” detectadas en Japón no son riesgosas	Link
1200786	Moderna admite que vacunas de Japón tienen acero; retiran lotes contaminados	Link
1200884	Moderna admitió que envió lote de vacunas contaminado con acero inoxidable a Japón	Link

Table 25: Other Stories(continued)

ID	Title	Link
1200994	Moderna dice que vacunas contra el COVID-19 contaminadas en Japón contenían acero	Link
1200996	Vacunas contra Covid-19 desechadas por Japón contenían plomo: Moderna | El Universal	Link
1201024	Moderna admite existencia de partículas de acero en vacunas anti Covid-19	Link
1201142	Moderna dice que vacunas contra el coronavirus enviadas a Japón contenían acero inoxidable	Link
1201314	Vacunas contra Covid desechadas por Japón contenían plomo: Moderna – Periodico Contacto	Link
1201375	Rovi encuentra partículas de acero en las vacunas de Moderna, pero asegura que no supone ningún riesgo	Link
1201377	¿Por qué Japón suspendió más de 1,6 millones de dosis de la vacuna anticovid de Moderna?	Link
1201451	Moderna: Vacunas enviadas a Japón contenían acero	Link
1201895	Moderna dice que vacunas enviadas a Japón contenían acero	Link
1201957	Moderna informa que vacunas enviadas a Japón contenían acero	Link
1202179	Moderna acepta que lotes de vacunas anticovid-19 enviados a Japón fueron contaminados con acero	Link
1202478	La farmacéutica española Rovi investiga la posible contaminación de 1,6 millones de vacunas de Moderna retiradas en Japón	Link
1203118	Los viales contaminados retrasan la campaña de vacunación en Japón con los contagios de covid al alza	Link
1204072	Moderna admitió que envió lote contaminado a Japón	Link
1204315	Japón retira 1,63 millones de vacunas anti-COVID de Moderna por una anomalía	Link
1205084	El golpe en bolsa a Rovi llega a los 1.000 millones por el lote nipón contaminado	Link
1206652	Investigan tercera muerte de vacunado en Japón con lote contaminado de España	Link
1206926	Investigan tercera muerte de vacunado con Moderna en Japón con lote contaminado de España	Link
1207183	Japón investiga una tercera muerte de un vacunado con el lote contaminado de España	Link
1207246	Muere una tercera persona después de recibir la vacuna Moderna contaminada	Link
1208015	Japón investiga la tercera muerte de un vacunado con el lote de Moderna contaminado	Link
1209437	Vacuna Moderna: Hallan la partícula 'culpable' de las dosis contaminadas en Japón	Link

Table 25: Other Stories(continued)

ID	Title	Link
1212168	Mueren dos personas en Japón días después de recibir vacunas de Moderna de un lote cuyo uso había sido suspendido por riesgo de contaminación	Link
1215581	Lo que sabemos sobre las vacunas COVID-19 de Moderna contaminadas en Japón	Link

Notes: Info adicional: Vacunas contaminadas con partículas de acero.

[Google translate: Additional info: Vaccines contaminated with steel particles.
]

10 Pfizer says substances found in COVID-19 vaccine vials in Japan harmless - Reports

Publication date	2021-09-15
Create date	2021-09-16
Score	123.37
Report id	1217459
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Pfizer says substances found in COVID-19 vaccine vials in Japan harmless - Reports United News of India

Click here to see the Original Article

Table 26: Places for report 1217459

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309
Americas	United States	United States	39.76	-98.5

Table 27: Drugs for report 1217459

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: US pharmaceutical company Pfizer has announced that 95 vials of its coronavirus vaccine had floating substances, which are undissolved residue and are thus harmless, the Japanese Kyodo news agency reported on Wednesday. [...] Speaking at a press conference in Tokyo, Pfizer's Japanese branch said that vials can contain a white undissolved residue that does not pose a health issue even if it does not get dissolved when the vial is turned over. At the same time, the company promised to look into the matter and report its findings. [...]

11 30 million 'contaminated' J&J vaccines destroyed in South Africa

Publication date	2021-09-23
Create date	2021-09-28
Score	122.27
Report id	1227495
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: 30 million 'contaminated' J&J vaccines destroyed in South Africa African Business Magazine

Click here to see the Original Article

Table 28: Places for report 1227495

Region Name	Country	Location	Latitude	Longitude
Southern Africa	South Africa	Republic of South Africa	-29	24

Table 29: Drugs for report 1227495

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 30: Other Stories

ID	Title	Link
1228506	30 million J&J vaccines destroyed in South Africa	Link

Notes: Thirty million Covid-19 vaccines manufactured by US pharmaceutical giant Johnson & Johnson (J&J) were destroyed at the Aspen Pharmacare facility in South Africa in June, weeks before a deadly third wave hit the country. The destroyed doses, manufactured at Aspen's Gqeberha facility, were compromised due to a contaminated drug substance supplied by J&J's

US partner Emergent Biosolutions, Aspen said. [...]

12 Contaminants found in Moderna vaccine not belonging to suspended lots

Publication date	2021-08-28
Create date	2021-09-13
Score	117.06
Report id	1195426
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Contaminants found in Moderna vaccine not belonging to suspended lots Kyodo News Plus

Click here to see the Original Article

Table 31: Places for report 1195426

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Okinawa	26.5	127.93333

Table 32: Drugs for report 1195426

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 33: Other Stories

ID	Title	Link
1195728	Vaccinations halted as another contaminated Moderna vial found in Japan	Link
1195781	Another contaminated Moderna vial discovered in Japan	Link
1195822	Japan blocks more Moderna vaccines over contamination fears	Link
1195823	Japan finds more contaminated vaccines	Link
1195861	Japan detects more Moderna vaccine contamination	Link

Table 33: Other Stories(continued)

ID	Title	Link
1195867	Japan finds more contaminated Moderna vaccines	Link
1195982	Okinawa Prefecture suspends use of Moderna vaccine over contaminated vial, syringes	Link
1196783	Japan's Okinawa suspends inoculation after more Moderna shots contaminated	Link
1198099	Japan health minister says Moderna vaccine contaminants likely from needle stick	Link
1199201	Japan says highly likely that contamination found in Moderna vaccines caused by needles	Link
1214053	Tainted Moderna vaccine found in Okinawa under 4th lot number | The Asahi Shimbun: Breaking News, Japan News and Analysis	Link
1214236	Rubber bits likely tainted Moderna vaccine in Okinawa shots | The Asahi Shimbun: Breaking News, Japan News and Analysis	Link
1214385	Rubber stopper debris cause of contaminated vaccines found in Okinawa: health ministry - The Mainichi	Link
1215436	Japanese Health Minister Says Vaccine Contaminants Likely Caused By Incorrect Needle Use, No Safety Issue With Moderna Shot	Link
1215588	Japan health minister says Okinawa vaccine contaminants likely from needle stick	Link

Notes: The Okinawa prefectural government said Saturday that it has found foreign matter in an unused vial of Moderna Inc.'s COVID-19 vaccine not belonging to batches already suspended from use following the discovery of contaminants. Japan's health ministry said Thursday that foreign substances have been confirmed in 39 unused vials at eight vaccination sites in five prefectures – Ibaraki, Saitama, Tokyo, Gifu and Aichi. Additional Information: ID 1196215 (https://english.kyodonews.net/news/2021/08/975bf8bfc1f8-okinawa-halts-vaccines-after-another-moderna-contaminated-lot-found.html): These four vials fall under the same lot number – 3005293 – which is different from the three other lot numbers identified by Japan's health ministry Thursday as potentially contaminated doses.

The Health, Labor and Welfare Ministry said Sunday that rubber pieces have likely fallen into the vials when a syringe needle was inserted into the rubber top of the vials. The ministry has found no major problem in vaccine quality, it added. [...]

13 Contaminated Pfizer Covid-19 vaccines found in Japan

Publication date	2021-09-14
Create date	2021-09-15
Score	115.68
Report id	1216365
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Contaminated Pfizer Covid-19 vaccines found in Japan Prensa Latina

Click here to see the Original Article

Table 34: Places for report 1216365

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Sakai	34.58333	135.46667
Eastern Asia	Japan	Kamakura	35.30889	139.55028
Eastern Asia	Japan	Kanagawa	35.41667	139.33333
Eastern Asia	Japan	Sagamihara-shi	35.55	139.35
Eastern Asia	Japan	Osaka	34.69374	135.50218

Table 35: Drugs for report 1216365

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 36: Other Stories

ID	Title	Link
1216737	Contaminants found in Pfizer vaccine in cities near Tokyo and Osaka	Link
1217483	Contaminants Found in Pfizer Vaccine in Japan	Link

Notes: Local governments of the Japan's Kanagawa and Osaka prefectures on Tuesday re-

ported the detection of strange substances in five vials of the Covid-19 vaccine produced by US drugmaker Pfizer, which had not been used.

According to the source, the vials with the floating white substance belong to the same batch, FF5357, and were found in Sagamihara and Kamakura cities, both in the Kanagawa prefecture; as well as in Sakai in the western Osaka province. [...] The local governments claimed that they did not use the doses containing the strange substance and continued administering doses with the same batch number after confirming they were not contaminated. [...]

14 Coronavirus - Africa: Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine

Publication date	2021-08-16
Create date	2021-09-01
Score	109.86
Report id	1179721
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Coronavirus - Africa: Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine Africanews English

Click here to see the Original Article

Table 37: Places for report 1179721

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
		Africa	7.1881	21.09375
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 38: Drugs for report 1179721

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 39: Other Stories

ID	Title	Link
1179936	BRIEF-WHO Says Falsified Covishield Vaccine Identified In Africa, South-East Asia	Link
1180400	WHO alerts to fake COVID-19 vaccines as FG receives more doses, begins vaccination	Link
1180665	WHO alert on falsified versions of Covishield in Uganda and India	Link

Table 39: Other Stories(continued)

ID	Title	Link
1181027	Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine	Link
1181154	Serum Institute confirms fake vaccine batches supplied in Uganda, India	Link
1181175	WHO alert on fake Covishield in Uganda, India	Link
1181229	WHO issues medical alert on fake Covishield vaccines	Link
1181685	Breaking News August 18 LIVE: WHO issues alert on fake Covishield vaccine doses circulating in India	Link
1181695	Coronavirus News LIVE Update: WHO Issues Alert on Fake Covidshield Vaccines; 4th Wave Wreaks Havoc in US, F	Link
1181760	Fake Covishield vaccines identified in India, Uganda; WHO issues alert	Link
1181844	WHO issues medical alert as fake Covishield vaccines found in India, Uganda	Link
1181922	Covishield: WHO flags fake jabs in India, Africa	Link
1182036	WHO issues alert over fake Covishield vaccine doses in India, Africa	Link
1182164	WHO redflags counterfeit Covishield vaccines circulation in India, Uganda	Link
1182534	WHO identifies counterfeit versions of Covishield in India	Link
1182619	WorldView: Fake COVID-19 vaccines seized in India and Africa; UK fears possible inflation	Link
1182733	WHO flags fake Covid vaccine in India and Africa	Link
1182794	WHO identifies fake Covishield in India, Uganda	Link
1182974	Covid update: US approves booster shot; states ease norms; WHO flags fake jabs	Link
1183414	Fake Covishield vaccines found in India, Uganda: WHO issues alert	Link
1183510	Fake versions of Covishield identified by WHO in India - 2021-08-19	Link
1183990	Report About Fake Covishield Vaccine Being Probed: Mandaviya	Link
1184006	Fake Covishield Vaccines Traced in India: WHO - Sentinelassam	Link
1184007	Report about fake Covishield vaccine being probed: Mandaviya	Link
1184162	Fake Covishield vax found in India, Uganda: WHO	Link
1184485	WHO identifies counterfeit Covid vaccines in India being administered as 'Covishield'	Link
1184754	Report About Fake Covishield Vaccine Being Probed: Union Health Minister	Link
1186645	Coronavirus – Africa: Medical Product Alert N °5/2021: Falsified COVISHIELD vaccine	Link

Table 39: Other Stories(continued)

ID	Title	Link
1186815	Coronavirus - Africa: Medical Product Alert N 5/2021: Falsified COVISHIELD vaccine	Link
1187108	City Buzz: Fake Covishield | COVID compensation guidelines | Swine flu in Delhi...and more	Link
1187501	WHO confirms existence of fake Covishield vaccines in India; Serum Institute pushes for a booster shot	Link
1192492	Fake Covishield vaccines reported in India and Uganda; WHO issues alert - Gaonconnection | Your Connection with Rural India	Link
1194407	Fake Covishield Vaccines: Odisha Govt Asks Collectors To Step Up Vigil	Link
1195045	Counterfeit Covid-19 Vaccine: Odisha Govt Asks Local Authorities To Be Vigilant	Link
1195057	Odisha issues alert over counterfeit Covishield vaccine,local authorities to be vigilant	Link
1195395	Odisha issues alert over fake Covishield vaccine,local authorities to be vigilant	Link
1195427	Odisha issues alert over fake Covishield vaccine	Link
1196067	India probing claim of counterfeit versions of Covishield: Union Min	Link
1200809	India's counterfeit Covishield vaccine reports being investigated: Health Minister	Link
1202662	Inquiry launched into fake vials of Covishield after WHO raised alert, says health minister	Link
1203624	WHO releases alert on falsified COVISHIELD vaccine	Link
1204552	WHO Alert On Fake Covishield COVID-19 Vaccine Circulating In India, Uganda	Link
1220030	WHO confirms fake Covishield vaccines in India, Africa; says it could 'pose serious risk'	Link
1220272	WHO finds fake Covishield in Kolkata	Link
1221576	Individuals Vaccinated with Fake Covid Vaccines Urged to Go for Authentic Jabs	Link

Notes: This WHO Medical Product Alert refers to falsified COVISHIELD (ChAdOx1 nCoV-19 Corona Virus Vaccines (Recombinant)) identified in the WHO African Region, and the WHO South-East Asia Region. The falsified products were reported to WHO in July and August 2021. The genuine manufacturer of COVISHIELD (Serum Institute of India Pvt. Ltd.) has confirmed that the products listed in this alert are falsified. These falsified products have been reported at the patient level in Uganda and India. [...] Batch 4121Z040 – the expiry date (10.08.2021) on this product is falsified. COVISHIELD 2ml – the genuine manufacturer does not produce COVISHIELD in 2ml (4 doses). [...]

15 Japon : plus d'un million de doses du vaccin Moderna suspendues pour anomalie [Google translate: Japan: more than a million doses of Moderna vaccine suspended for anomaly]

Publication date	2021-08-26
Create date	2021-09-17
Score	103.66
Report id	1192187
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Japon : plus d'un million de doses du vaccin Moderna suspendues pour anomalie Capital.fr
[Google translate: Japan: more than a million doses of Moderna vaccine suspended for anomaly Capital.fr]

Click here to see the Original Article

Table 40: Places for report 1192187

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309
Europe	Spain	Kingdom of Spain	40	-4

Table 41: Drugs for report 1192187

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 42: Other Stories

ID	Title	Link
1192125	Covid-19 : 1,63 million de vaccins suspendus au Japon, l'OMS alerte sur l'urgence à reprendre la recherche sur les origines du SARS-CoV-2	Link

Table 42: Other Stories(continued)

ID	Title	Link
1192298	1,63 million de doses de Moderna suspendues	Link
1192377	Covid-19: 1,63 million de vaccins Moderna suspendus au Japon à cause d'une anomalie	Link
1192835	Covid-19. 1,63 million de doses de vaccin Moderna suspendues au Japon pour anomalie	Link
1192890	Covid-19 : 1,6 million de doses du vaccin Moderna retirées au Japon à cause d'une anomalie	Link
1192967	Vaccins : plus d'un million de doses contenaient une anomalie	Link
1195217	Lots contaminés: le Japon enquête sur deux décès	Link
1195347	Japon : deux trentenaires décèdent après une injection de Moderna contaminée par des particules	Link
1195383	Le Japon suspend l'utilisation de 1,6 million de doses de Moderna pour anomalie	Link
1195508	Covid-19 : le Japon suspend l'utilisation de trois lots du vaccin de Moderna potentiellement contaminés par de	Link
1195528	Covid-19 : le Japon suspend l'utilisation de lots du vaccin de Moderna potentiellement contaminés par des impu	Link
1196069	Covid-19 : Melbourne prolonge son confinement, enquête sur des lots de vaccin contaminés au Japon	Link
1196209	Covid-19 : le Japon suspend de nouveaux lots du vaccin Moderna	Link
1196211	Vaccin Moderna: l'agent contaminant serait une particule métallique	Link
1196224	La région d'Okinawa suspend un nouveau lot de vaccin Moderna en raison d'anomalies	Link
1196358	Vaccins contre le Covid-19 : le Japon enquête sur deux décès après la découverte de lots contaminés de vaccins	Link
1199388	Contamination de vaccins Moderna : le Japon enquête sur deux décès	Link
1199685	Lots contaminés de vaccins Moderna au Japon : ce que l'on sait	Link
1199868	Covid : Un nouveau lot de vaccins Moderna suspendu au Japon	Link
1200451	Vaccins Moderna au Japon : ce que l'on sait des particules étrangères trouvées dans les doses de la firme américaine	Link
1201293	Covid : Les doses de vaccin Moderna suspendues au Japon contenaient des particules métalliques	Link
1202624	Laboratorios Farmaceuticos Rovi, S.A. : recule après la découverte d'un lot de vaccins Moderna défectueux	Link

Table 42: Other Stories(continued)

ID	Title	Link
1202730	COVID-19 : vaccins Moderna contaminés au Japon, début des administrations des doses de rappel et nouveaux variants sous surveillance…	Link
1204892	Covid-19. Les doses de vaccins Moderna suspendues au Japon contenaient des particules métalliques	Link
1205055	Covid-19 | Ce que l'on sait des lots contaminés de vaccins Moderna au Japon	Link
1205231	Coronavirus: Le Japon suspend 1 million de doses supplémentaires du vaccin Moderna	Link
1205290	Japon: Moderna retient 1.63 million de doses de vaccin après une contamination	Link
1207667	Le Japon achètera 150 millions de doses de Covid jab de Novavax produites par le fabricant de médicaments du pays Takeda	Link
1208084	Vaccin : Moderna a identifié l'origine de la contamination des lots japonais	Link
1208105	Substances noires découvertes dans le vaccin Moderna : le Japon suspend un million de doses supplémentaires	Link
1208316	Une TROISIÈME personne décède au Japon après avoir reçu le vaccin Moderna Covid d'un lot rappelé en raison d'une contamination à l'acier inoxydable	Link
1212456	Covid-19. Ce que l'on sait des lots contaminés de vaccins Moderna au Japon	Link
1252697	Covid-19 : une "erreur humaine" à l'origine de la contamination des vaccins Moderna	Link
1263628	Une 'erreur humaine' à l'origine de la contamination des vaccins Moderna	Link

Notes: Katay, 2021-09-17 00:27:57 Hide Le Japon suspend l'utilisation de 1,63 million de doses du vaccin de la biotech américaine Moderna contre le coronavirus. Le groupe pharmaceutique nippon Takeda, qui importe et distribue au Japon le vaccin de Moderna, a déclaré dans un communiqué avoir reçu "des signalements de plusieurs centres de vaccination, selon lesquels des corps étrangers ont été découverts dans des tubes de vaccin scellés venant de lots spécifiques". [...] Information additionnelle: ID 1192377 (https://www.la-croix.com/Covid-19-163-million-vaccins-Moderna-suspendus-Japon-cause-anomalie-2021-08-25-1301172362): Le présence de contaminants a été constatée dans 39 fioles scellées de vaccins, dans huit centres de vaccination différents au Japon, y compris à Tokyo, selon la chaîne de télévision publique japonaise NHK. Ces fioles provenaient toutes d'un seul des trois lots retirés de la distribution au Japon. L'utilisation des deux autres lots a été arrêtée par mesure de précaution, a expliqué jeudi le porte-parole du gouvernement Katsunobu Kato. [...] Information additionnelle: ID 1196211 (https://www.latribune.fr/entreprises-finance/industrie/chimie-pharmacie/vaccin-moderna-l-agent-contaminant-serait-une-particule-metallique-891335.html): Un responsable du ministère de la Santé a déclaré que l'identité de l'agent contaminant n'avait pas été

confirmée. Mais la NHK a rapporté que selon ses sources du ministère de Santé, la particule avait réagi à la présence d'aimants et était donc soupçonnée d'être un métal. [...] Le ministère avait déclaré que la suspension des lots Moderna était une précaution. Le ministère de la Santé affirmait que ces substances étrangères n'ont été découvertes pour l'instant que dans des flacons faisant partie du lot 3004667, mais les flacons de deux autres lots provenant de la même chaîne de production et fabriqués à la même période ont par précaution également été mis de côté. [...] Information additionnelle: ID 1205055 (https://www.lejsl.com/sante/2021/09/02/ce-que-l-on-sait-des-lots-contamines-de-vaccins-moderna-au-japon): Les craintes autour de ces fioles ont pris de l'ampleur au cours du week-end dernier après la mort de deux hommes, âgés de 30 et 38 ans, ayant reçu trois jours auparavant une dose de vaccin provenant d'un des trois lots suspects (les n°3004667, 3004734 et 3004956). Le ministère de la Santé a annoncé dans la foulée l'ouverture d'une enquête. Et Moderna a fini par identifier la nature et les causes de la contamination. [...]

[Google translate: Katay, 2021-09-17 00:27:57 Hide Japan is suspending the use of 1.63 million doses of the vaccine from the American biotech Moderna against the coronavirus. The Japanese pharmaceutical group Takeda, which imports and distributes Moderna's vaccine in Japan, said in a statement that it had received "reports from several vaccination centers that foreign bodies were found in sealed vaccine tubes from batches. specific ". [...] Additional information: ID 1192377 (https://www.la-croix.com/Covid-19-163-million-vaccins-Moderna-suspendus-Japon-cause-anomalie-2021-08-25-1301172362): Contaminants were found in 39 sealed vials of vaccines at eight different vaccination centers in Japan, including Tokyo, according to Japanese public broadcaster NHK. These vials all came from only one of the three lots withdrawn from distribution in Japan. The use of the other two batches was stopped as a precaution, government spokesman Katsunobu Kato said on Thursday. [...] Additional information: ID 1196211 (https://www.latribune.fr/entreprises-finance/industrie/chimie-pharmacie/vaccin-moderna-l-agent-contaminant-serai-une-particule-metallique-891335 .html): A health ministry official said the identity of the contaminating agent had not been confirmed. But NHK reported that according to its Health Ministry sources, the particle reacted to the presence of magnets and was therefore suspected of being a metal. [...] The ministry had declared that the suspension of the Moderna batches was a precaution. The Ministry of Health claimed that these foreign substances have so far only been discovered in vials that are part of batch 3004667, but vials from two other batches from the same production line and manufactured during the same period have as a precaution was also put aside. [...] Additional information: ID 1205055 (https://www.lejsl.com/sante/2021/09/02/ce-que-l-on-sait-des-lots-contamines-de-vaccins-moderna -in-japan): Fears around these vials escalated over the past weekend after the deaths of two men, aged 30 and 38, who were given a dose of vaccine three days earlier from 'one of the three suspect lots (nos. 3004667, 3004734 and 3004956). The Ministry of Health announced the opening of an investigation. And Moderna ended up identifying the nature and causes of the contamination. [...]]

16 Brokers sell Covishield vaccine on Myanmar's black market for millions of kyat

Publication date	2021-08-21
Create date	2021-09-13
Score	98.68
Report id	1211006
Category	Vaccine
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Brokers sell Covishield vaccine on Myanmar's black market for millions of kyat myanmar-now

Click here to see the Original Article

Table 43: Places for report 1211006

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
South-Eastern Asia	Myanmar	Yangon	16.80528	96.15611

Table 44: Drugs for report 1211006

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Myanmar black market retailers are selling the Indian-manufactured Covishield vaccine online at a mark-up of up to 25 times the original price as the public desperately attempts to protect themselves and their families from the Covid-19 crisis that has unfolded since the coup. [...] In a 90,000-member Myanmar Facebook group dedicated to the buying and selling of second hand items, a user named Htoo Thiri Khit posted on August 11 that those who wanted to obtain a Covishield vaccine could sign up through her. [...] The cost of two doses was 260,000 kyat ($158), she wrote. [...] Both she and Aung Min Ko noted that the Covishield vials imported unofficially from India had labels reading "Not for Sale" and "Use in India Only." This, they said, was evidence that they were authentic. Aung Min Ko admitted that they could

not guarantee that the cold chain had not been broken during the transportation process. [...] "There were some occasions where the carriers only stored the vials in coolers when they delivered them. The sellers would, of course, say that they were in the exact condition that they were when the factories produced them. There's no way for us to know for sure," he said. [...]

17 Le Japon suspend le vaccin anti-covid Moderna après un autre million de doses trouvées contaminées, portant le total à 2,6 millions [Google translate: Japan suspends Moderna covid vaccine after another million doses found contaminated, bringing total to 2.6 million]

Publication date	2021-08-31
Create date	2021-09-17
Score	94.24
Report id	1200061
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Le Japon suspend le vaccin anti-covid Moderna après un autre million de doses trouvées contaminées, portant le total à 2,6 millions Réseau International
[Google translate: Japan suspends Moderna covid vaccine after another million doses found contaminated, bringing total to 2.6 million]

Click here to see the Original Article

Table 45: Places for report 1200061

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309

Table 46: Drugs for report 1200061

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 47: Other Stories

ID	Title	Link
1218815	Le contaminant du vaccin Moderna à Okinawa, au Japon, probablement dû à l'insertion d'aiguilles, selon le ministre de la Santé, après la suspension de 2,6 millions de vaccins contre Covid	Link

Notes: Les autorités japonaises ont suspendu l'utilisation de millions de doses du vaccin Moderna Covid après que des substances étrangères ont été trouvées dans un certain nombre de lots et que deux personnes sont décédées après avoir reçu des injections des lots concernés. [...] La décision de suspendre un total de 2,6 millions de doses de vaccins Moderna intervient après l'arrêt de 1,63 million de vaccins la semaine dernière suite à la découverte de contaminants dans certains flacons d'un lot qui a été expédié à plus de 860 centres de vaccination à travers le pays. [...]

[Google translate: Japanese authorities have suspended the use of millions of doses of the Moderna Covid vaccine after foreign substances were found in a number of batches and two people died after receiving injections from the affected batches. [...] The decision to suspend a total of 2.6 million doses of Moderna vaccines comes after the stopping of 1.63 million vaccines last week following the discovery of contaminants in certain vials of a batch which has been shipped to more than 860 vaccination centers across the country. [...]]

18 Brazil Bans China's Sinovac Covid Vaccine Over Fears Of Contamination

Publication date	2021-09-06
Create date	2021-09-07
Score	92.42
Report id	1206268
Category	Vaccine
Quality	Substandard
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Brazil Bans China's Sinovac Covid Vaccine Over Fears Of Contamination OTV News

Click here to see the Original Article

Table 48: Places for report 1206268

Region Name	Country	Location	Latitude	Longitude
Americas	Brazil	Federative Republic of Brazil	-10	-55

Table 49: Drugs for report 1206268

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 50: Other Stories

ID	Title	Link
1206583	Brazil bans Chinas Sinovac Covid vax over fears of contaminations	Link

Notes: Brazil's health regulator has temporarily suspended the use of over 12.1 million doses of China's Sinovac Covid vaccine over fears of the vials being contaminated, media reports said. Anvisa, the regulator, suspended Sinovac for a period of three months after learning that vials containing the shots were filled at an unauthorised production base, the Washington Post re-

ported. The matter is being investigated.

The Butantan Institute, a Sao Paulo based biomedical centre that has partnered with Sinovac to fill the vaccine for local usage, notified Anvisa about the irregularity, the agency said. "The manufacturing unit responsible for the filling was not inspected and was not approved by Anvisa," the report quoted Anvisa as saying in a statement, adding: "Thus it is necessary to adopt a temporary measure to avoid the exposure of the population to a possible imminent risk."

Anvisa added that it has halted plans to distribute an additional 9 million doses of Sinovac, as they were also filled at a location that was not inspected by the health officials, the report said. [...] They aim to avoid the use of irregular or suspect products," Anvisa said. The lack of information about the environment at the production bases, combined with the need for vaccine shots to be made in strictly aseptic settings, persuaded officials to take the measure, Anvisa said. [...]

19 Alerta de Productos Médicos N°5/2021 Vacuna COVISHIELD

[Google translate: Medical Products Alert N ° 5/2021 COVISHIELD Vaccine]

Publication date	2021-08-16
Create date	2021-09-11
Score	74.36
Report id	1179798
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Alerta de Productos Médicos N°5/2021 Vacuna COVISHIELD WHO | World Health Organization
[Google translate: Medical Products Alert N ° 5/2021 COVISHIELD WHO Vaccine | World Health Organization]

Click here to see the Original Article

Table 51: Places for report 1179798

Region Name	Country	Location	Latitude	Longitude
		Africa	7.1881	21.09375
		Southern Asia	21.28937	78.66211

Table 52: Drugs for report 1179798

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 53: Other Stories

ID	Title	Link
1198476	Alerta de Productos Médicos N°5/2021 Vacuna COVISHIELD (Actualización)	Link

Notes: Los productos falsificados fueron reportados a la OMS en julio y agosto de 2021. El fabricante genuino de COVISHIELD (Serum Institute of India Pvt. Ltd) ha confirmado que los productos mencionados en esta alerta son falsificados. Estos productos falsificados se han notificado a nivel del paciente en Uganda, India y en Myanmar. [...] Lote 4121Z040 - la fecha de caducidad (10.08.2021) de este producto es falsa COVISHIELD 2ml - el fabricante original no produce COVISHIELD en 2ml (4 dosis). Lote 4126Z079 - el número de lote de este producto está falsificado y el nombre del producto: COVISHELD no es la ortografía correcta. [...]

[Google translate: The counterfeit products were reported to the WHO in July and August 2021. The genuine manufacturer of COVISHIELD (Serum Institute of India Pvt. Ltd) has confirmed that the products mentioned in this alert are counterfeit. These counterfeit products have been reported at the patient level in Uganda, India and Myanmar. [...] Lot 4121Z040 - the expiration date (10.08.2021) of this product is false COVISHIELD 2ml - The original manufacturer does not produce COVISHIELD in 2ml (4 doses). Lot 4126Z079 - the lot number of this product is falsified and the product name: COVISHELD is not the correct spelling. [...]]

20 Alerte produit médical N°5/2021 Vaccin COVISHIELD falsifié

[Google translate: Medical product alert N ° 5/2021 Falsified COVISHIELD vaccine]

Publication date	2021-08-16
Create date	2021-08-25
Score	72.42
Report id	1183943
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Alerte produit médical N°5/2021 Vaccin COVISHIELD falsifié Organisation mondiale de la Santé
[Google translate: Medical product alert N ° 5/2021 Falsified COVISHIELD vaccine World Health Organization]

Click here to see the Original Article

Table 54: Places for report 1183943

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
		Africa	7.1881	21.09375
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 55: Drugs for report 1183943

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 56: Other Stories

ID	Title	Link
1193892	News Press - Alerte produit médical N°5/2021 Vaccin COVISHIELD falsifié détecté dans en Afrique et en Asie du Sud-Est - OMS - Organisation Mondiale de la Santé	Link

Notes: La présente alerte produit médical de l'OMS concerne le vaccin COVISHIELD (vaccin ChAdOx1 nCoV-19 (recombinant)) falsifié détecté dans la Région africaine et dans la Région de l'Asie du Sud-Est de l'OMS. Ces produits falsifiés ont été signalés à l'OMS en juillet et en août 2021. Le fabricant de COVISHIELD (Serum Institute of India Pvt. Ltd.) a confirmé que les produits qui font l'objet de cette alerte sont falsifiés. Ces produits falsifiés ont été signalés par des patients en Ouganda et en Inde. [...] Lot 4121Z040 - la date de péremption (10.08.2021) de ce produit est falsifiée. COVISHIELD 2ml - le fabricant ne produit pas COVISHIELD en flacon de 2 ml (4 doses). [...]

[Google translate: This WHO medical product alert concerns the COVISHIELD vaccine (ChAdOx1 nCoV-19 vaccine (recombinant)) falsified detected in the African Region and the WHO South-East Asia Region. Those Falsified products were reported to WHO in July and August 2021. The manufacturer of COVISHIELD (Serum Institute of India Pvt. Ltd.) has confirmed that the products that are the subject of this alert are adulterated. These falsified products have been reported by patients in Uganda and India. [...] Lot 4121Z040 - the expiration date (10.08.2021) of this product has been falsified. COVISHIELD 2ml - the manufacturer does not produce COVISHIELD in a 2ml vial (4 doses). [...]]

21 Two suspected of administering fake Covid-19 vaccine

Publication date	2021-09-08
Create date	2021-09-09
Score	70.94
Report id	1208719
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Two suspected of administering fake Covid-19 vaccine Nairobi News

Click here to see the Original Article

Table 57: Places for report 1208719

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Kenya	Kasarani	-1.21743	36.89759
Eastern Africa	Kenya	Nairobi	-1.28333	36.81667

Table 58: Drugs for report 1208719

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 59: Other Stories

ID	Title	Link
1209298	Quack Doctors in Court for Selling and Administering Fake COVID-19 to Kenyans	Link
1209746	Nairobi: 2 Suspects Arrested for Administering Fake COVID-19 Vaccines in Kasarani Kenya News	Link
1209799	Two men arrested selling fake Johnson & Johnson COVID-19 vaccine in Kasarani arraigned	Link
1210200	Kenyans Arrested For Giving Fake Covid Jabs - Police	Link
1211132	Alert: Ministry of Health responds on fake Covid-19 vaccine in Kenya	Link

Table 59: Other Stories(continued)

ID	Title	Link
1211236	Two Arrested in Roysambu for Allegedly Administering Fake Covid-19 Vaccine	Link
1211301	Don't pay for vaccine, Kagwe says after J&J fake jabs case	Link
1217154	'Fake' doctors charged with administering Covid-19 jabs	Link

Notes: A Nairobi court has allowed two people suspected of administering fake Covid-19 vaccines to Kenyans to be detained for five days so as to allow Police to complete investigations. [...] Court documents seen by Nairobi news indicate, the two also impersonated a medical doctor and administered what was believed to be fake Johnson and Johnson Covid-19 jab to unsuspecting clients. "The illegal and fake Covid-19 vaccination occurred on diverse dates between the month of July and August 2021 and reported on September 7, 2021," [...] Additional information: ID 1209298 (https://www.mwakilishi.com/article/kenya-news/2021-09-08/quack-doctors-in-court-for-selling-and-administering-fake-covid-19): During their arrest, police recovered assorted consent sheets with details of their victims, who were charged up to Sh3,500 for the jab. "Victims of the two suspects upon noticing that they don't appear in the ministry of health database as those who are vaccinated were tormented mentally due to uncertainty of the contents of what they were administered with," read the affidavit. [...]

22 Alerte produit médical N°5/2021 Vaccin COVISHIELD falsifié (mise à jour)

[Google translate: Medical product alert N ° 5/2021 Falsified COVISHIELD vaccine (update)]

Publication date	2021-08-31
Create date	2021-09-02
Score	69.04
Report id	1198512
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Alerte produit médical N°5/2021 Vaccin COVISHIELD falsifié (mise à jour) Organisation mondiale de la Santé
[Google translate: Medical product alert N ° 5/2021 Falsified COVISHIELD vaccine (update) World Health Organization]

Click here to see the Original Article

Table 60: Places for report 1198512

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Myanmar	Union of Burma	21	96

Table 61: Drugs for report 1198512

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: La présente alerte produit médical de l'OMS concerne le vaccin COVISHIELD (vaccin ChAdOx1 nCoV-19 (recombinant)) falsifié détecté dans la Région africaine et dans la Région de l'Asie du Sud-Est de l'OMS. Ces produits falsifiés ont été signalés à l'OMS en juillet et en août 2021. Le fabricant de COVISHIELD (Serum Institute of India Pvt. Ltd.) a confirmé que les produits qui font l'objet de cette alerte sont falsifiés. Ces produits falsifiés ont été signalés par des patients en Ouganda, Inde et en Myanmar. [...] Lot 4126Z079 - le número de lot de ce

produit est falsifié et le nom du produit: COVISHELD n'est pas l'orthographe correcte. [...]

[Google translate: This WHO medical product alert concerns the COVISHIELD vaccine (ChAdOx1 nCoV-19 vaccine (recombinant)) falsified detected in the African Region and the WHO South-East Asia Region. Those Falsified products were reported to WHO in July and August 2021. The manufacturer of COVISHIELD (Serum Institute of India Pvt. Ltd.) has confirmed that the products that are the subject of this alert are adulterated. These falsified products have been reported by patients in Uganda, India and Myanmar. [...] Lot 4126Z079 - The batch number of this product is falsified and the product name: COVISHELD is not the correct spelling. [...]]

23 Winnipeg police investigating possible theft of COVID-19 vaccine from convention centre supersite

Publication date	2021-09-15
Create date	2021-09-16
Score	68.51
Report id	1217927
Category	Vaccine
Quality	Diverted/Unregistered
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Winnipeg police investigating possible theft of COVID-19 vaccine from convention centre supersite CBC.ca

Click here to see the Original Article

Table 62: Places for report 1217927

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Winnipeg	49.8844	-97.14704

Table 63: Drugs for report 1217927

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 64: Other Stories

ID	Title	Link
1218712	Winnipeg police investigating possible theft of COVID-19 vaccine from supersite	Link
1219111	Winnipeg police investigating missing box of COVID-19 vaccine from supersite	Link

Notes: The Winnipeg Police Service says it's investigating a possible theft of COVID-19 vaccine from the downtown RBC Convention Centre vaccination site. [...] "WPS were contacted on

Saturday regarding the theft of vaccine. It is currently being investigated," she said, adding no other information can be provided at this point.

"I can't get into any specifics regarding the initiation of the investigation or how it has progressed."

The province has "referred information to the Winnipeg Police Service regarding an unaccounted box of vaccine from the RBC supersite," a provincial spokesperson said in a statement to CBC, adding no further details are available right now. [...]

24 Nurses accused of selling siphoned COVID-19 vaccines in Turkey | Daily Sabah

Publication date	2021-09-13
Create date	2021-09-15
Score	67.18
Report id	1215059
Category	Vaccine
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Nurses accused of selling siphoned COVID-19 vaccines in Turkey | Daily Sabah Daily Sabah

Click here to see the Original Article

Table 65: Places for report 1215059

Region Name	Country	Location	Latitude	Longitude
Western Asia	Turkey	Republic of Turkey	39	35

Table 66: Drugs for report 1215059

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: A recent investigation into three nurses accused of selling fake vaccine passes revealed a more frightening possibility. A report by broadcaster TRT Haber revealed that the suspects also siphoned half the content of several vaccines to sell.

As a consequence of the nurses' scheme, an unknown number of people treated at the private hospital where they worked have unknowingly received half doses of COVID-19 vaccines. [...] The suspects are accused of selling the doses at $17.70 (TL 150) a vial, though it is unclear to whom they sold the vaccines in the country as vaccinations are free and easily accessed. [...] One of the suspects also sold a fourth dose she was eligible for, according to investigators. Under new rules, a fourth dose has been made available to all who have received three doses. [...]

25 Japan finds black particles in Moderna vaccine

Publication date	2021-08-31
Create date	2021-09-13
Score	65.26
Report id	1199556
Category	Vaccine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Japan finds black particles in Moderna vaccine BBC News

Click here to see the Original Article

Table 67: Places for report 1199556

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Kanagawa	35.41667	139.33333

Table 68: Drugs for report 1199556

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 69: Other Stories

ID	Title	Link
1199793	Vaccine panic as Japan finds 'black particles' in Moderna doses – all jabs suspended	Link
1200050	Covid-19: Japan withdraws vaccine batch due to black particles	Link
1200226	Black particles found in Moderna vaccine vial in Japan, forcing region to put shots from the batch on hold	Link
1200296	Moderna vaccine batch put on hold in Japan after black particles found in vial	Link
1200303	Moderna reveals source of COVID-19 vaccine contamination as Japan finds yet another suspect vial	Link

Table 69: Other Stories(continued)

ID	Title	Link
1200799	Stainless Steel Fragments Found in Moderna Vaccine Shots	Link
1201603	Japan finds another vial of contaminated Moderna virus jab	Link
1202451	Pharmacist in Japan finds black particles in Moderna vaccine	Link

Notes: A pharmacist saw several black particles in one vial of the vaccine in Kanagawa Prefecture, according to authorities.

Some 3,790 people had already received shots from the batch. The rest of the batch has now been put on hold. [...] The pharmacist found the black particles while checking for foreign substances before the vaccine's use.

The jab's domestic distributor has collected the vial suspected to be contaminated.

Local media reports say there is no evidence so far of any health hazards caused by the potentially contaminated vaccine. [...]

26 假疫苗警告!世卫确认印度Covishield疫苗出现假冒 已注射超4.86亿剂 - 2021-08-18

[Google translate: Fake vaccine warning! WHO confirms that India's Covishield vaccine is counterfeit, and over 486 million doses have been injected-2021-08-18]

Publication date	2021-08-18
Create date	2021-09-01
Score	62.19
Report id	1183139
Category	Vaccine
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: 面对来势汹汹的delta变体毒株,全球加强抗疫力量,继续加大疫苗接种力度,甚至一些国家推出加强针剂。但与此同时, 假疫苗 也浮现出来,世卫警告称印度Covishield新冠疫苗出现假货,已注射超4.86亿剂。

[Google translate: In the face of the menacing delta variant strain, the world has strengthened its anti-epidemic force, continued to increase vaccination efforts, and even introduced enhanced injections in some countries. But at the same time, fake vaccines have also emerged. The WHO has warned that India's Covishiield Covid-19 vaccine is fake, and more than 486 million doses have been injected.]

Click here to see the Original Article

Table 70: Places for report 1183139

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 71: Other Stories

ID	Title	Link
1183197	假疫苗警告！世卫确认印度Covishield疫苗出现假冒已注射超4.86亿剂_财经要闻	Link
1184963	疫苗都敢"造假售假",印度逐渐丧失人性,出口海外荼毒他国 - 2021-08-20	Link

Table 71: Other Stories(continued)

ID	Title	Link
1185189	印度Covishield新冠疫苗出现假货　世卫向全球发出医疗警告 - 2021-08-19	Link
1185190	"早知道买中国疫苗!"印度致命问题曝光,世卫忍无可忍发出警告 - 2021-08-19	Link
1185191	"大批疫苗造假!"印度曝出可怕真相,世卫组织警告,中国要当心 - 2021-08-20	Link
1185192	世卫证实:印度"AZ疫苗"出现假货,对全球公共卫生构成威胁 - 2021-08-19	Link
1185265	已注射超4.86亿剂!世卫警告:印度Covishield新冠疫苗出现假货 - 2021-08-19	Link
1185402	印度Covishield新冠疫苗出现假货　世卫向全球发出医疗警告 - 2021-08-18	Link
1186040	印度疫苗曝惊天丑闻,丧失人心道义制假货?国际舆论直接炸锅 - 2021-08-21	Link
1186041	世卫证实:印度"AZ疫苗"出现假货,对全球公共卫生构成威胁 - 2021-08-20	Link
1186283	「安东要闻」医疗警告!印度假疫苗曾出口多国? - 2021-08-19	Link
1186599	已注射超4.86亿剂!世卫警告:印度Covishield新冠疫苗出现假货 - 2021-08-17	Link
1186744	已注射超4.86亿剂!世卫警告:印度Covishield新冠疫苗出现假货 - 2021-08-18	Link
1188180	印度又搞出新洋相!接种4.86亿剂次的疫苗,却有大量的"假疫苗" - 2021-08-23	Link
1191065	"还是中国疫苗靠谱!"莫迪又坑了全世界,世卫这回终于忍无可忍 - 2021-08-24	Link
1191758	医药日报|医疗警告!印度假疫苗曾出口多国 医师法草案三审:建议... - 2021-08-18	Link
1192170	印度提供4.86亿剂疫苗后,世卫发现一致命问题,忍无可忍发出警告 - 2021-08-25	Link
1248783	孟买警方通报:在孟买超2000人注射了假疫苗- 2021-10-10	Link

Notes: 世界卫生组织(WHO)周三表示，假冒的Covishield疫苗在印度和乌干达流通，并要求两国政府紧急将发现的虚假批次通知世界卫生组织。

[Google translate: The World Health Organization (WHO) said on Wednesday that counterfeit Covishield vaccines are circulating in India and Uganda, and asked the governments of the two countries to urgently notify the World Health Organization of the false batches found.]

27 Health supervisor held for giving ‘fake’ Covid jabs

Publication date	2021-08-10
Create date	2021-08-17
Score	59.76
Report id	1171346
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Health supervisor held for giving ‘fake’ Covid jabs The Indian Express

Click here to see the Original Article

Table 72: Places for report 1171346

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Varanasi	25.31668	83.01041

Table 73: Drugs for report 1171346

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: The Varanasi police arrested a health supervisor posted at a primary community health centre for allegedly giving fake injections on the pretext of Covid vaccine. He was charging Rs 20-Rs 50 for each injection, police said. [...] A team of health officials went to the village to verify the claims because no such vaccination drive was on there. It was found that the arrested accused, 50-year-old Mohan Ram, was allegedly injecting Dexona (anti-allergic injection) and Aciloc (an injection for gas trouble) and taking money from villagers by claiming that they were being vaccinated against Covid-19. [...]

28 Three Moga women held for holding fake Covid vaccination camp

Publication date	2021-09-13
Create date	2021-09-15
Score	58.99
Report id	1215054
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Three Moga women held for holding fake Covid vaccination camp Hindustan Times

Click here to see the Original Article

Table 74: Places for report 1215054

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Himachal Pradesh	31.91667	77.25

Table 75: Drugs for report 1215054

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 76: Other Stories

ID	Title	Link
1215270	3 women booked for giving fake jabs in Dharamkot	Link
1215487	Moga: 3 women booked for giving fake jabs in Dharamkot	Link
1216312	Women behind fake vaccination camp in Moga wanted easy money	Link

Notes: Moga Police have arrested three women for allegedly organising a fake Covid-19 vaccination camp in Dharamkot. Police said they were administering multi-vitamins, but were

not taking any money from residents. The accused are Manpreet Kaur, of Pandori village, Lovepreet Kaur, of Lohgarh Basti, and Harpreet Kaur, of Mandir village in Moga. Dharamkot DSP Shubeg Singh said, "The women were impersonating ASHA workers and have been booked for cheating."

29 Navi Mumbai: 20-year-old held for black marketing of Covishield vaccine in Nerul

Publication date	2021-08-19
Create date	2021-08-25
Score	58.39
Report id	1183740
Category	Vaccine
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Navi Mumbai: 20-year-old held for black marketing of Covishield vaccine in Nerul Free Press Journal

Click here to see the Original Article

Table 77: Places for report 1183740

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Nerul	15.51031	73.78087

Table 78: Drugs for report 1183740

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Unit two of Crime Branch of Navi Mumbai police arrested a 20-year-old for allegedly selling Covishield vaccine in Nerul illegally on Wednesday evening. The police also seized one full and another half-filled vial of Covishield vaccine from him. [...] Police said that Khet had demanded Rs 4000 for each dose of Covishield. "We sent a dummy customer and he had brought 15 doses for Rs 60,000," said the official. He added that when he came around 3.45 pm near the flyover in Nerul, the team waiting for him caught him immediately.

When he was thoroughly searched, he was found with a full vial and another half-filled vial of Covishield vaccine. [...]

30 Allemagne : une infirmière suspectée d'avoir fait plus de 8 600 faux vaccins [Google translate: Germany nurse suspected of having given more than 8,600 fake vaccines]

Publication date	2021-08-11
Create date	2021-08-24
Score	53.69
Report id	1173043
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Allemagne : une infirmière suspectée d'avoir fait plus de 8 600 faux vaccins Le Point [Google translate: Germany nurse suspected of having given more than 8,600 fake vaccines]

Click here to see the Original Article

Table 79: Places for report 1173043

Region Name	Country	Location	Latitude	Longitude
Europe	Germany	Federal Republic of Germany	51.5	10.5

Table 80: Drugs for report 1173043

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 81: Other Stories

ID	Title	Link
1173045	Des milliers de personnes vaccinées à l'eau saline en Allemagne ?	Link
1173175	[En continu] En Allemagne, 8000 doses de vaccin remplacées par une solution saline	Link

Table 81: Other Stories(continued)

ID	Title	Link
1173245	[En continu] En Allemagne, 8000 doses de vaccins remplacées par une solution saline	Link
1173300	[En continu] En Allemagne, 8000 vaccins remplacés par une solution saline	Link
1173689	Covid-19 : une infirmière arrêtée après avoir vacciné avec de l'eau saline en Allemagne	Link
1174359	En Allemagne, une enquête vise une infirmière soupçonnée d'avoir administré de faux vaccins	Link
1174362	[En continu] En Allemagne, des solutions salines dans les seringues	Link
1174428	Allemagne : une infirmière soupçonnée d'avoir administré plus de 8.000 faux vaccins	Link
1174432	Coronavirus - Près de 8.600 personnes, surtout âgées, pourraient avoir reçu de l'eau saline à la place du vaccin entre le 5 mars et le 21 avril - Une infirmière "antivax" arrêtée	Link
1174783	Allemagne : une infirmière soupçonnée d'avoir injecté une solution saline à des milliers de personne	Link
1174826	En Allemagne, une infirmière antivax aurait trompé plus de 8 000 personnes	Link
1174855	Allemagne : une infirmière soupçonnée d'avoir injecté une solution saline à des milliers de personnes	Link
1174913	Des milliers d'Allemands ont reçu une solution saline au lieu d'un vaccin contre la COVID-19	Link
1175567	Une infirmière antivax a injecté de faux vaccins à 8 600 personnes	Link
1175620	Une infirmière allemande aurait changé le vaccin Covid avec une solution saline	Link
1176277	Une infirmière allemande suspectée d'avoir remplacé 8 500 doses de vaccin Pfizer par de l'eau	Link
1194722	Covid: une infirmière allemande vaccine 8.600 personnes… avec de l'eau	Link

Notes: Alors que la France lutte contre les faux pass sanitaires, l'Allemagne est également confrontée à un scandale lié à la vaccination contre le Covid-19. Le journal Der Tagesspiegel rapporte que plusieurs milliers de personnes vont devoir être à nouveau vaccinées en Basse-Saxe, dans le nord-est du pays. Une enquête de police a révélé qu'une infirmière de la Croix-Rouge, qui aurait affiché ses convictions antivax sur les réseaux sociaux, aurait administré une solution saline plutôt que le vaccin anti-Covid à des patients. Plus de 8 600 personnes pourraient être concernées. [...]

[Google translate: As France fights against fake health passes, Germany is also facing a scandal related to the Covid-19 vaccination. The newspaper Der Tagesspiegel reports that several thousand people will have to be vaccinated again in Lower Saxony, in the north-east of the

country. A police investigation has revealed that a Red Cross nurse, who allegedly posted her anti-ax beliefs on social media, administered saline instead of the Covid vaccine to patients. More than 8,600 people could be affected. [...]]

31 Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine (Update)

Publication date	2021-08-31
Create date	2021-09-01
Score	52.83
Report id	1198523
Category	Vaccine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine (Update) World Health Organization

Click here to see the Original Article

Table 82: Places for report 1198523

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Myanmar	Union of Burma	21	96

Table 83: Drugs for report 1198523

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 84: Other Stories

ID	Title	Link
1200217	WHO warns of more falsified Covishield vaccine in Myanmar - 2021-09-01	Link
1200238	Falsified Covishield vaccine identified in Africa and Asia	Link
1200991	Japan investigates two deaths after jab from contaminated Moderna batch	Link
1202408	WHO confirms fake Covishield vaccines in Myanmar; urges more vigilance in supply chains	Link

Table 84: Other Stories(continued)

ID	Title	Link
1205979	Centre warns States about fake Covid vaccines	Link

Notes: This WHO Medical Product Alert refers to falsified COVISHIELD (ChAdOx1 nCoV-19 Corona Virus Vaccines (Recombinant)) identified in the WHO African Region, and the WHO South-East Asia Region. [...] These falsified products have been reported at the patient level in Uganda, India and Myanmar. [...] Batch 4126Z079 - the batch number on this product is falsified and the product name: COVISHELD is not the correct spelling. [...]

32 2 in court for administering fake Covid vaccine – Zambia

Publication date	2021-08-04
Create date	2021-08-17
Score	50.90
Report id	1170735
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: 2 in court for administering fake Covid vaccine – Zambia diggers.news

Click here to see the Original Article

Table 85: Places for report 1170735

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Zambia	Lusaka	-15.40669	28.28713

Notes: (Need to subscribe) – TWO Lusaka residents have been dragged to court for allegedly obtaining money by false pretences and injecting an unsuspecting citizen with a fake COVID-19 vaccine. In this matter, Maybin Mwansa, 31, a businessman of Mtendere township and Yotam Shikupa, 42, a janitor, of Garden house are jointly charged with one count of personating public officers and one count of obtaining money by false pretences. [...]

33 ED raids on fake Covid-19 vaccines case at different locations in Kolkata

Publication date	2021-09-01
Create date	2021-09-03
Score	35.39
Report id	1200629
Category	Antiviral others, Other
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: ED raids on fake Covid-19 vaccines case at different locations in Kolkata United News of India

Click here to see the Original Article

Table 86: Places for report 1200629

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

Table 87: Drugs for report 1200629

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Table 88: Other Stories

ID	Title	Link
1200705	ED raids on fake Covid-19 vaccines case at different locations in Kolkata - Goa Chronicle	Link
1204451	Fake Vaccination Case: ED raid 10 hideouts simultaneously in Kolkata, links suspected to TMC leaders	Link

Notes: (Related to ID 1110971) – Kolkata, Sep 1 (UNI) The Enforcement Directorate (ED) on

Wednesday raided the residence of Debanjan Deb, the prime accused of fake vaccine case and different locations of his associates in the city. [...] Deb, who is now arrested by the Kolkata police for running a fake vaccines camp with a premium price of up to Rs 25,000 at Kasba in south Kolkata posing himself as an IAS official with the state government. Besides the fake vaccine camp, Deb was also allegedly involved in black marketing of oxygen, and remdesivir and other Covid-19 related medical equipment with high prices. [...]

34 Declaran ante el MP personas ligadas al decomiso de avioneta que traía vacunas rusas falsas a Honduras [Google translate: People linked to the seizure of a plane that brought fake Russian vaccines to Honduras testify before the MP]

Publication date	2021-08-11
Create date	2021-08-31
Score	30.28
Report id	1173604
Category	Vaccine
Quality	Substandard or Falsified
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: Declaran ante el MP personas ligadas al decomiso de avioneta que traía vacunas rusas falsas a Honduras Proceso Digital
[Google translate: People linked to the seizure of a plane that brought fake Russian vaccines to Honduras, Proceso Digital, testify to the MP]

Click here to see the Original Article

Table 89: Places for report 1173604

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102
Americas	Honduras	Republic of Honduras	15	-86.5

Table 90: Drugs for report 1173604

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: te miércoles declaran ante la Fiscalía un grupo de personas ligadas al decomiso de una avioneta que desde México trasladaba de forma irregular un lote de vacunas Sputnik V hacia Honduras [...] Ministerio Público toma declaraciones este día de varias personas involucradas en la introducción de la vacuna rusa que se pretendía hacer desde el aeropuerto de Campeche

[...] La aeronave con matrícula hondureña fue retenida el pasado 16 de marzo en el momento que se aprestaba a salir desde suelo azteca hacia San Pedro Sula, norte de Honduras. El lote de vacunas no presentaba documentación soporte.

[Google translate: On Wednesday, a group of people linked to the seizure of a plane that irregularly transferred a batch of Sputnik V vaccines to Honduras from Mexico testified before the Prosecutor's Office [...] The Public Ministry takes statements this day from several people involved in the introduction of the Russian vaccine that was intended to be made from the Campeche airport [...] The aircraft with Honduran registration was detained on March 16 as it was preparing to leave from Aztec soil for San Pedro Sula, northern Honduras. The batch of vaccines did not present supporting documentation.]

35 Illegal items intercepted by Louisville CBP setting records

Publication date	2021-08-16
Create date	2021-08-20
Score	25.37
Report id	1179830
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Illegal items intercepted by Louisville CBP setting records WDRB

Click here to see the Original Article

Table 91: Places for report 1179830

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Louisville	38.25424	-85.75941

Table 92: Other Stories

ID	Title	Link
1179889	Dangerous Items Intercepted by Louisville CBP are Setting Records	Link
1184320	Increase in illicit items seen at customs office in Louisville	Link
1190747	US CBP officials mark record-breaking increases in illicit, dangerous items arriving at port of Louisville	Link

Notes: U.S. Customs and Border Protection officers are reporting some of the highest increases in seizures ever in Louisville. [...] In addition to drugs, CBP reports seizing fake COVID-19 product materials, such as test kits and vaccination cards. [...]

36 WHO warns of falsified COVID-19 vaccines, remdesivir - 2021-08-18

Publication date	2021-08-18
Create date	2021-08-24
Score	22.40
Report id	1182127
Category	Antiviral others
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: The manufacturers of the genuine products - Serum Instiute of India and Gilead - have confirmed that the products are fake.

Click here to see the Original Article

Table 93: Places for report 1182127

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

Table 94: Other Stories

ID	Title	Link
1194469	Medical Product Alert N°4/2021: Falsified remdesivir	Link
1196403	WHO warns of falsified COVID-19 vaccines, remdesivir	Link

Notes: [...] The latest alert came just a few days after the WHO warned of two batches of falsified remdesivir injection – claiming to be the genuine product made by Gilead Sciences – had been identified in Mexico.There have been a number of earlier reports of counterfeit remdesivir in the US en route to Mexico and India.

"These falsified products have been reported at the patient level (including at a hospital) in Mexico and are illicitly supplied on the internet," according to the agency. [...]

37 福州这2人制造假新冠疫苗共牟利54万余元，目前已有200人接种！ - 2021-09-09

[Google translate: These two people in Fuzhou made a total of more than 540,000 yuan in the production of fake new crown vaccines , and currently 200 people have been vaccinated!-2021-09-09]

Publication date	2021-09-09
Create date	2021-09-23
Score	19.98
Report id	1209582
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: 原来，在2020年10月至12月间，被告人陈某与其丈夫林某（另案处理），以及其他同案人，为牟取暴利，通过微信方式向他人销售或提供 假疫苗 预约接种服务，共销售"生理盐水罐装制成的"假新冠疫苗454支，非法获利54万余元。
[Google translate: It turned out that between October and December 2020, the defendant Chen, her husband Lin (handled in another case), and other co-incidents, in order to make huge profits, sold or provided fake vaccination appointment services to others through WeChat. Selling 454 fake COVID-19 vaccines "made in cans of normal saline", making illegal profits of more than 540,000 yuan.]

Click here to see the Original Article

Table 95: Places for report 1209582

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	Fuzhou	26.06139	119.30611
Eastern Asia	China	Fujian Sheng	26.25	118

Table 96: Other Stories

ID	Title	Link
1210260	200人接种了假疫苗!福州有人用生理盐水冒充疫苗出售!其中一名还是... - 2021-09-08	Link

Table 96: Other Stories(continued)

ID	Title	Link
1210601	福建两人用生理盐水假冒疫苗牟利,两人被公诉 - 2021-09-08	Link
1210855	福建两人用生理盐水假冒疫苗牟利,两人被公诉 - 2021-09-09	Link

Notes: 在2020年10月至12月间，被告人陈某与其丈夫林某（另案处理），以及其他同案人，为牟取暴利，通过微信方式向他人销售或提供假疫苗预约接种服务，共销售"生理盐水罐装制成的"假新冠疫苗454支，非法获利54万余元。

[Google translate: Between October and December 2020, the defendant Chen, her husband Lin (a separate case dealt with), and other accomplices, in order to make huge profits, sold or provided fake vaccination appointment services to others through WeChat, and sold a total of " There were 454 fake new crown vaccines made from canned saline, which made an illegal profit of more than 540,000 yuan.]

38 Bail plea of those who black marketed life-saving injections during the corona period was rejected in Moradabad court

Publication date	2021-09-27
Create date	2021-10-01
Score	14.62
Report id	1232238
Category	Other
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Bail plea of those who black marketed life-saving injections during the corona period was rejected in Moradabad court News Track English

Click here to see the Original Article

Table 97: Places for report 1232238

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Morādābād	28.83893	78.77684

Table 98: Drugs for report 1232238

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: The criminals detained in connection with the black marketing of life saving injections at the time of corona infection will have to spend a few more days in jail. The Moradabad court has also rejected the bail application of the accused. The court also dismissed the petition terming the offence of the accused as a serious offence related to public health. [...] The patient is dying due to the non-availability of medicines during the covid infection. In such a situation, these people are blackmarketing life saving drugs. Their bail application is rejected. The Special Public Prosecutor has said that after hearing the case, the court also rejected the bail application of the accused for playing with public health.

39 44 drug samples including Cipla Remdesivir fail to qualify CDSCO test, 1 declared misbranded - 2021-08-14

Publication date	2021-08-14
Create date	2021-08-19
Score	2.96
Report id	1177368
Category	Antidiabetic, Antiparasitic, Antifungal, Antiviral others, Antipyretic, Cardiovascular medicine, Antibiotic, Anti-inflammatory medicine, Anti-malarial, Vitamin
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) flagged 44 medicine batches for failing to qualify a random drug sample test for the month of July, while 1 drug sample has been declared misbranded.These drugs samples which are declared not of standard quality include Piramal Enterprises Ltd's Supradyn tablet, Syncom Healthcare's Albendazole tablets IP 400 mg (ZEEBEE-Tablet), Quest Laboratories' Domperidone Suspension I.P., Bharat Parenteral's Quinine Sulphate Tablets IP 300 mg, Swiss Garnier Biotech's STATIX-20 (Atorvastatin Tablets IP 20 mg) etc.In addition, other popular drug samples that are declared not of standard quality include Paracetamol Tablets I.P. 500 mg (Biocin) manufactured by Danish Healthcare, Levofloxacin (Levoziv-500) Tablets I.P. 500 mg manufactured by Zee Laboratories, Brutab-400 (Ibuprofen Tablets IP 400 mg) manufactured by Neutec Healthcare, and Norfloxacin Tablets IP 400 mg manufactured by Unicure.Apart from this, the popular covid drug Remdesivir for Injection 100 mg/vial (CIPREMI) manufactured by Cipla and Remdesivir for injection manufactured by Teena Labs Ltd. are on the list. Additionally, Bharat Serums and Vaccines' Liposomal Amphotericin B Injection 50 mg (ABHOPE INJ.) and Amphotericin B Lipid Complex Injection I.V. (AMPHOLIP 50 MG/10 ML) are also on the list.Also Read:22 Drug Samples Including Sun Pharma Rosuvas Fail To Qualify CDSCO TestFurther, the list includes popular diabetes drugs DRMET FORTE G1 (Glimepiride & Metformin Hydrochloride SR Tablets) manufactured by Neptune Life Science Pvt. Ltd. and Glimepiride Tablets IP 1 mg manufactured by Trugen Pharmaceuticals Pvt. Ltd.This came after analysis and tests conducted by the CDSCO Drugs Control Department on 1028 samples. Out of these, 983 samples were found to be of standard quality while 44 of them were declared as Not of Standard Quality (NSQ) and 1 drug was declared misbranded.A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of disintegration, failure of the Vitamin D3 assay etc.Also Read: CDSCO Flags 22 Drugs As Not Of Standard QualityThe 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 July – 2021 Total number of samples tested 1028 Total number of samples declared as of Standard Quality 983 Total number of

samples declared as Not of Standard Quality 44 Total number of samples declared as Spurious 0 Total number of samples declared as Misbranded 01 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. Calcium Carbonate, Magnesium Oxide, Manganese Sulphate, Zinc & Vitamin D3 Tablets B. No.: MT191327 Mfg dt: 08/2019 Exp dt: 07/2021 Mfd by: M/s. Mascot Health Series Pvt. Ltd. Plot No. 79, 80, Sector - 6A, IIE, Sidcul, Haridwar- Uttarakhand -249403. Assay of Vitamin D3 CDSCO Sub-Zone, Guwahati RDTL, Guwahati 2. Supradyn (Multivitamin Tablets with Minerals and Trace Elements) B. No.: MH3388 Mfg dt: 10/2019 Exp dt: 09/2021 Mfd by: M/s. Piramal Enterprises Ltd., K-1, Addl., MIDC area, Mahad Maharashtra, 402302. Disintegration Drug Control Department Mizoram RDTL, Guwahati 3. Ramipril Tablets IP (ORMIPRO-2.5) B. No.: KM19001 Mfg dt: 11/2019 Exp dt: 10/2021 Mfd by: M/s. Ortin Laboratories Ltd. 275 & 278 (part) I.D.A. Pashamailaram Medak Distt. Telangana -502307. Assay Drug Control Department N.F. Railway Lumding RDTL, Guwahati 4. Albendazole tablets IP 400 mg (ZEEBEE - Tablet) B. No.: JDT0047 Mfg dt: 08/2018 Exp dt: 07/2021 Mfd by: M/s. Syncom Healthcare Ltd., Dehradun, Uttarakhand- Dissolution Drug Control Department Tezpur, Sonitpur RDTL, Guwahati 248197. 5. DRMET FORTE G1 (Glimepiride & Metformin Hydrochloride SR Tablets) B. No.: TN-2830 Mfg dt: 01/2020 Exp dt: 12/2021 Mfd by: M/s. Neptune Life Science Pvt. Ltd., 100-B, EPIP, Phase-II, Thana, Baddi-173205, Himachal Pradesh. Assay & Dissolution of Glimepiride Drug Control...

Click here to see the Original Article

Table 99: Places for report 1177368

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

Table 100: Drugs for report 1177368

Medicine Name	Medicine Class	Action	ATC Code
domperidone	Propulsives	propulsives	A03FA03
quinine	Methanolquinolines	antimalarials	P01BC01
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
levofloxacin	Fluoroquinolones	quinolone antibacterials	J01MA12
levofloxacin	Fluoroquinolones	antiinfectives	S01AE05
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 100: Drugs for report 1177368(continued)

Medicine Name	Medicine Class	Action	ATC Code
atorvastatin	HMG CoA reductase inhibitors	lipid modifying agents, plain	C10AA05
glimepiride	Sulfonylureas	blood glucose lowering drugs, excl. insulins	A10BB12
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
ibuprofen	Other throat preparations	throat preparations	R02AX02
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02
albendazole	Benzimidazole derivatives	antinematodal agents	P02CA03
norfloxacin	Fluoroquinolones	quinolone antibacterials	J01MA06
norfloxacin	Fluoroquinolones	antiinfectives	S01AE02
ramipril	ACE inhibitors, plain	ace inhibitors, plain	C09AA05

Notes: In its latest drug safety alert, the apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) flagged 44 medicine batches for failing to qualify a random drug sample test for the month of July, while 1 drug sample has been declared misbranded. [...]

Annex C

C.2. COVID-19 diagnostics

Medicine Quality Monitoring Globe

November 18, 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.

Translation Disclaimer:

THIS REPORT MAY CONTAIN TRANSLATIONS POWERED BY GOOGLE. GOOGLE DISCLAIMS ALL WARRANTIES RELATED TO THE TRANSLATIONS, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF ACCURACY, RELIABILITY, AND ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

This Medicine Quality Monitoring Globe report is issued by IDDO, University of Oxford, and some sections, indicated in blue, may have been translated for your convenience using translation software powered by Google Translate. Reasonable efforts have been made to provide an accurate translation, however, no automated translation is perfect nor is it intended to replace human translators. Translations are provided as a service to users of the Medicine Quality Monitoring Globe, and are provided "as is." No warranty of any kind, either expressed or implied, is made as to the accuracy, reliability, or correctness of any translations made from the source language (Chinese, French, Spanish, or Vietnamese) into English.

The official text is the version in the source language (Chinese, French, Spanish, or Vietnamese). Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the information contained in the translated text, refer to the text in the source language (Chinese, French, Spanish, or Vietnamese) which is the official version.

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	2021-08-01
End date	2021-09-30
Language	en
Report type	incident
Curation status	validated
Number of Reports	6

1 Rural Doctors in Thailand Opposed to China Made Covid Rapid Test Kits

Publication date	2021-08-14
Create date	2021-08-24
Score	48.82
Report id	1177994
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Rural Doctors in Thailand Opposed to China Made Covid Rapid Test Kits Chiang Rai Times

Click here to see the Original Article

Table 1: Places for report 1177994

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

Notes: [...] The Government Pharmaceutical Organization (GPO) over the purchases of 8.5 million Covid-19 antigen test kits despite many countries including the US, UK, Canada, Turkey and India banning them. [...] The statement cited as an example a study published in Virology Journal on 33,000 people in Pakistan, which found Lepu had a low sensitivity rate, compared to its 90% claim, and a 48% false-negative chance. [...]

2 Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC

Publication date 2021-08-21

Create date 2021-08-25

Score 46.88

Report id 1186319

Category Medical devices for disease prevention, Respiratory diseases medicine, Medical device for screening/diagnosis/monitoring, Other

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC sggpnews

Click here to see the Original Article

Table 2: Places for report 1186319

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Viet Nam	Ho Chi Minh City	10.82302	106.62965
South-Eastern Asia	Viet Nam	Bình Tân District	10.13489	105.75968
South-Eastern Asia	Viet Nam	Tân Phú District	11.39867	107.39976

Table 3: Drugs for report 1186319

Medicine Name	Medicine Class	Action	ATC Code
codeine	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA04

Notes: [...] On August 20, Thuan was seen carry a suspicious carton containing fake new drugs, so police officers stopped him to check; thereby, 150 boxes of Covid-19 treatment pills with the brand name Terpincodein were found out. At the police station, Thuan confessed that it was a

fake drug because Thuan bought the raw materials then produced and sold them to the market to make a profit. [...] According to the department, these cases are very worrisome amid the ongoing complicated development of the Covid-19 epidemic. Even, several businesses trading in medical equipment have showed signs of selling medical items without clear indications of origin. For example, in mid-August, the market management teams continuously detected and seized thousands of 3M masks, SARS-CoV-2 rapid test kits, oxygen ventilators without a clear indication of origin at warehouses in districts Binh Tan and Tan Phu. The owner of the items said that most of them will be provided to buyers via social networks, a few of them will be sold in stores. [...]

3 Concerned about unregulated sale of self-test kits

Publication date	2021-08-20
Create date	2021-08-25
Score	39.32
Report id	1185922
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Concerned about unregulated sale of self-test kits The Star Online

Click here to see the Original Article

Table 4: Places for report 1185922

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Malaysia	Malaysia	2.5	112.5

Table 5: Other Stories

ID	Title	Link
1189666	Covid-19: Pharmacists group urges more regulation on self-test kits to protect buyers	Link
1202814	Buy self-test kits only from registered pharmacists, private healthcare facilities, public urged	Link

Notes: THE Malaysian Pharmacists Society (MPS) is concerned about the unregulated sale of Covid-19 self-test kits especially via social media platforms including WhatsApp. We are particularly concerned about the rampant sale of fake kits as well as sales by unqualified sellers who are neither pharmacists nor doctors. [...] MPS has received numerous complaints from both the public and pharmacists of self-test kits that are being sold online and via WhatsApp at extremely low prices and with no guarantee of the product being genuine. [...]

4 Illegal items intercepted by Louisville CBP setting records

Publication date	2021-08-16
Create date	2021-08-20
Score	35.55
Report id	1179830
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Illegal items intercepted by Louisville CBP setting records WDRB

Click here to see the Original Article

Table 6: Places for report 1179830

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Louisville	38.25424	-85.75941

Table 7: Other Stories

ID	Title	Link
1179889	Dangerous Items Intercepted by Louisville CBP are Setting Records	Link
1184320	Increase in illicit items seen at customs office in Louisville	Link
1190747	US CBP officials mark record-breaking increases in illicit, dangerous items arriving at port of Louisville	Link

Notes: U.S. Customs and Border Protection officers are reporting some of the highest increases in seizures ever in Louisville. [...] In addition to drugs, CBP reports seizing fake COVID-19 product materials, such as test kits and vaccination cards. [...]

5 Thai pirated substandard oximeters serious threat to Covid-19 patients' lives

Publication date	2021-08-05
Create date	2021-08-13
Score	23.07
Report id	1166502
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Thai pirated substandard oximeters serious threat to Covid-19 patients' lives Pattaya Mail

Click here to see the Original Article

Table 8: Places for report 1166502

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

Table 9: Drugs for report 1166502

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Notes: [...] The Thai News Agency learned from rescue volunteers supplying oxygen generators and cylinders to the houses of severe COVID-19 patients that substandard oximeters affected the rescuers' assessment of patients' conditions and oxygen assistance for patients in need could be dangerously delayed. Substandard and pirate oximeters were readily available especially through online sales and they showed false readings, the rescuers said. [...]

6 COVID-19 & FAKE OXIMETERS Both dangerous

Publication date	2021-08-31
Create date	2021-10-01
Score	18.65
Report id	1199130
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19 & FAKE OXIMETERS Both dangerous Ceylon Daily News

Click here to see the Original Article

Table 10: Places for report 1199130

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Sri Lanka	Democratic Socialist Republic of Sri Lanka	7.75	80.75

Table 11: Other Stories

ID	Title	Link
1237412	COVID-19 & FAKE OXIMETERS Both dangerous	Link

Notes: [...] By now there is a severe shortage of high quality National Medicines Regulatory Authority (NMRA)-approved pulse oximeters in the market. Because of this shortage, a lot of people have put various types of very low quality or toy-type pulse oximeters on the market for extremely high prices, sometimes even at Rs. 5,000. But before the COVID-19 outbreak, the price of a pulse oximeter was a maximum Rs. 2,000. Some of those pulse oximeters are just pre-programmed toys. That means those instruments only show a value that was entered during the manufacturing process, but not the actual oxygen saturation level of the person who uses it. Some of those toy-type pulse oximeters which are being sold in some private pharmacies work even when a pen, stick or something like that is placed instead of a finger. [...] According to the few importers (around three) of high quality pulse oximeters with the NMRA approval, it is the responsibility of the NMRA to assist the police to raid fake/toy pulse oximeters available all over the country at extremely high prices. The police do not need to request the NMRA for assistance and it is the NMRA which should obtain the assistance for raids. Some media

reported recently the NMRA conducted a few raids and around 3,500 fake low quality pulse oximeters were taken into custody. The media also reported the possibility of introducing a price control for pulse oximeters. [...]

Annex C

C.3. Personal protective equipment

Medicine Quality Monitoring Globe

November 18, 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.

Translation Disclaimer:

THIS REPORT MAY CONTAIN TRANSLATIONS POWERED BY GOOGLE. GOOGLE DISCLAIMS ALL WARRANTIES RELATED TO THE TRANSLATIONS, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF ACCURACY, RELIABILITY, AND ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

This Medicine Quality Monitoring Globe report is issued by IDDO, University of Oxford, and some sections, indicated in blue, may have been translated for your convenience using translation software powered by Google Translate. Reasonable efforts have been made to provide an accurate translation, however, no automated translation is perfect nor is it intended to replace human translators. Translations are provided as a service to users of the Medicine Quality Monitoring Globe, and are provided "as is." No warranty of any kind, either expressed or implied, is made as to the accuracy, reliability, or correctness of any translations made from the source language (Chinese, French, Spanish, or Vietnamese) into English.

The official text is the version in the source language (Chinese, French, Spanish, or Vietnamese). Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the information contained in the translated text, refer to the text in the source language (Chinese, French, Spanish, or Vietnamese) which is the official version.

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	2021-08-01
End date	2021-09-30
Language	en
Report type	incident
Curation status	validated
Number of Reports	13

1 Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC

Publication date 2021-08-21

Create date 2021-08-25

Score 36.95

Report id 1186319

Category Medical devices for disease prevention, Respiratory diseases medicine, Medical device for screening/diagnosis/monitoring, Other

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC sggpnews

Click here to see the Original Article

Table 1: Places for report 1186319

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Viet Nam	Ho Chi Minh City	10.82302	106.62965
South-Eastern Asia	Viet Nam	Bình Tân District	10.13489	105.75968
South-Eastern Asia	Viet Nam	Tân Phú District	11.39867	107.39976

Table 2: Drugs for report 1186319

Medicine Name	Medicine Class	Action	ATC Code
codeine	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA04

Notes: [...] On August 20, Thuan was seen carry a suspicious carton containing fake new drugs, so police officers stopped him to check; thereby, 150 boxes of Covid-19 treatment pills with the brand name Terpincodein were found out. At the police station, Thuan confessed that it was a

fake drug because Thuan bought the raw materials then produced and sold them to the market to make a profit. [...] According to the department, these cases are very worrisome amid the ongoing complicated development of the Covid-19 epidemic. Even, several businesses trading in medical equipment have showed signs of selling medical items without clear indications of origin. For example, in mid-August, the market management teams continuously detected and seized thousands of 3M masks, SARS-CoV-2 rapid test kits, oxygen ventilators without a clear indication of origin at warehouses in districts Binh Tan and Tan Phu. The owner of the items said that most of them will be provided to buyers via social networks, a few of them will be sold in stores. [...]

2 Government In Dispute Over ‘not Fit For Purpose’ PPE Costing £1.2bn - Todayuknews

Publication date	2021-09-02
Create date	2021-09-06
Score	35.59
Report id	1202755
Category	Medical devices for disease prevention
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Government In Dispute Over ‘not Fit For Purpose’ PPE Costing £1.2bn - Todayuknews Todayuknews

Click here to see the Original Article

Notes: Boris Johnson’s government is currently in dispute with several companies over £1.2bn worth of personal protective equipment (PPE) deemed ”substandard” or undelivered, it has emerged. The government hopes to recover costs and is considering legal action over 40 separate contracts covering 1.7 billion items of PPE, a health minister has admitted. Lord Bethell said the health department was still is discussions over masks, gowns, google and gloves which ”have not been delivered or failed quality tests”. [...] In July it emerged that a former Tory councillor was given a £120m government contract for protective shields which were left unused because of concerns about their quality. [...]

3 Invisi Smart Technologies UK LTD - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 - Center for Devices and Radiological Health - 2021-08-24

Publication date	2021-08-24
Create date	2021-09-01
Score	26.72
Report id	1193000
Category	Medical devices for disease prevention
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Invisi Smart Technologies UK LTD MARCS-CMS 614512 — August 24, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Saba Yussouf Recipient Title CEO Invisi Smart Technologies UK LTD 112 Cumberland House 80 Scrubs Lane London NW10 6RF United Kingdom Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER August 24, 2021 Re: Invisi Smart Mask RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 Dear Ms. Saba Yussouf: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at https://www.invisismart.com/, https://shop.invisismart.com/, and https://twitter.com/InvisiSmart on, June 21, 2021. The FDA has observed that your websites offer the ISM5 Invisi Smart Mask, ISM5 Invisi Smart Mask (Black Edition) and the ISM30 Invisi Smart Mask 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). FDA's review of your websites revealed the following statements that establish that the masks are intended for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, including but not limited to: " ISM30 Invisi Smart Mask , Invisi Smart technology has been tested against the SARSCoV-2 virus's spike protein by the University of Cambridge." "Invisi Smart Mask™ has been tested against human coronavirus and not a weaker strain from the feline coronavirus subfamily." "Invisi Smart Mask™ kills viruses and bacteria as they come into contact with the mask allowing you to wear your mask with confidence all day… and for the next 30 days!" "Our self–disinfecting technology allows you to safely wear the Invisi Smart Mask™ without the need to wash it." "Our main ingredient, titanium dioxide, … is generally recognized as safe (GRAS) by the FDA, with up to 1% allowance in food products without having to add it to the ingredients label." Based on our review, your websites are offering for sale in the United States the above mentioned mask models without marketing approval, clearance, or authorization from the FDA. Accordingly, your devices 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 your intent to introduce them into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). FDA contacted your firm on October 8, 2020, and informed you that you must submit a premarket notification submission before marketing these devices in the U.S. On October 14, 2020, FDA contacted your firm again and discussed certain claims that remained on your website. FDA further reiterated that you must submit a premarket notification submission prior to distributing devices of this type in the U.S. FDA asked your firm to provide your plan regarding these masks to FDA by October 19, 2020. FDA had another teleconference meeting with your chief scientific officer per your request to discuss FDA regulations on October 15, 2020. On October 22, 2020, FDA sent an email in response to your written feedback request regarding FDA regulations and again asked your firm to provide a plan for premarket notification submission. FDA did not receive a response from you to this email. A review of your websites on June 21, 2021, shows that your products are still being marketed without FDA approval, clearance, or authorization. To date, FDA has not cleared, approved, or authorized the three mask models cited above. 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 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 such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. If you believe that your devices meet the requirements for Emergency Use Authorization (EUA) under section 564 of the FD&C Act for claims associated with use of your devices for COVID-19, please submit an email to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov. Guidance regarding the applicable criteria and the information to include in an EUA submission is available at https://www.fda.gov/media/97321/download . Our office requests that your firm immediately cease activities that result in the misbranding or adulteration of these devices, such as the commercial distribution of the devices for the uses discussed above. This letter is not meant to be an all-inclusive list of violations that exist in connection with the product(s) 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 are not misleadingly representing the product(s) as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, authorized by FDA and that you do not make representations that misbrand the product(s) in violation of the Act. 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 treatment or prevention 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 corrective actions and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. If you are not located in the United States, please note that products that appear to be adulterated or misbranded are subject to detention and refusal of 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 product(s) listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States. 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 correct 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 the corrections and/or corrective actions (which must address systemic problems) 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. Your firm's response should be comprehensive and address all violations included in this letter. If you believe that the product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Your firm's response should be sent 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, Rm 3657 10903 New Hampshire Ave. Silver Spring, MD 20993 Refer to the identification number CMS #614512 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: Cynthia J. Chang, Ph.D. at 301-796-6891. Sincerely yours, /S/ Binita S. Ashar, MD, MBA, FACS Director OHT4: Office of Surgical and Infection Control Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health _____1 COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China. 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-emergencyconcerning-novel-coronavirus-disease-covid-19-outbreak/ Content current as of: 08/26/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 3: Places for report 1193000

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	London	51.50853	-0.12574
Americas	United States	United States	39.76	-98.5

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at https://www.invisismart.com/, https://shop.invisismart.com/, and https://twitter.com/InvisiSmart on, June 21, 2021. The FDA has observed that your websites

offer the ISM5 Invisi Smart Mask, ISM5 Invisi Smart Mask (Black Edition) and the ISM30 Invisi Smart Mask for sale in the United States. [...] Based on our review, your websites are offering for sale in the United States the above mentioned mask models without marketing approval, clearance, or authorization from the FDA. [...]

4 PNP's Guy calls for investigation into fake PPE to public health staff

Publication date	2021-09-21
Create date	2021-10-20
Score	25.25
Report id	1259396
Category	Medical devices for disease prevention
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: PNP's Guy calls for investigation into fake PPE to public health staff Jamaica Observer

Click here to see the Original Article

Table 4: Places for report 1259396

Region Name	Country	Location	Latitude	Longitude
Americas	Jamaica	Jamaica	18.16667	-77.25

Notes: The Opposition Spokesman on Health and Wellness, Dr Morais Guy, has called for an urgent investigation into the procurement and distribution of counterfeit 3M-standard Personal Protective Equipment (PPE) which he alleges has been distributed to at least two health centres in Jamaica.

In a statement from 3M, dated August 9, 2021, the company issued a counterfeit alert on the 8210 model of the N95 face mask of specific lot codes stating that "there is a significant risk that they are counterfeit and should not be used." The company also added that it is working with law enforcement to remove the counterfeits from the market.

Dr Guy, in his statement released Tuesday, called for the immediate withdrawal of the sub-standard PPE from hospitals and other health staff and demanded the Integrity Commission to immediately investigate and identify the source of the fraudulent supply to the Government of Jamaica, as two of the fake batch codes have been recognised among the purchases by the government. He said these fake masks have been issued to hospitals and operating theatre staff since last weekend. [...]

5 Fake Face Masks Add to COVID-19 Dangers in Argentina

Publication date	2021-08-16
Create date	2021-08-20
Score	22.01
Report id	1179569
Category	Medical devices for disease prevention
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Fake Face Masks Add to COVID-19 Dangers in Argentina Insightcrime.org

Click here to see the Original Article

Table 5: Places for report 1179569

Region Name	Country	Location	Latitude	Longitude
Americas	Argentina	Buenos Aires	-34.61315	-58.37723

Notes: [...] On August 10, eight people were arrested in Buenos Aires for allegedly manufacturing fake face masks that mimicked those produced by leading commercial brands as well as those made by Argentina's National Scientific and Technical Research Council (Consejo Nacional de Investigaciones Científicas y Técnicas - CONICET). [...] Furthermore, the workshops were operating without licenses and failed to register with the government. Basic security and safety measures that are required to authenticate high-quality face masks were not in place. Equipment being used had not been sterilized and the resources being used were not up to standard. [...]

6 READ: What has been uncovered so far at Senate probe on Pharmally

Publication date	2021-09-27
Create date	2021-10-01
Score	20.16
Report id	1232067
Category	Medical devices for disease prevention
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: READ: What has been uncovered so far at Senate probe on Pharmally ABS-CBN News

Click here to see the Original Article

Table 6: Places for report 1232067

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Manila	40.85179	-124.16229

Table 7: Other Stories

ID	Title	Link
1232698	DOH probes Pharmally sale of substandard face shields	Link

Notes: The Senate Blue Ribbon Committee is conducting a probe on Pharmally Pharmaceuticals Corp., a company that supplied allegedly overpriced and substandard face masks, face shields and other medical equipment to the government. [...] A warehouse staff for Pharmally said the company asked workers to repack substandard face shields for the Department of Health.

According to the staff, they repacked face shields that were already yellowing, wet, old, and even dirty.

He also said that they were changing the stickers of ”expired” medical-grade face shields from 2020 to 2021. [...]

7 FDA warns health care workers to stop using N95 masks made by one Chinese manufacturer

Publication date	2021-08-26
Create date	2021-08-29
Score	19.55
Report id	1192621
Category	Medical devices for disease prevention
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA warns health care workers to stop using N95 masks made by one Chinese manufacturer PennLive

Click here to see the Original Article

Table 8: Places for report 1192621

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	Shanghai	31.22222	121.45806
Americas	United States	United States	39.76	-98.5

Table 9: Other Stories

ID	Title	Link
1194424	FDA warns health care workers: Stop using N95 masks from this Chinese manufacturer	Link
1195405	FDA warns health care workers to stop using N95 masks made by a Chinese manufacturer	Link
1198327	Use of certain N95 masks should stop due to 'serious' quality concerns, FDA says	Link
1198505	The FDA Has Issued a Recall for One Brand of N95 Mask	Link
1211866	COVID update: N95 mask recalls, kidney disease, long COVID	Link

Notes: The U.S. Food and Drug Administration has issued an alert to health care providers

about certain N95 respirator face masks.

The Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health has revoked its approval of N95 respirator face masks manufactured by Shanghai Dashen Health Products Manufacturing Co.

The FDA said the approvals were revoked "because the company did not implement, maintain, and control a quality management system. All previously authorized Shanghai Dasheng respirators are no longer authorized for emergency use as a result of the loss of NIOSH-approval." [...]

8 Westchester County bought counterfeit face masks from criminal

Publication date	2021-08-06
Create date	2021-08-16
Score	19.27
Report id	1167460
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Westchester County bought counterfeit face masks from criminal Westfair Online

Click here to see the Original Article

Table 10: Places for report 1167460

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Westchester	25.75482	-80.32727

Notes: (Need to subscribe) – August 6, 2021 Westchester County is suing to get back its money for 31,000 counterfeit face masks it bought from a known fraudster. Jason Brand's home/ manufacturing firm. The county is demanding $207,000 from Jason Brand and Essential Manufacturing Corp. of Melville, Suffolk County, in an Aug. 2 complaint filed in Westchester Supreme Court. In May 2020, in the early days of the Covid-19 pandemic, Westchester issued a request for bids for face masks for the county's Office of Emergency Management. The county specified 3M masks, "the gold standard," according to the complaint, for protection against airborne pathogens. Jason Brand submitted a bid for Essential on June 6, 2020. Westchester paid Essential $206,995 — $6.75 per mask — for 1,533 boxes with a total of 30,660 masks. This past February, 3M issued a fraud alert about counterfeit masks, according to the complaint, and 3M later verified that the masks from Essential are counterfeit. [...]

9 Facebook Allows Promotion of 'Fake Masks' for Children in Schools

Publication date	2021-09-20
Create date	2021-09-22
Score	18.96
Report id	1223601
Category	Medical devices for disease prevention
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Facebook Allows Promotion of 'Fake Masks' for Children in Schools Snopes.com

Click here to see the Original Article

Table 11: Places for report 1223601

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Ohio	40.25034	-83.00018

Notes: [...] The Fake Mask USA website was mentioned numerous times on Facebook, either inside or outside of groups. Christina, who said she was a mother, posted in a California group, "Have to send your kids to school in a mask? Try these." In the post, she linked to the website. A user named Shane also posted the website to his personal Facebook feed, saying "get your kids masks here." Videos from the website claimed that the company had fulfilled orders for at least hundreds of thousands of fake masks. [...] While the website did sell a see-through mask that was obviously fake and ineffective, it also sold a "Double Incognito Fake Mask." This mask was black and might appear to others to be an effective face covering to stop the spread of a deadly virus. However, the website said of all its products: "These masks do nothing at all." The website's FAQ mentioned nylon and polyester as some of the key materials used to make the masks. It also said: "Our masks do not stop the spread of COVID-19 and will not protect you from it either." [...]

10 Feds find 622K fake N95 masks intended for hospital system at Detroit warehouse

Publication date	2021-09-30
Create date	2021-10-05
Score	11.95
Report id	1237228
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Feds find 622K fake N95 masks intended for hospital system at Detroit warehouse The Detroit News

Click here to see the Original Article

Table 12: Places for report 1237228

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Detroit	42.33143	-83.04575

Notes: Federal officials on Thursday seized about 622,000 counterfeit masks at a Detroit storage facility intended for a hospital system in the region. The discovery was part of an ongoing probe tied to a Chinese company that has distributed counterfeit face coverings across the country, Vance Callender, Homeland Security Investigations special agent in charge for Michigan and Ohio, told The Detroit News. [...] A hospital system had spent some $3.5 million for the pieces, which were designed to resemble 3M N95 masks, Callender said. The hospital system was not identified. [...]

11 Stamford Man Pleads Guilty To Trafficking Counterfeit Pills

Publication date 2021-08-06

Create date 2021-08-13

Score 7.93

Report id 1167658

Category Opioid

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Stamford Man Pleads Guilty To Trafficking Counterfeit Pills Patch.com

Click here to see the Original Article

Table 13: Places for report 1167658

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Connecticut	41.66704	-72.66648
Americas	United States	Stamford	41.05343	-73.53873

Table 14: Drugs for report 1167658

Medicine Name	Medicine Class	Action	ATC Code
alprazolam	Benzodiazepine derivatives	anxiolytics	N05BA12
oxycodone	Natural opium alkaloids	opioids	N02AA05

Table 15: Other Stories

ID	Title	Link
1170208	Feds: Stamford man admits selling counterfeit oxycodone pills	Link

Notes: According to a news release from Leonard C. Boyle, Acting U.S. Attorney for the District

of Connecticut, Arber Isaku, a 31-year-old Stamford man, has pleaded guilty to manufacturing and distributing counterfeit oxycodone pills containing fentanyl analogues. [...] On April 3, 2018, Boyle noted, a court-authorized search of Decaro's residence found numerous pills containing approximately 330 grams of fentanyl and acetyl fentanyl, approximately 40 grams of fentanyl analogues in powder form, three pill presses, instructions on how to prepare the fentanyl analogue Carfentanil, a hazardous material suit, a gas/respirator-type mask, and numerous U.S. Postal mail envelopes. [...]

12 Hong Kong company fined HK$10,000 over substandard face masks

Publication date	2021-09-30
Create date	2021-10-05
Score	5.65
Report id	1236558
Category	Medical devices for disease prevention
Quality	Substandard
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Hong Kong company fined HK$10,000 over substandard face masks South China Morning Post

Click here to see the Original Article

Table 16: Places for report 1236558

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Hong Kong	Hong Kong	22.27832	114.17469
Eastern Asia	Hong Kong	San Po Kong	22.33546	114.19669

Notes: A Hong Kong company run by members of the now-defunct opposition party Demosisto has been fined HK$10,000 (US$1,280) for breaking trade description laws over its stock of more than 900 boxes of face masks with false performance claims. Customs officers raided the party's registered address in San Po Kong and seized the masks, stored in yellow boxes printed with the declaration "Not made in China", following complaints on May 22 last year. [...] Advertisement But a laboratory test revealed that the sample masks failed to attain the declared performance standard. [...] Deputy magistrate Denise Tso Yin-chee fined the company HK$10,000 and confiscated all 935 boxes, containing 32,725 masks with an estimated market value of about HK $93,500. [...]

13 Toyobo Co. Ltd. - CGMP/Finished Pharmaceuticals/ Adulterated - Shiga - 2021-08-19

Publication date	2021-08-19
Create date	2021-09-01
Score	1.15
Report id	1189894
Category	Not applicable
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Toyobo Co. Ltd. MARCS-CMS 614177 — August 19, 2021 Share Tweet Linkedin Email Print Delivery Method: Via Email Product: Drugs Recipient: Recipient Name Mr. Hidehiko Kanae Recipient Title General Manager Toyobo Co. Ltd. 2 Chome 1, Katata Otsu , Shiga 520-0292 Japan Issuing Office: Center for Drug Evaluation and Research | CDER United States Warning Letter 320-21-55 August 19, 2021 Dear Mr. Kanae: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Toyobo Co. Ltd., FEI 1000251214, at Toyobo (Kabu) Sogokenkyusho, 2 Chome 1, Katata, Otsu, Shiga, from February 15 to 19, 2021, on February 22, 2021, and from February 24 to 25, 2021. This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211). Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). We reviewed your March 18, 2021, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence. During our inspection, our investigators observed specific violations including, but not limited to, the following. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192). A. You did not adequately investigate significant particulate defects in your sterile drug product, including recurring incidents of extrinsic particle contamination. During 2019 and 2020, multiple batches of (b)(4) injection solution were found to have significant particulate contamination defects, many of which are defined in your procedure and response as ”foreign” (i.e., extrinsic). When extrinsic particulates were identified within batches, you failed to initiate a timely investigation to determine root causes and assess the drug product impact. Our review revealed that your in-process quality standards, limits, categories, and triggers for investigations do not sufficiently differentiate intrinsic from extrinsic particulate contamination. A recent investigation update, submitted to FDA on June 18, 2021 (four months after FDA’s inspection), indicates that you have improved your procedures and are performing supplier audits. While your investigation concluded that it is ”highly possible” that your washing and sterilization processes could not

remove certain particles adhered to the (b)(4) stoppers or vials, you failed to adequately address the upstream root causes of the contamination and implement timely corrective action and preventive actions (CAPA). In addition, you failed to address multiple instances of a ferrous- (b)(4) complex that was found during visible particle identification studies, including the potential for this contaminant to induce adverse events because of immunogenic response. Your firm indicated that the (b)(4) appears to be from the drug formulation. Your response discussed the 12 batches cited during the inspection that were found with visible particulates such as cellulose fibers, glass fibers, (b)(4) , black and white "particles," and "stain-" like particles of various colors. You also expanded the investigation to encompass (b)(4) batches that remained within expiry and identified further instances of extrinsic or "non-stopper material." Notably, stopper "stain" defects were also investigated in 2017. However, your stopper supplier indicated that their process was not the cause of the problem at the time, and your CAPA was inadequate to resolve the problem. Your response is inadequate. You failed to adequately investigate both extrinsic and intrinsic particulate contamination issues. You did not determine the root cause and implement a timely and effective CAPA to address persistent incidents of extrinsic particulate contamination in your sterile injectable product. Extrinsic particulate contamination should occur infrequently and be fully investigated. In response to this letter, provide: • A comprehensive, independent assessment of your overall system for investigating deviations, discrepancies, complaints, out-of-specification results, and failures. Provide a detailed action plan to remediate this system. Your action plan should include, but not be limited to, significant improvements in investigation competencies, scope determination, root cause evaluation, CAPA effectiveness, quality unit (QU) oversight, and written procedures. Address how your firm will ensure all phases of investigations are appropriately conducted. • An updated risk assessment regarding marketed batches, including: o An evaluation of extrinsic particulates found in batches within expiry period. o Protocol or sampling procedures and criteria used to select the vials examined as part of your investigation. o The potential impact of iron- (b)(4) complexes on safety (e.g., immunogenic response) and efficacy of your product. • An independent review of all injectable defect limits that includes but is not limited to: o Limits and associated rationales for both 100% inspection and Acceptable Quality Levels (AQL). o Provide a comprehensive list of all items that could trigger the initiation of an investigation related to foreign particulates. • An updated investigation into the extrinsic particulate contamination for (b)(4) injection solution, including root causes and all CAPA activities. B. Your investigation into data integrity breaches, reported to the agency in a (b)(4) , was insufficient to determine the scope of the problems at your facility. Your firm identified recurring instances of the following: • Operators failed to consistently ensure that personnel monitoring plates contacted gowning surfaces before leaving the ISO 7 area (Grade B). • Operators failed to consistently ensure that environmental monitoring plates contacted equipment surfaces located in ISO 5 (Grade A) and ISO 7 (Grade B) areas. • When surfaces were monitored, operators wiped equipment surfaces with (b)(4) before sampling the equipment surface. • Nonviable particle data for ISO 5 (Grade A) was reported as ISO 7 (Grade B) when particles results were higher than alert levels. • Operators failed to report ISO 5 (Grade A) airborne particulates values using a portable particulate counter, instead they repeated the monitoring of airborne particulates. Your investigation lacks sufficient information regarding the extent of the breaches of data integrity. Your investigation lacked a comprehensive assessment into the extent of the "falsification of airborne particles measurement records" and other breaches of data integrity occurring in the facility. Environmental monitoring (EM) data related to operators, equipment surfaces, and non-viable particulate monitoring was unreliable and raised product sterility assurance concerns. Your investigation also indicates the data integrity breaches were not isolated. You found that (b)(4) of (b)(4) operators were involved in manipulation of contact plate measurements, while all (b)(4)

environmental monitoring operators were involved in the manipulation of non-viable particles measurement data. Our inspection also cited additional weaknesses in the reliability of your documentation, including uncontrolled testing worksheets and deficient systems for reconciliation of laboratory documents. Based on your investigation, a total of (b)(4) batches of (b)(4) , manufactured from 2016 to 2020, could have been impacted by these practices. However, there was insufficient data in your response to support a full determination of the scope of potentially affected batches. Accurate microbiological data is fundamental to evaluating and maintaining the state of control of an aseptic processing operation. Awareness of microbial excursions in an aseptic processing operation is essential to trigger prompt actions that maintain environmental control. Additionally, timely and thorough evaluation of action level excursions, identifying potential routes of contamination, as well as identifying appropriate follow-up measures are necessary to prevent contamination risks to the product. Your failure to report accurate data compromised the sterility assurance of drug products released from the facility and may have increased risks to patients. Your response stated that a product impact risk assessment was conducted and that product sterility was not compromised. However, you lacked adequate justification for this conclusion, given the extent and nature of the data integrity breaches that occurred in the facility. In addition, while your response focused on environmental data and a review of "aseptic practices and sterility assurance training and oversight," its scope did not sufficiently address other areas of deficient data integrity. Your response mentions that the root cause is associated with "employees not understanding CGMP, the importance of data integrity, and pressure in handling deviations." We acknowledge your efforts to date of identifying data integrity deficiencies and actions toward improving accountability of all staff at your facility. However, further actions are needed to ensure competency of employees in performing and overseeing aseptic operations and improve quality systems effectiveness and data integrity oversight throughout your entire manufacturing operation. In response to this letter, provide: • Your plan to ensure appropriate aseptic practices and cleanroom behavior during production. Include steps to ensure routine and effective supervisory oversight for all production batches. Also, describe the frequency of QU oversight (e.g., daily activities, audits) during aseptic processing and its support operations. • A thorough retrospective review and risk assessment that evaluates how poor aseptic technique and cleanroom behavior may have affected the quality and sterility of your drugs. • A comprehensive risk assessment of all contamination hazards with respect to your aseptic processes, equipment, and facilities, including an independent assessment that includes, but is not limited to: o All human interactions within the ISO 5 area o Equipment placement and ergonomics o Air quality in the ISO 5 area and surrounding rooms o Facility layout o Personnel Flows and Material Flows (throughout all rooms used to conduct and support sterile operations) • A detailed remediation plan with timelines to address the findings of the contamination hazards risk assessment. Describe specific tangible improvements to be made to aseptic processing operation design and control. • A plan to perform testing (including sterility, as well as any other test identified by your risk assessments) of retain samples for all batches of sterile drug products manufactured at your facility that remain within expiry in the U.S. market. • A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to: o A determination of whether procedures used by your firm are robust and appropriate o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices o A complete and final review of each batch and its related information before the QU disposition decision o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products Describe how top management supports quality assurance and reliable operations, including but not limited to timely provision of resources to proactively address emerging manufacturing/

quality issues and to assure a continuing state of control. • Your CAPA plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance or documentation issues, appropriate staffing to perform activities robustly, improvements in capability when needed, adherence to appropriate preventive maintenance schedules, effective execution of repairs, timely technological upgrades to the equipment/facility infrastructure, and improved systems for both daily production supervision and overall operations management. Data Integrity Remediation Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. See FDA's guidance document Data Integrity and Compliance with Drug CGMP for guidance on establishing and following CGMP compliant data integrity practices at https://www.fda.gov/media/119267/download We acknowledge that you are using a consultant to audit your operation and assist in meeting FDA requirements. In response to this letter, provide the following: A. A comprehensive investigation into the extent of the inaccuracies in data records and reporting. Your investigation should include: • A detailed investigation protocol and methodology; a summary of all laboratories, manufacturing operations, and systems to be covered by the assessment; and a justification for any part of your operation that you propose to exclude. • Interviews of current and former employees to identify the nature, scope, and root cause of data inaccuracies. We recommend that these interviews be conducted by a qualified third party. • An assessment of the extent of data integrity deficiencies at your facility. Identify omissions, alterations, deletions, record destruction, non-contemporaneous record completion, and other deficiencies. Describe all parts of your facility's operations in which you discovered data integrity lapses. • A comprehensive retrospective evaluation of the nature of the manufacturing data integrity deficiencies. We recommend that a qualified third party with specific expertise in the area where potential breaches were identified should evaluate all data integrity lapses. B. A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analyses of the risks to patients caused by the release of drugs affected by a lapse of data integrity and analyses of the risks posed by ongoing operations. C. A management strategy for your firm that includes the details of your global CAPA plan. Your strategy should include: • A detailed corrective action plan that describes how you intend to ensure the reliability and completeness of all the data you generate including analytical data, manufacturing records, and all data submitted to FDA. • A comprehensive description of the root causes of your data integrity lapses including evidence that the scope and depth of the current action plan is commensurate with the findings of the investigation and risk assessment. Indicate whether individuals responsible for data integrity lapses remain able to influence CGMP-related or drug application data at your firm. • Interim measures describing the actions you have taken or will take to protect patients and to ensure the quality of your drugs, such as notifying your customers, recalling product, conducting additional testing, adding lots to your stability programs to assure stability, drug application actions, and enhanced complaint monitoring. • Long-term measures describing any remediation efforts and enhancements to procedures, processes, methods, controls, systems, management oversight, and human resources (e.g., training, staffing improvements) designed to ensure the integrity of your company's data. • A status report for any of the above activities already underway or completed. CGMP Consultant Recommended Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations and to assist your firm in meeting CGMP requirements. 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 CAPA 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 that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b). This also allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products. Correct any violations promptly. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to any violations. Failure to address any violations may also result in the FDA refusing admission of articles manufactured at Toyobo Co. Ltd., at Toyobo (Kabu) Sogokenkyusho, 2 Chome 1, Katata, Otsu, Shiga, Japan into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated or misbranded may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). 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 since our inspection to correct your 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 complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 1000251214 and ATTN: Rafael E. Arroyo. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research Content current as of: 08/24/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 17: Places for report 1189894

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Eastern Asia	Japan	Ōtsu	35	135.86667

Table 18: Other Stories

ID	Title	Link
1193261	FDA warns Japanese firm for particle contamination, takes mask-maker to task — again	Link

Notes: [...] This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). [...]

Annex C

C.4. Sanitisers and disinfectants

Medicine Quality Monitoring Globe

November 18, 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.

Translation Disclaimer:

THIS REPORT MAY CONTAIN TRANSLATIONS POWERED BY GOOGLE. GOOGLE DISCLAIMS ALL WARRANTIES RELATED TO THE TRANSLATIONS, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF ACCURACY, RELIABILITY, AND ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

This Medicine Quality Monitoring Globe report is issued by IDDO, University of Oxford, and some sections, indicated in blue, may have been translated for your convenience using translation software powered by Google Translate. Reasonable efforts have been made to provide an accurate translation, however, no automated translation is perfect nor is it intended to replace human translators. Translations are provided as a service to users of the Medicine Quality Monitoring Globe, and are provided "as is." No warranty of any kind, either expressed or implied, is made as to the accuracy, reliability, or correctness of any translations made from the source language (Chinese, French, Spanish, or Vietnamese) into English.

The official text is the version in the source language (Chinese, French, Spanish, or Vietnamese). Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the information contained in the translated text, refer to the text in the source language (Chinese, French, Spanish, or Vietnamese) which is the official version.

Filters applied for this report

Search	("wipes" OR "disinfectant" OR "sanitizer" OR "sanitizing" OR "iodoform" OR "sanitiser")
Start date	2021-08-01
End date	2021-09-30
Language	en
Report type	incident
Curation status	validated
Number of Reports	11

1 255 FDA-Recalled Hand Sanitizers to Beware of as COVID-19 Continues Spreading

Publication date	2021-08-17
Create date	2021-09-08
Score	17.46
Report id	1208377
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: 255 FDA-Recalled Hand Sanitizers to Beware of as COVID-19 Continues Spreading Newsweek

Click here to see the Original Article

Table 1: Places for report 1208377

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102
Europe	Poland	Republic of Poland	52	20
Eastern Asia	China	People's Republic of China	35	105
Americas	United States	United States	39.76	-98.5
Americas	Guatemala	Republic of Guatemala	15.5	-90.25
Western Asia	Republic of Korea	Republic of Korea	36.5	127.75
Western Asia	Turkey	Republic of Turkey	39	35

Table 2: Drugs for report 1208377

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: [...] One thing hasn't changed in the last 15 months, and that's the U.S. Food and Drug Administration's (FDA) list of recalled hand sanitizers. In fact, the list of recalled products is now longer than it has ever been during the pandemic.

The FDA has listed 255 different hand sanitizers, mostly produced and distributed in Mexico, that have been recalled. Not all recalled hand sanitizers are from Mexico, though. They come from China, South Korea, Guatemala, Poland, Turkey, Florida, Georgia, North Carolina, Ohio, Tennessee, Texas and Utah. [...] The number of recalled hand sanitizers quickly went from nine to 100, and then to 200, 215 and now 255. [...]

2 Recall alert: 75 hand sanitizers contaminated with toxic chemical

Publication date	2021-08-20
Create date	2021-08-25
Score	17.43
Report id	1186717
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Recall alert: 75 hand sanitizers contaminated with toxic chemical

Click here to see the Original Article

Table 3: Drugs for report 1186717

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: [...] The FDA notes: "Although all persons using these products on their hands are at risk for methanol poisoning, young children who accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute, are most at risk."

Most of the recalled products were made in Mexico, and some have been sold at Walmart and Costco and unnamed grocery stores. [...]

3 Tropicosmeticos SA de CV - 609041 - 08/10/2021 - 2021-08-17

Publication date	2021-08-17
Create date	2021-08-24
Score	15.96
Report id	1180886
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Finished Pharmaceuticals/Unapproved New Drug/Misbranded

Click here to see the Original Article

Table 4: Places for report 1180886

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Ecatepec	19.60492	-99.06064
Americas	United States	United States	39.76	-98.5
Americas	Mexico	Rústica Xalostoc	19.52264	-99.07392

Table 5: Drugs for report 1180886

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: [...] Britz HAND SANITIZER, labeled as manufactured at your facility, is labeled to contain 70% 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 product contained 0% ethanol and contained >50% 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. [...]

4 Spurious sanitisers might spread Covid: SPECS

Publication date	2021-08-04
Create date	2021-08-12
Score	13.80
Report id	1164808
Category	Antiseptic
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Spurious sanitisers might spread Covid: SPECS Daily Pioneer

Click here to see the Original Article

Table 6: Drugs for report 1164808

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: Spurious and toxic hand sanitisers might be the possible cause of the spread of Covid-19 and deaths caused by it across the State. The demand for sanitisers has risen since Covid hit Uttarakhand and due to its growing demand, many spurious hand sanitisers infused with toxic chemicals are being sold across the State. [...] The study revealed that 578 samples out of 1,050 samples of hand sanitisers collected from markets and households of the districts of Uttarakhand had extremely low amounts of alcohol that makes them ineffective against Covid-19.

The presence of toxic colours was also found in 278 samples of sanitisers while the highly toxic chemical methanol was also found in eight samples — which can severely affect the human body. The concentration of hydrogen peroxide was also found in excess in around 112 samples of sanitisers. [...]

5 Nanomateriales Químicos Avanzados, S.A. de C.V. - CGMP/ Finished Pharmaceuticals/Unapproved New Drug/Misbranded/ Adulterated - Nuevo León - 2021-09-15

Publication date	2021-09-15
Create date	2021-09-22
Score	13.79
Report id	1224668
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Nanomateriales Químicos Avanzados, S.A. de C.V. MARCS-CMS 609969 — September 15, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA UPS Product: Drugs Recipient: Recipient Name Mr. Joel Gutiérrez Antonio Recipient Title Director General/CEO Nanomateriales Químicos Avanzados, S.A. de C.V. Av Milimex 215 Col. Parque Industrial Milimex 66637 Apodaca , N.L. Mexico Issuing Office: Center for Drug Evaluation and Research | CDER United States Warning Letter 320-21-58 September 15, 2021 Dear Mr. Gutiérrez: Your facility is registered with the United States Food and Drug Administration (FDA) as a manufacturer of over-the-counter (OTC) drug products, including consumer antiseptic rub drug products (also referred to as a consumer hand sanitizer). The FDA conducted testing of a product, labeled as ZANILAST + Gel, 25 kg. This drug product was labeled as manufactured at your facility. Following an attempt to import ZANILAST + Gel, 25kg 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 labeled as manufactured at your facility is adulterated within the meaning of section 501(d)(2) of the FD&C Act, 21 U.S.C. 351(d)(2), in that a substance was substituted wholly or in part therefor. Additionally, FDA has reviewed the records you submitted in response to our initial April 22, 2020, request for records and other information, and subsequent correspondence, pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for your facility, Nanomateriales Químicos Avanzados, S.A. de C.V., formerly known as Nanomateriales S.A. de C.V., FEI 3010525809, at Av. Milimex 215, Col. Parque Industrial Milimex, Apodaca, Nuevo Leon 66637, Mexico. Based on information provided in response to our 704(a)(4) request and the substitution determined by FDA laboratory testing, the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of drugs do not conform to current good manufacturing practice (CGMP) within the meaning of section 501(a)(2)(B) of the FD&C Act. This warning letter also summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211). In addition, in response to our 704(a)(4) request you provided a

copy of the label for ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon. Our review of the label has determined that ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is an unapproved new drug in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a). Additionally, ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). 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). ZANILAST + GEL 25kg is misbranded under sections 502(f)(1), (a), (e)(1)(A), (c), and (x) of the FD&C Act, 21 U.S.C. 352(f)(1), (a), (e)(1)(A), (c), and (x). Introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(a) of the FD&C Act, 21 U.S.C. 331(a). These violations are described in more detail below. Adulteration Violations ZANILAST + Gel, 25kg bulk labeled as manufactured at your facility, is labeled to contain 65% 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 an average 0.0% ethanol and an average of 41% 1-propanol volume/volume (v/v). 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 1-propanol, a dangerous chemical when in contact with human skin or ingested. 1-propanol, not to be confused with isopropyl alcohol or 2-propanol, is not a permitted active ingredient in hand sanitizers intended for the United States. Exposure to 1-propanol may cause irritation to eyes, nose; throat; dry cracking skin; drowsiness, headache; ataxia, gastrointestinal pain; abdominal cramps, nausea, vomiting and diarrhea. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products, and adolescents and persons with alcohol addiction who drink these products as an alcohol (ethanol) substitute, are most at risk for 1-propanol poisoning. On August 17, 2020, FDA held a teleconference with you. We recommended you consider removing all of your firm's hand sanitizer drug products currently in distribution to the U.S. market. On August 17, 2020, FDA notified the public of the 1-propanol contamination substitution of your hand sanitizer drugs products at the following website: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use On August 26, 2020, you issued a voluntary nationwide recall of ZANILAST + Gel Hand Sanitizer because of the potential presence of undeclared 1-propanol, as noted on the following FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nanomaterials-sa-de-cv-issues-voluntary-nationwide-recall-all-lots-zanilastgel-due-presence-1 In response to this letter, provide the following: • A list of all raw materials used to manufacture all 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 United States. • Summary of corrective actions taken to ensure your hand sanitizer products can be manufactured at the label claim concentration of 65% v/v ethanol. • Details regarding your raw material identity testing of incoming active pharmaceutical ingredients and specifically how your test methods can distinguish between ethanol and 1-propanol. • Provide a complete, comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system. The substitution and contamination with 1-propanol in a drug product 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. 1 21 CFR parts 210 and 211 Violations Following review of records and other information provided pursuant to section 704(a)(4) of the FD&C Act,

significant violations were observed including, but not limited to, the following: 1. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)). Your response to our records request and other information under section 704(a)(4) indicated that you did not conduct adequate finished drug product testing on drug products shipped to the United States. Specifically, in response to our 704(a)(4) request for all finished product specifications and test methods used to evaluate them, you referenced an operational manual which stated that your hand sanitizer is only tested for pH, viscosity, density, and appearance and provided stability data for one batch in which only pH and viscosity were evaluated. In a subsequent response on September 5, 2020, you provided a procedure which stated that finished product must be tested according to its specifications before release, but you did not provide revised specifications for your hand sanitizer drug product. The documents you provided in response to our 704(a)(4) request indicate that you do not perform identity, assay, or purity testing of the active ingredient in your finished drug product. Full release testing including strength and identity testing of the active ingredient must be performed before drug release and distribution. In response to this letter, provide the following: • A list of chemical and microbial specifications, including test methods, used to analyze each lot of your drug products before a lot disposition decision. Specify which tests are performed by your facility and which if any are performed by a contract testing laboratory. o An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter. o A summary of all results obtained from testing reserve samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls. • Ethanol and 1-propanol test results for all batches of hand sanitizer shipped to the United States within expiry. 2. Your firm failed to conduct at least one test to verify the identity of each component of a drug product. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals (21 CFR 211.84(d)(1) and (2)). Based on the records and information you provided, you did not demonstrate adequate identity testing of incoming components used to manufacture your drug products, and you accepted test results from suppliers without verifying information provided by suppliers. We requested details about your raw material identity testing for each lot of each component and you stated that material test results are accepted from the supplier's Certificate of Analysis (COA). We asked again on August 25, 2020, and you stated that COA values are accepted from "reliable" suppliers. There is no evidence that you perform identity testing on each lot of incoming components. For your component suppliers, we requested the last date of supplier qualification, audit frequency, and the last three audit dates as applicable. You replied only that you did not have an audit frequency. We asked for supplier qualification information again on August 25, 2020, and you provided a procedure created July 3, 2020, describing the evaluation and selection of suppliers. However, this procedure does not provide any specific guidance on evaluating the quality of a supplier or the validity of data listed on a supplier's COAs. In response to this letter, provide the following: • The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing. • A description of how you will test each component lot for conformity with all appropriate specifications for identity, strength, quality, and purity. If you intend to accept any results from your supplier's COAs instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier's results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming

component lot. • A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your SOP that describes this COA validation program. • A summary of your program for qualifying and overseeing contract facilities that test the drug products you manufacture. • A comprehensive review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures. 3. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products (21 CFR 211.22(a)) The records and information you submitted demonstrate that your quality unit (QU) lacks adequate quality oversight over the manufacture and release of finished drug product shipped to the United States. Specifically, your drug substance supplier provided incorrect information that 1-propanol was an allowable active ingredient in hand sanitizer intended for use in the United States. You accepted this information and altered your drug product formula without evaluating the impact of this change on product quality. Subsequently, you released hand sanitizer batches (b)(4) which contained 1-propanol as the active ingredient. On September 9, 2020, we requested the labels for these batches. You provided these labels which declare "65.00% alcohol" and "70% ethyl alcohol" content respectively, demonstrating that your QU released mislabeled material. As of your September 10, 2020, response, you understood that 1-propanol is an unacceptable active ingredient in hand sanitizer, committed to test for 1-propanol in your future finished hand sanitizer products, and will no longer use that drug substance supplier. However, your response lacked documentation and sufficient detail to demonstrate that you are establishing appropriate operational programs, systems, and related procedures to ensure product quality, such as those responsible for manufacturing changes. You also failed to address the potential impact that your lack of quality oversight had on the quality of all drugs that you manufacture. Your firm must provide the QU with the appropriate authority and sufficient resources to carry out its responsibilities and consistently ensure drug quality. See FDA's guidance document, Quality Systems Approach to Pharmaceutical CGMP Regulations, for help implementing quality systems and risk management approaches to meet the requirements of the CGMP regulations (21 CFR, parts 210 and 211) at: https://www.fda.gov/media/71023/download . In response to this letter, provide the following: • A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to: o A determination of whether procedures used by your firm are robust and appropriate o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices o A complete and final review of each batch and its related information before the QU disposition decision o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products • A comprehensive assessment of your change management system. This assessment should include, but not be limited to, your procedure(s) to ensure changes are justified, reviewed, and approved by your QU. Your change management program should also include provisions for determining change effectiveness. Unapproved New Drug and Misbranding Violations ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon and ZANILAST + GEL, 25kg 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 use in 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, these products are intended for use as a consumer topical antiseptic. Examples of claims observed on the ZANILAST + GEL ANTI-

SEPTIC HAND SANITIZER, 1 gallon product label and labeling that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following: "ANTISPETIC HAND SANITIZER . . . Drug Facts…Antiseptic…Use…For hand washing to decrease bacteria on the skin" "wet hands thoroughly with product and allow to dry without wiping" 2 Documents you submitted in support of your August 2020 import entry for ZANILAST + GEL, 25kg including a product list, provide evidence of the product's intended use (as defined in 21 CFR 201.128) as a hand sanitizer drug product. Further, examples of claims observed on the ZANILAST + GEL, 25kg that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following: Product Label: "ZANILAST + GEL is a stabilized compound that contains 70% of ethanol. In order to maximize its biocidal power, a compound based on zinc oxide is added." "…formulated with broad-spectrum sanitizing agents, obtained by an advanced physicochemical process that gives it an ideal composition and particle size to guarantee a broad biocidal power against bacteria, fungi, and viruses." Accordingly, your firm's ZANILAST + GEL, 25kg is a drug within the meaning of section 201(g)(1)(D) of the FD&C Act. ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because it is 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 it is lawfully marketed under section 505G of the FD&C Act (which is not the case for this product, as further described below) or 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 ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon drug product is GRASE for use under the conditions suggested, recommended, or prescribed in its labeling. Accordingly, ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is an unapproved new drug 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 OTC topical antiseptic products had been the subject of rulemaking under the Agency's 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 as 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 antiseptic rub. Additionally, OTC consumer antiseptic washes were addressed in "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Proposed Rule, 78 FR 76444 (December 17, 2013) (Consumer Antiseptic Washes Proposed Rule) and "OTC Safety and Effectiveness of Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 81 FR 61106 (September 6, 2016). We note that ethyl alcohol is not one of the active ingredients that was classified as Category III for use as an active ingredient in a consumer antiseptic wash. Under the Consumer

Antiseptic Washes rulemaking, ethyl alcohol was determined to be ineligible for evaluation under the OTC Drug Review for use as an active ingredient in consumer antiseptic washes. 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 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, ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon does not confirm to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rubs Proposed Rule and 2013 Consumer Antiseptic Washes Proposed Rule, nor any other TFM, proposed rule, or final rule, and does not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. As previously noted, statements on the ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon label suggest both that the product is a consumer antiseptic wash and a consumer antiseptic rub. However, ethanol (in any concentration) is not an active ingredient permitted for use in consumer antiseptic hand wash under the 1994 TFM. Moreover, antiseptic washes are outside the scope of FDA's temporary policies for hand sanitizers. The introduction or delivery for introduction of an unapproved new drug into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d). ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is a nonprescription drug subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but does not comply with the requirements for marketing under that section and it is not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. Furthermore, ZANILAST + GEL is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), because its labeling fails to bear adequate directions for use. Specifically, ZANILAST + GEL's labeling does not contain sufficient information to enable laypersons to use the product safely and for the purposes for which it is intended, including frequency of administration, duration of administration, time of administration, route or method of administration, and preparation for use. 3 In addition, ZANILAST + GEL is misbranded under section 502(a) of the FD&C Act, 21 U.S.C 352(a), because its labeling is false or misleading. ZANILAST + GEL is labeled to contain ethanol 65% and 70%. Such a representation by itself is misleading. However, FDA laboratory analysis of a batch of this product demonstrate that the product contains no traceable amount of ethanol and contains a significant concentration of 1-propanol, an ingredient that is not declared on the product label. 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 label to disclose the presence of the 1-propanol in the product, causes this product to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). The failure of ZANILAST + GEL drug product to list 1-propanol as an ingredient on its label also causes it to be misbranded under section 502(e)(1)(A) of the FD&C Act, 21 U.S.C. 352(e)(1)(A). 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). Additional Concerns We note that according to the product label, ZANILAST + GEL

purportedly contains the active ingredient ethyl alcohol at both 65% and 70% v/v, However, as previously discussed, FDA laboratory analyses of a batch of this product detained at the border demonstrated that ZANILAST + GEL contains no traceable amount of ethanol. Such a product does not conform with 1994 TFM or the applicable requirements, nor is it consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. 4 FDA laboratory analyses also demonstrated that a batch of ZANILAST + GEL contain significant concentrations of undeclared ingredient1-propanol. Use of 1-propanol as an active ingredient is not in conformance with the 1994 TFM, nor is 1-propanol 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, the product is labeled with alcohol, water, glycerin D-limonene, triethanolamine, carbomer, zinc oxide, and zinc pyrithione as active ingredients. 5 Neither water, glycerin D-limonene, triethanolamine, carbomer, zinc oxide, nor zinc pyrithione are permitted active ingredients, as a sole ingredient or in combination with other ingredients like ethanol, for use as a consumer or health care personnel antiseptic rub drug products. Such a product is not permitted under the TFM or other applicable requirements, nor is it consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. 6 In addition, the labeling of ZANILAST + GEL indicates that it provides "biocidal power" against fungi and viruses. These labeled intended uses go beyond merely describing the general intended use of a topical antiseptic as set forth in the 1994 TFM, as amended by the 2016 proposed rule, and FDA's before-noted temporary policy. 7 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 August 31, 2020, and Import Alert 66-40 on January 12, 2021, 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 pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). 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 a 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. Until all violations are addressed completely, and we confirm your compliance with CGMP, they may be cause for FDA to withhold approval of any new drug applications or supplements listing your firm as a drug manufacturer. 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 completion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3010525809 and ATTN: Christina Capacci-Daniel. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research CC: Registered U.S. Agent: David Lennarz Register Corp 144 Research Drive Hampton, VA, 23666 757-224-0177 drugs@registrarcorp.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 a health care personnel hand rub) 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 labeled as manufactured at your facility, a review of the purported formulations on the drug products' labeling further indicates that such 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 We note that your ZANILAST + GEL ANTISEPTIC HAND SANITIZER labeling contains conflicting information regarding whether it should be used as a consumer antiseptic wash or a consumer antiseptic rub. The term "hand sanitizer" generally refers to consumer antiseptic rubs, and the Drug Facts Label of your product both indicates that the product is to be used for handwashing (presumably with water) and suggests that it should be used without water (i.e., "wet hands thoroughly with product and allow to dry without wiping"). The ZANILAST + GEL ANTISEPTIC HAND SANITIZER product, however, does not conform to the requirements for either a consumer antiseptic rub or a consumer antiseptic wash, as further described below. 3 We note that you include the statement, "Caution: For manufacturing, processing, or repacking," on your product label, perhaps in an attempt to claim the exemption from section 502(f)(1) under 21 CFR 201.122. However, to the extent that 21 CFR 201.122 applies, ZANILAST + GEL cannot claim the exemption because it is a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, and does not meet any of the conditions set forth in 21 CFR 201.122(a)-(c). 4 The 1994 TFM, which does not distinguish between antiseptic hand washes and rubs, proposed for antiseptic hand washes and healthcare personnel hand washes an alcohol concentration of 60 to 95% by volume in an aqueous solution denatured in accordance with Bureau of Alcohol, Tobacco and Firearms regulations. 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. 5 The labeling and formulation for ZANILAST + GEL is not consistent with the conditions proposed for OTC hand sanitizers (i.e., antiseptic rub) for consumer and/or health care personnel use under the 1994 TFM (see 59 FR 31402;

June 17, 1994), as further amended by subsequent proposed rules. Specifically, the label for ZANILAST + GEL does not distinguish active ingredients from inactive ingredients. Therefore, all of the labeled ingredients (alcohol, water, glycerin D-limonene, triethanolamine, carbomer, zinc oxide, and zinc pyrithione) are deemed to be represented as active ingredients, see 21 CFR 201.66(b)(2). 6 See, e.g., Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). 7 The 1994 TFM covers health care antiseptics that are indicated for use to help reduce bacteria that potentially can cause disease and health care and consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. Content current as of: 09/21/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 7: Places for report 1224668

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Apodaca	25.78195	-100.18839
Americas	United States	United States	39.76	-98.5

Table 8: Drugs for report 1224668

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
	Antiseptics	throat preparations	R02AA

Notes: [...] ZANILAST + Gel, 25kg bulk labeled as manufactured at your facility, is labeled to contain 65% 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 an average 0.0% ethanol and an average of 41% 1-propanol volume/volume (v/v). 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 1-propanol, a dangerous chemical when in contact with human skin or ingested. [...]

6 Advisory - Potential contamination of health products manufactured by Eco-Med Pharmaceuticals Inc. may po

Publication date	2021-08-25
Create date	2021-08-30
Score	12.01
Report id	1196204
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Advisory - Potential contamination of health products manufactured by Eco-Med Pharmaceuticals Inc. may po Benzinga

Click here to see the Original Article

Table 9: Places for report 1196204

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Ottawa	45.41117	-75.69812

Table 10: Drugs for report 1196204

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: [...] Health Canada, as a precaution, is advising Canadians to stop using and discard all products manufactured by Eco-Med Pharmaceuticals (ultrasound gels, transmission and massage lotions, hand sanitizers and first aid antiseptics) due to potential bacterial contamination with Burkholderia stabilis (B. stabilis). [...] Natural Health Products: hand sanitizers and first aid antiseptic:

Prevent+ (NPN 80097875);

Prevent+ Foam Sanitizer (NPN 80102490);

Prevent+ Rubbing Alcohol, Rubbing Alcohol 70% (NPN 80103917);

First Aid Antiseptic: Prevent+ Hydrogen Peroxide 3% USP, Hydrogen Peroxide 3% USP, (NPN 80107321).

7 Laboratorio Pharma International SRL - CGMP/Finished Pharmaceuticals/Unapproved New Drug/Misbranded/Adulterated - Center for Drug Evaluation and Research | CDER - 2021-09-15

Publication date	2021-09-15
Create date	2021-09-22
Score	6.44
Report id	1224667
Category	Anaesthetic, Other
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Laboratorio Pharma International SRL MARCS-CMS 614766 — September 15, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA UPS Product: Drugs Recipient: Recipient Name Aurelio Nembrini Recipient Title General Manager Laboratorio Pharma International SRL Pharma Internacional Bldg, Main Street, Colonia Los Angeles Tegucigalpa , 11101 Honduras anembrini@pdpharmaintusa.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Warning Letter 320-21-57 September 15, 2021 Dear Mr. Nembrini: Your facility is registered with the United States Food and Drug Administration (FDA) as a manufacturer of over-the-counter (OTC) drug products. FDA has reviewed the records you submitted in response to our November 6, 2020, request for records and other information pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including in response to follow-up correspondence on March 24, 2021, for your facility, Laboratorio Pharma International S. de R.L., FEI 3012015184, at Pharma Internacional Bldg, Main Street, Colonia Los Angeles, Tegucigalpa, Honduras 11101. This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations, parts 210 and 211 (21 CFR, parts 210 and 211). Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)). In addition, GELAZUL Topical Analgesic is an unapproved new drug in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and is misbranded under sections 502 (x) and (ee) of the FD&C Act, 21 U.S.C. 352(x) and (ee). 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). These violations are described in more detail below. 1. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of

identity, strength, quality, and purity (21 CFR 211.160(b)). Your response to our 704(a)(4) request and subsequent correspondence indicates that your firm failed to establish appropriate specifications for the lidocaine hydrochloride and menthol active ingredients in your GELAZUL finished drug product. For example, in your response to our request for records or other information pursuant to section 704(a)(4) you provided finished product testing records for lots identified as distributed to the U.S. Our review of these records indicates that you have failed to establish a specification for your active ingredient, menthol, in the finished drug product. In addition, it does not appear that you tested the incoming component of menthol. In response to this letter, provide the following: • A comprehensive, independent assessment and corrective action and preventive action (CAPA) plan to ensure the adequacy of your finished product testing. Your remediated program should include, but not be limited to: o Your commitment to using current USP compendial monograph specifications (as applicable). • A list of chemical and microbial specifications, including test methods, used to analyze each lot of your drug products before a lot disposition decision. o An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter. o A summary of all results obtained from testing retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls. • A comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system. 2. Your firm failed to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to use results of stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)). Your response to our 704(a)(4) request and subsequent correspondence indicates that your firm lacks an adequate stability testing program to show that the chemical properties of your drug products are acceptable throughout the labeled expiry period of three years. For example, we requested details about your stability program, including a list of all stability studies or any records or data (separate from an established stability program) used to support your documented 3-year labeled expiry for GELAZUL. You clarified that "all products have either accelerated or shelf or (real time) stability". However, your response to our request for records or other information pursuant to section 704(a)(4) indicates for product released and distributed to the United States, you have not established an adequate stability program, in that, lots which have been evaluated are not subjected to a quantitative assay determination to support your label claims over time. In addition, you did not provide adequate stability data to support the shelf life of hand sanitizer batches released and distributed to the United States. In response to this letter, provide the following: • A comprehensive, independent assessment and corrective actions and preventive actions (CAPA) plan to ensure the adequacy of your stability program. Your remediated program should include, but not be limited to: o Stability-indicating methods, including both analytical and microbiological test methods. o Stability studies for each drug product based on quantitative analysis to support label claim. o An ongoing program in which representative batches of each product are added each year to the program to determine if the shelf-life claim remains valid. o Detailed definition of the specific attributes to be tested at each station (timepoint). • All procedures that describe these and other elements of your remediated stability program. • Stability data to support your hand sanitizer's drug product shelf life. • Your action plan to address any product quality or patient safety risks for your drug products in U.S. distribution, including potential customer notifications, recalls, or market withdrawals. 3. Your firm failed to test samples of each component for conformity with all appropriate written specifications for purity, strength, and quality

(21 CFR 211.84(d)(2)). In response to our 704(a)(4) request and subsequent correspondence pertaining to testing of incoming component ingredients, your firm failed to demonstrate adequate testing for impurities or identity of incoming components used in the manufacture of your drug products before release and distribution to the United States. For example, your response to our request for records or other information pursuant to section 704(a)(4) indicated that you have failed to ensure appropriate component testing for Pharmaint Gel Hand Sanitizer 1 . Specifically, you have failed to evaluate the component ethyl alcohol for impurities and to execute an appropriate identification test. In response to this letter, provide the following: • The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing. • A description of how you will test each component lot for conformity with all appropriate specifications for identity, strength, quality, and purity. If other methods are used in lieu of established compendial methods, we request that you provide justification. If you intend to accept any results from your supplier's Certificates of Analysis (COA) instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier's results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot. • A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your SOP that describes this COA validation program. • A summary of your program for qualifying and overseeing contract facilities that test the drug products you manufacture. • A comprehensive, independent review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures. • Your action plan to address any product quality or patient safety risks for your drug products in U.S. distribution, including potential customer notifications, recalls, or market withdrawals. Unapproved New Drug and Misbranding Violations GELAZUL Topical Analgesic is a "drug" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because it is intended for use in 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 it is intended to affect the structure or any function of the body. Specifically, this product is intended for use as a consumer topical analgesic. Examples of claims observed on the GELAZUL Topical Analgesic product label and labeling that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following: "Topical Analgesic . . . Drug Facts …. Uses: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains." This topical external analgesic product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its 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 FD&C Act (which is not the case for this product, 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 this drug product, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your GELAZUL Topical Analgesic drug product is GRASE for use under the conditions suggested, recommended, or prescribed in its labeling. Accordingly, this product is an unapproved new drug marketed in violation of sections 505(a) and 301(d) of the

FD&C Act, 21 U.S.C 355(a) and 331(d). Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(1) of the FD&C Act, 21 U.S.C. 355h(a)(1), category I drugs that were subject to a tentative final monograph (TFM) that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 are deemed to be GRASE and not "new drugs," as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM and comply with all other applicable requirements. We note that over-the-counter (OTC) topical external analgesic products were addressed in the TFM for External Analgesic Drug Products for Over-the-Counter Human Use (external analgesic TFM; 48 FR 5852, February 8, 1983) and subsequent rulemakings. Under 505G(b)(8) of the FD&C Act, 21 U.S.C. 355h(b)(8), the 1983 external analgesic TFM, in combination with subsequent determinations, is deemed to be a final administrative order. However, your GELAZUL Topical Analgesic product does not conform to the final administrative order, because it is inconsistent with the applicable TFM or any other applicable TFM or proposed rule, and it accordingly does not meet the conditions under section 505G(a)(1) of the FD&C Act for marketing without an approved application under section 505. Specifically, your product purports to contain 3% menthol and 4% lidocaine. The indication labeled on your product ("For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains") would be consistent with that of a "counterirritant" described in the applicable TFM (see 48 FR 5852, at 5868). While menthol at a concentration of 1.25 to 16 percent as a counterirritant active ingredient would be consistent with the applicable TFM, the combination of lidocaine and menthol is not permitted for this indication. In fact, lidocaine as a counterirritant active ingredient, in any combination or as a sole ingredient, is not consistent with the applicable TFM. The TFM does permit combinations of menthol and lidocaine, with a labeled indication as an external analgesic, which is different from that of a counterirritant. However, a combination would be permitted only at a concentration of menthol 0.1-1% and lidocaine 0.5-4%, respectively, and your product exceeds the level of menthol that would be consistent with the TFM. In addition, GELAZUL Topical Analgesic is misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x), because the product label fails 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. Lastly, this product is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because GELAZUL Topical Analgesic is a nonprescription drug subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but does not comply with the requirements for marketing under that section and is 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). Beta-Lactam Containment The records you provided also indicate that you manufacture potent compounds such as beta-lactams at your facility in addition to other finished drug products. In response to multiple requests that you clarify beta-lactam production controls, the records provided in each of your responses do not assure complete and comprehensive separation was established between beta-lactam and non-beta-lactam production. For example, the following controls for monitoring and personnel flow were not established: • Environmental monitoring data that establishes containment. • Limitations on personnel flow in shared areas, such as, breakrooms and gymnasium facilities. Due to the extremely low threshold dose at which an allergic response could occur, beta-lactam facilities need to be complete and comprehensively separated from non-beta-lactam facilities. For additional information, please refer to the guidance for industry, "Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination," available at https://www.fda.gov/media/79971/download . Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility/in connection with your products. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations. FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-40 on June 16, 2021. 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 a 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. In addition, shipments of articles manufactured at Laboratorio Pharma International S. de R.L. Pharma, Internacional Bldg, Main Street, Colonia Los Angeles, Tegucigalpa, Honduras 11101, into the United States that appear to be adulterated or misbranded are subject to being detained or refused admission pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until violations are completely addressed and we confirm your compliance with CGMP. Failure to address any violations may also result in FDA continuing to refuse admission of articles manufactured at Laboratorio Pharma International S. de R.L. Pharma, Internacional Bldg, Main Street, Colonia Los Angeles, Tegucigalpa, Honduras 11101, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated or misbranded may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). 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 deviations and 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 complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. If you decide you want to manufacture drugs intended for U.S. distribution in the future, request a Regulatory Meeting to discuss your corrective actions as well as the adequacy of your beta-lactam containment to prevent cross-contamination. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3012015184 and ATTN: Matthew R. Dionne, Pharm.D., Compliance Officer. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research CC: Carlos Barahona, U.S. Agent 999 Ponce De Leon Blvd., Suite 650 Coral Gables, FL 33134 cbarahona@pdpharmaintusa.com _____1 Due to 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 August 7, 2020. 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 rub) 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. A review of the formulations on the drug product labeling further indicates that your product was 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. Content current as of: 09/21/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 11: Places for report 1224667

Region Name	Country	Location	Latitude	Longitude
Americas	Honduras	Tegucigalpa	14.0818	-87.20681
Americas	United States	United States	39.76	-98.5

Table 12: Drugs for report 1224667

Medicine Name	Medicine Class	Action	ATC Code
lidocaine	Antiarrhythmics, class Ib	antiarrhythmics, class i and iii	C01BB01
lidocaine	Local anesthetics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AD01
lidocaine	Anesthetics for topical use	antipruritics, incl. antihistamines, anesthetics, etc.	D04AB01
lidocaine	Amides	anesthetics, local	N01BB02
lidocaine	Anesthetics, local	throat preparations	R02AD02
lidocaine	Local anesthetics	local anesthetics	S01HA07
lidocaine	Analgesics and anesthetics	other otologicals	S02DA01

Notes: [...] This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations, parts 210 and 211 (21 CFR, parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)).

In addition, GELAZUL Topical Analgesic is an unapproved new drug in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and is misbranded under sections 502 (x) and (ee) of the FD&C Act, 21 U.S.C. 352(x) and (ee). 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). These violations are described in more detail below. [...]

8 BBC Group Limited - 614659 - 08/04/2021 - 2021-08-10

Publication date	2021-08-10
Create date	2021-08-17
Score	5.14
Report id	1171766
Category	Other, Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

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

Click here to see the Original Article

Table 13: Places for report 1171766

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	Zhangzhou	24.51333	117.65556
Americas	United States	United States	39.76	-98.5

Table 14: Drugs for report 1171766

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: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, BBC Group Limited, FEI 3010165327, at Yangxia Development Zone, Pumei Town, Yunxiao County, Zhangzhou, China, from March 22 to March 26, 2021.

This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding

do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). [...]

9 Three arrested for selling banned and counterfeit drugs in Dhaka

Publication date 2021-09-19

Create date 2021-09-21

Score 3.15

Report id 1221864

Category Dermatological medicine, Antifungal, Antacid, Nutritional supplement, Other, Anti-inflammatory medicine

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Three arrested for selling banned and counterfeit drugs in Dhaka bdnews24.com

Click here to see the Original Article

Table 15: Places for report 1221864

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Bangladesh	Dhaka	23.7104	90.40744

Table 16: Drugs for report 1221864

Medicine Name	Medicine Class	Action	ATC Code
betamethasone	Corticosteroids acting locally	intestinal antiinflammatory agents	A07EA04
betamethasone	Corticosteroids	agents for treatment of hemorrhoids and anal fissures for topical use	C05AA05
betamethasone	Corticosteroids, potent (group III)	corticosteroids, plain	D07AC01
betamethasone	Corticosteroids, potent, other combinations	corticosteroids, other combinations	D07XC01
betamethasone	Glucocorticoids	corticosteroids for systemic use, plain	H02AB01

Table 16: Drugs for report 1221864(continued)

Medicine Name	Medicine Class	Action	ATC Code
betamethasone	Corticosteroids	decongestants and other nasal preparations for topical use	R01AD06
betamethasone	Glucocorticoids	other drugs for obstructive airway diseases, inhalants	R03BA04
betamethasone	Corticosteroids, plain	antiinflammatory agents	S01BA06
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01
naproxen	Antiinflammatory products for vaginal administration	other gynecologicals	G02CC02
naproxen	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE02
naproxen	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA12
miconazole	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB09
miconazole	Imidazole derivatives	intestinal antiinfectives	A07AC01
miconazole	Imidazole and triazole derivatives	antifungals for topical use	D01AC02
miconazole	Imidazole derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AF04
miconazole	Imidazole derivatives	antimycotics for systemic use	J02AB01
miconazole	Antiinfectives	antiinfectives	S02AA13
neomycin	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB08
neomycin	Antibiotics	intestinal antiinfectives	A07AA01
neomycin	Antiinfectives	irrigating solutions	B05CA09
neomycin	Other antibiotics for topical use	antibiotics for topical use	D06AX04

Table 16: Drugs for report 1221864(continued)

Medicine Name	Medicine Class	Action	ATC Code
neomycin	Other aminoglycosides	aminoglycoside antibacterials	J01GB05
neomycin	Antibiotics	throat preparations	R02AB01
neomycin	Antibiotics	antiinfectives	S01AA03
neomycin	Antiinfectives	antiinfectives	S02AA07
clioquinol	Quinoline derivatives	antiseptics and disinfectants	D08AH30
clioquinol	Medicated dressings with antiinfectives	medicated dressings	D09AA10
clioquinol	Quinoline derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AC02
clioquinol	Hydroxyquinoline derivatives	agents against amoebiasis and other protozoal diseases	P01AA02
clioquinol	Antiinfectives	antiinfectives	S02AA05

Table 17: Other Stories

ID	Title	Link
1222172	Three arrested at Mitford market for selling counterfeit medicine	Link
1222269	Three arrested in joint drive against counterfeit medicines	Link
1223394	Three arrested in joint drive against counterfeit medicine...	Link

Notes: Dhaka Metropolitan Police detectives have arrested three men for selling fake medicines and salves and banned drugs under the names of famous and expensive local and foreign brands. [...] The three were arrested following joint operations by detectives from the DMP's Lalbagh Division and the Directorate General of Drug Administration at pharmacies in Dhaka's Mitford area on Saturday.

Among the pharmaceuticals recovered in the raid were i-pill, Super Gold Kosturi, Naproxen Plus, Betnovate C, Protobit, Eno Sanagro, Periactin Moov, Ring Guard, Wheatfield, Nix Rubbing Balm, Vicks Cold Plus, Vicks and Gacozema. [...] "As the capital's Mitford market is a wholesale market for pharmaceuticals, a counterfeit drug production and marketing ring has been using it as a hiding place to spread fake medicine across the country," Alam said. [...]

10 Toyobo Co. Ltd. - CGMP/Finished Pharmaceuticals/ Adulterated - Shiga - 2021-08-19

Publication date	2021-08-19
Create date	2021-09-01
Score	1.23
Report id	1189894
Category	Not applicable
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Toyobo Co. Ltd. MARCS-CMS 614177 — August 19, 2021 Share Tweet Linkedin Email Print Delivery Method: Via Email Product: Drugs Recipient: Recipient Name Mr. Hidehiko Kanae Recipient Title General Manager Toyobo Co. Ltd. 2 Chome 1, Katata Otsu , Shiga 520-0292 Japan Issuing Office: Center for Drug Evaluation and Research | CDER United States Warning Letter 320-21-55 August 19, 2021 Dear Mr. Kanae: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Toyobo Co. Ltd., FEI 1000251214, at Toyobo (Kabu) Sogokenkyusho, 2 Chome 1, Katata, Otsu, Shiga, from February 15 to 19, 2021, on February 22, 2021, and from February 24 to 25, 2021. This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211). Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). We reviewed your March 18, 2021, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence. During our inspection, our investigators observed specific violations including, but not limited to, the following. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192). A. You did not adequately investigate significant particulate defects in your sterile drug product, including recurring incidents of extrinsic particle contamination. During 2019 and 2020, multiple batches of (b)(4) injection solution were found to have significant particulate contamination defects, many of which are defined in your procedure and response as ”foreign” (i.e., extrinsic). When extrinsic particulates were identified within batches, you failed to initiate a timely investigation to determine root causes and assess the drug product impact. Our review revealed that your in-process quality standards, limits, categories, and triggers for investigations do not sufficiently differentiate intrinsic from extrinsic particulate contamination. A recent investigation update, submitted to FDA on June 18, 2021 (four months after FDA’s inspection), indicates that you have improved your procedures and are performing supplier audits. While your investigation concluded that it is ”highly possible” that your washing and sterilization processes could not

remove certain particles adhered to the (b)(4) stoppers or vials, you failed to adequately address the upstream root causes of the contamination and implement timely corrective action and preventive actions (CAPA). In addition, you failed to address multiple instances of a ferrous- (b)(4) complex that was found during visible particle identification studies, including the potential for this contaminant to induce adverse events because of immunogenic response. Your firm indicated that the (b)(4) appears to be from the drug formulation. Your response discussed the 12 batches cited during the inspection that were found with visible particulates such as cellulose fibers, glass fibers, (b)(4) , black and white "particles," and "stain-" like particles of various colors. You also expanded the investigation to encompass (b)(4) batches that remained within expiry and identified further instances of extrinsic or "non-stopper material." Notably, stopper "stain" defects were also investigated in 2017. However, your stopper supplier indicated that their process was not the cause of the problem at the time, and your CAPA was inadequate to resolve the problem. Your response is inadequate. You failed to adequately investigate both extrinsic and intrinsic particulate contamination issues. You did not determine the root cause and implement a timely and effective CAPA to address persistent incidents of extrinsic particulate contamination in your sterile injectable product. Extrinsic particulate contamination should occur infrequently and be fully investigated. In response to this letter, provide: • A comprehensive, independent assessment of your overall system for investigating deviations, discrepancies, complaints, out-of-specification results, and failures. Provide a detailed action plan to remediate this system. Your action plan should include, but not be limited to, significant improvements in investigation competencies, scope determination, root cause evaluation, CAPA effectiveness, quality unit (QU) oversight, and written procedures. Address how your firm will ensure all phases of investigations are appropriately conducted. • An updated risk assessment regarding marketed batches, including: o An evaluation of extrinsic particulates found in batches within expiry period. o Protocol or sampling procedures and criteria used to select the vials examined as part of your investigation. o The potential impact of iron- (b)(4) complexes on safety (e.g., immunogenic response) and efficacy of your product. • An independent review of all injectable defect limits that includes but is not limited to: o Limits and associated rationales for both 100% inspection and Acceptable Quality Levels (AQL). o Provide a comprehensive list of all items that could trigger the initiation of an investigation related to foreign particulates. • An updated investigation into the extrinsic particulate contamination for (b)(4) injection solution, including root causes and all CAPA activities. B. Your investigation into data integrity breaches, reported to the agency in a (b)(4) , was insufficient to determine the scope of the problems at your facility. Your firm identified recurring instances of the following: • Operators failed to consistently ensure that personnel monitoring plates contacted gowning surfaces before leaving the ISO 7 area (Grade B). • Operators failed to consistently ensure that environmental monitoring plates contacted equipment surfaces located in ISO 5 (Grade A) and ISO 7 (Grade B) areas. • When surfaces were monitored, operators wiped equipment surfaces with (b)(4) before sampling the equipment surface. • Nonviable particle data for ISO 5 (Grade A) was reported as ISO 7 (Grade B) when particles results were higher than alert levels. • Operators failed to report ISO 5 (Grade A) airborne particulates values using a portable particulate counter, instead they repeated the monitoring of airborne particulates. Your investigation lacks sufficient information regarding the extent of the breaches of data integrity. Your investigation lacked a comprehensive assessment into the extent of the "falsification of airborne particles measurement records" and other breaches of data integrity occurring in the facility. Environmental monitoring (EM) data related to operators, equipment surfaces, and non-viable particulate monitoring was unreliable and raised product sterility assurance concerns. Your investigation also indicates the data integrity breaches were not isolated. You found that (b)(4) of (b)(4) operators were involved in manipulation of contact plate measurements, while all (b)(4)

environmental monitoring operators were involved in the manipulation of non-viable particles measurement data. Our inspection also cited additional weaknesses in the reliability of your documentation, including uncontrolled testing worksheets and deficient systems for reconciliation of laboratory documents. Based on your investigation, a total of (b)(4) batches of (b)(4) , manufactured from 2016 to 2020, could have been impacted by these practices. However, there was insufficient data in your response to support a full determination of the scope of potentially affected batches. Accurate microbiological data is fundamental to evaluating and maintaining the state of control of an aseptic processing operation. Awareness of microbial excursions in an aseptic processing operation is essential to trigger prompt actions that maintain environmental control. Additionally, timely and thorough evaluation of action level excursions, identifying potential routes of contamination, as well as identifying appropriate follow-up measures are necessary to prevent contamination risks to the product. Your failure to report accurate data compromised the sterility assurance of drug products released from the facility and may have increased risks to patients. Your response stated that a product impact risk assessment was conducted and that product sterility was not compromised. However, you lacked adequate justification for this conclusion, given the extent and nature of the data integrity breaches that occurred in the facility. In addition, while your response focused on environmental data and a review of "aseptic practices and sterility assurance training and oversight," its scope did not sufficiently address other areas of deficient data integrity. Your response mentions that the root cause is associated with "employees not understanding CGMP, the importance of data integrity, and pressure in handling deviations." We acknowledge your efforts to date of identifying data integrity deficiencies and actions toward improving accountability of all staff at your facility. However, further actions are needed to ensure competency of employees in performing and overseeing aseptic operations and improve quality systems effectiveness and data integrity oversight throughout your entire manufacturing operation. In response to this letter, provide: • Your plan to ensure appropriate aseptic practices and cleanroom behavior during production. Include steps to ensure routine and effective supervisory oversight for all production batches. Also, describe the frequency of QU oversight (e.g., daily activities, audits) during aseptic processing and its support operations. • A thorough retrospective review and risk assessment that evaluates how poor aseptic technique and cleanroom behavior may have affected the quality and sterility of your drugs. • A comprehensive risk assessment of all contamination hazards with respect to your aseptic processes, equipment, and facilities, including an independent assessment that includes, but is not limited to: o All human interactions within the ISO 5 area o Equipment placement and ergonomics o Air quality in the ISO 5 area and surrounding rooms o Facility layout o Personnel Flows and Material Flows (throughout all rooms used to conduct and support sterile operations) • A detailed remediation plan with timelines to address the findings of the contamination hazards risk assessment. Describe specific tangible improvements to be made to aseptic processing operation design and control. • A plan to perform testing (including sterility, as well as any other test identified by your risk assessments) of retain samples for all batches of sterile drug products manufactured at your facility that remain within expiry in the U.S. market. • A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to: o A determination of whether procedures used by your firm are robust and appropriate o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices o A complete and final review of each batch and its related information before the QU disposition decision o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products Describe how top management supports quality assurance and reliable operations, including but not limited to timely provision of resources to proactively address emerging manufacturing/

quality issues and to assure a continuing state of control. • Your CAPA plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance or documentation issues, appropriate staffing to perform activities robustly, improvements in capability when needed, adherence to appropriate preventive maintenance schedules, effective execution of repairs, timely technological upgrades to the equipment/facility infrastructure, and improved systems for both daily production supervision and overall operations management. Data Integrity Remediation Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. See FDA's guidance document Data Integrity and Compliance with Drug CGMP for guidance on establishing and following CGMP compliant data integrity practices at https://www.fda.gov/media/119267/download We acknowledge that you are using a consultant to audit your operation and assist in meeting FDA requirements. In response to this letter, provide the following: A. A comprehensive investigation into the extent of the inaccuracies in data records and reporting. Your investigation should include: • A detailed investigation protocol and methodology; a summary of all laboratories, manufacturing operations, and systems to be covered by the assessment; and a justification for any part of your operation that you propose to exclude. • Interviews of current and former employees to identify the nature, scope, and root cause of data inaccuracies. We recommend that these interviews be conducted by a qualified third party. • An assessment of the extent of data integrity deficiencies at your facility. Identify omissions, alterations, deletions, record destruction, non-contemporaneous record completion, and other deficiencies. Describe all parts of your facility's operations in which you discovered data integrity lapses. • A comprehensive retrospective evaluation of the nature of the manufacturing data integrity deficiencies. We recommend that a qualified third party with specific expertise in the area where potential breaches were identified should evaluate all data integrity lapses. B. A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analyses of the risks to patients caused by the release of drugs affected by a lapse of data integrity and analyses of the risks posed by ongoing operations. C. A management strategy for your firm that includes the details of your global CAPA plan. Your strategy should include: • A detailed corrective action plan that describes how you intend to ensure the reliability and completeness of all the data you generate including analytical data, manufacturing records, and all data submitted to FDA. • A comprehensive description of the root causes of your data integrity lapses including evidence that the scope and depth of the current action plan is commensurate with the findings of the investigation and risk assessment. Indicate whether individuals responsible for data integrity lapses remain able to influence CGMP-related or drug application data at your firm. • Interim measures describing the actions you have taken or will take to protect patients and to ensure the quality of your drugs, such as notifying your customers, recalling product, conducting additional testing, adding lots to your stability programs to assure stability, drug application actions, and enhanced complaint monitoring. • Long-term measures describing any remediation efforts and enhancements to procedures, processes, methods, controls, systems, management oversight, and human resources (e.g., training, staffing improvements) designed to ensure the integrity of your company's data. • A status report for any of the above activities already underway or completed. CGMP Consultant Recommended Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations and to assist your firm in meeting CGMP requirements. 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 CAPA 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 that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b). This also allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products. Correct any violations promptly. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to any violations. Failure to address any violations may also result in the FDA refusing admission of articles manufactured at Toyobo Co. Ltd., at Toyobo (Kabu) Sogokenkyusho, 2 Chome 1, Katata, Otsu, Shiga, Japan into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated or misbranded may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). 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 since our inspection to correct your 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 complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 1000251214 and ATTN: Rafael E. Arroyo. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research Content current as of: 08/24/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 18: Places for report 1189894

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Eastern Asia	Japan	Ōtsu	35	135.86667

Table 19: Other Stories

ID	Title	Link
1193261	FDA warns Japanese firm for particle contamination, takes mask-maker to task — again	Link

Notes: [...] This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). [...]

11 Invisi Smart Technologies UK LTD - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 - Center for Devices and Radiological Health - 2021-08-24

Publication date	2021-08-24
Create date	2021-09-01
Score	0.94
Report id	1193000
Category	Medical devices for disease prevention
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Invisi Smart Technologies UK LTD MARCS-CMS 614512 — August 24, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Saba Yussouf Recipient Title CEO Invisi Smart Technologies UK LTD 112 Cumberland House 80 Scrubs Lane London NW10 6RF United Kingdom Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER August 24, 2021 Re: Invisi Smart Mask RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 Dear Ms. Saba Yussouf: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at https://www.invisismart.com/, https://shop.invisismart.com/, and https://twitter.com/InvisiSmart on, June 21, 2021. The FDA has observed that your websites offer the ISM5 Invisi Smart Mask, ISM5 Invisi Smart Mask (Black Edition) and the ISM30 Invisi Smart Mask 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). FDA's review of your websites revealed the following statements that establish that the masks are intended for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, including but not limited to: " ISM30 Invisi Smart Mask , Invisi Smart technology has been tested against the SARSCoV-2 virus's spike protein by the University of Cambridge." "Invisi Smart Mask™ has been tested against human coronavirus and not a weaker strain from the feline coronavirus subfamily." "Invisi Smart Mask™ kills viruses and bacteria as they come into contact with the mask allowing you to wear your mask with confidence all day… and for the next 30 days!" "Our self–disinfecting technology allows you to safely wear the Invisi Smart Mask™ without the need to wash it." "Our main ingredient, titanium dioxide, … is generally recognized as safe (GRAS) by the FDA, with up to 1% allowance in food products without having to add it to the ingredients label." Based on our review, your websites are offering for sale in the United States the above mentioned mask models without marketing approval, clearance, or authorization from the FDA. Accordingly, your devices 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 your intent to introduce them into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). FDA contacted your firm on October 8, 2020, and informed you that you must submit a premarket notification submission before marketing these devices in the U.S. On October 14, 2020, FDA contacted your firm again and discussed certain claims that remained on your website. FDA further reiterated that you must submit a premarket notification submission prior to distributing devices of this type in the U.S. FDA asked your firm to provide your plan regarding these masks to FDA by October 19, 2020. FDA had another teleconference meeting with your chief scientific officer per your request to discuss FDA regulations on October 15, 2020. On October 22, 2020, FDA sent an email in response to your written feedback request regarding FDA regulations and again asked your firm to provide a plan for premarket notification submission. FDA did not receive a response from you to this email. A review of your websites on June 21, 2021, shows that your products are still being marketed without FDA approval, clearance, or authorization. To date, FDA has not cleared, approved, or authorized the three mask models cited above. 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 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 such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. If you believe that your devices meet the requirements for Emergency Use Authorization (EUA) under section 564 of the FD&C Act for claims associated with use of your devices for COVID-19, please submit an email to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov. Guidance regarding the applicable criteria and the information to include in an EUA submission is available at https://www.fda.gov/media/97321/download . Our office requests that your firm immediately cease activities that result in the misbranding or adulteration of these devices, such as the commercial distribution of the devices for the uses discussed above. This letter is not meant to be an all-inclusive list of violations that exist in connection with the product(s) 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 are not misleadingly representing the product(s) as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, authorized by FDA and that you do not make representations that misbrand the product(s) in violation of the Act. 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 treatment or prevention 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 corrective actions and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. If you are not located in the United States, please note that products that appear to be adulterated or misbranded are subject to detention and refusal of 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 product(s) listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States. 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 correct 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 the corrections and/or corrective actions (which must address systemic problems) 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. Your firm's response should be comprehensive and address all violations included in this letter. If you believe that the product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Your firm's response should be sent 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, Rm 3657 10903 New Hampshire Ave. Silver Spring, MD 20993 Refer to the identification number CMS #614512 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: Cynthia J. Chang, Ph.D. at 301-796-6891. Sincerely yours, /S/ Binita S. Ashar, MD, MBA, FACS Director OHT4: Office of Surgical and Infection Control Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health _____1 COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China. 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-emergencyconcerning-novel-coronavirus-disease-covid-19-outbreak/ Content current as of: 08/26/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 20: Places for report 1193000

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	London	51.50853	-0.12574
Americas	United States	United States	39.76	-98.5

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at https://www.invisismart.com/, https://shop.invisismart.com/, and https://twitter.com/InvisiSmart on, June 21, 2021. The FDA has observed that your websites

offer the ISM5 Invisi Smart Mask, ISM5 Invisi Smart Mask (Black Edition) and the ISM30 Invisi Smart Mask for sale in the United States. [...] Based on our review, your websites are offering for sale in the United States the above mentioned mask models without marketing approval, clearance, or authorization from the FDA. [...]

Annex C

C.5. COVID-19 medicines

Medicine Quality Monitoring Globe

November 18, 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.

Translation Disclaimer:

THIS REPORT MAY CONTAIN TRANSLATIONS POWERED BY GOOGLE. GOOGLE DISCLAIMS ALL WARRANTIES RELATED TO THE TRANSLATIONS, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF ACCURACY, RELIABILITY, AND ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

This Medicine Quality Monitoring Globe report is issued by IDDO, University of Oxford, and some sections, indicated in blue, may have been translated for your convenience using translation software powered by Google Translate. Reasonable efforts have been made to provide an accurate translation, however, no automated translation is perfect nor is it intended to replace human translators. Translations are provided as a service to users of the Medicine Quality Monitoring Globe, and are provided "as is." No warranty of any kind, either expressed or implied, is made as to the accuracy, reliability, or correctness of any translations made from the source language (Chinese, French, Spanish, or Vietnamese) into English.

The official text is the version in the source language (Chinese, French, Spanish, or Vietnamese). Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the information contained in the translated text, refer to the text in the source language (Chinese, French, Spanish, or Vietnamese) which is the official version.

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 ”fingolimod” 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	2021-08-01
End date	2021-09-30
Language	en
Report type	incident
Curation status	validated
Number of Reports	30

1 44 drug samples including Cipla Remdesivir fail to qualify CDSCO test, 1 declared misbranded - 2021-08-14

Publication date	2021-08-14
Create date	2021-08-19
Score	57.85
Report id	1177368
Category	Antidiabetic, Antiparasitic, Antifungal, Antiviral others, Antipyretic, Cardiovascular medicine, Antibiotic, Anti-inflammatory medicine, Anti-malarial, Vitamin
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) flagged 44 medicine batches for failing to qualify a random drug sample test for the month of July, while 1 drug sample has been declared misbranded.These drugs samples which are declared not of standard quality include Piramal Enterprises Ltd's Supradyn tablet, Syncom Healthcare's Albendazole tablets IP 400 mg (ZEEBEE-Tablet), Quest Laboratories' Domperidone Suspension I.P., Bharat Parenteral's Quinine Sulphate Tablets IP 300 mg, Swiss Garnier Biotech's STATIX-20 (Atorvastatin Tablets IP 20 mg) etc.In addition, other popular drug samples that are declared not of standard quality include Paracetamol Tablets I.P. 500 mg (Biocin) manufactured by Danish Healthcare, Levofloxacin (Levoziv-500) Tablets I.P. 500 mg manufactured by Zee Laboratories, Brutab-400 (Ibuprofen Tablets IP 400 mg) manufactured by Neutec Healthcare, and Norfloxacin Tablets IP 400 mg manufactured by Unicure.Apart from this, the popular covid drug Remdesivir for Injection 100 mg/vial (CIPREMI) manufactured by Cipla and Remdesivir for injection manufactured by Teena Labs Ltd. are on the list. Additionally, Bharat Serums and Vaccines' Liposomal Amphotericin B Injection 50 mg (ABHOPE INJ.) and Amphotericin B Lipid Complex Injection I.V. (AMPHOLIP 50 MG/10 ML) are also on the list.Also Read:22 Drug Samples Including Sun Pharma Rosuvas Fail To Qualify CDSCO TestFurther, the list includes popular diabetes drugs DRMET FORTE G1 (Glimepiride & Metformin Hydrochloride SR Tablets) manufactured by Neptune Life Science Pvt. Ltd. and Glimepiride Tablets IP 1 mg manufactured by Trugen Pharmaceuticals Pvt. Ltd.This came after analysis and tests conducted by the CDSCO Drugs Control Department on 1028 samples. Out of these, 983 samples were found to be of standard quality while 44 of them were declared as Not of Standard Quality (NSQ) and 1 drug was declared misbranded.A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of disintegration, failure of the Vitamin D3 assay etc.Also Read: CDSCO Flags 22 Drugs As Not Of Standard QualityThe 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 July – 2021 Total number of samples tested 1028 Total number of samples declared as of Standard Quality 983 Total number of

samples declared as Not of Standard Quality 44 Total number of samples declared as Spurious 0 Total number of samples declared as Misbranded 01 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. Calcium Carbonate, Magnesium Oxide, Manganese Sulphate, Zinc & Vitamin D3 Tablets B. No.: MT191327 Mfg dt: 08/2019 Exp dt: 07/2021 Mfd by: M/s. Mascot Health Series Pvt. Ltd. Plot No. 79, 80, Sector - 6A, IIE, Sidcul, Haridwar- Uttarakhand -249403. Assay of Vitamin D3 CDSCO Sub-Zone, Guwahati RDTL, Guwahati 2. Supradyn (Multivitamin Tablets with Minerals and Trace Elements) B. No.: MH3388 Mfg dt: 10/2019 Exp dt: 09/2021 Mfd by: M/s. Piramal Enterprises Ltd., K-1, Addl., MIDC area, Mahad Maharashtra, 402302. Disintegration Drug Control Department Mizoram RDTL, Guwahati 3. Ramipril Tablets IP (ORMIPRO-2.5) B. No.: KM19001 Mfg dt: 11/2019 Exp dt: 10/2021 Mfd by: M/s. Ortin Laboratories Ltd. 275 & 278 (part) I.D.A. Pashamailaram Medak Distt. Telangana -502307. Assay Drug Control Department N.F. Railway Lumding RDTL, Guwahati 4. Albendazole tablets IP 400 mg (ZEEBEE - Tablet) B. No.: JDT0047 Mfg dt: 08/2018 Exp dt: 07/2021 Mfd by: M/s. Syncom Healthcare Ltd., Dehradun, Uttarakhand- Dissolution Drug Control Department Tezpur, Sonitpur RDTL, Guwahati 248197. 5. DRMET FORTE G1 (Glimepiride & Metformin Hydrochloride SR Tablets) B. No.: TN-2830 Mfg dt: 01/2020 Exp dt: 12/2021 Mfd by: M/s. Neptune Life Science Pvt. Ltd., 100-B, EPIP, Phase-II, Thana, Baddi-173205, Himachal Pradesh. Assay & Dissolution of Glimepiride Drug Control...

Click here to see the Original Article

Table 1: Places for report 1177368

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

Table 2: Drugs for report 1177368

Medicine Name	Medicine Class	Action	ATC Code
domperidone	Propulsives	propulsives	A03FA03
quinine	Methanolquinolines	antimalarials	P01BC01
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
levofloxacin	Fluoroquinolones	quinolone antibacterials	J01MA12
levofloxacin	Fluoroquinolones	antiinfectives	S01AE05
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 2: Drugs for report 1177368(continued)

Medicine Name	Medicine Class	Action	ATC Code
atorvastatin	HMG CoA reductase inhibitors	lipid modifying agents, plain	C10AA05
glimepiride	Sulfonylureas	blood glucose lowering drugs, excl. insulins	A10BB12
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
ibuprofen	Other throat preparations	throat preparations	R02AX02
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02
albendazole	Benzimidazole derivatives	antinematodal agents	P02CA03
norfloxacin	Fluoroquinolones	quinolone antibacterials	J01MA06
norfloxacin	Fluoroquinolones	antiinfectives	S01AE02
ramipril	ACE inhibitors, plain	ace inhibitors, plain	C09AA05

Notes: In its latest drug safety alert, the apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) flagged 44 medicine batches for failing to qualify a random drug sample test for the month of July, while 1 drug sample has been declared misbranded. [...]

2 NBI 7 chief: Refrain from buying drugs for Covid-19 treatment sold on black market

Publication date	2021-09-27
Create date	2021-10-01
Score	42.88
Report id	1232292
Category	Immunosuppressant, Anti-inflammatory medicine
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: NBI 7 chief: Refrain from buying drugs for Covid-19 treatment sold on black market SunStar Philippines

Click here to see the Original Article

Table 3: Places for report 1232292

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

Table 4: Drugs for report 1232292

Medicine Name	Medicine Class	Action	ATC Code
tocilizumab	Interleukin inhibitors	immunosuppressants	L04AC07
baricitinib	Selective immunosuppressants	immunosuppressants	L04AA37

Notes: NATIONAL Bureau of Investigation (NBI) 7 Director Rennan Augustus Oliva has warned the public to refrain from acquiring drugs and medicines for Covid-19 treatment on the black market. Aside from being illegal, resorting to the black market could lead to the purchase of fake drugs.

Oliva issued the reminder on Monday, Sept. 27, 2021, following the arrests of a doctor and his daughter and another person for allegedly smuggling 10 pieces of Tocilizumab and 25 boxes

of Baricitinib tablets threefold the maximum price. These drugs are used in treating Covid-19 patients.

According to Oliva, Tocilizumab has a maximum suggested retail price of P25,000 per 400 mg/ 20mL vial; however, it is sold for more than P100,000 on the black market. It is an anti-inflammatory drug used for the treatment of severely affected Covid-19 patients. [...]

3 10,000 doses of fake COVID-19 vaccines destroyed by ZAMRA

Publication date	2021-09-01
Create date	2021-09-02
Score	38.05
Report id	1199738
Category	Vaccine
Quality	Diverted/Unregistered
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: 10,000 doses of fake COVID-19 vaccines destroyed by ZAMRA mwebantu.com

Click here to see the Original Article

Table 5: Places for report 1199738

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Zambia	Lusaka	-15.40669	28.28713

Table 6: Drugs for report 1199738

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 7: Other Stories

ID	Title	Link
1199667	The fake Covid vaccine scandal: How Findlay's company imported 10,000 doses without permit, license – Zambia	Link
1201176	MoH distances itself from Findlay's fake Covid Vaccine – Zambia	Link
1201354	Get to root of fake vaccines – Zambia Daily Mail	Link

Notes: THE Zambia Medicines Regulatory Authority (ZAMRA) has intercepted and destroyed 10,000 doses of a suspected COVID-19 vaccine imported into the country without authorisation. On July, 2 this year, the vaccine labelled as Hayat Vax [SARS-COV-2 Vaccine] (Vero

Cell) inactivated, with batch number HV0025, was brought into the country by an importer named Chrismar Earthmoving Equipment. In a media statement, ZAMRA said it seized the consignment which was worth USD150, 000 was seized at Kenneth Kaunda International Airport in conjunction with the Zambia Revenue Authority. The authority said the named vaccine is unauthorised for use on the Zambian market as it is not registered by ZAMRA. "In addition, the vaccine is not under the World Health Organization Emergency Use Listing.The WHO EUL procedure is one of the regulatory reliance mechanisms which ZAMRA utilizes, like other national regulatory authorities in other jurisdictions, to consider COVID 19 vaccines for national use. According to the documentation (Invoice) which was furnished to ZAMRA, the purported manufacturer of Hayat Vax vaccine is Gulf Pharmaceutical Industries while the selling entity is G42 Medications Trading LLC of the United Arab Emirates," reads the statement. [...]

4 37 drug samples including Cipla Acivir-200DT fail to clear CDSCO test, 1 declared misbranded

Publication date 2021-09-11

Create date 2021-09-13

Score 34.52

Report id 1212321

Category Analgesic, Antacid, Antiviral others, Other, Antipyretic, Antibiotic, Cardiovascular medicine, Antiseptic

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: 37 drug samples including Cipla Acivir-200DT fail to clear CDSCO test, 1 declared misbranded Medical Dialogues

Click here to see the Original Article

Table 8: Places for report 1212321

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

Table 9: Drugs for report 1212321

Medicine Name	Medicine Class	Action	ATC Code
ranitidine	H2-receptor antagonists	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BA02
dexamethasone	Corticosteroids for local oral treatment	stomatological preparations	A01AC02
dexamethasone	Corticosteroids	agents for treatment of hemorrhoids and anal fissures for topical use	C05AA09
dexamethasone	Corticosteroids, moderately potent (group II)	corticosteroids, plain	D07AB19

Table 9: Drugs for report 1212321(continued)

Medicine Name	Medicine Class	Action	ATC Code
dexamethasone	Corticosteroids, moderately potent, other combinations	corticosteroids, other combinations	D07XB05
dexamethasone	Corticosteroids, combinations for treatment of acne	anti-acne preparations for topical use	D10AA03
dexamethasone	Glucocorticoids	corticosteroids for systemic use, plain	H02AB02
dexamethasone	Corticosteroids	decongestants and other nasal preparations for topical use	R01AD03
dexamethasone	Corticosteroids, plain	antiinflammatory agents	S01BA01
phenytoin	Hydantoin derivatives	antiepileptics	N03AB02
oseltamivir	Neuraminidase inhibitors	direct acting antivirals	J05AH02
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
aciclovir	Antivirals	chemotherapeutics for topical use	D06BB03
aciclovir	Nucleosides and nucleotides excl. reverse transcriptase inhibitors	direct acting antivirals	J05AB01
aciclovir	Antivirals	antiinfectives	S01AD03
atorvastatin	HMG CoA reductase inhibitors	lipid modifying agents, plain	C10AA05
favipiravir	Other antivirals	direct acting antivirals	J05AX27
norfloxacin	Fluoroquinolones	quinolone antibacterials	J01MA06
norfloxacin	Fluoroquinolones	antiinfectives	S01AE02

Table 10: Other Stories

ID	Title	Link
1212375	37 drug samples including Cipla Acivir-200DT fail to clear CDSCO test, 1 declared misbranded - 2021-09-11	Link

Notes: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO), flagged 37 medicine batches for failing to qualify for a random drug sample test for the month of August, while 1 drug sample has been declared misbranded. [...] This came after analysis and tests conducted by the CDSCO Drugs Control Department

on 1245 samples. Out of these, 1207 samples were found to be of standard quality while 37 of them were declared as Not of Standard Quality (NSQ) and 1 drug was declared misbranded. A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of disintegration, failure of the Uniformity of Dispersion test, failure of Identification test & Assay etc. [...]

5 Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC

Publication date 2021-08-21

Create date 2021-08-25

Score 33.17

Report id 1186319

Category Medical devices for disease prevention, Respiratory diseases medicine, Medical device for screening/diagnosis/monitoring, Other

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC sggpnews

Click here to see the Original Article

Table 11: Places for report 1186319

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Viet Nam	Ho Chi Minh City	10.82302	106.62965
South-Eastern Asia	Viet Nam	Bình Tân District	10.13489	105.75968
South-Eastern Asia	Viet Nam	Tân Phú District	11.39867	107.39976

Table 12: Drugs for report 1186319

Medicine Name	Medicine Class	Action	ATC Code
codeine	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA04

Notes: [...] On August 20, Thuan was seen carry a suspicious carton containing fake new drugs, so police officers stopped him to check; thereby, 150 boxes of Covid-19 treatment pills with the brand name Terpincodein were found out. At the police station, Thuan confessed that it was a

fake drug because Thuan bought the raw materials then produced and sold them to the market to make a profit. [...] According to the department, these cases are very worrisome amid the ongoing complicated development of the Covid-19 epidemic. Even, several businesses trading in medical equipment have showed signs of selling medical items without clear indications of origin. For example, in mid-August, the market management teams continuously detected and seized thousands of 3M masks, SARS-CoV-2 rapid test kits, oxygen ventilators without a clear indication of origin at warehouses in districts Binh Tan and Tan Phu. The owner of the items said that most of them will be provided to buyers via social networks, a few of them will be sold in stores. [...]

6 Mumbai Police: Trio used same method to resolve disputes, source remdesivir

Publication date	2021-08-20
Create date	2021-08-25
Score	24.42
Report id	1185560
Category	Antiviral others
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Mumbai Police: Trio used same method to resolve disputes, source remdesivir The Indian Express

Click here to see the Original Article

Table 13: Places for report 1185560

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

Notes: The men who were arrested by Mumbai Police for allegedly impersonating NCP chief Sharad Pawar on a phone call and seeking the transfer of a government official had earlier used similar methods to settle business disputes and even source remdesivir during the second Covid wave and selling it in the black market. [...] Police said that Kakade and Gurav had been using this method to fool others and had even contacted persons affiliated with the medicine industry pretending to be Pawar to source remdesivir during the second wave of Covid-19, when there was shortage of the medicine. The duo had then sold this medicine in the black market at Rs 25,000 per vial.

7 Fake drug manufacturing unit busted in Dhaka, 7 held

Publication date 2021-09-03

Create date 2021-09-06

Score 23.50

Report id 1202811

Category Respiratory diseases medicine, Antacid, Other, Anti-inflammatory medicine

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Fake drug manufacturing unit busted in Dhaka, 7 held United News of Bangladesh

Click here to see the Original Article

Table 14: Places for report 1202811

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Bangladesh	Dhaka	23.7104	90.40744

Table 15: Drugs for report 1202811

Medicine Name	Medicine Class	Action	ATC Code
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01
naproxen	Antiinflammatory products for vaginal administration	other gynecologicals	G02CC02
naproxen	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE02
naproxen	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA12
montelukast	Leukotriene receptor antagonists	other systemic drugs for obstructive airway diseases	R03DC03

Table 16: Other Stories

ID	Title	Link
1202878	Police arrest 7 for making counterfeit drugs in Demra factory	Link
1203298	7 busted with counterfeit medicines	Link
1204273	Counterfeit medicine	Link
1208044	Seven arrested for making counterfeit drugs	Link
1230394	Counterfeit medicines flood market	Link
1231345	Fraudulent activities in drug market must be contained	Link
1244711	Of fake and date expired drugs	Link

Notes: Police on Friday claimed to have busted a factory producing counterfeit drugs in the capital. [...] "During the drive, 700 boxes of ACME-brand medicine Monas, 50 boxes of Square company's Seclo, 748 boxes of Jenith's Naproxen-plus and a number of other fake medicines, and dices and boxes, have been seized from the possession of the arrestees," said Additional Commissioner of DB, AKM Hafiz Akter. Tariqul Islam and Sayed Al Mamun had set up the illegal factory, where Saidul Islam was the main manufacturer and Monwar and Abdul Latif were working as his assistants, said AC Hafiz. After manufacturing, Nazmul Dhali used to distribute the counterfeit medicines in the market through some groups in the Mitford area, he said. [...]

8 Invisi Smart Technologies UK LTD - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 - Center for Devices and Radiological Health - 2021-08-24

Publication date	2021-08-24
Create date	2021-09-01
Score	21.89
Report id	1193000
Category	Medical devices for disease prevention
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Invisi Smart Technologies UK LTD MARCS-CMS 614512 — August 24, 2021 Share Tweet Linkedin Email Print Product: Medical Devices Recipient: Recipient Name Saba Yussouf Recipient Title CEO Invisi Smart Technologies UK LTD 112 Cumberland House 80 Scrubs Lane London NW10 6RF United Kingdom Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER August 24, 2021 Re: Invisi Smart Mask RE: Adulterated and Misbranded Products Related to Coronavirus Disease 2019 Dear Ms. Saba Yussouf: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at https://www.invisismart.com/, https://shop.invisismart.com/, and https://twitter.com/InvisiSmart on, June 21, 2021. The FDA has observed that your websites offer the ISM5 Invisi Smart Mask, ISM5 Invisi Smart Mask (Black Edition) and the ISM30 Invisi Smart Mask 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). FDA's review of your websites revealed the following statements that establish that the masks are intended for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, including but not limited to: " ISM30 Invisi Smart Mask , Invisi Smart technology has been tested against the SARSCoV-2 virus's spike protein by the University of Cambridge." "Invisi Smart Mask™ has been tested against human coronavirus and not a weaker strain from the feline coronavirus subfamily." "Invisi Smart Mask™ kills viruses and bacteria as they come into contact with the mask allowing you to wear your mask with confidence all day… and for the next 30 days!" "Our self–disinfecting technology allows you to safely wear the Invisi Smart Mask™ without the need to wash it." "Our main ingredient, titanium dioxide, … is generally recognized as safe (GRAS) by the FDA, with up to 1% allowance in food products without having to add it to the ingredients label." Based on our review, your websites are offering for sale in the United States the above mentioned mask models without marketing approval, clearance, or authorization from the FDA. Accordingly, your devices 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 your intent to introduce them into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). FDA contacted your firm on October 8, 2020, and informed you that you must submit a premarket notification submission before marketing these devices in the U.S. On October 14, 2020, FDA contacted your firm again and discussed certain claims that remained on your website. FDA further reiterated that you must submit a premarket notification submission prior to distributing devices of this type in the U.S. FDA asked your firm to provide your plan regarding these masks to FDA by October 19, 2020. FDA had another teleconference meeting with your chief scientific officer per your request to discuss FDA regulations on October 15, 2020. On October 22, 2020, FDA sent an email in response to your written feedback request regarding FDA regulations and again asked your firm to provide a plan for premarket notification submission. FDA did not receive a response from you to this email. A review of your websites on June 21, 2021, shows that your products are still being marketed without FDA approval, clearance, or authorization. To date, FDA has not cleared, approved, or authorized the three mask models cited above. 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 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 such unapproved, uncleared, and unauthorized products for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. If you believe that your devices meet the requirements for Emergency Use Authorization (EUA) under section 564 of the FD&C Act for claims associated with use of your devices for COVID-19, please submit an email to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov. Guidance regarding the applicable criteria and the information to include in an EUA submission is available at https://www.fda.gov/media/97321/download . Our office requests that your firm immediately cease activities that result in the misbranding or adulteration of these devices, such as the commercial distribution of the devices for the uses discussed above. This letter is not meant to be an all-inclusive list of violations that exist in connection with the product(s) 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 are not misleadingly representing the product(s) as safe and/or effective for a COVID-19-related use for which they have not been approved, cleared, authorized by FDA and that you do not make representations that misbrand the product(s) in violation of the Act. 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 treatment or prevention 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 corrective actions and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. If you are not located in the United States, please note that products that appear to be adulterated or misbranded are subject to detention and refusal of 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 product(s) listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States. 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 correct 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 the corrections and/or corrective actions (which must address systemic problems) 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. Your firm's response should be comprehensive and address all violations included in this letter. If you believe that the product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Your firm's response should be sent 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, Rm 3657 10903 New Hampshire Ave. Silver Spring, MD 20993 Refer to the identification number CMS #614512 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: Cynthia J. Chang, Ph.D. at 301-796-6891. Sincerely yours, /S/ Binita S. Ashar, MD, MBA, FACS Director OHT4: Office of Surgical and Infection Control Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health _____1 COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China. 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-emergencyconcerning-novel-coronavirus-disease-covid-19-outbreak/ Content current as of: 08/26/2021 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 17: Places for report 1193000

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	London	51.50853	-0.12574
Americas	United States	United States	39.76	-98.5

Notes: This is to advise you that the United States Food and Drug Administration (FDA) reviewed your websites at https://www.invisismart.com/, https://shop.invisismart.com/, and https://twitter.com/InvisiSmart on, June 21, 2021. The FDA has observed that your websites

offer the ISM5 Invisi Smart Mask, ISM5 Invisi Smart Mask (Black Edition) and the ISM30 Invisi Smart Mask for sale in the United States. [...] Based on our review, your websites are offering for sale in the United States the above mentioned mask models without marketing approval, clearance, or authorization from the FDA. [...]

9 Three arrested for selling banned and counterfeit drugs in Dhaka

Publication date 2021-09-19

Create date 2021-09-21

Score 21.61

Report id 1221864

Category Dermatological medicine, Antifungal, Antacid, Nutritional supplement, Other, Anti-inflammatory medicine

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Three arrested for selling banned and counterfeit drugs in Dhaka bdnews24.com

Click here to see the Original Article

Table 18: Places for report 1221864

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Bangladesh	Dhaka	23.7104	90.40744

Table 19: Drugs for report 1221864

Medicine Name	Medicine Class	Action	ATC Code
betamethasone	Corticosteroids acting locally	intestinal antiinflammatory agents	A07EA04
betamethasone	Corticosteroids	agents for treatment of hemorrhoids and anal fissures for topical use	C05AA05
betamethasone	Corticosteroids, potent (group III)	corticosteroids, plain	D07AC01
betamethasone	Corticosteroids, potent, other combinations	corticosteroids, other combinations	D07XC01
betamethasone	Glucocorticoids	corticosteroids for systemic use, plain	H02AB01

Table 19: Drugs for report 1221864(continued)

Medicine Name	Medicine Class	Action	ATC Code
betamethasone	Corticosteroids	decongestants and other nasal preparations for topical use	R01AD06
betamethasone	Glucocorticoids	other drugs for obstructive airway diseases, inhalants	R03BA04
betamethasone	Corticosteroids, plain	antiinflammatory agents	S01BA06
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01
naproxen	Antiinflammatory products for vaginal administration	other gynecologicals	G02CC02
naproxen	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE02
naproxen	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA12
miconazole	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB09
miconazole	Imidazole derivatives	intestinal antiinfectives	A07AC01
miconazole	Imidazole and triazole derivatives	antifungals for topical use	D01AC02
miconazole	Imidazole derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AF04
miconazole	Imidazole derivatives	antimycotics for systemic use	J02AB01
miconazole	Antiinfectives	antiinfectives	S02AA13
neomycin	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB08
neomycin	Antibiotics	intestinal antiinfectives	A07AA01
neomycin	Antiinfectives	irrigating solutions	B05CA09
neomycin	Other antibiotics for topical use	antibiotics for topical use	D06AX04

Table 19: Drugs for report 1221864(continued)

Medicine Name	Medicine Class	Action	ATC Code
neomycin	Other aminoglycosides	aminoglycoside antibacterials	J01GB05
neomycin	Antibiotics	throat preparations	R02AB01
neomycin	Antibiotics	antiinfectives	S01AA03
neomycin	Antiinfectives	antiinfectives	S02AA07
clioquinol	Quinoline derivatives	antiseptics and disinfectants	D08AH30
clioquinol	Medicated dressings with antiinfectives	medicated dressings	D09AA10
clioquinol	Quinoline derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AC02
clioquinol	Hydroxyquinoline derivatives	agents against amoebiasis and other protozoal diseases	P01AA02
clioquinol	Antiinfectives	antiinfectives	S02AA05

Table 20: Other Stories

ID	Title	Link
1222172	Three arrested at Mitford market for selling counterfeit medicine	Link
1222269	Three arrested in joint drive against counterfeit medicines	Link
1223394	Three arrested in joint drive against counterfeit medicine...	Link

Notes: Dhaka Metropolitan Police detectives have arrested three men for selling fake medicines and salves and banned drugs under the names of famous and expensive local and foreign brands. [...] The three were arrested following joint operations by detectives from the DMP's Lalbagh Division and the Directorate General of Drug Administration at pharmacies in Dhaka's Mitford area on Saturday.

Among the pharmaceuticals recovered in the raid were i-pill, Super Gold Kosturi, Naproxen Plus, Betnovate C, Protobit, Eno Sanagro, Periactin Moov, Ring Guard, Wheatfield, Nix Rubbing Balm, Vicks Cold Plus, Vicks and Gacozema. [...] "As the capital's Mitford market is a wholesale market for pharmaceuticals, a counterfeit drug production and marketing ring has been using it as a hiding place to spread fake medicine across the country," Alam said. [...]

10 Advisory - Potential contamination of health products manufactured by Eco-Med Pharmaceuticals Inc. may po

Publication date	2021-08-25
Create date	2021-08-30
Score	20.15
Report id	1196204
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Advisory - Potential contamination of health products manufactured by Eco-Med Pharmaceuticals Inc. may po Benzinga

Click here to see the Original Article

Table 21: Places for report 1196204

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Ottawa	45.41117	-75.69812

Table 22: Drugs for report 1196204

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: [...] Health Canada, as a precaution, is advising Canadians to stop using and discard all products manufactured by Eco-Med Pharmaceuticals (ultrasound gels, transmission and massage lotions, hand sanitizers and first aid antiseptics) due to potential bacterial contamination with Burkholderia stabilis (B. stabilis). [...] Natural Health Products: hand sanitizers and first aid antiseptic:

Prevent+ (NPN 80097875);

Prevent+ Foam Sanitizer (NPN 80102490);

Prevent+ Rubbing Alcohol, Rubbing Alcohol 70% (NPN 80103917);

First Aid Antiseptic: Prevent+ Hydrogen Peroxide 3% USP, Hydrogen Peroxide 3% USP, (NPN 80107321).

11 Customs seizes fake drugs, cosmetics worth N120 million – The Sun Nigeria

Publication date	2021-09-20
Create date	2021-09-22
Score	17.88
Report id	1223149
Category	Anti-malarial
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Customs seizes fake drugs, cosmetics worth N120 million – The Sun Nigeria Daily Sun

Click here to see the Original Article

Table 23: Places for report 1223149

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Benin City	6.33815	5.62575

Table 24: Drugs for report 1223149

Medicine Name	Medicine Class	Action	ATC Code
artesunate	Artemisinin and derivatives, plain	antimalarials	P01BE03

Table 25: Other Stories

ID	Title	Link
1223261	Customs seize fake, contraband goods worth N120m in 2 months	Link
1223325	Customs seize fake drugs, cosmetics, others worth N120m in two months	Link
1223470	Customs intercepts N9m fake malaria drug in Edo – The Sun Nigeria	Link
1224082	Smugglers forfeit N120m worth of goods in South East	Link
1224150	Customs Seizes Fake Drugs, Cosmetics, Other Contraband Worth Over N120M	Link

Table 25: Other Stories(continued)

ID	Title	Link
1224557	Customs seizes N120m fake drugs, cosmetics	Link
1227570	How we seized N120 million 'fake products' in Lagos, Benin, Enugu roads — Customs	Link
1228410	Customs Intercepts N9m Fake Malaria Drugs In Edo	Link
1231757	Customs Intercepts N9m Fake Malaria Drug In Edo	Link

Notes: Comptroller Yusuf Lawal who announced this on Monday while briefing newsmen gave the list of the fake drugs to include 440 cartons of Artesunate injection zensunate without the National Agency for Food and Drugs Administration and Control (NAFDAC) number, worth N8,580,000. [...]

12 Manipur: Bihar resident caught with hundreds of fake Remdesivir tablets

Publication date	2021-08-03
Create date	2021-08-12
Score	15.33
Report id	1163133
Category	Antiviral others
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Manipur: Bihar resident caught with hundreds of fake Remdesivir tablets EastMojo

Click here to see the Original Article

Table 26: Places for report 1163133

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

Table 27: Other Stories

ID	Title	Link
1163057	Man held with fake Covid medicines	Link
1163239	Suspected fake Remdesivir bottles seized in Manipur	Link
1163397	Imphal: Man from Bihar held with 'fake' Remdesivir vials worth Rs 14 lakh	Link
1163817	One held with fake Remdesivir medicines : 04th aug21	Link
1164039	Manipur : Police Nabs Bihar Resident With Fake Remdesivir Injections	Link

Notes: A Bihar resident was nabbed by the Imphal East Police Team for illegal possession of 441 pieces of DESREM (Remdesivir 100 mg) injection, which are suspected to be fake. [...]

13 Spurious sanitisers might spread Covid: SPECS

Publication date	2021-08-04
Create date	2021-08-12
Score	15.05
Report id	1164808
Category	Antiseptic
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Spurious sanitisers might spread Covid: SPECS Daily Pioneer

Click here to see the Original Article

Table 28: Drugs for report 1164808

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: Spurious and toxic hand sanitisers might be the possible cause of the spread of Covid-19 and deaths caused by it across the State. The demand for sanitisers has risen since Covid hit Uttarakhand and due to its growing demand, many spurious hand sanitisers infused with toxic chemicals are being sold across the State. [...] The study revealed that 578 samples out of 1,050 samples of hand sanitisers collected from markets and households of the districts of Uttarakhand had extremely low amounts of alcohol that makes them ineffective against Covid-19.

The presence of toxic colours was also found in 278 samples of sanitisers while the highly toxic chemical methanol was also found in eight samples — which can severely affect the human body. The concentration of hydrogen peroxide was also found in excess in around 112 samples of sanitisers. [...]

14 WHO warns of falsified COVID-19 vaccines, remdesivir - 2021-08-18

Publication date	2021-08-18
Create date	2021-08-24
Score	14.11
Report id	1182127
Category	Antiviral others
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: The manufacturers of the genuine products - Serum Instiute of India and Gilead - have confirmed that the products are fake.

Click here to see the Original Article

Table 29: Places for report 1182127

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

Table 30: Other Stories

ID	Title	Link
1194469	Medical Product Alert N°4/2021: Falsified remdesivir	Link
1196403	WHO warns of falsified COVID-19 vaccines, remdesivir	Link

Notes: [...] The latest alert came just a few days after the WHO warned of two batches of falsified remdesivir injection – claiming to be the genuine product made by Gilead Sciences – had been identified in Mexico.There have been a number of earlier reports of counterfeit remdesivir in the US en route to Mexico and India.

"These falsified products have been reported at the patient level (including at a hospital) in Mexico and are illicitly supplied on the internet," according to the agency. [...]

15 Fake medicines seized from drug suspect

Publication date 2021-09-26

Create date 2021-09-29

Score 10.88

Report id 1230985

Category Antacid, Other, Antibiotic, Anti-inflammatory medicine

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Fake medicines seized from drug suspect SunStar Philippines

Click here to see the Original Article

Table 31: Places for report 1230985

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Guagua	14.9653	120.6325

Table 32: Drugs for report 1230985

Medicine Name	Medicine Class	Action	ATC Code
erythropoietin	Other antianemic preparations	other antianemic preparations	B03XA01
cefuroxime	Second-generation cephalosporins	other beta-lactam antibacterials	J01DC02
cefuroxime	Antibiotics	antiinfectives	S01AA27
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01
etoricoxib	Coxibs	antiinflammatory and antirheumatic products, non-steroids	M01AH05
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04

Table 32: Drugs for report 1230985(continued)

Medicine Name	Medicine Class	Action	ATC Code
celecoxib	Other antineoplastic agents	other antineoplastic agents	L01XX33
celecoxib	Coxibs	antiinflammatory and antirheumatic products, non-steroids	M01AH01

Table 33: Other Stories

ID	Title	Link
1231820	7 sacks of counterfeit antibiotics, ulcer drugs seized in Pampanga	Link

Notes: A SUSPECTED drug peddler who was arrested during an anti-illegal operation in Guagua town, Pampanga yielded sacks of medicines believed to be counterfeit. [...] During his arrest, police discovered several sacks of various counterfeit medicines inside the suspect's residence.

A total of seven sacks of fake drugs including a sack each of Celecoxib, Cefuroxime, Etoricoxib, Emeprozole and Recombinant Human Erythropoietin, and two sacks of Co-Amoxiclax were recovered by police from Simon. [...]

16 Gang arrested for manufacturing and selling counterfeit lifesaving cancer drugs

Publication date	2021-09-10
Create date	2021-09-13
Score	10.40
Report id	1211497
Category	Chemotherapy
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Gang arrested for manufacturing and selling counterfeit lifesaving cancer drugs India TV News

Click here to see the Original Article

Table 34: Places for report 1211497

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Faridabad	28.41124	77.31316
Southern Asia	Bangladesh	Bangladesh	24	90
Southern Asia	India	Karnāl	29.69197	76.98448

Table 35: Drugs for report 1211497

Medicine Name	Medicine Class	Action	ATC Code
lenvatinib	Protein kinase inhibitors	other antineoplastic agents	L01XE29
ibrutinib	Protein kinase inhibitors	other antineoplastic agents	L01XE27
osimertinib	Protein kinase inhibitors	other antineoplastic agents	L01XE35
palbociclib	Protein kinase inhibitors	other antineoplastic agents	L01XE33
crizotinib	Protein kinase inhibitors	other antineoplastic agents	L01XE16

Table 36: Other Stories

ID	Title	Link
1210622	Fake medicines for cancer patients seized, 3 arrested	Link
1212623	Delhi Police busts inter-state gang for manufacturing & selling fake cancer drugs; 4 held	Link
1230203	Fake cancer drugs racket trail leads cops to Karnal	Link
1237742	Delhi: Four arrested for selling fake cancer drugs	Link
1237997	Mumbai: Woman arrested for selling fake medicine to cancer patients	Link

Notes: At least four persons were arrested on Friday for manufacturing and selling counterfeit lifesaving Cancer drugs in Faridabad and Karnal in Haryana.

141 Pack of Spurious Life-Saving Cancer Drugs such as Palbocent-125 mg, Lenvanix-10, Osicent-80 mg, Crizocent-250 mg, and Ibrucent-140, Empty Outer Cartons, One Printing Machine (used for printing of Batch No. Expiry Date, etc. on Drug Carton) and one Spurious Drug Manufacturing Machine were recovered after the bust. [...] Accused persons encashed the opportunity and started manufacturing fake/spurious/counterfeit Lifesaving Cancer medicines purportedly manufactured in Bangladesh. After manufacturing, these spurious / counterfeited medicines are then been sold out by the accused persons in Grey Market at handsome rates and earned huge profits. Accused persons have set up a network of individuals who supply the injections on demand. [...] Meanwhile, raids are being conducted to locate other manufacturing units/ plants, seizure of machines, and raw material used to manufacturing these spurious drugs, and also for unearthing their entire network including sources of raw material, printers, dealers/ distributors, doctors, hospitals, etc. – involved in the present case.

17 Public Notification: Themra Epimedyumlu Bitkisel Karisimli Macun contains hidden drug ingredient - 2021-08-18

Publication date	2021-08-18
Create date	2021-08-24
Score	9.37
Report id	1182608
Category	Nutritional supplement
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: The Food and Drug Administration is advising consumers not to purchase or use Themra Epimedyumlu Bitkisel Karisimli Macun, a product promoted for sexual enhancement and increasing energy on various websites and possibly in some retail stores. This product was discovered during an examination of impo

Click here to see the Original Article

Table 37: Places for report 1182608

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

Notes: [...] FDA laboratory analysis confirmed that Themra Epimedyumlu Bitkisel Karisimli Macun contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction. [...]

18 ED raids on fake Covid-19 vaccines case at different locations in Kolkata

Publication date	2021-09-01
Create date	2021-09-03
Score	9.26
Report id	1200629
Category	Antiviral others, Other
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: ED raids on fake Covid-19 vaccines case at different locations in Kolkata United News of India

Click here to see the Original Article

Table 38: Places for report 1200629

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

Table 39: Drugs for report 1200629

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Table 40: Other Stories

ID	Title	Link
1200705	ED raids on fake Covid-19 vaccines case at different locations in Kolkata - Goa Chronicle	Link
1204451	Fake Vaccination Case: ED raid 10 hideouts simultaneously in Kolkata, links suspected to TMC leaders	Link

Notes: (Related to ID 1110971) – Kolkata, Sep 1 (UNI) The Enforcement Directorate (ED) on

Wednesday raided the residence of Debanjan Deb, the prime accused of fake vaccine case and different locations of his associates in the city. [...] Deb, who is now arrested by the Kolkata police for running a fake vaccines camp with a premium price of up to Rs 25,000 at Kasba in south Kolkata posing himself as an IAS official with the state government. Besides the fake vaccine camp, Deb was also allegedly involved in black marketing of oxygen, and remdesivir and other Covid-19 related medical equipment with high prices. [...]

19 CBP snares 'unapproved' Viagra, Cialis shipment - 2021-09-27

Publication date	2021-09-27
Create date	2021-10-01
Score	9.21
Report id	1232390
Category	Erectile dysfunction medicine
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: The shipment - worth $460k - was arriving from Hong Kong and headed to an individual in Montreal, Canada.

Click here to see the Original Article

Table 41: Places for report 1232390

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Montréal	45.50884	-73.58781
Americas	United States	Louisville	38.25424	-85.75941
Eastern Asia	Hong Kong	Hong Kong	22.27832	114.17469

Table 42: Drugs for report 1232390

Medicine Name	Medicine Class	Action	ATC Code
sildenafil	Drugs used in erectile dysfunction	urologicals	G04BE03
tadalafil	Drugs used in erectile dysfunction	urologicals	G04BE08

Table 43: Other Stories

ID	Title	Link
1232397	CBP snares 'unapproved' Viagra, Cialis shipment	Link

Table 43: Other Stories(continued)

ID	Title	Link
1232499	6780 Unapproved Viagra & Cialis Pills Seized by Louisville CBP	Link

Notes: Customs and Border Protection (CBP) officers in Louisville seized a shipment containing 4,780 'unapproved' Viagra pills and 2,000 unapproved Cialis pills.

The shipment was arriving from Hong Kong and was headed to an individual in Montreal, Canada. If genuine, and approved by the FDA, the pills would have had an estimated manufacturer's suggested retail price (MSRP) of more than $460,000. [...]

20 Counterfeit medicines - Truth, for its own sake.

Publication date	2021-08-25
Create date	2021-08-26
Score	9.17
Report id	1191088
Category	Nutritional supplement
Quality	Substandard or Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Counterfeit medicines - Truth, for its own sake. New Era

Click here to see the Original Article

Table 44: Places for report 1191088

Region Name	Country	Location	Latitude	Longitude
Southern Africa	South Africa	Republic of South Africa	-29	24
Southern Africa	Namibia	Republic of Namibia	-22	17

Notes: [...] This unscheduled product was found to be circulating in Namibia and marketed as herbal sex booster for men. The manufacturer as well as the batch number were not indicated on the labelling. The NMRC laboratory tested the product and found that it contained sildenafil, a scheduled active ingredient found in Viagra® tablets. [...]

21 Man held for fake green chiretta capsules

Publication date	2021-08-03
Create date	2021-08-12
Score	8.30
Report id	1163268
Category	Herbal medicine
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Man held for fake green chiretta capsules Bangkok Post

Click here to see the Original Article

Table 45: Places for report 1163268

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Thailand	Nakhon Pathom	13.8196	100.04427

Table 46: Other Stories

ID	Title	Link
1163763	Thailand's Health Department Warns Over Fake Green Chiretta Products	Link

Notes: Authorities warned consumers about fake green chiretta products after a man was arrested with capsules in Nakhon Pathom province amid high demand for herbs to fight Covid-19. [...] Officials found with him 450 bottles of capsules claimed to contain green chiretta (Fah Talai Jone in Thai), about 60,000 capsules containing powdered herbs, 300 unlabelled packs of capsules and 6,000 empty bottles with caps. They believed fake green chiretta capsules were made at the house. [...]

22 Drug makers Granules India, Jubilant Cadista recall products in US market

Publication date	2021-09-12
Create date	2021-09-13
Score	8.08
Report id	1213635
Category	Alzheimer's medicine, Anti-inflammatory medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Drug makers Granules India, Jubilant Cadista recall products in US market ETHealthworld.com

Click here to see the Original Article

Table 47: Places for report 1213635

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
Americas	United States	United States	39.76	-98.5

Table 48: Drugs for report 1213635

Medicine Name	Medicine Class	Action	ATC Code
naproxen	Antiinflammatory products for vaginal administration	other gynecologicals	G02CC02
naproxen	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE02
naproxen	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA12
donepezil	Anticholinesterases	anti-dementia drugs	N06DA02

Notes: Generic drug makers Granules India and Jubilant Cadista are recalling different products in the US, the world's largest market for medicines, for different reasons. As per the latest Enforcement Report by US Food and Drug Administration (USFDA), the US-based unit of Granules India is recalling over 1.14 crore Naproxen Sodium tablets, a non-steroidal anti-inflammatory drug used to treat pain, menstrual cramps, inflammatory diseases such as rheumatoid arthritis, gout and fever. [...] The affected lot has been manufactured at Granules India's Telangana-based plant. The lot has been distributed in the US by New Jersey-based Granules USA, Inc, the report stated. [...] USFDA further said US-based Jubilant Cadista Pharmaceuticals Inc is recalling 14,544 bottles of Donepezil HCL Tablets, which is used to treat mild to moderate dementia in Alzheimer's disease. The company is recalling the affected lot due to it being "subpotent," it added. [...]

23 Nanomateriales Químicos Avanzados, S.A. de C.V. - CGMP/ Finished Pharmaceuticals/Unapproved New Drug/Misbranded/ Adulterated - Nuevo León - 2021-09-15

Publication date	2021-09-15
Create date	2021-09-22
Score	6.94
Report id	1224668
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Nanomateriales Químicos Avanzados, S.A. de C.V. MARCS-CMS 609969 — September 15, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA UPS Product: Drugs Recipient: Recipient Name Mr. Joel Gutiérrez Antonio Recipient Title Director General/CEO Nanomateriales Químicos Avanzados, S.A. de C.V. Av Milimex 215 Col. Parque Industrial Milimex 66637 Apodaca , N.L. Mexico Issuing Office: Center for Drug Evaluation and Research | CDER United States Warning Letter 320-21-58 September 15, 2021 Dear Mr. Gutiérrez: Your facility is registered with the United States Food and Drug Administration (FDA) as a manufacturer of over-the-counter (OTC) drug products, including consumer antiseptic rub drug products (also referred to as a consumer hand sanitizer). The FDA conducted testing of a product, labeled as ZANILAST + Gel, 25 kg. This drug product was labeled as manufactured at your facility. Following an attempt to import ZANILAST + Gel, 25kg 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 labeled as manufactured at your facility is adulterated within the meaning of section 501(d)(2) of the FD&C Act, 21 U.S.C. 351(d)(2), in that a substance was substituted wholly or in part therefor. Additionally, FDA has reviewed the records you submitted in response to our initial April 22, 2020, request for records and other information, and subsequent correspondence, pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for your facility, Nanomateriales Químicos Avanzados, S.A. de C.V., formerly known as Nanomateriales S.A. de C.V., FEI 3010525809, at Av. Milimex 215, Col. Parque Industrial Milimex, Apodaca, Nuevo Leon 66637, Mexico. Based on information provided in response to our 704(a)(4) request and the substitution determined by FDA laboratory testing, the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of drugs do not conform to current good manufacturing practice (CGMP) within the meaning of section 501(a)(2)(B) of the FD&C Act. This warning letter also summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211). In addition, in response to our 704(a)(4) request you provided a

copy of the label for ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon. Our review of the label has determined that ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is an unapproved new drug in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a). Additionally, ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). 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). ZANILAST + GEL 25kg is misbranded under sections 502(f)(1), (a), (e)(1)(A), (c), and (x) of the FD&C Act, 21 U.S.C. 352(f)(1), (a), (e)(1)(A), (c), and (x). Introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(a) of the FD&C Act, 21 U.S.C. 331(a). These violations are described in more detail below. Adulteration Violations ZANILAST + Gel, 25kg bulk labeled as manufactured at your facility, is labeled to contain 65% 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 an average 0.0% ethanol and an average of 41% 1-propanol volume/volume (v/v). 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 1-propanol, a dangerous chemical when in contact with human skin or ingested. 1-propanol, not to be confused with isopropyl alcohol or 2-propanol, is not a permitted active ingredient in hand sanitizers intended for the United States. Exposure to 1-propanol may cause irritation to eyes, nose; throat; dry cracking skin; drowsiness, headache; ataxia, gastrointestinal pain; abdominal cramps, nausea, vomiting and diarrhea. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products, and adolescents and persons with alcohol addiction who drink these products as an alcohol (ethanol) substitute, are most at risk for 1-propanol poisoning. On August 17, 2020, FDA held a teleconference with you. We recommended you consider removing all of your firm's hand sanitizer drug products currently in distribution to the U.S. market. On August 17, 2020, FDA notified the public of the 1-propanol contamination substitution of your hand sanitizer drugs products at the following website: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use On August 26, 2020, you issued a voluntary nationwide recall of ZANILAST + Gel Hand Sanitizer because of the potential presence of undeclared 1-propanol, as noted on the following FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nanomaterials-sa-de-cv-issues-voluntary-nationwide-recall-all-lots-zanilastgel-due-presence-1 In response to this letter, provide the following: • A list of all raw materials used to manufacture all 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 United States. • Summary of corrective actions taken to ensure your hand sanitizer products can be manufactured at the label claim concentration of 65% v/v ethanol. • Details regarding your raw material identity testing of incoming active pharmaceutical ingredients and specifically how your test methods can distinguish between ethanol and 1-propanol. • Provide a complete, comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system. The substitution and contamination with 1-propanol in a drug product 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. 1 21 CFR parts 210 and 211 Violations Following review of records and other information provided pursuant to section 704(a)(4) of the FD&C Act,

significant violations were observed including, but not limited to, the following: 1. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)). Your response to our records request and other information under section 704(a)(4) indicated that you did not conduct adequate finished drug product testing on drug products shipped to the United States. Specifically, in response to our 704(a)(4) request for all finished product specifications and test methods used to evaluate them, you referenced an operational manual which stated that your hand sanitizer is only tested for pH, viscosity, density, and appearance and provided stability data for one batch in which only pH and viscosity were evaluated. In a subsequent response on September 5, 2020, you provided a procedure which stated that finished product must be tested according to its specifications before release, but you did not provide revised specifications for your hand sanitizer drug product. The documents you provided in response to our 704(a)(4) request indicate that you do not perform identity, assay, or purity testing of the active ingredient in your finished drug product. Full release testing including strength and identity testing of the active ingredient must be performed before drug release and distribution. In response to this letter, provide the following: • A list of chemical and microbial specifications, including test methods, used to analyze each lot of your drug products before a lot disposition decision. Specify which tests are performed by your facility and which if any are performed by a contract testing laboratory. o An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter. o A summary of all results obtained from testing reserve samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls. • Ethanol and 1-propanol test results for all batches of hand sanitizer shipped to the United States within expiry. 2. Your firm failed to conduct at least one test to verify the identity of each component of a drug product. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals (21 CFR 211.84(d)(1) and (2)). Based on the records and information you provided, you did not demonstrate adequate identity testing of incoming components used to manufacture your drug products, and you accepted test results from suppliers without verifying information provided by suppliers. We requested details about your raw material identity testing for each lot of each component and you stated that material test results are accepted from the supplier's Certificate of Analysis (COA). We asked again on August 25, 2020, and you stated that COA values are accepted from "reliable" suppliers. There is no evidence that you perform identity testing on each lot of incoming components. For your component suppliers, we requested the last date of supplier qualification, audit frequency, and the last three audit dates as applicable. You replied only that you did not have an audit frequency. We asked for supplier qualification information again on August 25, 2020, and you provided a procedure created July 3, 2020, describing the evaluation and selection of suppliers. However, this procedure does not provide any specific guidance on evaluating the quality of a supplier or the validity of data listed on a supplier's COAs. In response to this letter, provide the following: • The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing. • A description of how you will test each component lot for conformity with all appropriate specifications for identity, strength, quality, and purity. If you intend to accept any results from your supplier's COAs instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier's results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming

component lot. • A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your SOP that describes this COA validation program. • A summary of your program for qualifying and overseeing contract facilities that test the drug products you manufacture. • A comprehensive review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures. 3. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products (21 CFR 211.22(a)) The records and information you submitted demonstrate that your quality unit (QU) lacks adequate quality oversight over the manufacture and release of finished drug product shipped to the United States. Specifically, your drug substance supplier provided incorrect information that 1-propanol was an allowable active ingredient in hand sanitizer intended for use in the United States. You accepted this information and altered your drug product formula without evaluating the impact of this change on product quality. Subsequently, you released hand sanitizer batches (b)(4) which contained 1-propanol as the active ingredient. On September 9, 2020, we requested the labels for these batches. You provided these labels which declare "65.00% alcohol" and "70% ethyl alcohol" content respectively, demonstrating that your QU released mislabeled material. As of your September 10, 2020, response, you understood that 1-propanol is an unacceptable active ingredient in hand sanitizer, committed to test for 1-propanol in your future finished hand sanitizer products, and will no longer use that drug substance supplier. However, your response lacked documentation and sufficient detail to demonstrate that you are establishing appropriate operational programs, systems, and related procedures to ensure product quality, such as those responsible for manufacturing changes. You also failed to address the potential impact that your lack of quality oversight had on the quality of all drugs that you manufacture. Your firm must provide the QU with the appropriate authority and sufficient resources to carry out its responsibilities and consistently ensure drug quality. See FDA's guidance document, Quality Systems Approach to Pharmaceutical CGMP Regulations, for help implementing quality systems and risk management approaches to meet the requirements of the CGMP regulations (21 CFR, parts 210 and 211) at: https://www.fda.gov/media/71023/download . In response to this letter, provide the following: • A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to: o A determination of whether procedures used by your firm are robust and appropriate o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices o A complete and final review of each batch and its related information before the QU disposition decision o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products • A comprehensive assessment of your change management system. This assessment should include, but not be limited to, your procedure(s) to ensure changes are justified, reviewed, and approved by your QU. Your change management program should also include provisions for determining change effectiveness. Unapproved New Drug and Misbranding Violations ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon and ZANILAST + GEL, 25kg 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 use in 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, these products are intended for use as a consumer topical antiseptic. Examples of claims observed on the ZANILAST + GEL ANTI-

SEPTIC HAND SANITIZER, 1 gallon product label and labeling that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following: "ANTISPETIC HAND SANITIZER . . . Drug Facts…Antiseptic…Use…For hand washing to decrease bacteria on the skin" "wet hands thoroughly with product and allow to dry without wiping" 2 Documents you submitted in support of your August 2020 import entry for ZANILAST + GEL, 25kg including a product list, provide evidence of the product's intended use (as defined in 21 CFR 201.128) as a hand sanitizer drug product. Further, examples of claims observed on the ZANILAST + GEL, 25kg that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following: Product Label: "ZANILAST + GEL is a stabilized compound that contains 70% of ethanol. In order to maximize its biocidal power, a compound based on zinc oxide is added." "…formulated with broad-spectrum sanitizing agents, obtained by an advanced physicochemical process that gives it an ideal composition and particle size to guarantee a broad biocidal power against bacteria, fungi, and viruses." Accordingly, your firm's ZANILAST + GEL, 25kg is a drug within the meaning of section 201(g)(1)(D) of the FD&C Act. ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because it is 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 it is lawfully marketed under section 505G of the FD&C Act (which is not the case for this product, as further described below) or 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 ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon drug product is GRASE for use under the conditions suggested, recommended, or prescribed in its labeling. Accordingly, ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is an unapproved new drug 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 OTC topical antiseptic products had been the subject of rulemaking under the Agency's 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 as 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 antiseptic rub. Additionally, OTC consumer antiseptic washes were addressed in "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Proposed Rule, 78 FR 76444 (December 17, 2013) (Consumer Antiseptic Washes Proposed Rule) and "OTC Safety and Effectiveness of Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 81 FR 61106 (September 6, 2016). We note that ethyl alcohol is not one of the active ingredients that was classified as Category III for use as an active ingredient in a consumer antiseptic wash. Under the Consumer

Antiseptic Washes rulemaking, ethyl alcohol was determined to be ineligible for evaluation under the OTC Drug Review for use as an active ingredient in consumer antiseptic washes. 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 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, ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon does not confirm to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rubs Proposed Rule and 2013 Consumer Antiseptic Washes Proposed Rule, nor any other TFM, proposed rule, or final rule, and does not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. As previously noted, statements on the ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon label suggest both that the product is a consumer antiseptic wash and a consumer antiseptic rub. However, ethanol (in any concentration) is not an active ingredient permitted for use in consumer antiseptic hand wash under the 1994 TFM. Moreover, antiseptic washes are outside the scope of FDA's temporary policies for hand sanitizers. The introduction or delivery for introduction of an unapproved new drug into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d). ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because ZANILAST + GEL ANTISEPTIC HAND SANITIZER, 1 gallon is a nonprescription drug subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but does not comply with the requirements for marketing under that section and it is not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. Furthermore, ZANILAST + GEL is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), because its labeling fails to bear adequate directions for use. Specifically, ZANILAST + GEL's labeling does not contain sufficient information to enable laypersons to use the product safely and for the purposes for which it is intended, including frequency of administration, duration of administration, time of administration, route or method of administration, and preparation for use. 3 In addition, ZANILAST + GEL is misbranded under section 502(a) of the FD&C Act, 21 U.S.C 352(a), because its labeling is false or misleading. ZANILAST + GEL is labeled to contain ethanol 65% and 70%. Such a representation by itself is misleading. However, FDA laboratory analysis of a batch of this product demonstrate that the product contains no traceable amount of ethanol and contains a significant concentration of 1-propanol, an ingredient that is not declared on the product label. 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 label to disclose the presence of the 1-propanol in the product, causes this product to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). The failure of ZANILAST + GEL drug product to list 1-propanol as an ingredient on its label also causes it to be misbranded under section 502(e)(1)(A) of the FD&C Act, 21 U.S.C. 352(e)(1)(A). 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). Additional Concerns We note that according to the product label, ZANILAST + GEL

purportedly contains the active ingredient ethyl alcohol at both 65% and 70% v/v, However, as previously discussed, FDA laboratory analyses of a batch of this product detained at the border demonstrated that ZANILAST + GEL contains no traceable amount of ethanol. Such a product does not conform with 1994 TFM or the applicable requirements, nor is it consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. 4 FDA laboratory analyses also demonstrated that a batch of ZANILAST + GEL contain significant concentrations of undeclared ingredient1-propanol. Use of 1-propanol as an active ingredient is not in conformance with the 1994 TFM, nor is 1-propanol 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, the product is labeled with alcohol, water, glycerin D-limonene, triethanolamine, carbomer, zinc oxide, and zinc pyrithione as active ingredients. 5 Neither water, glycerin D-limonene, triethanolamine, carbomer, zinc oxide, nor zinc pyrithione are permitted active ingredients, as a sole ingredient or in combination with other ingredients like ethanol, for use as a consumer or health care personnel antiseptic rub drug products. Such a product is not permitted under the TFM or other applicable requirements, nor is it consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency. 6 In addition, the labeling of ZANILAST + GEL indicates that it provides "biocidal power" against fungi and viruses. These labeled intended uses go beyond merely describing the general intended use of a topical antiseptic as set forth in the 1994 TFM, as amended by the 2016 proposed rule, and FDA's before-noted temporary policy. 7 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 August 31, 2020, and Import Alert 66-40 on January 12, 2021, 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 pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). 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 a 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. Until all violations are addressed completely, and we confirm your compliance with CGMP, they may be cause for FDA to withhold approval of any new drug applications or supplements listing your firm as a drug manufacturer. 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 completion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3010525809 and ATTN: Christina Capacci-Daniel. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research CC: Registered U.S. Agent: David Lennarz Register Corp 144 Research Drive Hampton, VA, 23666 757-224-0177 drugs@registrarcorp.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 a health care personnel hand rub) 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 labeled as manufactured at your facility, a review of the purported formulations on the drug products' labeling further indicates that such 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 We note that your ZANILAST + GEL ANTISEPTIC HAND SANITIZER labeling contains conflicting information regarding whether it should be used as a consumer antiseptic wash or a consumer antiseptic rub. The term "hand sanitizer" generally refers to consumer antiseptic rubs, and the Drug Facts Label of your product both indicates that the product is to be used for handwashing (presumably with water) and suggests that it should be used without water (i.e., "wet hands thoroughly with product and allow to dry without wiping"). The ZANILAST + GEL ANTISEPTIC HAND SANITIZER product, however, does not conform to the requirements for either a consumer antiseptic rub or a consumer antiseptic wash, as further described below. 3 We note that you include the statement, "Caution: For manufacturing, processing, or repacking," on your product label, perhaps in an attempt to claim the exemption from section 502(f)(1) under 21 CFR 201.122. However, to the extent that 21 CFR 201.122 applies, ZANILAST + GEL cannot claim the exemption because it is a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, and does not meet any of the conditions set forth in 21 CFR 201.122(a)-(c). 4 The 1994 TFM, which does not distinguish between antiseptic hand washes and rubs, proposed for antiseptic hand washes and healthcare personnel hand washes an alcohol concentration of 60 to 95% by volume in an aqueous solution denatured in accordance with Bureau of Alcohol, Tobacco and Firearms regulations. 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. 5 The labeling and formulation for ZANILAST + GEL is not consistent with the conditions proposed for OTC hand sanitizers (i.e., antiseptic rub) for consumer and/or health care personnel use under the 1994 TFM (see 59 FR 31402;

June 17, 1994), as further amended by subsequent proposed rules. Specifically, the label for ZANILAST + GEL does not distinguish active ingredients from inactive ingredients. Therefore, all of the labeled ingredients (alcohol, water, glycerin D-limonene, triethanolamine, carbomer, zinc oxide, and zinc pyrithione) are deemed to be represented as active ingredients, see 21 CFR 201.66(b)(2). 6 See, e.g., Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). 7 The 1994 TFM covers health care antiseptics that are indicated for use to help reduce bacteria that potentially can cause disease and health care and consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. Content current as of: 09/21/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 49: Places for report 1224668

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Apodaca	25.78195	-100.18839
Americas	United States	United States	39.76	-98.5

Table 50: Drugs for report 1224668

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
	Antiseptics	throat preparations	R02AA

Notes: [...] ZANILAST + Gel, 25kg bulk labeled as manufactured at your facility, is labeled to contain 65% 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 an average 0.0% ethanol and an average of 41% 1-propanol volume/volume (v/v). 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 1-propanol, a dangerous chemical when in contact with human skin or ingested. [...]

24 Letters and medicine recalls sent to healthcare professionals in July 2021

Publication date	2021-08-16
Create date	2021-08-24
Score	6.32
Report id	1181511
Category	Other, Antipsychotic, Antibiotic, Psychoactive substance
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Letters and medicine recalls sent to healthcare professionals in July 2021 GOV.UK

Click here to see the Original Article

Table 51: Places for report 1181511

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	United Kingdom of Great Britain and Northern Ireland	54.75844	-2.69531

Table 52: Drugs for report 1181511

Medicine Name	Medicine Class	Action	ATC Code
magnesium sulfate	Osmotically acting laxatives	drugs for constipation	A06AD04
magnesium sulfate	Magnesium	other mineral supplements	A12CC02
magnesium sulfate	Electrolyte solutions	i.v. solution additives	B05XA05
magnesium sulfate	Other dermatologicals	other dermatological preparations	D11AX05
magnesium sulfate	Tests for bile duct patency	other diagnostic agents	V04CC02
droperidol	Butyrophenone derivatives	antipsychotics	N05AD08

Table 52: Drugs for report 1181511(continued)

Medicine Name	Medicine Class	Action	ATC Code
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04
lymecycline	Tetracyclines	tetracyclines	J01AA04
morphine	Natural opium alkaloids	opioids	N02AA01

Notes: In July 2021, recalls and notifications for medicines were issued on: Class 2 Medicines Recall: Kyowa Kirin Limited, Xomolix 2.5 mg/ml solution for injection, EL (21)A/15. Issued 1 July 2021. Two batches of Xomolix (droperidol) 2.5mg/ml solution for injection are being recalled as a precautionary measure due to reports of contamination with glass and cellulose fibres. [...] Company led medicines recall: Morphine Syringe 50mg/50ml (unlicensed medicine) and Magnesium Sulphate 8mmol/20ml infusion (unlicensed medicine). Issued 1 July 2021. A batch of each of the unlicensed medicines morphine syringe 50mg/50ml and magnesium sulphate 8mmol/20ml infusion are being recalled by the company. [...] Class 4 Medicines Defect Information, Tetralysal 300mg Hard Capsules, (PL 10590/0019), EL (21)A/16. Issued 6 July 2021. Several batches of Tetralysal (lymecycline) 300mg Hard Capsules have been identified to include older versions of the Patient Information Leaflet in the product packs. [...] Class 4 Medicines Defect Information, Sevredol 10 mg and 20mg tablets, (PL 16950/0063, PL 16950/0064), EL (21)A/17. Issued 12 July 2021. Several batches of Sevredol (morphine sulfate) 10mg and 20mg tablets have been identified to include older versions of the Patient Information Leaflet. [...] Class 4 Medicines Defect Information, Amoxicillin 500 mg/ 5 ml Powder for oral suspension, (PL 25298/0248), EL (21)A/18. Issued 19 July 2021. Batches of Amoxicillin 500mg/5ml Powder for oral suspension have been identified that state an incorrect amount of the excipient sodium benzoate. [...]

25 Ellensburg teen dies of suspected Fentanyl overdose, police say

Publication date	2021-09-16
Create date	2021-09-20
Score	6.13
Report id	1218899
Category	Opioid
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Ellensburg teen dies of suspected Fentanyl overdose, police say NBC Right Now

Click here to see the Original Article

Table 53: Places for report 1218899

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Ellensburg	46.99651	-120.54785

Table 54: Drugs for report 1218899

Medicine Name	Medicine Class	Action	ATC Code
oxycodone and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ17

Notes: The Ellensburg Police Department (EPD) posted on social media that a 16-year-old girl passed away Wednesday evening of an apparent overdose of counterfeit Percocet, otherwise known as fentanyl. [...] ”We want to remind you of the dangers of ”blue pills” that resemble a Percocet pill,” wrote the Ellensburg PD. [...]

26 Medical Product Alert N°3/2021: Falsified CYTOTEC

Publication date	2021-08-10
Create date	2021-09-03
Score	5.76
Report id	1201459
Category	Abortive medicine
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Falsified CYTOTEC identified in WHO region of Africa

Click here to see the Original Article

Table 55: Places for report 1201459

Region Name	Country	Location	Latitude	Longitude
Central Africa	Cameroon	Republic of Cameroon	6	12.5
Central Africa	Democratic Republic of the Congo	Democratic Republic of the Congo	-2.5	23.5
Western Africa	Ghana	Republic of Ghana	8.1	-1.2
Western Africa	Nigeria	Federal Republic of Nigeria	10	8

Table 56: Drugs for report 1201459

Medicine Name	Medicine Class	Action	ATC Code
misoprostol	Prostaglandins	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BB01
misoprostol	Prostaglandins	uterotonics	G02AD06

Table 57: Other Stories

ID	Title	Link
1206016	Cameroon:Health Minister raises alarm on circulation of fake drugs - Journalducameroun.com	Link

Notes: This WHO Medical Product Alert refers to two batches of falsified CYTOTEC (misoprostol) 200 microgram tablets identified in the WHO Region of Africa and reported to WHO in July 2021. The genuine manufacturer of CYTOTEC has confirmed that the products listed in this Alert are falsified because these products failed laboratory analysis and/or display falsified variable data. These falsified products have been reported at wholesale and patient level in Cameroon, the Democratic Republic of Congo, Ghana and Nigeria. [...] Batch B16519 – batch number does not correspond to genuine manufactured CYTOTEC. Laboratory analysis of samples has also confirmed the product does not contain any active ingredient and does not comply with specifications; Batch 14660 – the expiry date (12/2021) on this product is falsified. [...]

27 Pakistan's counterfeit medicine problem

Publication date	2021-09-12
Create date	2021-09-21
Score	5.60
Report id	1220395
Category	Analgesic, Antacid, Other, Antibiotic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Pakistan's counterfeit medicine problem Profit by Pakistan Today

Click here to see the Original Article

Table 58: Places for report 1220395

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Islamic Republic of Pakistan	30	70

Table 59: Drugs for report 1220395

Medicine Name	Medicine Class	Action	ATC Code
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
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01

Table 59: Drugs for report 1220395(continued)

Medicine Name	Medicine Class	Action	ATC Code
ciprofloxacin	Fluoroquinolones	quinolone antibacterials	J01MA02
ciprofloxacin	Fluoroquinolones	antiinfectives	S01AE03
ciprofloxacin	Antiinfectives	antiinfectives	S02AA15
ciprofloxacin	Antiinfectives	antiinfectives	S03AA07
cefixime	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD08

Notes: [...] Preying on the sick and helpless, making them pay exorbitant amounts of money only to give them fake or subpar medicine, is truly a low one would hope to never witness. Unfortunately, Pakistan is a country where substandard and counterfeit drugs are sold openly and no one is going to lay a finger on a single hair of the mafia behind the buying and selling of these fake drugs. According to a survey conducted by Profit, more than 40 percent of medicines sold in Pakistani markets are either counterfeit or substandard. Similarly, 4,000 pharmaceutical companies are registered in the country, while more than 100,000 companies are making and selling drugs without anyone asking. There is not a single government civil or military hospital in the whole country where the ruling classes or government bureaucrats like to get their treatment. [...] Abbas revealed that not only in Lahore but all over the country, many counterfeit medicines with similar names of Novidat, Risek, Skilax, Voltral, Cefiget and many others are easily available in the market. "Now consider that Novidat is an antibiotic medicine and is used by a patient who is trying to get rid of an infection. Now a similar name Novaedaxin is easily found in the market and it is a counterfeit medicine. Interestingly, the manufacturer of the counterfeit medicine has not only prepared the packaging of his medicine like the real Novidat but has also put a price of RS 450 on it. This counterfeit medicine is now available in our market for RS 30 to 40 while the price of real medicine is between four to five hundred rupees. Think for yourself what will be the material in counterfeit medicine for forty to fifty rupees," he explains. [...]

28 NDA Impounds Drugs Worth Shs 163.5M from Unlicensed Outlets in Northern Uganda

Publication date	2021-09-25
Create date	2021-09-29
Score	5.31
Report id	1230108
Category	Medical device for screening/diagnosis/monitoring, Anti-malarial
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: NDA Impounds Drugs Worth Shs 163.5M from Unlicensed Outlets in Northern Uganda chimpreports.com

Click here to see the Original Article

Table 60: Places for report 1230108

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Kenya	Republic of Kenya	1	38
Eastern Africa	Uganda	Acholi	3.8	32.55
Eastern Africa	Uganda	Otuke District	2.48372	33.34201
Eastern Africa	Uganda	Republic of Uganda	1.25	32.5

Table 61: Drugs for report 1230108

Medicine Name	Medicine Class	Action	ATC Code
artemether and lumefantrine	Artemisinin and derivatives, combinations	antimalarials	P01BF01

Table 62: Other Stories

ID	Title	Link
1230318	Veterinary doctor arrested as NDA impounds drugs worth Shs160m	Link

Notes: The National Drug Authority (NDA) has impounded 545 boxes of assorted drugs and other medical supplies worth Shs163.5M from 349 unlicensed drug outlets in Acholi, Lango and Karamoja. [...] "We impounded drugs labeled 'Government of Uganda, not for Sale' (Lumarterm, Artemether/Lumefantrine, HIV RDT kits, Determine HIV) from Gen Rwoth Drug Shop in Apaa, Amuru District," Rwamwiri said. He added that unregistered medicines labelled (Kifaro) smuggled from Kenya were also impounded from Ave Maria Drug Shop in Otuke district and the operators of the drug shop are on the run. [...] Of the 763 outlets, 2 were pharmacies, 711 human and 23 veterinary drug shops and 25 clinics. 401 outlets were licensed. [...]

29 Turkish police seize fake COVID-19 pills

Publication date	2021-09-24
Create date	2021-09-28
Score	4.97
Report id	1229014
Category	Not applicable
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Turkish police seize fake COVID-19 pills China.org.cn

Click here to see the Original Article

Table 63: Places for report 1229014

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

Notes: Turkish police seized a large number of counterfeit medical products, including COVID-19 pills, and detained one suspect in Turkey's largest city Istanbul, local media reported on Friday. Acting upon a clue that some fake COVID-19 drugs would be released to the market, the Istanbul Police Department carried out an operation to an address in the Maltepe district, according to the Cumhuriyet daily.

In the raid, the police seized 92,139 items of medical products, including pills used to treat COVID-19.

Authorities have reportedly found that the drugs worth 4.2 million Turkish liras (about 475,123 U.S. dollars) were manufactured in unqualified environments, endangering public health.

30 Laboratorio Pharma International SRL - CGMP/Finished Pharmaceuticals/Unapproved New Drug/Misbranded/Adulterated - Center for Drug Evaluation and Research | CDER - 2021-09-15

Publication date	2021-09-15
Create date	2021-09-22
Score	2.51
Report id	1224667
Category	Anaesthetic, Other
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Laboratorio Pharma International SRL MARCS-CMS 614766 — September 15, 2021 Share Tweet Linkedin Email Print Delivery Method: VIA UPS Product: Drugs Recipient: Recipient Name Aurelio Nembrini Recipient Title General Manager Laboratorio Pharma International SRL Pharma Internacional Bldg, Main Street, Colonia Los Angeles Tegucigalpa , 11101 Honduras anembrini@pdpharmaintusa.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Warning Letter 320-21-57 September 15, 2021 Dear Mr. Nembrini: Your facility is registered with the United States Food and Drug Administration (FDA) as a manufacturer of over-the-counter (OTC) drug products. FDA has reviewed the records you submitted in response to our November 6, 2020, request for records and other information pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including in response to follow-up correspondence on March 24, 2021, for your facility, Laboratorio Pharma International S. de R.L., FEI 3012015184, at Pharma Internacional Bldg, Main Street, Colonia Los Angeles, Tegucigalpa, Honduras 11101. This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations, parts 210 and 211 (21 CFR, parts 210 and 211). Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)). In addition, GELAZUL Topical Analgesic is an unapproved new drug in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and is misbranded under sections 502 (x) and (ee) of the FD&C Act, 21 U.S.C. 352(x) and (ee). 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). These violations are described in more detail below. 1. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of

identity, strength, quality, and purity (21 CFR 211.160(b)). Your response to our 704(a)(4) request and subsequent correspondence indicates that your firm failed to establish appropriate specifications for the lidocaine hydrochloride and menthol active ingredients in your GELAZUL finished drug product. For example, in your response to our request for records or other information pursuant to section 704(a)(4) you provided finished product testing records for lots identified as distributed to the U.S. Our review of these records indicates that you have failed to establish a specification for your active ingredient, menthol, in the finished drug product. In addition, it does not appear that you tested the incoming component of menthol. In response to this letter, provide the following: • A comprehensive, independent assessment and corrective action and preventive action (CAPA) plan to ensure the adequacy of your finished product testing. Your remediated program should include, but not be limited to: o Your commitment to using current USP compendial monograph specifications (as applicable). • A list of chemical and microbial specifications, including test methods, used to analyze each lot of your drug products before a lot disposition decision. o An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter. o A summary of all results obtained from testing retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls. • A comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system. 2. Your firm failed to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to use results of stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)). Your response to our 704(a)(4) request and subsequent correspondence indicates that your firm lacks an adequate stability testing program to show that the chemical properties of your drug products are acceptable throughout the labeled expiry period of three years. For example, we requested details about your stability program, including a list of all stability studies or any records or data (separate from an established stability program) used to support your documented 3-year labeled expiry for GELAZUL. You clarified that "all products have either accelerated or shelf or (real time) stability". However, your response to our request for records or other information pursuant to section 704(a)(4) indicates for product released and distributed to the United States, you have not established an adequate stability program, in that, lots which have been evaluated are not subjected to a quantitative assay determination to support your label claims over time. In addition, you did not provide adequate stability data to support the shelf life of hand sanitizer batches released and distributed to the United States. In response to this letter, provide the following: • A comprehensive, independent assessment and corrective actions and preventive actions (CAPA) plan to ensure the adequacy of your stability program. Your remediated program should include, but not be limited to: o Stability-indicating methods, including both analytical and microbiological test methods. o Stability studies for each drug product based on quantitative analysis to support label claim. o An ongoing program in which representative batches of each product are added each year to the program to determine if the shelf-life claim remains valid. o Detailed definition of the specific attributes to be tested at each station (timepoint). • All procedures that describe these and other elements of your remediated stability program. • Stability data to support your hand sanitizer's drug product shelf life. • Your action plan to address any product quality or patient safety risks for your drug products in U.S. distribution, including potential customer notifications, recalls, or market withdrawals. 3. Your firm failed to test samples of each component for conformity with all appropriate written specifications for purity, strength, and quality

(21 CFR 211.84(d)(2)). In response to our 704(a)(4) request and subsequent correspondence pertaining to testing of incoming component ingredients, your firm failed to demonstrate adequate testing for impurities or identity of incoming components used in the manufacture of your drug products before release and distribution to the United States. For example, your response to our request for records or other information pursuant to section 704(a)(4) indicated that you have failed to ensure appropriate component testing for Pharmaint Gel Hand Sanitizer 1 . Specifically, you have failed to evaluate the component ethyl alcohol for impurities and to execute an appropriate identification test. In response to this letter, provide the following: • The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing. • A description of how you will test each component lot for conformity with all appropriate specifications for identity, strength, quality, and purity. If other methods are used in lieu of established compendial methods, we request that you provide justification. If you intend to accept any results from your supplier's Certificates of Analysis (COA) instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier's results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot. • A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your SOP that describes this COA validation program. • A summary of your program for qualifying and overseeing contract facilities that test the drug products you manufacture. • A comprehensive, independent review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures. • Your action plan to address any product quality or patient safety risks for your drug products in U.S. distribution, including potential customer notifications, recalls, or market withdrawals. Unapproved New Drug and Misbranding Violations GELAZUL Topical Analgesic is a "drug" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because it is intended for use in 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 it is intended to affect the structure or any function of the body. Specifically, this product is intended for use as a consumer topical analgesic. Examples of claims observed on the GELAZUL Topical Analgesic product label and labeling that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following: "Topical Analgesic . . . Drug Facts …. Uses: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains." This topical external analgesic product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its 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 FD&C Act (which is not the case for this product, 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 this drug product, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your GELAZUL Topical Analgesic drug product is GRASE for use under the conditions suggested, recommended, or prescribed in its labeling. Accordingly, this product is an unapproved new drug marketed in violation of sections 505(a) and 301(d) of the

FD&C Act, 21 U.S.C 355(a) and 331(d). Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(1) of the FD&C Act, 21 U.S.C. 355h(a)(1), category I drugs that were subject to a tentative final monograph (TFM) that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 are deemed to be GRASE and not "new drugs," as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM and comply with all other applicable requirements. We note that over-the-counter (OTC) topical external analgesic products were addressed in the TFM for External Analgesic Drug Products for Over-the-Counter Human Use (external analgesic TFM; 48 FR 5852, February 8, 1983) and subsequent rulemakings. Under 505G(b)(8) of the FD&C Act, 21 U.S.C. 355h(b)(8), the 1983 external analgesic TFM, in combination with subsequent determinations, is deemed to be a final administrative order. However, your GELAZUL Topical Analgesic product does not conform to the final administrative order, because it is inconsistent with the applicable TFM or any other applicable TFM or proposed rule, and it accordingly does not meet the conditions under section 505G(a)(1) of the FD&C Act for marketing without an approved application under section 505. Specifically, your product purports to contain 3% menthol and 4% lidocaine. The indication labeled on your product ("For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains") would be consistent with that of a "counterirritant" described in the applicable TFM (see 48 FR 5852, at 5868). While menthol at a concentration of 1.25 to 16 percent as a counterirritant active ingredient would be consistent with the applicable TFM, the combination of lidocaine and menthol is not permitted for this indication. In fact, lidocaine as a counterirritant active ingredient, in any combination or as a sole ingredient, is not consistent with the applicable TFM. The TFM does permit combinations of menthol and lidocaine, with a labeled indication as an external analgesic, which is different from that of a counterirritant. However, a combination would be permitted only at a concentration of menthol 0.1-1% and lidocaine 0.5-4%, respectively, and your product exceeds the level of menthol that would be consistent with the TFM. In addition, GELAZUL Topical Analgesic is misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x), because the product label fails 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. Lastly, this product is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because GELAZUL Topical Analgesic is a nonprescription drug subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but does not comply with the requirements for marketing under that section and is 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). Beta-Lactam Containment The records you provided also indicate that you manufacture potent compounds such as beta-lactams at your facility in addition to other finished drug products. In response to multiple requests that you clarify beta-lactam production controls, the records provided in each of your responses do not assure complete and comprehensive separation was established between beta-lactam and non-beta-lactam production. For example, the following controls for monitoring and personnel flow were not established: • Environmental monitoring data that establishes containment. • Limitations on personnel flow in shared areas, such as, breakrooms and gymnasium facilities. Due to the extremely low threshold dose at which an allergic response could occur, beta-lactam facilities need to be complete and comprehensively separated from non-beta-lactam facilities. For additional information, please refer to the guidance for industry, "Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination," available at https://www.fda.gov/media/79971/download . Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility/in connection with your products. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations. FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-40 on June 16, 2021. 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 a 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. In addition, shipments of articles manufactured at Laboratorio Pharma International S. de R.L. Pharma, Internacional Bldg, Main Street, Colonia Los Angeles, Tegucigalpa, Honduras 11101, into the United States that appear to be adulterated or misbranded are subject to being detained or refused admission pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until violations are completely addressed and we confirm your compliance with CGMP. Failure to address any violations may also result in FDA continuing to refuse admission of articles manufactured at Laboratorio Pharma International S. de R.L. Pharma, Internacional Bldg, Main Street, Colonia Los Angeles, Tegucigalpa, Honduras 11101, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated or misbranded may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B). 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 deviations and 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 complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. If you decide you want to manufacture drugs intended for U.S. distribution in the future, request a Regulatory Meeting to discuss your corrective actions as well as the adequacy of your beta-lactam containment to prevent cross-contamination. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3012015184 and ATTN: Matthew R. Dionne, Pharm.D., Compliance Officer. Sincerely, /S/ Francis Godwin Director Office of Manufacturing Quality Office of Compliance Center for Drug Evaluation and Research CC: Carlos Barahona, U.S. Agent 999 Ponce De Leon Blvd., Suite 650 Coral Gables, FL 33134 cbarahona@pdpharmaintusa.com _____1 Due to 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 August 7, 2020. 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 rub) 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. A review of the formulations on the drug product labeling further indicates that your product was 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. Content current as of: 09/21/2021 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 64: Places for report 1224667

Region Name	Country	Location	Latitude	Longitude
Americas	Honduras	Tegucigalpa	14.0818	-87.20681
Americas	United States	United States	39.76	-98.5

Table 65: Drugs for report 1224667

Medicine Name	Medicine Class	Action	ATC Code
lidocaine	Antiarrhythmics, class Ib	antiarrhythmics, class i and iii	C01BB01
lidocaine	Local anesthetics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AD01
lidocaine	Anesthetics for topical use	antipruritics, incl. antihistamines, anesthetics, etc.	D04AB01
lidocaine	Amides	anesthetics, local	N01BB02
lidocaine	Anesthetics, local	throat preparations	R02AD02
lidocaine	Local anesthetics	local anesthetics	S01HA07
lidocaine	Analgesics and anesthetics	other otologicals	S02DA01

Notes: [...] This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations, parts 210 and 211 (21 CFR, parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)).

In addition, GELAZUL Topical Analgesic is an unapproved new drug in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and is misbranded under sections 502 (x) and (ee) of the FD&C Act, 21 U.S.C. 352(x) and (ee). 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). These violations are described in more detail below. [...]

Annex C

C.6. Ventilation & Oxygenation equipment and consumables

Medicine Quality Monitoring Globe

November 18, 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.

Translation Disclaimer:

THIS REPORT MAY CONTAIN TRANSLATIONS POWERED BY GOOGLE. GOOGLE DISCLAIMS ALL WARRANTIES RELATED TO THE TRANSLATIONS, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF ACCURACY, RELIABILITY, AND ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

This Medicine Quality Monitoring Globe report is issued by IDDO, University of Oxford, and some sections, indicated in blue, may have been translated for your convenience using translation software powered by Google Translate. Reasonable efforts have been made to provide an accurate translation, however, no automated translation is perfect nor is it intended to replace human translators. Translations are provided as a service to users of the Medicine Quality Monitoring Globe, and are provided "as is." No warranty of any kind, either expressed or implied, is made as to the accuracy, reliability, or correctness of any translations made from the source language (Chinese, French, Spanish, or Vietnamese) into English.

The official text is the version in the source language (Chinese, French, Spanish, or Vietnamese). Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the information contained in the translated text, refer to the text in the source language (Chinese, French, Spanish, or Vietnamese) which is the official version.

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	2021-08-01
End date	2021-09-30
Language	en
Report type	incident
Curation status	validated
Number of Reports	9

1 Fake oximeters: Oxygen levels detected in a pencil

Publication date	2021-08-21
Create date	2021-08-25
Score	20.62
Report id	1186843
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Fake oximeters: Oxygen levels detected in a pencil The Star Online

Click here to see the Original Article

Table 1: Places for report 1186843

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Malaysia	Malaysia	2.5	112.5

Table 2: Drugs for report 1186843

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Notes: WITH the heightened interest in oximeters, some irresponsible sellers have duped consumers into buying fake devices.

The Federation of Malaysian Consumers Associations (Fomca) tells Sunday Star that it has received over 15 complaints about fake oximeters since last month.

”In one case, a consumer used an oximeter on a pencil and it ‘detected’ oxygen levels. [...]

2 Thai pirated substandard oximeters serious threat to Covid-19 patients' lives

Publication date	2021-08-05
Create date	2021-08-13
Score	19.43
Report id	1166502
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Thai pirated substandard oximeters serious threat to Covid-19 patients' lives Pattaya Mail

Click here to see the Original Article

Table 3: Places for report 1166502

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

Table 4: Drugs for report 1166502

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Notes: [...] The Thai News Agency learned from rescue volunteers supplying oxygen generators and cylinders to the houses of severe COVID-19 patients that substandard oximeters affected the rescuers' assessment of patients' conditions and oxygen assistance for patients in need could be dangerously delayed. Substandard and pirate oximeters were readily available especially through online sales and they showed false readings, the rescuers said. [...]

3 COVID-19 & FAKE OXIMETERS Both dangerous

Publication date	2021-08-31
Create date	2021-10-01
Score	16.57
Report id	1199130
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19 & FAKE OXIMETERS Both dangerous Ceylon Daily News

Click here to see the Original Article

Table 5: Places for report 1199130

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Sri Lanka	Democratic Socialist Republic of Sri Lanka	7.75	80.75

Table 6: Other Stories

ID	Title	Link
1237412	COVID-19 & FAKE OXIMETERS Both dangerous	Link

Notes: [...] By now there is a severe shortage of high quality National Medicines Regulatory Authority (NMRA)-approved pulse oximeters in the market. Because of this shortage, a lot of people have put various types of very low quality or toy-type pulse oximeters on the market for extremely high prices, sometimes even at Rs. 5,000. But before the COVID-19 outbreak, the price of a pulse oximeter was a maximum Rs. 2,000. Some of those pulse oximeters are just pre-programmed toys. That means those instruments only show a value that was entered during the manufacturing process, but not the actual oxygen saturation level of the person who uses it. Some of those toy-type pulse oximeters which are being sold in some private pharmacies work even when a pen, stick or something like that is placed instead of a finger. [...] According to the few importers (around three) of high quality pulse oximeters with the NMRA approval, it is the responsibility of the NMRA to assist the police to raid fake/toy pulse oximeters available all over the country at extremely high prices. The police do not need to request the NMRA for assistance and it is the NMRA which should obtain the assistance for raids. Some media

reported recently the NMRA conducted a few raids and around 3,500 fake low quality pulse oximeters were taken into custody. The media also reported the possibility of introducing a price control for pulse oximeters. [...]

4 Scam involving the sale of fake pulse oximeters uncovered

Publication date	2021-08-27
Create date	2021-08-30
Score	12.16
Report id	1194346
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Scam involving the sale of fake pulse oximeters uncovered NewsWire

Click here to see the Original Article

Table 7: Places for report 1194346

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Sri Lanka	Democratic Socialist Republic of Sri Lanka	7.75	80.75

Notes: A scam involving the sale of fake pulse oximeters has been uncovered in Sri Lanka.

Business leader Srimal Wijetunga revealed that a majority of oximeters sold in Sri Lanka at present are fake products.

Speaking during an interview with senior journalist Chamuditha Samarawickrama, the importer of oximeters approved by the National Medicines Regulatory Authority (NMRA) said the fake products provide false readings and tend to work even on a pen, instead of a finger.

Stating that imports of pulse oximeters are permitted only through approval from the NMRA, Wijetunga said, however, many fake products have flooded the local market. [...]

5 Substandard oximeter racket in several places of the island, busted

Publication date	2021-08-28
Create date	2021-08-30
Score	12.05
Report id	1195371
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard or Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Substandard oximeter racket in several places of the island, busted Newsfirst.lk

Click here to see the Original Article

Table 8: Places for report 1195371

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Sri Lanka	Galle	6.0367	80.217
Southern Asia	Sri Lanka	Colombo	6.93194	79.84778

Table 9: Other Stories

ID	Title	Link
1196022	CAA launches operations to find substandard oximeters - nation.lk	Link

Notes: The National Drug Regulatory Authority has seized a stock of substandard oximeters during raids conducted in Colombo and Galle. [...] He said that four suspects and more than 600 substandard oximeters were taken into custody. In another raid conducted in Galle, Karapitiya, Baddegama and Ambalangoda, the National Drug Regulatory Authority has seized another 252 substandard oximeters. [...]

6 Fake Oximeters Are Being Sold Online. Here's How To Check If You're Buying A Real One

Publication date	2021-08-11
Create date	2021-08-19
Score	10.96
Report id	1172925
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Fake Oximeters Are Being Sold Online. Here's How To Check If You're Buying A Real One SAYS

Click here to see the Original Article

Table 10: Places for report 1172925

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
South-Eastern Asia	Malaysia	Malaysia	2.5	112.5
Eastern Asia	Taiwan	Taiwan	24	121
		Earth	0	0

Notes: [...] In a news segment by Formosa TV, a Taiwanese customer found that the pulse oximeter he bought online was able to give him a reading after testing it on a stuffed toy.

India Today reported that consumers in India have also found oximeters that could obtain readings from other inanimate objects such as pens and toothbrushes. [...]

7 Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC

Publication date 2021-08-21

Create date 2021-08-25

Score 8.54

Report id 1186319

Category Medical devices for disease prevention, Respiratory diseases medicine, Medical device for screening/diagnosis/monitoring, Other

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Police arrest man in crackdown on production, trading of fake Covid-19 treatment drugs in HCMC sggpnews

Click here to see the Original Article

Table 11: Places for report 1186319

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Viet Nam	Ho Chi Minh City	10.82302	106.62965
South-Eastern Asia	Viet Nam	Bình Tân District	10.13489	105.75968
South-Eastern Asia	Viet Nam	Tân Phú District	11.39867	107.39976

Table 12: Drugs for report 1186319

Medicine Name	Medicine Class	Action	ATC Code
codeine	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA04

Notes: [...] On August 20, Thuan was seen carry a suspicious carton containing fake new drugs, so police officers stopped him to check; thereby, 150 boxes of Covid-19 treatment pills with the brand name Terpincodein were found out. At the police station, Thuan confessed that it was a

fake drug because Thuan bought the raw materials then produced and sold them to the market to make a profit. [...] According to the department, these cases are very worrisome amid the ongoing complicated development of the Covid-19 epidemic. Even, several businesses trading in medical equipment have showed signs of selling medical items without clear indications of origin. For example, in mid-August, the market management teams continuously detected and seized thousands of 3M masks, SARS-CoV-2 rapid test kits, oxygen ventilators without a clear indication of origin at warehouses in districts Binh Tan and Tan Phu. The owner of the items said that most of them will be provided to buyers via social networks, a few of them will be sold in stores. [...]

8 ED raids on fake Covid-19 vaccines case at different locations in Kolkata

Publication date	2021-09-01
Create date	2021-09-03
Score	7.03
Report id	1200629
Category	Antiviral others, Other
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: ED raids on fake Covid-19 vaccines case at different locations in Kolkata United News of India

Click here to see the Original Article

Table 13: Places for report 1200629

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

Table 14: Drugs for report 1200629

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Table 15: Other Stories

ID	Title	Link
1200705	ED raids on fake Covid-19 vaccines case at different locations in Kolkata - Goa Chronicle	Link
1204451	Fake Vaccination Case: ED raid 10 hideouts simultaneously in Kolkata, links suspected to TMC leaders	Link

Notes: (Related to ID 1110971) – Kolkata, Sep 1 (UNI) The Enforcement Directorate (ED) on

Wednesday raided the residence of Debanjan Deb, the prime accused of fake vaccine case and different locations of his associates in the city. [...] Deb, who is now arrested by the Kolkata police for running a fake vaccines camp with a premium price of up to Rs 25,000 at Kasba in south Kolkata posing himself as an IAS official with the state government. Besides the fake vaccine camp, Deb was also allegedly involved in black marketing of oxygen, and remdesivir and other Covid-19 related medical equipment with high prices. [...]

9 Fake vaccine scam: ED raids in Kolkata

Publication date 2021-09-01

Create date

Score 6.86

Report id 1199863

Category Antiviral others, Other

Quality Diverted/Unregistered

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Fake vaccine scam: ED raids in Kolkata News Today

Click here to see the Original Article

Table 16: Places for report 1199863

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kolkata	22.56263	88.36304
Southern Asia	India	Chennai	13.08784	80.27847

Table 17: Drugs for report 1199863

Medicine Name	Medicine Class	Action	ATC Code
oxygen	Medical gases	all other therapeutic products	V03AN01

Notes: