Medical Product Quality Report – COVID-19 Issues

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UNIVERSITY OF OXFORD

IDDO INFECTIOUS DISEASES DATA OBSERVATORY

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1. Summary of findings

This year we first saw a wave of substandard and falsified (SF) COVID diagnostics together with a rising number of problems linked to personal protective equipment. From June to August there was a growing number of articles linked to SF hand sanitizers but that has reduced from September mainly due to a lower number of incidents identified in the United States. In October the MQM Globe yielded the lowest number of new articles linked to SF COVID-19 supplies since February.

There have been several recent alerts on SF hand sanitizers in Canada whose list of recalls is growing. We have also seen a decrease in number of incidents linked to SF personal protective equipment, especially for masks.

Although there are very encouraging reports of three COVID-19 vaccines trials, no vaccine has fully completed all three phases of the clinical trial process. However, falsified versions are allegedly circulating in Brazil, the United States of America (USA) and in Myanmar. For October the MQM Globe did not yield reports on SF corticosteroids and dexamethasone in particular, the only proven effective treatment against severe COVID-19. Remdesivir has no or little effect[1], nevertheless people are making profit out of it on the black market. Although Eli Lilly & Co is developing a Covid-19 antibody therapy, the US Food and Drug Administration found serious quality-control problems at one of their production plants.

Although we captured fewer articles on SF COVID-19 products in October, monitoring and data sharing remain key as patients health remains at risk in low, middle and high income countries. Since the beginning of the pandemic, we identified incidents worldwide (figure 1) and all levels of the supply chain seem to have been affected. Focus should be on optimizing risk-based post-marketing surveillance to prevent, detect and respond to SF COVID-19 medical products. An objective evidence base is needed to plan risk-based post market surveillance for COVID-19 vaccines for when they are approved and distributed.

[1] WHO. Solidarity clinical trial for COVID-19 treatments. Published October 15, 2020. Accessed November 20, 2020. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

Figure 1. Incidents on poor quality medicines and medical products from January to October 2020 linked to COVID-19. This image was generated with the Medicine Quality Monitoring Globe using COVID-19 (and synonyms) as search terms . It includes incidents identified by the system in English, French, Vietnamese, Mandarin and Spanish languages.
The data are geographically heterogeneous and an important caveat is that no/few news or reports from a country or area does not imply that medical product quality there is good but that there are no/few accessible data from that country or area, or that articles were not published in the languages included in our system. Similarly, many news and reports of poor quality medical products in a country does not imply that medical product quality there is universally grave in comparison to elsewhere. Countries with many news reports should be lauded for facilitating such reporting. Only English articles are described in the monthly COVID-19 issues.

2. Introduction

During the COVID-19 pandemic, the demand for COVID-19 related medical supplies has inevitably ballooned with an increased demand for personal protective equipment (PPE), diagnostics and preventive & curative pharmaceuticals. The high demand and related shortages of genuine products contributes to an increased global risk of substandard and falsified (SF) medical products, for COVID-19 and for many other essential medicines. The media have been reporting diverse examples of SF products flooding the market.

This monthly report aims to collate information and reports in the public domain on the quality of medicinal products that are currently in use, or that are being trialled for COVID-19's prevention or treatment. We also include reports on key subjects such as access, affordability or off label use for COVID-19 if they mention concern of the quality of the products. We do not aim to include discussion of the multiple fraudulent claims and quackery.

We use the terminology for different types of poor quality medical products as defined by the World Health Organisation (WHO, 2017)[2]:

[2]Source: World Health Organisation. Appendix 3 WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS WORKING DEFINITIONS. In: *Seventieth World Health Assembly*. ; 2017. Accessed August 14, 2020. https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

- **Substandard medical products**
  Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- **Unregistered/unlicensed medical products**
  Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
- **Falsified medical products**
  Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

We emphasise the difference between the use of the terms ‘falsified’ and ‘counterfeit’ medical products. ‘Falsified’ is a broad term including all the various types of deliberate misrepresentation of a medical product from a public health perspective. The term ‘counterfeit’ is specifically linked to intellectual property rights, ‘trademark counterfeit goods’[3] and ‘pirated copyright goods’[4] as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The reports presented were mostly extracted from the Medicines Quality Monitoring Globe (the MQM Globe is accessible on the IDDO website[5]), a system that scrapes online newspapers (referenced in Google News) for early warnings of substandard and falsified medical products. In addition, alerts and reports by national and international organisations are included when captured by the members of the team or shared by colleagues. This report also includes scientific literature and policy documents related to COVID-19 medical products quality identified by manual searches in PubMed and Google Scholar. These will be displayed on the Medicine Quality COVID-19 Surveyor to be released in the coming months. We also include preprint of articles. Please note that preprints should be viewed with additional caution as they have not been peer-reviewed. They should not be relied on to guide clinical practice or health-related behaviour and should not be reported in news media as established information.

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[3] *Trademark counterfeit goods*: any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.
Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed August 14, 2020. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

[4] *Pirated copyright goods*: any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production, and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.
Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed August 14, 2020. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

[5] Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. https://www.iddo.org/medicine-quality-monitoring-globe

Please note the caveats for the lay literature (MQM Globe disclaimer and caveats are accessible on the IDDO website[6]); we include abstracts and extracts from articles that are subject to a take down policy. If we are contacted by a potential rights-holder who objects to the presence of material, we will remove the material in question from the report and Globe until we have been able to assess the case. Where material is removed for valid reasons of copyright, its removal will be considered as lasting until copyright in the material expires, or until the rights-holder agrees that the material can be reinstated.

This fifth issue of the monthly report 'Medical Product Quality Report – COVID-19 Issues' covers information published during the month of October. The previous issues covered publications from January 1st to September 30th 2020 and are available on the IDDO website[7]. We also include publications and reports published prior to October 2020 that were missed in the previous issues of the report. We are developing a system for scraping regulatory authority and international organisation websites for alerts. Any remarks or additions to content are greatly appreciated (please write to medicinequality@iddo.org).

3. Scientific literature

3.1. General

Badnjević A, Pokvić LG, Džemić Z, Bečić F. **Risks of emergency use authorizations for medical products during outbreak situations: a COVID-19 case study.** *Biomed Eng Online*. 2020;19(1):75. doi:10.1186/s12938-020-00820-0

> Abstract. *« (*)Background. The world is facing an unprecedented outbreak affecting all aspects of human lives which is caused by the COVID-19 pandemic. Due to the virus novelty, healthcare systems are challenged by a high rate of patients and the shortage of medical products. To address an increased need for essential medical products, national authorities, worldwide, made various legislative concessions. This has led to essential medical products being produced by automotive, textile and other companies from various industries and approved under the emergency use authorizations or legal concessions of national regulatory bodies. This paper presents a narrative commentary of the available documentation on emergency use authorizations and legal concessions for medical products during COVID-19 pandemic.*
> *(*)Methodology. The basis for narrative commentary includes scientific articles published in Web of Science, Scopus, PubMed and Embase databases, official publications of international organizations: Food and Drug Agency, World Health Organisation, World Bank and United Nations, and national regulatory agency reports in native languages (English, German, Bosnian, and Croatian) published from November 1, 2019 to May 1, 2020. This paper focuses on three types of essential medical products: mechanical ventilators, personal protective equipment and diagnostic tests. Evidence-informed commentary of available data and potential identified risks of emergency use authorizations and legal concessions is presented.*
> *(*)Discussion. It is recognized that now more than ever, raising global awareness and knowledge about the importance of respecting the essential requirements is needed to guarantee the*

[6]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 19, 2020. https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats

[7]Infectious Diseases Data Observatory. Medical Product Quality Reports. News. Published 2020. Accessed October 10, 2020. https://www.iddo.org/mq/research/medical-product-quality-report

appropriate quality, performance and safety of medical products, especially during outbreak situation, such as the COVID-19 pandemic. Emergency use authorizations for production, import and approval of medical products should be strictly specified and clearly targeted from case to case and should not be general or universal for all medical products, because all of them are associated with different risk level.
(*)Conclusion. Presented considerations and experiences should be taken as a guide for all possible future outbreak situations to prevent improvised reactions of national regulatory bodies. »

Islam MT, Talukder AK, Siddiqui MN, Islam T. **Tackling the COVID-19 pandemic: the Bangladesh perspective.** *J Public health Res*. 2020;9(4):1794. doi:10.4081/jphr.2020.1794

Extract from the paper. *« Lack of safety equipment. There is inadequate supply of personal protection equipment (PPE), standard masks, and hand gloves to the health service providers, which is one of the major constraints in providing treatment facilities. A significant lack of safety equipment is fueling the concern for frontline health service providers like doctors and nurses. Some corrupt officials of health ministry were involved in importing low quality protective equipments. Some factories were also involved in producing cheap and poor quality antiseptic liquids, face masks, hand gloves and PPE all over Bangladesh. These low quality healthcare products are now posing great risk to public health amid the ongoing pandemic COVID-19. A large number of doctors, nurses, and persons of law enforcing agencies have already diagnosed as COVID-19 patients in the country. Of note, until August 11, 2020, approximately 92 doctors have been died of this disease in Bangladesh. Collectively, the limitation of PPE and inadequate test facilities of real-time RT-PCR are the big challenges for Bangladesh. The government has to make available more test facilities and import high quality of these protective gears immediately. »*

Jairoun AA, Al-Hemyari SS, Shahwan M, El-Dahiyat F, Jamshed S. **Scale validation for the identification of falsified hand sanitizer: public and regulatory authorities perspectives from United Arab Emirates.** *BMC Public Health*. 2020;20(1):1595. doi:10.1186/s12889-020-09707-0

Abstract. *« (*)Background. Since the time of declaration of global pandemic of COVID-19 by World Health Organization (WHO), falsified hand sanitizers surfaced regularly in markets, posing possible harm to public due to unlisted inclusion of methanol. The current research is an attempt to develop and validate a tool to document falsified hand sanitizer in the UAE community.*
(*)Method. A descriptive cross-sectional community-based study was conducted among 1280 randomly selected participants. Respondents were sent a web-based electronic link to the survey via email. Content validity, factor analyses and known group validity were used to develop and validate a new scale to identify falsified hand sanitizer. Test-retest reliability, internal consistency, item internal consistency (IIC), and intraclass correlation coefficients (ICCs) were used to assess the reliability of the scale. SPSS version 24 was used to conduct data analysis.
(*)Results. A total of 1280 participants were enrolled in the study. The content validity index (CVI) was 0.83 with the final scale of 12 items. The Kaiser-Meyer-Olkin (KMO) value was 0.788, with the Bartlett test of sphericity achieving statistical significance ($p < 0.001$). Our factor analysis revealed a 3-component model. The 3-factor solution was confirmed by PCFA analysis and had associations with good fit values. The PCFA for NFI was 0.970, CFI 0.978, and TLI 0.967. All values were in excess of 0.95, with RMSEA values below 0.06 at 0.03; all of these values indicated a good model fit. The Cronbach's alpha was good overall (0.867). All factors had a Cronbach's alpha value in excess of 0.70. The instrument demonstrated that every item met the IIC correlation standard ≥0.40. The scale displayed good overall ICC statistics of 0.867 (95% CI 0.856–0.877) with statistical significance ($p < 0.001$). The scale's test-retest reliability was assessed through correlation of the falsified hand sanitizer identification score of respondents at the two time points. The test-retest correlation coefficient was 0.770 (p value < 0.01). Participants with post-graduate education were more likely to identify the falsified hand sanitizer compared to

those with high school education. (p < 0.001).
(*)Conclusions. This study developed and validated a new scale for the measurement of falsified hand sanitizer. This is expected to improve and promote collaboration between the health regulators and the public and hereby encourage customer satisfaction and participation. »

Mukherjee S, Bonatsos V, Raza A. **The Urologist, Personal Protective Equipment (PPE) and COVID-19.** *J Endoluminal Endourol*. 2020;3(4):e1-e14. doi:10.22374/jeleu.v3i4.104

Extract from the paper. *« Substandard or poor-quality PPE. As well as shortages of PPE there have been reports of poor-quality PPE supplies that do not meet safety standards putting both patients and HCW's lives at risk of contracting COVID-19 infection. The Health and Safety Executive (HSE) has issued a safety alert against the use of KN95 facemasks as there is no independent assurance of their quality and it has been confirmed by testing that they do not meet safety standards. HSE has recalled around 1.5 million KN95 masks and halted around 25 million items of inappropriate FFP3 respirators entering the supply chain. There was also a surge in homemade and non-medical companies providing PPE to the NHS free of charge i.e. homemade visors; however, such equipment should not be used unless it has been approved by HSE or the local NHS Trust for safe use. The British Medical Association Guidance states that if adequate amounts of properly tested PPE are not available this matter should be raised with the local trust and HCWs can refuse to treat patients if staff PPE is deemed to be unsafe or inappropriate. »*

Nigro F, Tavares M, Sato de Souza de Bustamante Monteiro M, et al. **Changes in workflow to a University Pharmacy to facilitate compounding and distribution of antiseptics for use against COVID-19.** *Res Soc Adm Pharm*. Published online 2020. doi:10.1016/j.sapharm.2020.09.016

Abstract. « *This article is a report from an experience about a work developed by Farmácia Universitária at UFRJ (FU-UFRJ) during the nCov-19 pandemic period. The aim of this work was to describe its contribution in the production of antiseptic supplies used to prevent contagion by the new coronavirus. The work routine at the pharmacy has been changed to allow the implementation of local workflow during the pandemic, and to adapt the protection rules to meet the safety measures. FU-UFRJ started to manipulate two antiseptic formulations: 70% ethyl alcohol and gel alcohol, which are included in the National Form, manufacturing around 100 L of these formulations, weekly, to donate to different health units. The experience enabled the adaptation to emergency health standards, planning and meaningful guidance to pharmacists and technicians to attend clinics at university hospitals, vaccination center and UFRJ city hall, in order to facilitate the access to adequate hand hygiene to the population.* »

Ogunleye OO, Basu D, Mueller D, et al. **Response to the Novel Corona Virus (COVID-19) Pandemic Across Africa: Successes, Challenges, and Implications for the Future.** *Front Pharmacol*. 2020;11. doi:10.3389/fphar.2020.01205

Abstract. « *(*)Background. The COVID-19 pandemic has already claimed considerable lives. There are major concerns in Africa due to existing high prevalence rates for both infectious and non-infectious diseases and limited resources in terms of personnel, beds and equipment. Alongside this, concerns that lockdown and other measures will have on prevention and management of other infectious diseases and non-communicable diseases (NCDs). NCDs are an increasing issue with rising morbidity and mortality rates. The World Health Organization (WHO) warns that a lack of nets and treatment could result in up to 18 million additional cases of malaria and up to 30,000 additional deaths in sub-Saharan Africa.*
(*)Objective. Document current prevalence and mortality rates from COVID-19 alongside economic and other measures to reduce its spread and impact across Africa. In addition, suggested ways forward among all key stakeholder groups.
(*)Our Approach. Contextualise the findings from a wide range of publications including internet-based publications coupled with input from senior-level personnel.

(*)Ongoing Activities. Prevalence and mortality rates are currently lower in Africa than among several Western countries and the USA. This could be due to a number of factors including early instigation of lockdown and border closures, the younger age of the population, lack of robust reporting systems and as yet unidentified genetic and other factors. Innovation is accelerating to address concerns with available equipment. There are ongoing steps to address the level of misinformation and its consequences including fines. There are also ongoing initiatives across Africa to start addressing the unintended consequences of COVID-19 activities including lockdown measures and their impact on NCDs including the likely rise in mental health disorders, exacerbated by increasing stigma associated with COVID-19. Strategies include extending prescription lengths, telemedicine and encouraging vaccination. However, these need to be accelerated to prevent increased morbidity and mortality.
(*)Conclusion. There are multiple activities across Africa to reduce the spread of COVID-19 and address misinformation, which can have catastrophic consequences, assisted by the WHO and others, which appear to be working in a number of countries. Research is ongoing to clarify the unintended consequences given ongoing concerns to guide future activities. Countries are learning from each other. »

3.2. Seizures/Surveys/Case Reports/Reviews

Berardi A, Cenci-Goga B, Grispoldi L, Cossignani L, Perinelli DR. **Analysis of Commercial Hand Sanitisers amid CoViD-19: Are We Getting the Products that We Need?** *AAPS PharmSciTech*. 2020;21(7):1-6. doi:10.1208/s12249-020-01818-6

Abstract. *« The CoViD-19 pandemic has caused a sudden spike in demand and production of hand sanitisers. Concerns are rising regarding the quality of such products, as the safeguard of consumers is a priority worldwide. We analyse here the ethanolic content of seven off-the-shelf hand sanitiser gels (two biocides and five cosmetics) from the Italian market, using gas chromatography. The WHO recommends that products containing ethanol should have 60–95% (v/v) alcohol. Four of the tested hand gels have ethanolic contents within the recommended range, while three products (all cosmetics) contain < 60% (v/v), i.e. 52.1% (w/w), ethanol. The product with the lowest alcoholic content has 37.1% w/w ethanol. Toxic methanol is not found in any of the hand sanitisers. We show, in addition, that products with the highest ethanolic content have generally greater antibacterial activity. In conclusion, all tested products are complying with the EU regulations, as the three "substandard" products are classified as cosmetics, whose purpose is cleaning and not disinfecting. Nevertheless, if such hand cleaners were inappropriately used as hand disinfectants, they might be ineffective. Thus, consumer safety relays on awareness and ability to distinguish between biocidal and cosmetics hand gels. The obtained results might sensitise the scientific community, health agencies and ultimately consumers towards the risks of using hand sanitisers of substandard alcoholic concentration. If the wrong product is chosen by consumers, public health can be compromised by the inappropriate use of "low-dosed" cosmetic gels as disinfectants, particularly during the period of the CoViD-19 pandemic. »*

Brochot C, Saidi MN, Bahloul A. **How Effective Is the Filtration of 'KN95' Filtering Facepiece Respirators During the COVID-19 Pandemic?** *Ann Work Expo Heal*. 2020;2020:1-9. doi:10.1093/annweh/wxaa101

Abstract. *« (*)Objectives. The high demand of filtering facepiece respirators (FFRs) worldwide during the period of the COVID-19 pandemic has led to a critical situation for decision-makers regarding their supply. After authorizing the use of FFRs certified by other regions of the world, decision-makers in many countries have published alerts, particularly concerning the 'KN95' type. (*)Methods. This paper investigated the filtration performance of different FFRs using an experimental setup already employed during several studies on FFRs filtration performance. Its high-resolution measuring devices permit to determine filtration performance according to the normative criteria: the pressure drop and the filtration efficiency. Eight different FFRs have been used: four NIOSH-approved FFRs and four not NIOSH-approved with a 'KN95' shape available*

during the beginning of the COVID-19 pandemic.
(*)Results. The data show a high disparity between different FFRs purchased by healthcare establishments, and between those that are NIOSH-approved and those that are not NIOSH-approved. The results confirm that the NIOSH certification offers good protection according to the normative criteria. The 'KN95' types present pressure drops which correspond to the normative value, however their efficiencies are lower than the efficiencies of FFRs certified by NIOSH and lower than 95% at the most penetrate particle size.
(*)Conclusions. FFRs marking is not sufficient to conclude on the FFRs' efficiency. Visual inspection cannot determine which samples are counterfeit or have manufacturing defects. »

Eboibi FE. **Cybercriminals and Coronavirus cybercrimes in Nigeria, the United States of America and the United Kingdom: cyber hygiene and preventive enforcement measures.** *Commonw Law Bull*. Published online 2020. doi:10.1080/03050718.2020.1834424

Abstract. *« There seems to be no lockdown for cybercriminals who are capitalizing on the global lockdown to perpetrate cyber coronavirus crimes. Qualitatively, this paper examines these crimes, their peculiarities, and how they can be curtailed. Although the United States of America (US) and the United Kingdom (UK) have put in place cyber hygiene and preventive enforcement measures to curtail the activities of cybercriminals in cyberspace, the same cannot be said of Nigeria. Arguably, cybercrime institutions in Nigeria lack adequate capacity building, professional competence, and inter-agency cooperation concerning cyber coronavirus crimes. Consequently, it calls for the adaptation of the US and UK measures to protect cybercitizens. »*

4. International organisations

UNODC. **Good Practices Compendium on Combating Corruption in the Response to COVID-19.** 2020. Accessed November 20, 2020. https://www.unodc.org/pdf/corruption/G20_Compendium_COVID-19_FINAL.pdf

Executive summary. *« The rapid spread of the COVID-19 pandemic and its ensuing consequences have affected almost every aspect of society and created opportunities for corruption to thrive and grow, as actions taken to quickly address the needs presented by the crisis may lead to sacrifices in transparency and accountability. Corruption risks have proliferated across a variety of fields threatening life-saving aid and further hurting the most marginalized and vulnerable populations. In response to these growing threats, the G20 Anti-Corruption Working Group (ACWG) sought to identify key anti-corruption practices undertaken by G20 countries to address COVID-19. A survey was disseminated to all G20 countries in July 2020 to better understand the new and existing anti-corruption threats and countermeasures used to respond to the crisis and share experiences to inform global policy and strengthen international cooperation. 22 countries responded, with many using similar strategies and techniques to address common corruption risks arising from or exacerbated by COVID-19, with unique manifestations depending on national contexts and priorities. »*

Extract from the text. *« The number of G20 countries that identified certain corruption risks emanating from the COVID-19 crisis. Nine countries indicated risks pertaining to cyberfraud which include the utilization of new Information and Communication Technologies and cyber-scams. 13 countries reported increased corruption vulnerabilities in the exploitation of stimulus packages including dedicated employment furlough schemes and other economic aid. 15 countries identified heightened health-related fraud which includes risks emanating from counterfeit medicines, overpriced medical equipment, health procurement collusion, among others. It is worth noting that these risks were also identical to the new and emerging risks identified by G20 countries. »*

UNODC. **Research Brief: The Impact of COVID-19 on Organized Crime.** 2020. Accessed November 20, 2020. https://www.unodc.org/documents/data-and-analysis/covid/RB_COVID_organized_crime_july13_web.pdf

Extract from the text. *« The aim of this research brief is to present an abbreviated assessment of the growing impact of the COVID-19 pandemic on OCGs' [organized criminal groups] infiltration of the legal economy and their illegal governance activities. »*

« High demand coupled with low supply in key sectors opens way for OCGs. The pandemic has brought dramatic spikes in demand to some sectors, for example medical devices, pharmaceutical products, e-commerce, food retail, cleaning, and funeral services. The demand for sanitary masks, breathing devices, and medicines has also risen notably. As governments seek to shore up their defences against the pandemic, procurement procedures in some countries have been relaxed. There is already evidence from countries around the world that organized crime has moved into these sectors – especially where traditional means of making illicit profits, such as illicit drugs and firearms trafficking and smuggling of migrants are being tightly constricted by restrictions on movement. For The impact of covid-19 on organized crime 2 example, falsified medical masks have been seized in Spain and Italy, attempts to smuggle vital equipment have been stopped in Ukraine, Iran, and Azerbaijan; one Mexican cartel has been promoting the production of falsified COVID-19 medical products and forcing pharmacies to sell them. »

UNODC. **Research Brief: COVID-19 and the Drug Supply Chain: From Production and Trafficking to Use.** 2020. Accessed November 20, 2020. https://www.unodc.org/documents/data-and-analysis/covid/Covid-19-and-drug-supply-chain-Mai2020.pdf

Extract from the text. *« The aim of this research brief is to present a rapid assessment of the impact of the COVID-19 pandemic on the drug supply chain, from drug production and trafficking to consumption. »*

« Organized criminal groups react adaptively to market changes. Past experience has demonstrated the capacity of such groups to rapidly adapt their modus operandi or switch market in response to shocks or new opportunities. For example, following a poppy blight in Afghanistan in 2010 and concurrent political developments, cannabis was increasingly produced in the country and international drug trafficking groups increased trafficking in cannabis products from Afghanistan to Europe. In the past, in some parts of Peru, coca cultivation was scaled back concurrently with an increase in illicit mining in response to increases in the price of gold. The rapid adaptation of organized criminal groups to new environments has already been reported in some Balkan countries where certain organized criminal groups involved in drug trafficking are moving into forms of crime linked to the COVID-19 virus, such as cybercrime and trafficking in falsified medicines. »

5. Miscellaneous

Publications prior to October 2020

NABP. **Rogue Online Pharmacies in the Time of Pandemic: Capitalizing on Misinformation and Fear.** 2020. Accessed November 13, 2020. https://nabp.pharmacy/wp-content/uploads/2020/05/Rogue-Rx-Activity-Report-May-2020.pdf

> Extract from the text. « *In an effort to protect vulnerable consumers, government agencies are cracking down on COVID-related cybercrime. NABP applauds these efforts. Regulators, members of Congress, and state attorneys general are also asking the private sector for assistance. Many internet intermediaries have stepped up to the plate, shutting down fraudulent face mask, vaccine, and test kit sellers. However, illegal internet "pharmacies" continue, largely unabated, to peddle falsified, substandard, and dangerous drugs, including purported treatments for COVID-19. This behavior is predictable; these bad actors have been around for over 20 years. We can – and must – stop it now.* »

6. Lay literature

6.1 Disclaimer & Notes

The information included below is based on the data used to create the Medicine Quality Monitoring Globe[8] (MQM Globe). It contains publicly available information on the quality of medical products from non-peer-reviewed lay literature. We report the information as it is stated in the articles and can thus be biased towards the authors perspective. It does not necessarily reflect our vision or judgment on the issue. Also, this information usually will not have scientific confirmation. Therefore, the information needs to be interpreted with the greatest caution. We regard the reports as early warnings of potential problems. No or few articles from a region does not imply that the medical product quality there is good, but probably reflects a lack of accessible information. Full disclaimer and caveats can be found at MQM Globe disclaimer and caveats[9].

The Google News search tool is used to capture data from online news sources. Articles matching the search terms are loaded into a database and curated by trained analysts. Because the Globe system extracts newspaper articles from journals referenced in Google News only, reports not referenced in Google News would not be captured. Please consult the IDDO website for full methodology[10]. On the 20th of March, the search terms were adapted to capture more papers on substandard and falsified (SF) medical supplies for COVID-19 from Google News.

The news articles discussed in the sections below are available in the Globe-reports, in this report's annexes, or on the online MQM Globe using the report ID (six digits code). The MQM Globe-reports are generated with pre-defined search terms, which enable quick access to reports of (a) COVID vaccines, (b) COVID diagnostics, (c) Personal Protective Equipment (PPE), (d) Sanitisers and disinfectants, (e) COVID medicines, and (f) Ventilators and Positive end-expiratory pressure. For alerts from January to September the Globe-report for PPE included sanitisers and disinfectants. From October onwards sanitisers and disinfectants are grouped in a separate Globe-report. The search terms applied to search the Globe database to compile the Globe-reports were revised in October. Therefore caution is required when interpreting the number of alerts or articles over time.

In this report we share articles captured by the MQM Globe that are linked to medical products potentially used in the context of COVID-19 or to active pharmaceutical ingredients (APIs) that are being trialled for COVID-19 treatment and/or prevention. In theory there is a distinction between (a) SF incidents that are due to or increased by the COVID-19 epidemic; and (b) incidents that would have happened in any case. It can be difficult to make the distinction between the two types of incidents and some

[8]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. https://www.iddo.org/medicine-quality-monitoring-globe

[9] Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 19, 2020. https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats

[10]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed October 19, 2020. https://www.iddo.org/medicine-quality-monitoring-globe-methodology

reports cited below are not directly linked to the treatment of COVID-19. Nevertheless we have included them as crossover risks and to assess the evolution of the alerts on these medical products over time. Although oxycodone is trialled[11], we do not include issues related to oxycodone as the system would become swamped by reports on its inappropriate use and cases of pills laced with fentanyl due to its wide occurrence on the black market.

For this report, we only included data that were published in English. For articles in French, Spanish, Mandarin, and Vietnamese; please consult the online MQM Globe. We will continuously work to improve the MQM Globe and plan to add in articles in other languages to this report. Any remarks or additions to content are encouraged (please write to medicinequality@iddo.org).

6.2 Articles on substandard or falsified medical products for COVID-19: main characteristics

Since the beginning of the pandemic we have identified over 414 relevant articles on quality problems of COVID-19 medical products (see table 1). For October we report on 35 articles linked to SF COVID-19 supplies alerted through the MQM Globe database. Within those articles, 3 alerted on falsified vaccines, 4 on diagnostics, 12 are linked to personal protective equipment (PPE), 7 to hand sanitisers and disinfectants, and 16 report on COVID-19 related treatments (see figure 2 and 3). Since June, the MQM Globe did not identify any report linked to ventilation equipment.

Table 1. Number of articles on the Medicines Quality Monitoring Globe linked to substandard or falsified COVID-19 supplies by month. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH AS SHOWN IN FIGURE 2 AND 3 MAY EXCEED THE SUM OF ARTICLES PER MONTH OF TABLE 1.

Month	Number of articles
January	2
February	10
March	49
April	50
May	47
June	64
July	42
August	62
September	53
October	**35**

[11]Hashemian SRM. Evaluation the effects of Oxycodone administration on pain control in patients with COVID-19. Iranian Registry of Clinical Trials. Published June 8, 2020. Accessed October 9, 2020. https://en.irct.ir/trial/48534

In the beginning of October an article reported on several seizures performed by the US Customs and Border Protection (US CBP) throughout the Mid-Atlantic region in the United States of America (USA) in the 6 previous weeks including falsified masks, COVID-19 related medication, and COVID-19 test kits (report ID 757518). In the end of October an FDA official released the results of operation called “Quack Hack”, launched in March (report ID 786684). The aim to proactively identify threats to consumers linked to COVID-19 related products led to 120 US FDA warning letters, 270 reports sent to online marketplaces and 225 complaints sent to domain registrars. The US FDA identified more than 1100 fraudulent and unproven COVID-19 related medical products such as medicines, tests and PPE.

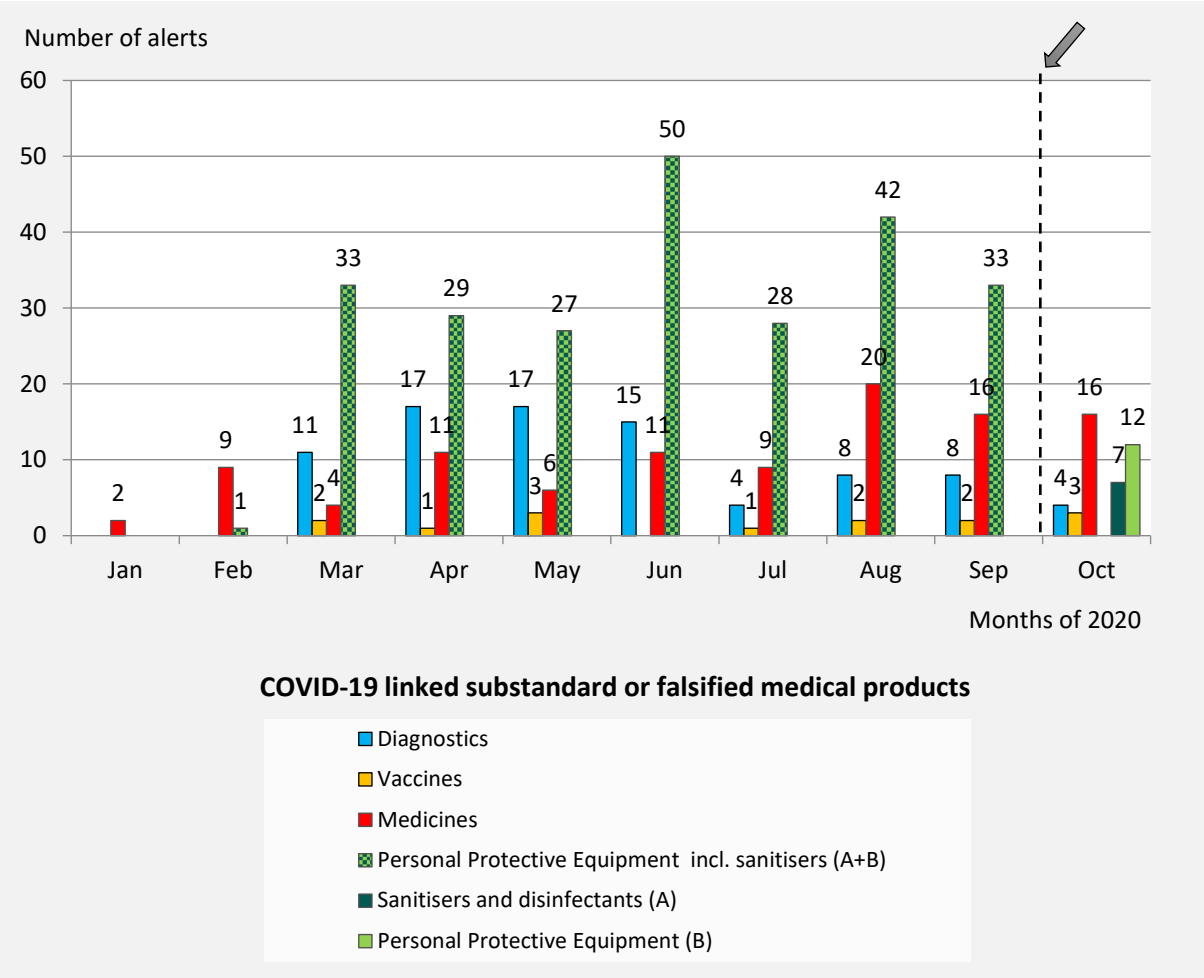

Figure 2. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month.

ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN TABLE 1.

THE ARROW INDICATES THE END OF SEPTEMBER WHEN THE CATEGORY OF “PERSONAL PROTECTIVE EQUIPMENT INCL. SANITISERS” WAS SPLIT IN TWO DISTINCT CATEGORIES: (A) SANITISERS AND DISINFECTANTS, AND (B) PERSONAL PROTECTIVE EQUIPMENT.

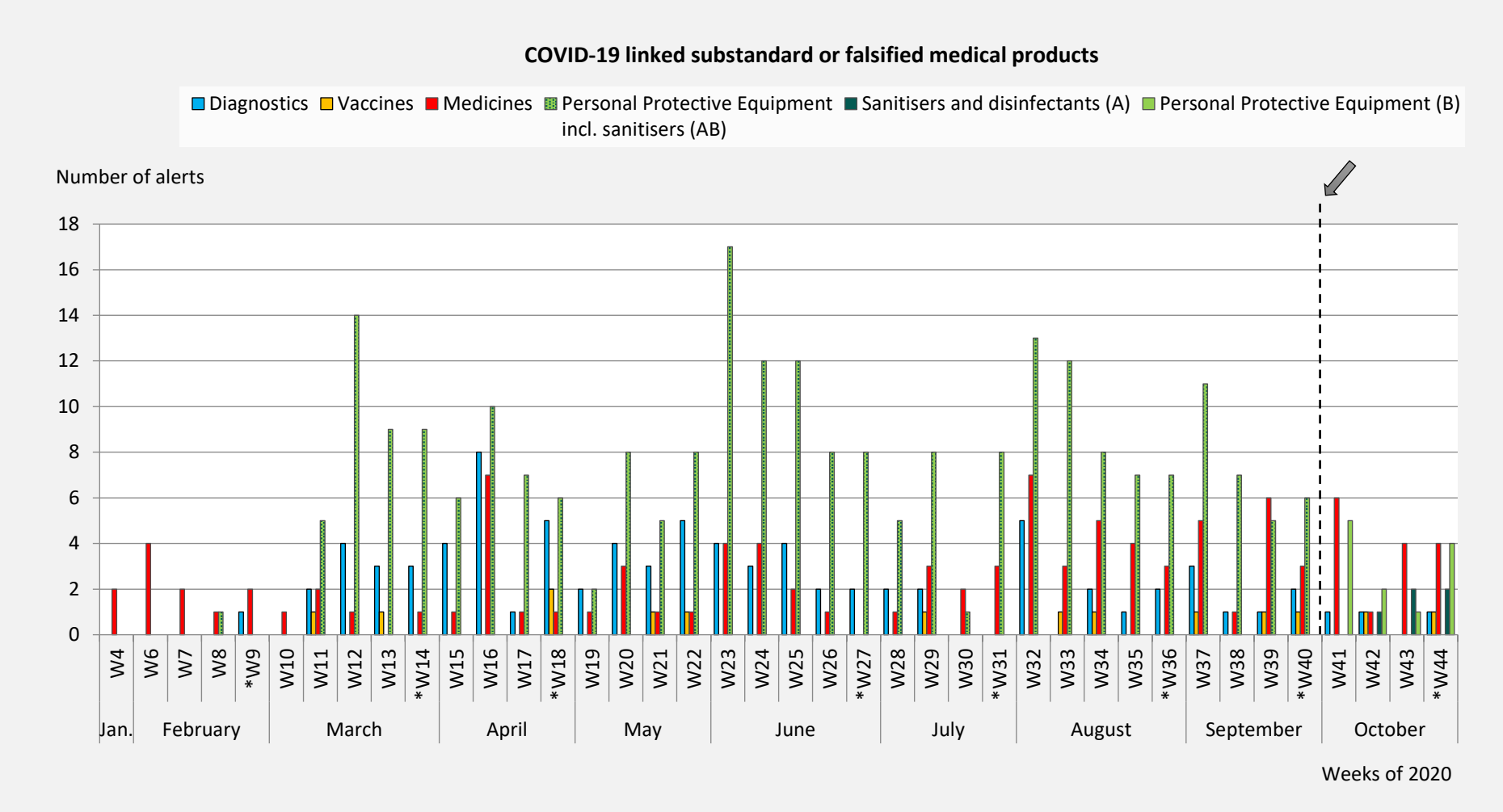

Figure 3. Number of alerts on the Medicines Quality Monitoring Globe by category and by week.

ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. WEEK 4 STARTS ON MONDAY 20TH OF JANUARY 2020 AND WEEK 44 ENDS ON WEDNESDAY 31TH OF OCTOBER 2020. WEEKS WITH AN ASTERISK ARE OVERLAPPING 2 MONTHS, EACH TIME THE WEEK IS ATTRIBUTED TO THE EARLIEST MONTH. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN TABLE 1. THE ARROW INDICATES THE END OF SEPTEMBER WHEN THE CATEGORY OF "PERSONAL PROTECTIVE EQUIPMENT INCL. SANITISERS" WAS SPLIT IN TWO DISTINCT CATEGORIES: (A) SANITISERS AND DISINFECTANTS, AND (B) PERSONAL PROTECTIVE EQUIPMENT.

6.3 Vaccines

No vaccine has fully completed all three phases of the clinical trial process. Both in Myanmar and in the USA, the Food and Drug Administrations warned the public for falsified COVID-19 vaccines (report ID 750450, 787356). In the USA the warning is mainly linked to online sales. In Myanmar "COVID-19 vaccines" are being smuggled into the country and sold online. Brazilian authorities report the sale of falsified COVID-19 vaccines in Rio de Janeiro state (report ID 764662). Those are allegedly sold as the vaccine developed by AstraZeneca and the University of Oxford.

6.4 COVID-19 diagnostics

Substandard antibody test kits were allegedly imported into Nigeria (report ID 765842). The tests did not meet the minimum acceptable criteria. The authorities warned to only use validated rapid and PCR test kits. In Myanmar COVID-19 tests allegedly coming from China are sold on Facebook (report ID 750450). Amongst other products, the US CBP of the Mid-Atlantic region seized several counterfeit or unapproved test kits in the past few weeks (report ID 757518).

6.5 Personal protective equipment

In the light of pandemic-related crimes, Taiwan authorities revealed that they have seized almost 260 million falsified masks so far (report ID 785855). In October an article reported on seizures performed by the US CBP throughout the Mid-Atlantic region in the 6 previous weeks including approximately 59,000 falsified masks during 21 seizures (report ID 757518). Two articles report on the Indian police performing raids at factories and performing seizures of 437 masks and 1,532 trademark symbols at one clandestine manufacturer (report ID 787164) and 5,000 falsified masks and printing equipment from another manufacturer (report ID 760491).

In shops in the United Kingdom "*basic masks*" were seized together with other falsified coronavirus protection products (report ID: 778246). The packaging stated that the masks were of KN95 standards. In the USA an investigation by 'Associated Press' and the PBS series "Frontline" found that falsified masks are available in the market in multiple sectors (report ID 758727). Analysis of 'a handful of different masks' at the University of North Carolina showed that "*All of it was counterfeit, as defined by OSHA's definition of counterfeit or fraudulently labelled"*, some showed less than 50% effectiveness. Falsified Makrite N95 respirators were unwillingly distributed to employees of a hospital group in Rhode Island, USA (report ID 768161). The group was alerted due to a lower performance of the fit-test of the respirators and their fear was confirmed by Makrite. During spring, the Estonian government bought FFP3 respirators from a Chinese company (report ID 758487). One hundred thousand respirators appeared to be of substandard quality.

Since the beginning of the pandemic several lawsuits related to masks have been filed in the USA. From October the MQM Globe yielded an article about a distributor of personal protective equipment suing two mask vendors allegedly importing defective KN95 medical masks from China (report ID 765212). The masks came with falsified FDA certification documents and for one the nose clips were glued-on, instead of sewn-in. The company 3M, works together with law enforcement agencies to act

against falsified 3M products (report ID 755069). In the last few months, 1,200 seizures and raids leading to falsified 3M N95 respirators were conducted worldwide. The article sums up some of the recent seizures of falsified N95 respirators: 150,000 N95 respirators in Vietnam, 600,000 in the United Arab Emirates, 100,000 in South Africa and 10,000 in Latin America. Another article reported on a seizure by Hong Kong authorities of 100,000 falsified 3M respirators that were destined to be sent abroad (report ID 788080).

6.6 Sanitisers and disinfectants

Health Canada launched several recalls of hand sanitizers. One example is the recall of a falsified version of 'Zytec Germ Buster Hand Sanitizer' (report ID 749766). The falsified version wears the same national registration number and the same lot number as the genuine product. However the black and white labelling on 1 litre bottles differed from the genuine product which has coloured labels on 3.78 litre bottles. Another example is the registered 'Daily Shield' hand sanitizer, which was recalled after a falsified version was found (report ID 772302). Both products had the same national registration number but a different lot number. Between June and the end of October Health Canada's list of recalled hand sanitizers grew to more than 100 products (report ID 786925, 779042). Sanitizers on the list do not contain the recommended amount of ethanol or contain denaturants which are not permitted such as methanol.

In the Medicine Quality COVID-19 Product Report for the month of July we included an article reporting on 4 deaths in the USA related to exposure to methanol-tainted hand sanitizers. At the beginning of October this number rose to 17 deaths (report ID 749267). In addition, the FDA received 2,000 reports of non-lethal injuries from exposure to hand sanitizers contaminated by methanol. The article further highlights that the US FDA has a Do-Not-Use-List to guide consumers and health care professionals on which hand sanitizers they should avoid for quality reasons. However the FDA does not have the authority to force recalls of hand sanitizers. FDA does send warning letters, asking manufacturers to issue recalls. Most manufacturers act upon the warning letter by launching manufacturer recalls for sanitizers with quality concerns, some however delay taking action. For imported products FDA can place import alerts on the concerned products (for example report ID 782839).

An article published in October highlights the problem of substandard and falsified hand sanitizers in South Africa and raises the concern that there is no regulatory system in place for these products they only rely on companies voluntary compliance with standards (report ID 774016). In this context, sometimes manufacturers falsely claim that their products are certified by the South African Bureau of Standards. An analysis performed in May on 11 hand sanitisers bought from retailers found that 2 products were contaminated with 1-propanol and 4 had a lower alcohol content than claimed on the packaging. The same article also refers to incidents of hand sanitisers with substandard levels of alcohol in the past months in Australia, Guyana, Kenya, Nigeria, Rwanda, United Arab Emirates and Zambia.

6.7 COVID-19 medicines

For October the MQM Globe does not hold reports on SF corticosteroids. We have found no alerts on falsified remdesivir so far but a recall was issued by the Pakistan Drug Regulatory Authority, for 'Redzi 100mg solution for injection' that did not comply with quality standards (report ID 779461). In India two men were arrested for the alleged black-marketing of 'Remdac 100mg injections' (report ID 755217). The US FDA sent out warning letters to 2 companies selling online chloroquine phosphate for veterinary use: one was selling an unapproved product and the other was selling an adulterated product (report ID 782898, 782899). The websites were not promoting the products for human use but nevertheless vigilance is needed as there are reports of people taking those chloroquine products against COVID-19 (report ID 787356).

Many other repurposed and investigational antiviral and immune-based COVID-19 therapies are being trialled[12]. In addition, patients turn to some medicines that are generally used for a cold, pain, fever or to boost the immunity. For all these medicines vigilance is needed considering the risk of substandard or falsified versions.

Acetyl salicylic acid: The US Drug Enforcement Administration saw a rise in seizures of illegal drugs in the past year. They warn for tablets with illicit drugs that are manufactured without quality control and might be disguised as baby aspirin (report ID 776012).

Antibody therapy: Eli Lilly & Co is developing a Covid-19 antibody therapy. During an inspection in August, the FDA found quality-control problems at the plant in New Jersey, USA. They talk about incidents that "*leave room for significant potential impact on product quality*" (report ID 774525).

Metformin[13]: Articles in the USA reported on substandard metformin containing N-nitrosodimethylamine (NDMA). Sun Pharma is the seventh manufacturer that recently launched a recall for metformin (report ID 757820). An article reports on Amneal Pharmaceuticals Inc being sued in federal court for producing and selling NDMA contaminated metformin (report ID: 757820).

Sildenafil: Falsified 'Viagra' has been seized by customs: 15,000 tablets in the USA coming from Turkey (report ID 756371) and 960 tablets with poor packaging in Puerto Rico (report ID 768254).

Miscellaneous: In the USA, a men sells fraudulent COVID-19 prevention treatments in his practice and on his Facebook page, federal authorities are trying to stop the sale (report ID 760484). Myanmar's FDA warns for illegally smuggled COVID-19 medicines in the market (report ID 750450). In the first nine months of 2020 the Counter-counterfeit committee in Cambodia performed at least 12 seizures involving COVID-19 medicines (report ID 775466).

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[12]Infectious Diseases Data Observatory. COVID-19 Clinical Trials Interactive tool. Published 2020. Accessed October 19, 2020. https://www.iddo.org/tool/COVID-19-clinical-trials-interactive-tool

[13] Prior issues of the Medical Product Quality Report do not include articles related to metformin. Now it is included in the search terms for the Globe-report on COVID-19 medicines since it is one of the multiple molecules that is trialed for its use in COVID-19.

7. Annexes

The annexes contain the reports generated by the MQM-Globe using pre-defined search terms. The report IDs (six digits code) discussed in section 6 ‘Lay literature’ are detailed in the annexes or available on the online MQM Globe[14], using the report ID in the search box.

7.1 Vaccines

7.2 COVID-19 diagnostics

7.3 Personal protective equipment

7.4 Sanitisers and disinfectants

7.5 COVID-19 medicines

[14]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. https://www.iddo.org/medicine-quality-monitoring-globe

Annex

7.1 Vaccines

Medicine Quality Monitoring Globe

November 23, 2020

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

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

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

Filters applied for this report

Search	("vaccine") AND ("CV19" OR "新冠病毒" OR "武汉新型冠状病毒" OR "非典" OR "SARS" OR "CoV-2" OR "vi rút corona" OR "武汉肺炎" OR "COVID-19" OR "COVID" OR "新冠疫情" OR "新型冠状病毒肺炎" OR "SARS-CoV-2" OR "CV" OR "Coronavirus" OR "CV-19" OR "SRAS" OR "新型冠状病毒" OR "新冠")
Start date	2020-10-01
End date	2020-10-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	3

1 Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines

Publication date	2020-10-02
Create date	2020-10-07
Score	18.46
Report id	750450
Category	Vaccine, Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines The Irrawaddy News Magazine

Click here to see the Original Article

Table 1: Places for report 750450

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

Table 2: Drugs for report 750450

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 3: Other Stories

ID	Title	Link
781680	Burma : Myanmar Health Agency warns that fake COVID-19 vaccines are in circulation - 2020-10-26	Link

Notes: Yangon — Myanmar's Food and Drug Administration (FDA) has warned the public against so-called COVID-19 vaccines being sold in the country. The government said it is taking steps to prevent the smuggling and sale of fake vaccines and pills, a director of the FDA,

who asked not to be named, told The Irrawaddy. "Not only vaccines but also pills have been illegally smuggled into the country and are being sold online. Those medicines are illegal," the director told The Irrawaddy. The Ministry of Health and Sports on Thursday said there has been no COVID-19 vaccine endorsed by the World Health Organization (WHO) and no supplier has completed the three-phase clinical trial process. On Facebook, retailers are selling COVID-19 tests for 20,000 kyats (US$15) and COVID-19 drugs, which they claim are made in China.[...] [Covid-19 treatment] [COVID-19 test kits, testing kits]

2 9:26 Sales of fake Covid-19 vaccine in Brazil reported

Publication date	2020-10-13
Create date	2020-10-14
Score	18.36
Report id	764662
Category	Vaccine
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: 9:26 Sales of fake Covid-19 vaccine in Brazil reported Prensa Latina

Click here to see the Original Article

Table 4: Places for report 764662

Region Name	Country	Location	Latitude	Longitude
Americas	Brazil	Niterói	-22.88333	-43.10361

Table 5: Drugs for report 764662

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 6: Other Stories

ID	Title	Link
765767	Fake Covid-19 Vaccine Sold in Brazil's city of Niterói, Regulatory Body Alerts	Link

Notes: Sales of fake Covid-19 vaccine in Brazil reportedBrasilia, Oct 13 (Prensa Latina) Brazil's National Health Surveillance Agency (ANVISA) denounced it has reports of the sale of a fake Covid-19 vaccine in the city of Niteroi, Rio de Janeiro state. According to the G1 news portal, the document mentions a company that negotiates the fake immunizer as if it were the vaccine developed by the University of Oxford (United Kingdom) and the Anglo-Swedish laboratory AstraZeneca. [...] The regulatory body reiterates that there is still no Covid-19 drug authorized for marketing in Brazil.

It details there are some potential drugs against the pathogen in the country, but exclusively for use in clinical studies. 'There is no permission for the marketing and distribution of these vaccines,' it reiterated.

3 FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online

Publication date	2020-10-30
Create date	2020-11-01
Score	10.25
Report id	787356
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online CBS Pittsburgh

Click here to see the Original Article

Table 7: Places for report 787356

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pittsburgh	40.44062	-79.99589

Table 8: Drugs for report 787356

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Scammers are always searching for new ways to prey on people's misery.

The latest attempt has caught the attention of the Food and Drug Administration. The FDA has previously warned of unauthorized coronavirus tests that can be taken and processed at home.

Now, the FDA is warning consumers about bogus vaccines and treatments being sold online. [...] The FDA is working with dozens of retailers to remove misleading products from the internet and store shelves. Security has also been boosted at ports of entry to ensure that they do not come through U.S. borders.

Annex

7.2 COVID-19 diagnostics

Medicine Quality Monitoring Globe

November 23, 2020

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

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

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

Filters applied for this report

Search ("thermometer")OR (("RDT" OR "test" OR "lateral flow assay" OR "LFA" OR "Medical device for screening/diagnosis/monitoring" OR "rapid diagnostic test" OR "antigen test" OR "test cassette" OR "cassette test" OR "RT-PCR" OR "testing kit" OR "qPCR" OR "antibody test" OR "PCR" OR "polymerase chain reaction" OR "ELISA") AND ("CV19" OR "新冠病毒" OR "武汉新型冠状病毒" OR "非典" OR "SARS" OR "CoV-2" OR "vi rút corona" OR "武汉肺炎" OR "COVID-19" OR "COVID" OR "新冠疫情" OR "新型冠状病毒肺炎" OR "SARS-CoV-2" OR "CV" OR "Coronavirus" OR "CV-19" OR "SRAS" OR "新型冠状病毒" OR "新冠"))

Start date	2020-10-01
End date	2020-10-31
Language	en
Report type	incident
Curation status	validated

Number of Reports	11

1 Medical scientists allege importation of substandard COVID-19 test kits

Publication date	2020-10-14
Create date	2020-10-15
Score	82.02
Report id	765842
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Medical scientists allege importation of substandard COVID-19 test kits Guardian

Click here to see the Original Article

Table 1: Places for report 765842

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Abuja	9.05785	7.49508

Table 2: Other Stories

ID	Title	Link
777374	How Council saved Nigeria from substandard COVID-19 test kits	Link
777191	Medical scientists allege importation of substandard COVID-19 test kits	Link

Notes: The Medical Laboratory Science Council of Nigeria (MLSCN) has claimed that substandard antibody test kits are being imported into the country. According to the body, it validated 33 test kits and systems for COVID-19 but all antigen and antibody test kits failed to meet the minimum acceptable criteria. The said the council received 43 brands of test kits for validation, while 33 were validated and 22 fulfilled the requirements of rapid test kits, none met the characteristics of sensitivity and specificity to qualify for deployment for purposes of testing in disease surveillance and routine diagnosis. [...] The Registrar and Chief Executive Officer of the council, Dr. Tosan Erhabor, told reporters yesterday in Abuja that the use of any non-validated Rapid/ PCR Test Kits for COVID-19 testing would attract sanctions from

the body. [...] Erhabor said the highest sensitivity of 60.4 per cent found in such kits was too low to be used for detecting SARS-CoV-2 infection. According to him, it is also far below the generally acceptable minimum in-vitro diagnostics (IVD) sensitivity and specificity of 95 per cent.

2 Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs

Publication date 2020-10-07

Create date 2020-10-08

Score 35.59

Report id 757518

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

Quality Falsified

Source Airport

Curation Manually curated

Incident or General Incident

Snippet: Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs Fox Baltimore

Click here to see the Original Article

Table 3: Places for report 757518

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Philadelphia	40.00764	-75.13396
Americas	United States	Harrisburg	40.2737	-76.88442
Americas	United States	Pittsburgh International Airport	40.49608	-80.25547
Americas	United States	Washington	47.50012	-120.50147
Americas	United States	Baltimore	39.29038	-76.61219
Americas	United States	Wilmington	39.74595	-75.54659

Table 4: Other Stories

ID	Title	Link
757539	Customs and Border Patrol agents say they've seized nearly $2.5 million worth of counterfeit COVID-19 masks	Link
758311	Bogus Face Masks, COVID Tests Seized By Feds In MD: Patch PM	Link
758065	Scammers overseas flying in counterfeit COVID-19 products into Pittsburgh International Airport	Link

Table 4: Other Stories(continued)

ID	Title	Link
763963	Counterfeit COVID-19 tests, medications seized by customs officials	Link
758592	Nearly 59,000 'potentially dangerous' counterfeit COVID-19 face masks seized, feds say	Link
758593	U.S. Customs and Border Protection seizes thousands of fake COVID-19 facemasks, test kits, and medications	Link
758857	US Customs seizes nearly 60K counterfeit facemasks	Link
757843	Baltimore Customs Agents Seize Over 50K Counterfeit Face Masks	Link
759157	Feds Seize Counterfeit Masks, Unapproved Coronavirus Meds in DMV, Along East Coast	Link
757897	Counterfeit COVID-19 tests, medications seized by customs officials	Link
758668	Illegitimate Coronavirus Tests, Masks Seized: Baltimore Customs	Link
765354	Counterfeit masks, unapproved COVID-19 meds seized in Baltimore	Link
763576	Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs	Link
758720	US customs seize 'astonishing' amount of counterfeit COVID-19 masks	Link
758471	Nearly 59,000 counterfeit masks, hundreds of fake COVID-19 tests seized at Mid-Atlantic ports, including Baltimore	Link
758483	Counterfeit masks, unapproved COVID-19 meds seized in Baltimore	Link
793058	Nearly 59,000 'potentially dangerous' counterfeit COVID-19 face masks seized, feds say	Link

Notes: The U.S. Customs and Border Protection officers throughout the Mid-Atlantic region are still seizing counterfeit or unapproved COVID-19 medications, facemasks and test kits that arrived in express consignment in the last 6 weeks.

Topping the seizures are 58,846 facemasks that violated trademark protections of numerous brands, including designer consumer brands, sports teams, vehicle manufacturers, cartoon characters and others. [...] Oftentimes, counterfeit products are manufactured in unregulated facilities with substandard materials that could potentially harm American consumers. [...] Since August 13, CBP officers at the Area Ports of Philadelphia, Baltimore and Washington, and the Ports of Harrisburg, Pa., Pittsburgh and Wilmington, Del., have seized: * 58,846 counterfeit facemasks during 21 seizures; * 916 tablets of COVID-related medications during two seizures; and * 134 COVID-19 test kits and antibody tests during six seizures

CBP is withholding specific details of individual seizures as many cases remain under investigation.

The products arrived from Finland, Hong Kong, Nigeria, Philippines, Poland, South Africa,

Spain, Thailand, United Arab Emirates, United Kingdom, and Vietnam.

The parcels were destined to addresses in Florida, North Carolina, Pennsylvania, and Virginia,

Read previous notifications of CBP's Baltimore Field Office COVID-related product seizures at:

CBP announces 11 COVID-related products seizure August 7; CBP announces 18 COVID-related product seizures on June 5; and CBP announces 18 COVID-related product seizures on May 11.

3 Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines

Publication date	2020-10-02
Create date	2020-10-07
Score	32.74
Report id	750450
Category	Vaccine, Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines The Irrawaddy News Magazine

Click here to see the Original Article

Table 5: Places for report 750450

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

Table 6: Drugs for report 750450

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 7: Other Stories

ID	Title	Link
781680	Burma : Myanmar Health Agency warns that fake COVID-19 vaccines are in circulation - 2020-10-26	Link

Notes: Yangon — Myanmar's Food and Drug Administration (FDA) has warned the public against so-called COVID-19 vaccines being sold in the country. The government said it is taking steps to prevent the smuggling and sale of fake vaccines and pills, a director of the FDA,

who asked not to be named, told The Irrawaddy. "Not only vaccines but also pills have been illegally smuggled into the country and are being sold online. Those medicines are illegal," the director told The Irrawaddy. The Ministry of Health and Sports on Thursday said there has been no COVID-19 vaccine endorsed by the World Health Organization (WHO) and no supplier has completed the three-phase clinical trial process. On Facebook, retailers are selling COVID-19 tests for 20,000 kyats (US$15) and COVID-19 drugs, which they claim are made in China.[...] [Covid-19 treatment] [COVID-19 test kits, testing kits]

4 FDA cracking down on fake COVID-19 products

Publication date 2020-10-30

Create date 2020-11-01

Score 28.35

Report id 786684

Category Medical devices for disease prevention, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Not applicable

Curation Manually curated

Incident or General Incident

Snippet: FDA cracking down on fake COVID-19 products WILX

Click here to see the Original Article

Table 8: Places for report 786684

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

Notes: The FDA says it's cracked down on more than 1,000 fraudulent or unproven COVID-19 products.

In a Tweet Thursday FDA Commissioner Stephen Hahn revealed the results of operation "Quack Hack." The goal was to proactively classify threats to consumers.

Hahn says the agency has sent 120 warning letters, 270 reports to virtual marketplaces, and 225 complaints to domain registrars.

The products targeted include bogus drugs, tests, and PPE. Operation Quack Hack launched in March. [...]

5 CBD Product Data Shouldn't Fly Under the Radar – InsideSources

Publication date	2020-10-20
Create date	2020-10-20
Score	13.47
Report id	773466
Category	Analgesic
Quality	Substandard or Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: CBD Product Data Shouldn't Fly Under the Radar – InsideSources InsideSources

Click here to see the Original Article

Table 9: Places for report 773466

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

Table 10: Drugs for report 773466

Medicine Name	Medicine Class	Action	ATC Code
cannabinoids	Other analgesics and antipyretics	other analgesics and antipyretics	N02BG10

Notes: As the coronavirus pandemic continues to impact our lives with high infection rates, a number of cannabis companies are toeing a precarious line with therapeutic declarations that their cannabidiol (CBD) products may help mitigate COVID symptoms, boost immunity against the virus and even cure COVID-19.

These predatory marketing schemes that are quite prevalent on the internet and in no small number of brick-and-mortar stores come with no viable proof and in fact, may be in direct contrast to the scientific evidence. [...] FDA staff tested and analyzed 147 CBD products for accurate labeling and contaminants as well as levels of Tetrahydrocannabinol (THC), which is the chemical responsible for the psychoactive effects of marijuana. THC has been linked to potential harmful side effects on infected coronavirus patients.

The vast majority of CBD products tested were found to be mislabeled or adulterated. More

than half contained either more or less CBD than advertised and in fact, nearly 40 products had more than 120 percent CBD than the level listed. [...] Moreover, nearly 20 products contained THC without disclosure. This means consumers could unknowingly ingest the substance (or unwittingly give THC to pets or children) which can negatively impact personal safety, driving ability, mental health, drug test results, and more — all unbeknownst to them. [...] Setting aside all of the recent findings regarding the mislabeling of CBD products, these CBD products do not comply with good manufacturing processes, and thus are not thoroughly tested for therapeutic value.

6 COVID-19 Product Distributor Says Vendors Sold Faulty Masks

Publication date	2020-10-13
Create date	2020-10-14
Score	12.05
Report id	765212
Category	Medical devices for disease prevention
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19 Product Distributor Says Vendors Sold Faulty Masks Law360

Click here to see the Original Article

Table 11: Places for report 765212

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

Table 12: Other Stories

ID	Title	Link
771565	COVID-19 Product Distributor Says Vendors Sold Faulty Masks	Link

Notes: Law360 (October 13, 2020, 7:57 PM EDT) – A distributor of personal protective equipment to safeguard against the coronavirus sued two mask importers in California federal court, saying that it received $210,000 of worthless and defective KN95 medical masks from China.

Pacific Medical Products LLC, which serves the Washington state medical and health care industry, says in a Friday complaint that California Coco Tree Inc., Seven Bubbles Inc. and Wei Zhou, the vendors' shared president, provided it with possibly counterfeit certification documents from the U.S. Food and Drug Administration and misrepresented the origin of the masks, which allegedly had faulty nose clips. [...] In April, Pacific Medical purchased 90,000 KN95 masks from the vendors after assurances that the two manufacturers for the shipment met FDA standards, backed by a copy of the FDA Medical Device Registration for their masks.

Yet when a hospital client received a portion of the mask shipment the following month, it

rejected 20,000, citing a discrepancy between the promised product with a sewn-in metal nose clip and the actual product with a glued-on nose clip that was easily removed, according to the complaint.

At the same time, the maker of another 40,000 masks purchased by Pacific Medical was added to a list of 65 Chinese manufacturers banned from exporting face masks by the FDA when a test run by the Centers for Disease Control and Prevention showed only a 47% filtration rate, Pacific Medical said. [...] The suit is one among a spate of mask-related suits filed since April. Several Chinese manufacturers are facing claims they sold misbranded and defective masks with false FDA certification documents. The Federal Trade Commission and state attorneys general have also lodged a bevy of price-gouging claims against online retailers.

7 Lucrative Fake Medicine Trade In ASEAN

Publication date	2020-10-31
Create date	2020-11-01
Score	11.18
Report id	787622
Category	Not applicable
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Lucrative Fake Medicine Trade In ASEAN The ASEAN Post

Click here to see the Original Article

Table 13: Places for report 787622

Region Name	Country	Location	Latitude	Longitude
		South Eastern Asia	6.83917	116.45508

Table 14: Other Stories

ID	Title	Link
806005	South East Asia : Fake medicines, one of ASEAN's biggest problems - 2020-11-16	Link

Notes: ASEAN's reputation as a hub for fake medicine is nothing to sneeze at.

Increasing amounts of falsified medicines are being produced in the region, in part as a result of legitimate, and illegitimate, pharmaceutical producers based in India and China having transferred or outsourced some manufacturing processes to Malaysia, Vietnam, Myanmar and Cambodia to avoid tougher regulations and enforcement – and to benefit from lower production costs – according to a 2019 report by the United Nations Office on Drugs and Crime (UNODC). [...] These counterfeit medicines range from falsified anti-cancer treatments to drugs for infertility and weight loss, and the issue is a greater threat in remote areas, where poor health systems may drive patients to rely on unregulated medicines providers. [...] In March 2020, crime control organisation Interpol coordinated a global operation targeting the online sale of illicit medicines and medical devices and seized more than 34,000 fake medical goods. Based on their report, the most counterfeited products are medicines (antivirals, herbal medicines and anti-malarial), medical equipment (face masks, disinfectants, fake coronavirus test kits, gloves

and ventilators), and sanitisers (substandard hand sanitisers, soaps and cleaning wipes).

Likewise, the UNODC has also stated that previous tests have shown that 47 percent of anti-malarial medicines tested in Southeast Asia were found to be fraudulent – but the true figure could be much higher.[...]

8 Medical supply chain shortages led to deadly consequences

Publication date	2020-10-06
Create date	2020-10-13
Score	10.97
Report id	758727
Category	Medical devices for disease prevention
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Medical supply chain shortages led to deadly consequences The Columbian

Click here to see the Original Article

Table 15: Places for report 758727

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

Table 16: Other Stories

ID	Title	Link
761652	US medical supply chains failed, COVID deaths followed	Link
760230	How safe is my N95 mask?	Link

Notes: Nurse Sandra Oldfield's patient didn't have the usual symptoms of COVID-19 — yet. But then he tested positive for the virus, and it was clear that Oldfield — a veteran, 53-year-old caregiver — had been exposed. [...] She and her colleagues said they had felt unsafe at work and had raised concerns with their managers. They needed N95 masks, powerful protection against contracting COVID-19. Kaiser Permanente had none for Sandra Oldfield. Instead, she was issued a less effective surgical mask, leaving her vulnerable to the deadly virus.

Many others were similarly vulnerable, and not just at this 169-bed hospital in Fresno. From the very moment the pandemic reached America's shores, the country was unprepared. Hospitals, nursing homes and other health care facilities didn't have the masks and equipment needed to protect their workers. Some got sick and spread the virus. Some died. [...] Amid the chaos, AP and "FRONTLINE" found counterfeit masks flooded the market, tracking some back to a factory in China. Dr. Philip Clapp at the University of North Carolina tested a handful of

different masks collected by the AP, including ones imported by a non-profit relief organization, others donated to frontline workers by major tech firms, and masks AP had handed out to its own staff.

"All of it was counterfeit, as defined by OSHA's definition of counterfeit or fraudulently labeled," said Clapp. Every mask. Some were less than 50% effective, about the same as a cotton T-shirt.

9 Lilly Plant Making Covid Drug Is Flagged Again by FDA Inspectors

Publication date	2020-10-20
Create date	2020-10-22
Score	9.85
Report id	774525
Category	Not applicable
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Lilly Plant Making Covid Drug Is Flagged Again by FDA Inspectors BloombergQuint

Click here to see the Original Article

Table 17: Places for report 774525

Region Name	Country	Location	Latitude	Longitude
Americas	United States	New Jersey	40.16706	-74.49987

Notes: U.S. drug-safety inspectors have found continuing quality-control problems problems at a New Jersey plant Eli Lilly & Co. is using to help produce its Covid-19 antibody therapy, posing a potential obstacle to the company meeting its goal of producing 1 million doses by year-end. [...] The assessment was based on a four-week site inspection at the Branchburg, New Jersey, facility that ended on Aug. 21, the details of which haven't previously been reported. [...] FDA officials didn't test any products made at the facility, but the compliance officers said in the letter the incidents they described "leave room for significant potential impact on product quality." In one case described by FDA inspectors, a Lilly employee allegedly used the wrong material in a critical purification step. In another, after routine checks revealed a potential impurity in a drug product, an employee retested it to get a passing result, according to the documents, instead of attempting to figure out why there were signs of an impurity in the sample. Lilly managers downplayed quality missteps in a data-management system FDA has access to during inspections called TrackWise, according to inspection documents. Drugmakers use such workflow tracking systems to record the outcomes of quality checks during the manufacturing process.

10 FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online

Publication date	2020-10-30
Create date	2020-11-01
Score	6.92
Report id	787356
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online CBS Pittsburgh

Click here to see the Original Article

Table 18: Places for report 787356

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pittsburgh	40.44062	-79.99589

Table 19: Drugs for report 787356

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Scammers are always searching for new ways to prey on people's misery.

The latest attempt has caught the attention of the Food and Drug Administration. The FDA has previously warned of unauthorized coronavirus tests that can be taken and processed at home.

Now, the FDA is warning consumers about bogus vaccines and treatments being sold online. [...] The FDA is working with dozens of retailers to remove misleading products from the internet and store shelves. Security has also been boosted at ports of entry to ensure that they do not come through U.S. borders.

11 FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it

Publication date	2020-10-01
Create date	2020-10-07
Score	2.84
Report id	749267
Category	Antiseptic
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it NBC News

Click here to see the Original Article

Table 20: Places for report 749267

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

Table 21: Other Stories

ID	Title	Link
749580	17 people died this year from methanol-tainted hand sanitizer: report	Link
749848	Methanol-tainted hand sanitizer has killed 17 this year: report	Link
756032	17 deaths related to methanol-spiked hand sanitizer but FDA limited in actions	Link
757349	People are going blind and dying from drinking hand sanitizer: CDC	Link
751488	Why can I still buy toxic hand sanitizer?	Link
750070	String of fatal poisonings from ingesting toxic hand sanitizer highlights limits of FDA powers	Link

Notes: A 44-year-old man in the Southwest, seeking medical treatment after his vision suddenly

deteriorated in late spring, admitted that he had been drinking hand sanitizer for a few days. Blood tests revealed he had been poisoned by methanol, an extremely toxic form of alcohol that is never supposed to be used in consumer products like hand sanitizer. Despite treatment, he was left permanently blind.

The case was part of a disturbing trend that toxicologists in New Mexico and Arizona caught wind of beginning in May. Dr. Steven Seifert, medical director of the New Mexico Poison and Drug Information Center, noticed that two adults had been hospitalized after drinking hand sanitizer made with methanol. In June, the center treated three more adults who had been poisoned by methanol, making it "absolutely clear that there was something circulating in our state," said Seifert, who notified New Mexico's Department of Public Health.

The coronavirus pandemic has triggered a huge spike in demand for hand sanitizer, and with it, a shortage of ethanol, which is typically used as the active ingredient in hand sanitizers. That may be leading to the use of a highly toxic substitute — methanol, or wood alcohol — in products that have been rushed onto store shelves in the United States. The FDA has counted 17 deaths from exposure to methanol-tainted sanitizer this year, and spokesman Jeremy Kahn says the agency has received an additional 2,000 reports of exposure or injuries.

It's a vivid example of the Food and Drug Administration's lack of authority to crack down on dangerous over-the-counter drugs, a category that includes hand sanitizers. The FDA has responded by issuing numerous alerts about the dangers of ingesting methanol-containing sanitizers and asking manufacturers to issue recalls. But the agency lacks authority to force recalls, and some manufacturers have delayed taking action, according to warnings issued by the FDA and a FairWarning review of the agency's database of hand sanitizers to avoid. [...] "I think consumers would be shocked to learn that the FDA doesn't have authority to pull those products," said Dr. Michael Carome, director of the Health Research Group at the advocacy organization Public Citizen, which has argued for giving the FDA the power to force recalls of prescription and over-the-counter drugs. (Hand sanitizer is classified as an over-the-counter drug.) [...] FDA officials declined comment on whether the agency should have recall authority over drugs. But in a written statement, they said that patient safety is its "top priority. The FDA continues to warn consumers and health care professionals not to use the nearly 200 entries currently on the agency's hand sanitizer list." According to the statement, "The agency has taken additional action to help prevent certain hand sanitizers from entering the United States by placing them on an import alert. " [...] The FDA has long had the power to order recalls of defective medical devices. It gained authority to force recalls of contaminated food under the Food Safety Modernization Act signed into law in 2011. A year later, the agency used the power for the first time to shut down a peanut butter factory linked to salmonella poisoning that sickened 41 people. [...] Most producers of methanol-containing sanitizers have agreed to recall their products after the FDA flagged them, according to a review of the FDA's database, but more brands continue to be added to the FDA's warning list, which included nearly 200 products as of Sept. 17. The agency does not have a breakdown of how many problem hand sanitizers are still for sale in the U.S. compared to how many have been voluntarily recalled.

Annex

7.3 Personal Protective Equipment

Medicine Quality Monitoring Globe

November 23, 2020

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

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

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

Filters applied for this report

Search ("Personal protective equipment" OR "PPE" OR "protective glasses" OR "apron" OR "n95" OR "gowns" OR "facemask" OR "Medical devices for disease prevention" OR "visor" OR "gloves" OR "goggles" OR "respirator" OR "KN95" OR "mask") OR ((Medical devices for disease prevention) AND ("CV19" OR "新冠病毒" OR "武汉新型冠状病毒" OR "非典" OR "SARS" OR "CoV-2" OR "vi rút corona" OR "武汉肺炎" OR "COVID-19" OR "COVID" OR "新冠疫情" OR "新型冠状病毒肺炎" OR "SARS-CoV-2" OR "CV" OR "Coronavirus" OR "CV-19" OR "SRAS" OR "新型冠状病毒" OR "新冠"))

Start date	2020-10-01
End date	2020-10-31
Language	en
Report type	incident
Curation status	validated

Number of Reports	22

1 COVID-19 Product Distributor Says Vendors Sold Faulty Masks

Publication date	2020-10-13
Create date	2020-10-14
Score	47.29
Report id	765212
Category	Medical devices for disease prevention
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19 Product Distributor Says Vendors Sold Faulty Masks Law360

Click here to see the Original Article

Table 1: Places for report 765212

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

Table 2: Other Stories

ID	Title	Link
771565	COVID-19 Product Distributor Says Vendors Sold Faulty Masks	Link

Notes: Law360 (October 13, 2020, 7:57 PM EDT) – A distributor of personal protective equipment to safeguard against the coronavirus sued two mask importers in California federal court, saying that it received $210,000 of worthless and defective KN95 medical masks from China.

Pacific Medical Products LLC, which serves the Washington state medical and health care industry, says in a Friday complaint that California Coco Tree Inc., Seven Bubbles Inc. and Wei Zhou, the vendors' shared president, provided it with possibly counterfeit certification documents from the U.S. Food and Drug Administration and misrepresented the origin of the masks, which allegedly had faulty nose clips. [...] In April, Pacific Medical purchased 90,000 KN95 masks from the vendors after assurances that the two manufacturers for the shipment met FDA standards, backed by a copy of the FDA Medical Device Registration for their masks.

Yet when a hospital client received a portion of the mask shipment the following month, it

rejected 20,000, citing a discrepancy between the promised product with a sewn-in metal nose clip and the actual product with a glued-on nose clip that was easily removed, according to the complaint.

At the same time, the maker of another 40,000 masks purchased by Pacific Medical was added to a list of 65 Chinese manufacturers banned from exporting face masks by the FDA when a test run by the Centers for Disease Control and Prevention showed only a 47% filtration rate, Pacific Medical said. [...] The suit is one among a spate of mask-related suits filed since April. Several Chinese manufacturers are facing claims they sold misbranded and defective masks with false FDA certification documents. The Federal Trade Commission and state attorneys general have also lodged a bevy of price-gouging claims against online retailers.

2 Medical scientists allege importation of substandard COVID-19 test kits

Publication date	2020-10-14
Create date	2020-10-15
Score	45.95
Report id	765842
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Medical scientists allege importation of substandard COVID-19 test kits Guardian

Click here to see the Original Article

Table 3: Places for report 765842

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Abuja	9.05785	7.49508

Table 4: Other Stories

ID	Title	Link
777374	How Council saved Nigeria from substandard COVID-19 test kits	Link
777191	Medical scientists allege importation of substandard COVID-19 test kits	Link

Notes: The Medical Laboratory Science Council of Nigeria (MLSCN) has claimed that substandard antibody test kits are being imported into the country. According to the body, it validated 33 test kits and systems for COVID-19 but all antigen and antibody test kits failed to meet the minimum acceptable criteria. The said the council received 43 brands of test kits for validation, while 33 were validated and 22 fulfilled the requirements of rapid test kits, none met the characteristics of sensitivity and specificity to qualify for deployment for purposes of testing in disease surveillance and routine diagnosis. [...] The Registrar and Chief Executive Officer of the council, Dr. Tosan Erhabor, told reporters yesterday in Abuja that the use of any non-validated Rapid/ PCR Test Kits for COVID-19 testing would attract sanctions from

the body. [...] Erhabor said the highest sensitivity of 60.4 per cent found in such kits was too low to be used for detecting SARS-CoV-2 infection. According to him, it is also far below the generally acceptable minimum in-vitro diagnostics (IVD) sensitivity and specificity of 95 per cent.

3 100,000 substandard respirators acquired through PPE procurement | News

Publication date	2020-10-08
Create date	2020-10-09
Score	37.19
Report id	758487
Category	Medical devices for disease prevention
Quality	Substandard
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: 100,000 substandard respirators acquired through PPE procurement | News ERR News

Click here to see the Original Article

Table 5: Places for report 758487

Region Name	Country	Location	Latitude	Longitude
Europe	Estonia	Tallinn	59.43696	24.75353

Notes: 100,000 substandard respirators were acquired from China at the peak of the coronavirus emergency situation in spring. [...] The minister wrote: "All equipment in the contract concluded with Jiangxi Shunkang Pharmaceutical Group Co Ltd has arrived in Estonia. At the same time, 100,000 FFP3 respirators do not meet our requirements. By our assessment, we are dealing with lower-grade PPE. We have not paid our partner for this."

4 FDA cracking down on fake COVID-19 products

Publication date 2020-10-30

Create date 2020-11-01

Score 34.96

Report id 786684

Category Medical devices for disease prevention, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Not applicable

Curation Manually curated

Incident or General Incident

Snippet: FDA cracking down on fake COVID-19 products WILX

Click here to see the Original Article

Table 6: Places for report 786684

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

Notes: The FDA says it's cracked down on more than 1,000 fraudulent or unproven COVID-19 products.

In a Tweet Thursday FDA Commissioner Stephen Hahn revealed the results of operation "Quack Hack." The goal was to proactively classify threats to consumers.

Hahn says the agency has sent 120 warning letters, 270 reports to virtual marketplaces, and 225 complaints to domain registrars.

The products targeted include bogus drugs, tests, and PPE. Operation Quack Hack launched in March. [...]

5 Medical supply chain shortages led to deadly consequences

Publication date	2020-10-06
Create date	2020-10-13
Score	32.09
Report id	758727
Category	Medical devices for disease prevention
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Medical supply chain shortages led to deadly consequences The Columbian

Click here to see the Original Article

Table 7: Places for report 758727

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

Table 8: Other Stories

ID	Title	Link
761652	US medical supply chains failed, COVID deaths followed	Link
760230	How safe is my N95 mask?	Link

Notes: Nurse Sandra Oldfield's patient didn't have the usual symptoms of COVID-19 — yet. But then he tested positive for the virus, and it was clear that Oldfield — a veteran, 53-year-old caregiver — had been exposed. [...] She and her colleagues said they had felt unsafe at work and had raised concerns with their managers. They needed N95 masks, powerful protection against contracting COVID-19. Kaiser Permanente had none for Sandra Oldfield. Instead, she was issued a less effective surgical mask, leaving her vulnerable to the deadly virus.

Many others were similarly vulnerable, and not just at this 169-bed hospital in Fresno. From the very moment the pandemic reached America's shores, the country was unprepared. Hospitals, nursing homes and other health care facilities didn't have the masks and equipment needed to protect their workers. Some got sick and spread the virus. Some died. [...] Amid the chaos, AP and "FRONTLINE" found counterfeit masks flooded the market, tracking some back to a factory in China. Dr. Philip Clapp at the University of North Carolina tested a handful of

different masks collected by the AP, including ones imported by a non-profit relief organization, others donated to frontline workers by major tech firms, and masks AP had handed out to its own staff.

"All of it was counterfeit, as defined by OSHA's definition of counterfeit or fraudulently labeled," said Clapp. Every mask. Some were less than 50% effective, about the same as a cotton T-shirt.

6 Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs

Publication date 2020-10-07

Create date 2020-10-08

Score 31.71

Report id 757518

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

Quality Falsified

Source Airport

Curation Manually curated

Incident or General Incident

Snippet: Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs Fox Baltimore

Click here to see the Original Article

Table 9: Places for report 757518

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Philadelphia	40.00764	-75.13396
Americas	United States	Harrisburg	40.2737	-76.88442
Americas	United States	Pittsburgh International Airport	40.49608	-80.25547
Americas	United States	Washington	47.50012	-120.50147
Americas	United States	Baltimore	39.29038	-76.61219
Americas	United States	Wilmington	39.74595	-75.54659

Table 10: Other Stories

ID	Title	Link
757539	Customs and Border Patrol agents say they've seized nearly $2.5 million worth of counterfeit COVID-19 masks	Link
758311	Bogus Face Masks, COVID Tests Seized By Feds In MD: Patch PM	Link
758065	Scammers overseas flying in counterfeit COVID-19 products into Pittsburgh International Airport	Link

Table 10: Other Stories(continued)

ID	Title	Link
763963	Counterfeit COVID-19 tests, medications seized by customs officials	Link
758592	Nearly 59,000 'potentially dangerous' counterfeit COVID-19 face masks seized, feds say	Link
758593	U.S. Customs and Border Protection seizes thousands of fake COVID-19 facemasks, test kits, and medications	Link
758857	US Customs seizes nearly 60K counterfeit facemasks	Link
757843	Baltimore Customs Agents Seize Over 50K Counterfeit Face Masks	Link
759157	Feds Seize Counterfeit Masks, Unapproved Coronavirus Meds in DMV, Along East Coast	Link
757897	Counterfeit COVID-19 tests, medications seized by customs officials	Link
758668	Illegitimate Coronavirus Tests, Masks Seized: Baltimore Customs	Link
765354	Counterfeit masks, unapproved COVID-19 meds seized in Baltimore	Link
763576	Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs	Link
758720	US customs seize 'astonishing' amount of counterfeit COVID-19 masks	Link
758471	Nearly 59,000 counterfeit masks, hundreds of fake COVID-19 tests seized at Mid-Atlantic ports, including Baltimore	Link
758483	Counterfeit masks, unapproved COVID-19 meds seized in Baltimore	Link
793058	Nearly 59,000 'potentially dangerous' counterfeit COVID-19 face masks seized, feds say	Link

Notes: The U.S. Customs and Border Protection officers throughout the Mid-Atlantic region are still seizing counterfeit or unapproved COVID-19 medications, facemasks and test kits that arrived in express consignment in the last 6 weeks.

Topping the seizures are 58,846 facemasks that violated trademark protections of numerous brands, including designer consumer brands, sports teams, vehicle manufacturers, cartoon characters and others. [...] Oftentimes, counterfeit products are manufactured in unregulated facilities with substandard materials that could potentially harm American consumers. [...] Since August 13, CBP officers at the Area Ports of Philadelphia, Baltimore and Washington, and the Ports of Harrisburg, Pa., Pittsburgh and Wilmington, Del., have seized: * 58,846 counterfeit facemasks during 21 seizures; * 916 tablets of COVID-related medications during two seizures; and * 134 COVID-19 test kits and antibody tests during six seizures

CBP is withholding specific details of individual seizures as many cases remain under investigation.

The products arrived from Finland, Hong Kong, Nigeria, Philippines, Poland, South Africa,

Spain, Thailand, United Arab Emirates, United Kingdom, and Vietnam.

The parcels were destined to addresses in Florida, North Carolina, Pennsylvania, and Virginia,

Read previous notifications of CBP's Baltimore Field Office COVID-related product seizures at:

CBP announces 11 COVID-related products seizure August 7; CBP announces 18 COVID-related product seizures on June 5; and CBP announces 18 COVID-related product seizures on May 11.

7 Care New England says it unknowingly purchased counterfeit N95 masks

Publication date	2020-10-15
Create date	2020-10-16
Score	27.44
Report id	768161
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Care New England says it unknowingly purchased counterfeit N95 masks WPRI.com

Click here to see the Original Article

Table 11: Places for report 768161

Region Name	Country	Location	Latitude	Longitude
Americas	United States	New England	46.53918	-102.86822
Americas	United States	Providence	41.82399	-71.41283

Table 12: Other Stories

ID	Title	Link
779556	Care New England says it received counterfeit N95 masks from supplier	Link
768303	Care New England says it received counterfeit N95 masks from supplier	Link
769136	Care New England Says It Received Some Counterfeit Masks	Link
769165	Care New England says it received some counterfeit masks	Link

Notes: One of Rhode Island's top hospital groups is mitigating the accidental distribution of counterfeit N95 respirator masks to its employees.

Care New England notified all staff members Thursday that at least one lot of Makrite N95 respirator masks they have in stock is counterfeit. [...] The masks, according to Care New

England, did not show any of the telltale signs of being counterfeit upon purchasing. "Despite reassurance from our vendor, after experiencing a high than usual fit-testing fall-rate and hearing that others in the state had received counterfeit product, we submitted pictures of the mask, its packaging, and lot number director to Makrite," the hospital group explained. "We were subsequently notified that the lot number submitted was not an authentic product."

8 Fake coronavirus protection products discovered for sale in West Sussex

Publication date	2020-10-23
Create date	2020-10-26
Score	24.67
Report id	778246
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Fake coronavirus protection products discovered for sale in West Sussex Chichester Observer

Click here to see the Original Article

Table 13: Places for report 778246

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	Burgess Hill	50.95843	-0.13287
Europe	United Kingdom	Chichester	50.83673	-0.78003
Europe	United Kingdom	Horsham	51.06314	-0.32757
Europe	United Kingdom	Crawley	51.11303	-0.18312

Table 14: Other Stories

ID	Title	Link
778247	Fake Coronavirus protection products found on sale by Trading Standards officers	Link
785248	Fake PPE found for sale in West Sussex	Link
781417	Trading standards catch covid fraudsters selling fake protection	Link

Notes: UV lights, cards worn around the neck to 'sterilise the air' and face coverings are just some of the misleading items found for sale, a Trading Standards spokesman said.

Basic face coverings claiming to be made to a 'KN95' standard were purchased by officers in 23 high street shops across the county including Chichester, Burgess Hill, Crawley and Horsham.

[...] Products which allegedly kill 99 per cent of viruses using UV lights have also been found online. [...] A card which claims to 'sterilise the air' around the user by emitting chlorine dioxide was also found for sale on UK online platforms by officers. [...] "All of these products were falsely labelled.

9 Hong Kong customs seizes largest haul of fake masks meant for overseas market

Publication date	2020-10-30
Create date	2020-11-03
Score	23.21
Report id	788080
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Hong Kong customs seizes largest haul of fake masks meant for overseas market South China Morning Post

Click here to see the Original Article

Table 15: Places for report 788080

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Hong Kong	Yuen Long	22.44518	114.02621
Eastern Asia	Hong Kong	Hong Kong	22.27832	114.17469

Table 16: Other Stories

ID	Title	Link
788554	The Latest: Hong Kong raid leads to 100K counterfeit masks - McKinnon Broadcasting	Link
787152	Hong Kong's authorities seize 100,000 fake masks to be sold overseas.	Link

Notes: Hong Kong authorities have made their largest seizure yet of counterfeit masks, worth HK$3 million (US$387,000) that were destined for the overseas market. A 71-year-old owner of a local trading company was arrested on suspicion of violating the Trade Descriptions Ordinance – an offence that carries a maximum penalty of five years in jail and a HK$500,000 fine. The haul of about 100,000 bogus 3M-brand N95 respirators was found hidden in a warehouse in Yuen Long on Wednesday, according to the Customs and Excise Department. [...] He said investigation showed the fakes were to be sold to buyers at the price of HK$30 each. In Hong

Kong, a genuine respirator of similar kind is priced around HK$50. [...]

10 3M's efforts on counterfeit N95 mask crackdown leads to raids in Vietnam, UAE

Publication date	2020-10-05
Create date	2020-10-07
Score	23.01
Report id	755069
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: 3M's efforts on counterfeit N95 mask crackdown leads to raids in Vietnam, UAE yoursun.com

Click here to see the Original Article

Table 17: Places for report 755069

Region Name	Country	Location	Latitude	Longitude
		South America	-14.60485	-57.65625
		Central America	25.32417	-99.66797
Western Asia	United Arab Emirates	United Arab Emirates	23.75	54.5
		Europe	48.69096	9.14062
Americas	United States	United States	39.76	-98.5
South-Eastern Asia	Viet Nam	Socialist Republic of Vietnam	16.16667	107.83333

Table 18: Other Stories

ID	Title	Link
755068	3M Anti-Counterfeit Campaign Targets Respirator Knockoffs	Link

Notes: 3M said it has investigated more than 7,700 fraud reports globally, up from 4,000-cases in mid-July. The company has filed 19 lawsuits, up one from then.
3M's online actions also have greatly increased.

The company has now removed more than 13,500 false or deceptive social media posts; over 11,500 fraudulent e-commerce offerings; and at least 235 deceptive domain names.

The mask chicanery is global, with 3.5 million fake masks seized since the pandemic began. [...] In Vietnam, a 3M investigation led to a factory raid and seizure of more than 150,000 counterfeit respirators. Hanoi and Ho Chi Minh City authorities also seized equipment used to manufacture phony respirators. [...] In the United Arab Emirates, 3M has worked with police and the Dubai Department of Economic Development to seize over 600,000 fake N95s. And in South Africa, 3M is investigating numerous frauds; the country's customs authority has already seized over 100,000 N95 counterfeits. [...] Also, 3M has worked with customs agencies in Latin American in 15 cases, seizing more than 10,000 counterfeit N95s being imported from other parts of the world. 3M working with law enforcement in the U.S. and European Union, too.

11 El Paso man accused of offering fake coronavirus prevention treatment

Publication date	2020-10-09
Create date	2020-10-14
Score	19.89
Report id	760484
Category	Not applicable, Antiviral others
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: El Paso man accused of offering fake coronavirus prevention treatment KFOX El Paso

Click here to see the Original Article

Table 19: Places for report 760484

Region Name	Country	Location	Latitude	Longitude
Americas	United States	El Paso	31.75872	-106.48693

Table 20: Other Stories

ID	Title	Link
767199	El Paso man accused of offering fake coronavirus prevention treatment	Link

Notes: Federal authorities have obtained a civil injunction against 39-year-old El Paso resident Hugo Chico in an effort to combat alleged fraud related to the coronavirus (COVID-19) pandemic, according to federal officials.

The purpose of the civil injunction is to stop Chico's sale of fraudulent COVID-19 prevention treatments through his business and his Facebook webpage, "Centro de Medicina Fisica y Rehabilitacion."

According to court records, Chico allegedly met with undercover agents on Monday to sell, and administer, COVID-19 prevention treatments.

This action will ensure Chico, and any others working with him, stop advertising or performing any COVID-19 treatments. In so doing, the government is employing a federal statute that permits federal courts to issue injunctions to prevent harm to potential victims of fraudulent

schemes.

12 Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines

Publication date	2020-10-02
Create date	2020-10-07
Score	18.17
Report id	750450
Category	Vaccine, Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines The Irrawaddy News Magazine

Click here to see the Original Article

Table 21: Places for report 750450

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

Table 22: Drugs for report 750450

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 23: Other Stories

ID	Title	Link
781680	Burma : Myanmar Health Agency warns that fake COVID-19 vaccines are in circulation - 2020-10-26	Link

Notes: Yangon — Myanmar's Food and Drug Administration (FDA) has warned the public against so-called COVID-19 vaccines being sold in the country. The government said it is taking steps to prevent the smuggling and sale of fake vaccines and pills, a director of the FDA,

who asked not to be named, told The Irrawaddy. "Not only vaccines but also pills have been illegally smuggled into the country and are being sold online. Those medicines are illegal," the director told The Irrawaddy. The Ministry of Health and Sports on Thursday said there has been no COVID-19 vaccine endorsed by the World Health Organization (WHO) and no supplier has completed the three-phase clinical trial process. On Facebook, retailers are selling COVID-19 tests for 20,000 kyats (US$15) and COVID-19 drugs, which they claim are made in China.[...] [Covid-19 treatment] [COVID-19 test kits, testing kits]

13 Lucrative Fake Medicine Trade In ASEAN

Publication date	2020-10-31
Create date	2020-11-01
Score	15.11
Report id	787622
Category	Not applicable
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Lucrative Fake Medicine Trade In ASEAN The ASEAN Post

Click here to see the Original Article

Table 24: Places for report 787622

Region Name	Country	Location	Latitude	Longitude
		South Eastern Asia	6.83917	116.45508

Table 25: Other Stories

ID	Title	Link
806005	South East Asia : Fake medicines, one of ASEAN's biggest problems - 2020-11-16	Link

Notes: ASEAN's reputation as a hub for fake medicine is nothing to sneeze at.

Increasing amounts of falsified medicines are being produced in the region, in part as a result of legitimate, and illegitimate, pharmaceutical producers based in India and China having transferred or outsourced some manufacturing processes to Malaysia, Vietnam, Myanmar and Cambodia to avoid tougher regulations and enforcement – and to benefit from lower production costs – according to a 2019 report by the United Nations Office on Drugs and Crime (UNODC). [...] These counterfeit medicines range from falsified anti-cancer treatments to drugs for infertility and weight loss, and the issue is a greater threat in remote areas, where poor health systems may drive patients to rely on unregulated medicines providers. [...] In March 2020, crime control organisation Interpol coordinated a global operation targeting the online sale of illicit medicines and medical devices and seized more than 34,000 fake medical goods. Based on their report, the most counterfeited products are medicines (antivirals, herbal medicines and anti-malarial), medical equipment (face masks, disinfectants, fake coronavirus test kits, gloves

and ventilators), and sanitisers (substandard hand sanitisers, soaps and cleaning wipes).

Likewise, the UNODC has also stated that previous tests have shown that 47 percent of anti-malarial medicines tested in Southeast Asia were found to be fraudulent – but the true figure could be much higher.[...]

14 3 arrested for making face masks with fake logo

Publication date	2020-10-09
Create date	2020-10-12
Score	14.45
Report id	760491
Category	Medical devices for disease prevention
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: 3 arrested for making face masks with fake logo Times of India

Click here to see the Original Article

Table 26: Places for report 760491

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Coimbatore	11.00555	76.96612

Notes: Coimbatore: The Tirupur city police on Friday arrested three men for manufacturing face masks under a popular company's brand name. Ramraj Cotton, which is manufacturing three-layer face masks that bear the 'RR' trademark symbol, had lodged a complaint with central crime branch of Tirupur city police on Thursday after R S Seenu, a Tirupur-based ornament manufacturing unit owner, posted a message on his Facebook page announcing sale of masks made by the firm. [...] They seized 437 face masks and 1,532 fake trademark symbols from them.

15 Mumbai police raid fake N-95 mask factory in UP, arrest one

Publication date	2020-10-30
Create date	2020-11-01
Score	13.88
Report id	787164
Category	Medical devices for disease prevention
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Mumbai police raid fake N-95 mask factory in UP, arrest one Outlook India

Click here to see the Original Article

Table 27: Places for report 787164

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Ghāziābād	28.66535	77.43915
Southern Asia	India	Mumbai	19.07283	72.88261

Table 28: Other Stories

ID	Title	Link
787660	Mumbai police raid fake N-95 mask factory in Uttar Pradesh, arrest one	Link

Notes: The crime branch of Mumbai Police raided a factory at Ghaziabad in Uttar Pradesh where fake N-95 masks were being manufactured, an official said on Friday. [...] During the raid, the police seized 5,000 sub-standard masks, a printing machine and two printing screens worth Rs 11 lakh, he said, adding that one person was arrested. [...] On July 28, crime branch Unit-3 officials had seized sub-standard N-95 masks worth Rs 21.39 lakh in Lower Parel in Central Mumbai and arrested one person.

16 People make a beeline for fake Covid medicine, drugs controller intervenes

Publication date	2020-10-19
Create date	2020-10-20
Score	12.64
Report id	773000
Category	Respiratory diseases medicine
Quality	Falsified
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: People make a beeline for fake Covid medicine, drugs controller intervenes The New Indian Express

Click here to see the Original Article

Table 29: Places for report 773000

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kozhikode	11.24802	75.7804

Table 30: Other Stories

ID	Title	Link
780054	People make a beeline for fake Covid medicine, drugs controller intervenes	Link

Notes: Thanks to an ENT physician's 'discovery' of nasal drops which can 'resist Covid' and a prominent vernacular daily reporting it, a medical store in Koyilandy here is making a quick buck. E Sukumaran, a Koyilandy-based senior ENT surgeon and former deputy director of health department, has claimed that nasal drops — the 'medication' has a 25 per cent glucose content — can eliminate the coronavirus from the throat itself. [...] Though scientists and the medical fraternity have outrightly rejected Sukumaran's claims, calling them highly unscientific and totally misleading, what happened in Koyilandy was that people thronged a drug store which started selling this glucose-based nasal drop. A 15 ml bottle was priced at '50 in the beginning. Later, the price was slashed to '30 and now it is being sold for '20. This medical store has special licence which allows it to sell drugs manufactured by mixing the components.

”People queue up in front of the medical store to buy the drug. Though many of them were aware that it doesn’t prevent Covid, they are convinced that it will not cause any side effects either. The drug store is the biggest beneficiary of this fake discovery,” said a health department source. However, the biggest threat posed by this drug is that it will give a false sense of Covid immunity to gullible people and instigate them to breach Covid protocol. This correspondent bought the bottle directly from the said store without prescription. Along with the drug, there was also a piece of advice on how to administer it: ”Two droplets in each nostril twice daily.”

Meanwhile, after coming to know of the ‘miracle discovery’ through TNIE, the state drugs controller has ordered a probe. Sujith Kumar K, Assistant Drugs Controller, Kozhikode, told TNIE that he had sent two of his officials to investigate the matter. According to him, he will see to it that the nasal drop is not sold without a doctor’s prescription. ”We cannot prevent the sale of glucose water if there is a prescription as it is being used for other purposes such as drip. But it cannot be sold as a remedy for Covid,” he said.

17 Taiwan joins US, Japan, Australia in holding global workshop on pandemic-related crime

Publication date	2020-10-28
Create date	
Score	9.98
Report id	785855
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Taiwan joins US, Japan, Australia in holding global workshop on pandemic-related crime Taiwan News

Click here to see the Original Article

Table 31: Places for report 785855

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taiwan	24	121

Notes:

18 Gujarat: Two booked for blackmarketing of Covid drug

Publication date	2020-10-05
Create date	2020-10-07
Score	9.57
Report id	755217
Category	Antiviral others
Quality	Diverted/Unregistered
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Gujarat: Two booked for blackmarketing of Covid drug The Indian Express

Click here to see the Original Article

Table 32: Places for report 755217

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Rajkot	22.29161	70.79322

Notes: A wholesale medical seller and a medical representative (MR) were booked by the Rajkot city Crime Branch on Monday for the alleged blackmarketing of REMDAC 100 MG injections [remdesivir], used in the treatment of Covid-19, wherein the accused produced fake bills of the critical injections. According to police officials of Detection of Crime Branch, Rajkot city, the main accused Paresh Patel (35), a resident of Janakpur society at Sheri Sadhuvasvani road in Rajkot, who runs 'New Ideal Agencies', a wholesale medicine shop and other accused RajniKant Patel (29), a resident of Sanskar Avenue at bypass road in Rajkot, who works as a medical representative, were booked by the police.

While Paresh was detained, the other accused Rajnikant Patel is already lodged in Rajkot sub jail in another case of fraud lodged at DCB police station in Rajkot. "A few days ago, Dr Anand Chauhan of Anand Clinic in Rajkot had approached the police stating that the owner of New Ideal Agencies had given him a bill of 24 REMDAC injections worth Rs 46,473 but he had not purchased it. Upon the complaint, officials of Food and Drug Safety department visited the Anand clinic and probed the fake bill," said an officer at Rajkot DCB.

"The role of the wholesaler and MR came into light and a raid was conducted and the accused Paresh has been detained. The license of New Ideal agencies has been cancelled," the officer added.

19 Anderson Co. coroner warns of street drug use dangers after several recent deaths

Publication date	2020-10-02
Create date	2020-10-07
Score	6.76
Report id	750943
Category	Opioid
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Anderson Co. coroner warns of street drug use dangers after several recent deaths WSPA 7News

Click here to see the Original Article

Table 33: Places for report 750943

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Anderson	34.50344	-82.65013

Table 34: Drugs for report 750943

Medicine Name	Medicine Class	Action	ATC Code
oxycodone	Natural opium alkaloids	opioids	N02AA05
		opioids	N02A
cocaine	Esters of benzoic acid	anesthetics, local	N01BC01
cocaine	Anesthetics, local	throat preparations	R02AD03
cocaine	Local anesthetics	local anesthetics	S01HA01
cocaine	Analgesics and anesthetics	other otologicals	S02DA02
fentanyl	Opioid anesthetics	anesthetics, general	N01AH01
fentanyl	Phenylpiperidine derivatives	opioids	N02AB03

Table 35: Other Stories

ID	Title	Link
751297	'Alarming': Anderson County coroner sends out warning after rash of fentanyl-related deaths	Link

Notes: This photo provided by the U.S. Attorneys Office for Utah and introduced as evidence in a 2019 trial shows fentanyl-laced fake oxycodone pills collected during an investigation. In a resumption of a brutal trend, nearly 71,000 Americans died of drug overdoses in 2019 according to the Centers for Disease Control and Prevention, a new record high that predates the COVID-19 crisis. The numbers were driven by fentanyl and similar synthetic opioids, which accounted for 36,500 overdose deaths. (U.S. Attorneys Office for Utah via AP) ANDERSON COUNTY, S.C. (WSPA) – Anderson County Coroner Greg Shore is sending a warning that street level drugs may be deadlier than some think. He advised that his office is currently investigating several incidents in which victims have died of illicit drug use over the last several days. Shore said in the course of the investigations, the drug Fentanyl seems to be a common denominator to the individual deaths and he is concerned that persons with an addiction problem may be obtaining street level Fentanyl that is more than just Fentanyl. "Fentanyl in itself is a deadly drug that can and does result in death. However, the most recent deaths are alarming based on the fact that they are so close together and over a short time period," he said in a news release on Friday. He said that the Anderson County community may have some street level Fentanyl being distributed that may also contain Carfentanil. This combination is even deadlier than the Fentanyl alone, according to the coroner. "Carfentanil is typically utilized for anaesthetizing large animals, such as elephants. Carfentanil, a synthetic Opioid, is a white powdery substance that looks like it could be Cocaine or Heroin. Drug dealers mix it with Heroin to presumably make the Heroin stronger," Shore said. Deaths involving illicitly manufactured Fentanyl and other synthetic Opioids are on the rise, and have been since 2018, he advised. Street drugs such as Heroin, Cocaine and Methamphetamines are being laced with Fentanyl as are other counterfeit drugs made to look like the real ones, like Xanax. Fentanyl works in the brain to block pain and is in the same class of drugs such as Morphine or Hydrocodone but is about 50-100 times more potent. Just 2 milligrams of Fentanyl can kill a person. Fentanyl blocks Opioid receptors and its most dangerous side effect, like other Opioids, is respiratory depression which can quickly lead to coma and death. Carfentanil is 10,000 times more potent than Morphine and 100 times more potent than Fentanyl. Shore wants to send a warning to people with an addiction disorder, that the street level Fentanyl, Cocaine and/or Heroin they are obtaining may be deadlier than they think, Shore said. He is encouraging individuals with an addiction disorder to seek help and to be aware that this drug has resulted in several deaths in Anderson County.

20 'Wild, wild west': No charges laid against 300 companies making false PPE claims

Publication date	2020-10-15
Create date	2020-11-19
Score	6.40
Report id	779042
Category	Antiseptic
Quality	Substandard or Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: 'Wild, wild west': No charges laid against 300 companies making false PPE claims CTV News

Click here to see the Original Article

Table 36: Places for report 779042

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Notes: Health Canada continues to add to a long list – now at 108 – of recalled hand sanitizers.

The recalls are for ingredients that aren't allowed in Canada or for improper labelling. Many of the sanitizers contain unacceptable grades of ethanol or denaturants that have not been reviewed for safety or efficacy. Denaturants taste bad and are added to ethanol to discourage ingestion, especially by children.

Two unauthorized denaturants that have been found in hand sanitizers sold in Canada are ethyl acetate, which with frequent use can cause dry skin, leading to irritation or cracking, and methanol, which can cause dermatitis, eye irritation, upper respiratory system irritation and headaches.

21 Pakistan drug regulator recalls remdesivir, other drugs over glass contamination

Publication date 2020-10-24

Create date 2020-10-26

Score 6.27

Report id 779461

Category Analgesic, Antibiotic, Antiviral others, Antiparasitic, Anti-inflammatory medicine, Other

Quality Substandard

Source Unknown

Curation Manually curated

Incident or General Incident

Snippet: Pakistan drug regulator recalls remdesivir, other drugs over glass contamination SAMAA

Click here to see the Original Article

Table 37: Places for report 779461

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Islamabad	33.72148	73.04329
Southern Asia	Pakistan	Karachi	24.8608	67.0104
Southern Asia	Pakistan	Lahore	31.558	74.35071

Table 38: Drugs for report 779461

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
albendazole	Benzimidazole derivatives	antinematodal agents	P02CA03
diclofenac	Other dermatologicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic products, non-steroids	M01AB05

Table 38: Drugs for report 779461(continued)

Medicine Name	Medicine Class	Action	ATC Code
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03
ceftriaxone	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD04
			J05
metronidazole	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB17
metronidazole	Other chemotherapeutics	chemotherapeutics for topical use	D06BX01
metronidazole	Imidazole derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AF01
metronidazole	Imidazole derivatives	other antibacterials	J01XD01
metronidazole	Nitroimidazole derivatives	agents against amoebiasis and other protozoal diseases	P01AB01

Table 39: Other Stories

ID	Title	Link
779642	SAMAA - Pakistan drug regulator recalls remdesivir, other drugs over glass contamination	Link

Notes: The Drug Regulatory Authority of Pakistan has issued recall alerts for substantial and adulterated drugs in the market. Glass particles were reportedly found in some of the drugs. [...] The drugs are: 1. Kanbact 500mg injection: antibiotic ceftriaxone used for various bacterial infections 2. Fenaclod injection: diclofenac sodium used as a painkiller 3. Oxiphin 1g injection: antibiotic ceftriaxone 4. Flazol infusion 500mg/100ml: antibiotic metronidazole used for stomach infections 5. Parapals Infusion 100ml 6. Medisol Compound Sodium Lactate IV infusion 500ml: solution for IV drips 7. Zental suspension: albendazole for worm infections 8. Redzi 100mg solution for injection: antiviral remdesivir being used in COVID-19 treatment 9. Water for injection b#wfi-237 [...]

22 FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it

Publication date	2020-10-01
Create date	2020-10-07
Score	5.80
Report id	749267
Category	Antiseptic
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it NBC News

Click here to see the Original Article

Table 40: Places for report 749267

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

Table 41: Other Stories

ID	Title	Link
749580	17 people died this year from methanol-tainted hand sanitizer: report	Link
749848	Methanol-tainted hand sanitizer has killed 17 this year: report	Link
756032	17 deaths related to methanol-spiked hand sanitizer but FDA limited in actions	Link
757349	People are going blind and dying from drinking hand sanitizer: CDC	Link
751488	Why can I still buy toxic hand sanitizer?	Link
750070	String of fatal poisonings from ingesting toxic hand sanitizer highlights limits of FDA powers	Link

Notes: A 44-year-old man in the Southwest, seeking medical treatment after his vision suddenly

deteriorated in late spring, admitted that he had been drinking hand sanitizer for a few days. Blood tests revealed he had been poisoned by methanol, an extremely toxic form of alcohol that is never supposed to be used in consumer products like hand sanitizer. Despite treatment, he was left permanently blind.

The case was part of a disturbing trend that toxicologists in New Mexico and Arizona caught wind of beginning in May. Dr. Steven Seifert, medical director of the New Mexico Poison and Drug Information Center, noticed that two adults had been hospitalized after drinking hand sanitizer made with methanol. In June, the center treated three more adults who had been poisoned by methanol, making it "absolutely clear that there was something circulating in our state," said Seifert, who notified New Mexico's Department of Public Health.

The coronavirus pandemic has triggered a huge spike in demand for hand sanitizer, and with it, a shortage of ethanol, which is typically used as the active ingredient in hand sanitizers. That may be leading to the use of a highly toxic substitute — methanol, or wood alcohol — in products that have been rushed onto store shelves in the United States. The FDA has counted 17 deaths from exposure to methanol-tainted sanitizer this year, and spokesman Jeremy Kahn says the agency has received an additional 2,000 reports of exposure or injuries.

It's a vivid example of the Food and Drug Administration's lack of authority to crack down on dangerous over-the-counter drugs, a category that includes hand sanitizers. The FDA has responded by issuing numerous alerts about the dangers of ingesting methanol-containing sanitizers and asking manufacturers to issue recalls. But the agency lacks authority to force recalls, and some manufacturers have delayed taking action, according to warnings issued by the FDA and a FairWarning review of the agency's database of hand sanitizers to avoid. [...] "I think consumers would be shocked to learn that the FDA doesn't have authority to pull those products," said Dr. Michael Carome, director of the Health Research Group at the advocacy organization Public Citizen, which has argued for giving the FDA the power to force recalls of prescription and over-the-counter drugs. (Hand sanitizer is classified as an over-the-counter drug.) [...] FDA officials declined comment on whether the agency should have recall authority over drugs. But in a written statement, they said that patient safety is its "top priority. The FDA continues to warn consumers and health care professionals not to use the nearly 200 entries currently on the agency's hand sanitizer list." According to the statement, "The agency has taken additional action to help prevent certain hand sanitizers from entering the United States by placing them on an import alert. " [...] The FDA has long had the power to order recalls of defective medical devices. It gained authority to force recalls of contaminated food under the Food Safety Modernization Act signed into law in 2011. A year later, the agency used the power for the first time to shut down a peanut butter factory linked to salmonella poisoning that sickened 41 people. [...] Most producers of methanol-containing sanitizers have agreed to recall their products after the FDA flagged them, according to a review of the FDA's database, but more brands continue to be added to the FDA's warning list, which included nearly 200 products as of Sept. 17. The agency does not have a breakdown of how many problem hand sanitizers are still for sale in the U.S. compared to how many have been voluntarily recalled.

Annex

7.4 Sanitisers and disinfectants

Medicine Quality Monitoring Globe

November 23, 2020

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

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

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

Filters applied for this report

Search "antiseptic" OR "wipes" OR "disinfectant" OR "sanitizer" OR "sanitizing" OR "iodoform" OR "sanitiser"

Start date	2020-10-01
End date	2020-10-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	17

1 New hand sanitizer recalls bring Health Canada list to more than 80

Publication date	2020-10-30
Create date	2020-11-01
Score	16.16
Report id	786925
Category	Antiseptic
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: New hand sanitizer recalls bring Health Canada list to more than 80 Toronto.com

Click here to see the Original Article

Table 1: Places for report 786925

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Notes: Three new hand sanitizers, as well as several from the brand Bio Life Sciences Corp., are the latest to be added to Health Canada's growing list of recalls.

Since June, Health Canada has recalled more than 80 types of hand sanitizers that contain ethanol or denaturants that are not permitted for use in these products in Canada. [...]

2 Quimica Magna de Mexico, S.A. de C.V. - 608751 - 10/15/2020 - 2020-10-27

Publication date	2020-10-27
Create date	2020-10-28
Score	16.13
Report id	782839
Category	Antiseptic
Quality	Substandard
Source	Land point of entry
Curation	Manually curated
Incident or General	Incident

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

Click here to see the Original Article

Table 2: Places for report 782839

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Saltillo	25.42321	-101.0053
Americas	United States	United States	39.76	-98.5

Table 3: Drugs for report 782839

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Table 4: Other Stories

ID	Title	Link
784145	Mexican Hand Sanitizer Maker Flagged By FDA	Link

Notes: [...] Datsen Hand Sanitizer, declared as manufactured at your facility, is labeled to contain 75% v/v of the active ingredient alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that the drug product contained only 15% ethanol v/v. Additionally, the drug product Alcohol Antiseptic 62% Topical Solution Hand Sanitizer, labeled as manufactured by your facility, is labeled to contain 62% v/v of the

active ingredient alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that the drug product contained only 50% v/v ethanol. These hand sanitizer drug products are adulterated under section 501(c) of the Act in that the active ingredient of ethanol is present at levels in the products lower than that which is declared on their labeling. [...]

3 Health Canada issues recall of counterfeit hand sanitizer

Publication date	2020-10-01
Create date	2020-10-07
Score	16.04
Report id	749766
Category	Antiseptic
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Health Canada issues recall of counterfeit hand sanitizer CTV News

Click here to see the Original Article

Table 5: Places for report 749766

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Table 6: Other Stories

ID	Title	Link
761565	Health Canada issues recall of counterfeit hand sanitizer	Link

Notes: Health Canada says it has announced a recall after discovering a company selling a counterfeit version of one of the hand sanitizers on its approved list.

In a release Thursday, the agency says they had become aware that the distributor Northern National Sales Inc. was selling a fake version of Zytec Germ Buster Hand Sanitizer.

Health Canada says it worked with Emback Spraytech Inc., the company behind the authorized product, in order to make sure the counterfeit version was not one of theirs. s the demand for hand sanitizer grew early on in the pandemic, Health Canada released a list of approved hand sanitizers that met the government's requirement for sale in Canada, in order to ensure that consumers would not be taken in by products claiming to be hand sanitizer that did not match up to regulations.

Zytec Germ Buster Hand Sanitizer is authorized for sale in Canada, but officials say the counterfeit version claiming this name is not. Health Canada states that they had reached out to

the distributor of the counterfeit and instructed them to recall the product. [...] Health Canada says both versions of the product carry the same NPN, or Natural Product Number, 80015625, and the same lot number, 3329733126.

However, the real product has a colour label, and the version with those two numbers only comes in 3.78 litres, while the counterfeit version has a black and white label and uses those numbers on a one-litre bottle.

Health Canada says anyone who possess the counterfeit version should stop using it immediately, and contact health-care practitioners if you have used it and are feeling concerned about your health.

Northern National Sales Inc. has confirmed that they are no longer selling the product, according to Health Canada.

4 Lucrative Fake Medicine Trade In ASEAN

Publication date	2020-10-31
Create date	2020-11-01
Score	15.54
Report id	787622
Category	Not applicable
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Lucrative Fake Medicine Trade In ASEAN The ASEAN Post

Click here to see the Original Article

Table 7: Places for report 787622

Region Name	Country	Location	Latitude	Longitude
		South Eastern Asia	6.83917	116.45508

Table 8: Other Stories

ID	Title	Link
806005	South East Asia : Fake medicines, one of ASEAN's biggest problems - 2020-11-16	Link

Notes: ASEAN's reputation as a hub for fake medicine is nothing to sneeze at.

Increasing amounts of falsified medicines are being produced in the region, in part as a result of legitimate, and illegitimate, pharmaceutical producers based in India and China having transferred or outsourced some manufacturing processes to Malaysia, Vietnam, Myanmar and Cambodia to avoid tougher regulations and enforcement – and to benefit from lower production costs – according to a 2019 report by the United Nations Office on Drugs and Crime (UNODC). [...] These counterfeit medicines range from falsified anti-cancer treatments to drugs for infertility and weight loss, and the issue is a greater threat in remote areas, where poor health systems may drive patients to rely on unregulated medicines providers. [...] In March 2020, crime control organisation Interpol coordinated a global operation targeting the online sale of illicit medicines and medical devices and seized more than 34,000 fake medical goods. Based on their report, the most counterfeited products are medicines (antivirals, herbal medicines and anti-malarial), medical equipment (face masks, disinfectants, fake coronavirus test kits, gloves

and ventilators), and sanitisers (substandard hand sanitisers, soaps and cleaning wipes).

Likewise, the UNODC has also stated that previous tests have shown that 47 percent of anti-malarial medicines tested in Southeast Asia were found to be fraudulent – but the true figure could be much higher.[...]

5 FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it

Publication date	2020-10-01
Create date	2020-10-07
Score	15.50
Report id	749267
Category	Antiseptic
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it NBC News

Click here to see the Original Article

Table 9: Places for report 749267

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

Table 10: Other Stories

ID	Title	Link
749580	17 people died this year from methanol-tainted hand sanitizer: report	Link
749848	Methanol-tainted hand sanitizer has killed 17 this year: report	Link
756032	17 deaths related to methanol-spiked hand sanitizer but FDA limited in actions	Link
757349	People are going blind and dying from drinking hand sanitizer: CDC	Link
751488	Why can I still buy toxic hand sanitizer?	Link
750070	String of fatal poisonings from ingesting toxic hand sanitizer highlights limits of FDA powers	Link

Notes: A 44-year-old man in the Southwest, seeking medical treatment after his vision suddenly

deteriorated in late spring, admitted that he had been drinking hand sanitizer for a few days. Blood tests revealed he had been poisoned by methanol, an extremely toxic form of alcohol that is never supposed to be used in consumer products like hand sanitizer. Despite treatment, he was left permanently blind.

The case was part of a disturbing trend that toxicologists in New Mexico and Arizona caught wind of beginning in May. Dr. Steven Seifert, medical director of the New Mexico Poison and Drug Information Center, noticed that two adults had been hospitalized after drinking hand sanitizer made with methanol. In June, the center treated three more adults who had been poisoned by methanol, making it "absolutely clear that there was something circulating in our state," said Seifert, who notified New Mexico's Department of Public Health.

The coronavirus pandemic has triggered a huge spike in demand for hand sanitizer, and with it, a shortage of ethanol, which is typically used as the active ingredient in hand sanitizers. That may be leading to the use of a highly toxic substitute — methanol, or wood alcohol — in products that have been rushed onto store shelves in the United States. The FDA has counted 17 deaths from exposure to methanol-tainted sanitizer this year, and spokesman Jeremy Kahn says the agency has received an additional 2,000 reports of exposure or injuries.

It's a vivid example of the Food and Drug Administration's lack of authority to crack down on dangerous over-the-counter drugs, a category that includes hand sanitizers. The FDA has responded by issuing numerous alerts about the dangers of ingesting methanol-containing sanitizers and asking manufacturers to issue recalls. But the agency lacks authority to force recalls, and some manufacturers have delayed taking action, according to warnings issued by the FDA and a FairWarning review of the agency's database of hand sanitizers to avoid. [...] "I think consumers would be shocked to learn that the FDA doesn't have authority to pull those products," said Dr. Michael Carome, director of the Health Research Group at the advocacy organization Public Citizen, which has argued for giving the FDA the power to force recalls of prescription and over-the-counter drugs. (Hand sanitizer is classified as an over-the-counter drug.) [...] FDA officials declined comment on whether the agency should have recall authority over drugs. But in a written statement, they said that patient safety is its "top priority. The FDA continues to warn consumers and health care professionals not to use the nearly 200 entries currently on the agency's hand sanitizer list." According to the statement, "The agency has taken additional action to help prevent certain hand sanitizers from entering the United States by placing them on an import alert. " [...] The FDA has long had the power to order recalls of defective medical devices. It gained authority to force recalls of contaminated food under the Food Safety Modernization Act signed into law in 2011. A year later, the agency used the power for the first time to shut down a peanut butter factory linked to salmonella poisoning that sickened 41 people. [...] Most producers of methanol-containing sanitizers have agreed to recall their products after the FDA flagged them, according to a review of the FDA's database, but more brands continue to be added to the FDA's warning list, which included nearly 200 products as of Sept. 17. The agency does not have a breakdown of how many problem hand sanitizers are still for sale in the U.S. compared to how many have been voluntarily recalled.

6 Health Canada recalls counterfeit hand sanitizer sold at Dollarama

Publication date	2020-10-19
Create date	2020-10-20
Score	15.28
Report id	772302
Category	Antiseptic
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Health Canada recalls counterfeit hand sanitizer sold at Dollarama CTV News

Click here to see the Original Article

Table 11: Places for report 772302

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Thunder Bay	48.38202	-89.25018

Table 12: Other Stories

ID	Title	Link
771342	'Counterfeit' hand sanitizer possibly sold in Manitoba	Link
785941	Recall of Daily Shield hand sanitizer expanded, manufacturer's licence suspended	Link
773911	Today's coronavirus news: 1 in 4 Canadians say mental health is worse now; Health Canada recalls counterfeit hand sanitizer sold at Dollarama in Ontario; Argentina passes 1M cases	Link
802597	Health Canada recalls counterfeit hand sanitizer sold at Dollarama	Link
773704	Health Canada recalls counterfeit hand sanitizer sold at Dollarama in Ontario	Link
781665	Canada : Batch of fake hand sanitizer containing methanol identified - 2020-10-26	Link
775266	CANADA: Experts say counterfeit hand sanitizer recall at Dollarama is a lesson for retailers	Link

Table 12: Other Stories(continued)

ID	Title	Link
774527	Experts say counterfeit hand sanitizer recall at Dollarama is a lesson for retailers - Business News	Link
780415	Health Canada recalls counterfeit hand sanitizer sold at Dollarama in Ontario	Link
795790	Health Canada recalls counterfeit hand sanitizer sold at Dollarama in Ontario	Link
773804	Today's coronavirus news: 1 in 4 Canadians say mental health is worse now; Health Canada recalls counterfeit hand sanitizer sold at Dollarama in Ontario; Argentina passes 1M cases	Link
784817	Health Canada expands recall of Daily Shield hand sanitizer nationwide	Link
774325	Experts say counterfeit hand sanitizer recall at Dollarama is a lesson for retailers	Link
794553	Counterfeit hand sanitizer found in Ontario Dollarama store contained deadly methanol	Link
773818	Counterfeit hand sanitizer found in Ontario Dollarama store contained deadly methanol	Link
805062	Health Canada recalls counterfeit hand sanitizer sold at Dollarama in Ontario	Link
790216	Health Canada expands recall of Daily Shield hand sanitizer nationwide	Link
773076	Health Canada recalls counterfeit hand sanitizer found at Dollarama in Ontario	Link
775898	Dollarama recalls bogus hand sanitizer	Link

Notes: Health Canada has announced a recall after discovering a company selling a counterfeit version of one of the hand sanitizers on its approved list.

The recall, issued Sunday, says the agency became aware that a counterfeit version of the authorized Daily Shield hand sanitizer was found for sale at a Dollarama store in Thunder Bay, Ont. and may have been sold at stores across Canada. [...] "Counterfeit products may contain ingredients not listed on the label, dangerous additives or other contaminants. In addition, they may not contain the active ingredients that Canadians would expect them to contain," the recall said. [...] Health Canada says both versions of the product carry the same NPN, or Natural Product Number, 80098979, but have different lot numbers.

The real product has bright blue and red colouring on its label, and comes in 236 millilitre or 1 litre bottles, while the counterfeit version uses deep blue and dark red on its label and comes in a 250 millilitre format.

The counterfeit products is also labelled with Lot 6942; Expiry May 2023.

7 'Wild, wild west': No charges laid against 300 companies making false PPE claims

Publication date	2020-10-15
Create date	2020-11-19
Score	15.09
Report id	779042
Category	Antiseptic
Quality	Substandard or Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: 'Wild, wild west': No charges laid against 300 companies making false PPE claims CTV News

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Table 13: Places for report 779042

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Notes: Health Canada continues to add to a long list – now at 108 – of recalled hand sanitizers.

The recalls are for ingredients that aren't allowed in Canada or for improper labelling. Many of the sanitizers contain unacceptable grades of ethanol or denaturants that have not been reviewed for safety or efficacy. Denaturants taste bad and are added to ethanol to discourage ingestion, especially by children.

Two unauthorized denaturants that have been found in hand sanitizers sold in Canada are ethyl acetate, which with frequent use can cause dry skin, leading to irritation or cracking, and methanol, which can cause dermatitis, eye irritation, upper respiratory system irritation and headaches.

8 Ningbo Pulisi Daily Chemical Products Co., Ltd - 577795 - 08/13/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	11.10
Report id	754679
Category	Antiseptic
Quality	Old News
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated/Misbranded

Click here to see the Original Article

Table 14: Places for report 754679

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	Yuyao	30.05	121.14944
Americas	United States	United States	39.76	-98.5

Table 15: Drugs for report 754679

Medicine Name	Medicine Class	Action	ATC Code
salicylic acid	Other antifungals for topical use	antifungals for topical use	D01AE12
salicylic acid	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC08
	Zinc	other mineral supplements	A12CB

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Ningbo Pulisi Daily Chemical Products Co., Ltd. at Fangjia Road Xiaocao'e Town, Yuyao City, Zhejiang Province, from February 25 to 28, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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, Ningbo Pulisi Daily Chemical Products Co., Ltd manufactures Foaming Acne Scrub that is misbranded under section 502(c) of the FD&C Act, 21 U.S.C. 352(c). You also manufacture AuraFresh instant Hand Sanitizer 1.8 oz (Berries, Original, Lavender, Fresh Citrus); AuraFresh Instant Hand Sanitizer 8 oz (Vitamin E and Aloe, Aloe Vera & Moisturizers); AuraFresh INSTANT Hand Sanitizer 2 x 2 oz (Aloe Vera, Vitamin E); HALSA SHAMPOO; SPA MYSTIQUE Skin Relief Oatmeal and SPA MYSTIQUE Skin Protection Soothing Relief that are misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x). Introduction of such products into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

We reviewed your March 10, 2019, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to perform, 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, and appropriate laboratory testing of each batch of drug product required to be free of objectionable microorganisms (21 CFR 211.165(a) and (b)). You released your over-the-counter (OTC) drug products without adequate testing, including identity testing for each active ingredient. For example, you did not test drug products Halsa Anti-Dandruff Shampoo and Oil Free Acne Wash for their labelled active ingredients zinc pyrithione and salicylic acid, respectively, prior to release. [...] 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)). [...] 3. Your firm failed to follow an adequate written testing program designed to assess the stability characteristics of drug products. (21 CFR 211.166(a)). [...] Misbranding Charges

Foaming Acne Scrub; AuraFresh instant Hand Sanitizer 1.8 oz (Berries, Original, Lavender, Fresh Citrus); AuraFresh Instant Hand Sanitizer 8 oz (Vitamin E and Aloe, Aloe Vera & Moisturizers); AuraFresh INSTANT Hand Sanitizer 2 x 2 oz (Aloe Vera, Vitamin E); HALSA SHAMPOO; SPA MYSTIQUE Skin Relief Oatmeal; and SPA MYSTIQUE Skin Protection Soothing Relief

9 South Africans aren't being protected from fake sanitisers: what needs to be done

Publication date	2020-10-20
Create date	2020-10-20
Score	10.84
Report id	774016
Category	Antiseptic
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: South Africans aren't being protected from fake sanitisers: what needs to be done The Conversation Africa

Click here to see the Original Article

Table 16: Places for report 774016

Region Name	Country	Location	Latitude	Longitude
Melanesia	Australia	Commonwealth of Australia	-25	135
Southern Africa	South Africa	Republic of South Africa	-29	24
Western Africa	Nigeria	Federal Republic of Nigeria	10	8
Americas	Guyana	Co-operative Republic of Guyana	5	-59
Western Asia	United Arab Emirates	United Arab Emirates	23.75	54.5
Eastern Africa	Zambia	Zambia	-14.33333	28.5
Europe	Netherlands	Kingdom of the Netherlands	52.25	5.75

Table 17: Other Stories

ID	Title	Link
774952	South Africa: What Needs to Be Done About Fake Sanitisers	Link

Table 17: Other Stories(continued)

ID	Title	Link
778577	South Africans aren't being protected from fake sanitisers. Here's what needs to be done	Link
784513	South Africans aren't being protected from fake sanitisers: what needs to be done	Link
774818	Fake sanitisers in SA could have deadly consequences: What needs to be done	Link
775343	ANALYSIS: What needs to be done to protect South Africans from fake sanitisers	Link
778952	South Africans aren't being protected from fake sanitiser	Link
783835	South Africans aren't being protected from fake sanitisers: What needs to be done	Link

Notes: [...[In South Africa, the Bureau of Standards recently issued a press release, raising concerns about substandard sanitisers produced by "unscrupulous" manufacturers who were falsely claiming that their products had been certified. Reference was made to low-quality versions that can trigger skin allergies and can damage the skin, often presenting as a form of eczema.

In May 2020, a laboratory found that two out of the 11 hand sanitisers bought from retailers in the city of Pietermaritzburg contained 1-propanol. Four contained only between 46% and 67% alcohol while claiming to contain 70%.

10 Sunstar Americas Inc. Issues Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% due to microbial contamination

Publication date	2020-10-27
Create date	2020-10-28
Score	7.34
Report id	783547
Category	Antiseptic
Quality	Substandard
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Sunstar Americas Inc. Issues Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% due to microbial contamination PRNewswire

Click here to see the Original Article

Table 18: Places for report 783547

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Chicago	41.85003	-87.65005

Table 19: Drugs for report 783547

Medicine Name	Medicine Class	Action	ATC Code
chlorhexidine	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB03
chlorhexidine	Antiinfectives	irrigating solutions	B05CA02
chlorhexidine	Biguanides and amidines	antiseptics and disinfectants	D08AC02
chlorhexidine	Medicated dressings with antiinfectives	medicated dressings	D09AA12
chlorhexidine	Antiseptics	throat preparations	R02AA05
chlorhexidine	Other antiinfectives	antiinfectives	S01AX09

Table 19: Drugs for report 783547(continued)

Medicine Name	Medicine Class	Action	ATC Code
chlorhexidine	Antiinfectives	antiinfectives	S02AA09
chlorhexidine	Antiinfectives	antiinfectives	S03AA04

Table 20: Other Stories

ID	Title	Link
789768	Prescription oral rinse product recalled due to microbial contamination	Link
785928	Burkholderia contamination prompts recall of Paroex® Chlorhexidine Gluconate Oral Rinse	Link
789836	Sunstar Americas Inc. Issues Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% Due to Microbial Contamination	Link
785998	This Mouthwash Has Been Recalled Due to Potential Contamination	Link
784750	Sunstar recalls gingivitis drug due to potential bacterial contamination	Link
790153	GUM Paroex Mouthwash Recalled for Bacteria Contamination	Link
784265	Sunstar Americas Inc. Issues Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% Due to Microbial Contamination - 2020-10-28	Link
784307	Sunstar Americas Inc. Issues Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% Due to Microbial Contamination	Link

Notes: CHICAGO, Oct. 27, 2020 /PRNewswire/ – Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% products bearing an expiration date from 6/30/22 – 9/30/22 (see specific lots below) to the consumer level. This product may be contaminated with the bacteria Burkholderia lata. [...] AFFECTED LOTS

Product name: Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% NDC # 052376-021-02 P/N 1789P 16 fl oz

Lot #

Exp Date

Lot #

Exp Date

Lot #

Exp Date

C170FY

6/30/22

C191KT
7/31/22
C205BL
7/31/22
C170FZ
6/30/22
C191KU
7/31/22
C205BM
7/31/22
C170GA
6/30/22
C191KW
7/31/22
C205BN
7/31/22
C170GB
6/30/22
C191KX
7/31/22
C219DS
8/31/22
C170GC
6/30/22
C191KY
7/31/22
C240GM
9/30/22
C177GP
6/30/22
C198LJ
7/31/22
C219DK
8/31/22
C177GQ
6/30/22
C198LK
7/31/22
C219DL
8/31/22
C177GR
6/30/22

C198LL
7/31/22
C219DM
8/31/22
C240GP
9/30/22
C198LM
7/31/22
C219DN
8/31/22
C240GQ
9/30/22
C205BH
7/31/22
C219DP
8/31/22
C240GR
9/30/22
C205BJ
7/31/22
C219DQ
8/31/22
C191KS
7/31/22
C205BK
7/31/22
C219DR
8/31/22
Product name: Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% NDC # 052376-021-04 P/N 1788P 4.0 fl oz
Lot #: C191KR EXP Date: 07/31/22

11 Essential Pharmaceutical Corp - 597677 - 09/03/2020 - 2020-10-06

Publication date	2020-10-06
Create date	2020-10-08
Score	6.89
Report id	756020
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved New Drugs/Misbranded

Click here to see the Original Article

Table 21: Places for report 756020

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pomona	34.05529	-117.75228

Table 22: Drugs for report 756020

Medicine Name	Medicine Class	Action	ATC Code
	Cosmetics	all other non-therapeutic products	V07AT
	Antiseptics	throat preparations	R02AA
benzalkonium	Quaternary ammonium compounds	antiseptics and disinfectants	D08AJ01
benzalkonium	Medicated dressings with antiinfectives	medicated dressings	D09AA11
benzalkonium	Antiseptics	throat preparations	R02AA16
phenylephrine	Adrenergic and dopaminergic agents	cardiac stimulants excl. cardiac glycosides	C01CA06
phenylephrine	Sympathomimetics, plain	decongestants and other nasal preparations for topical use	R01AA04

Table 22: Drugs for report 756020(continued)

Medicine Name	Medicine Class	Action	ATC Code
phenylephrine	Sympathomimetics, combinations excl. corticosteroids	decongestants and other nasal preparations for topical use	R01AB01
phenylephrine	Sympathomimetics	nasal decongestants for systemic use	R01BA03
phenylephrine	Sympathomimetics excl. antiglaucoma preparations	mydriatics and cycloplegics	S01FB01
phenylephrine	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA05
			J07

Notes: The United States Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility, Essential Pharmaceutical Corp, located at 1906 W. Holt Ave, Pomona, CA, on October 8-10 and 17, 2019. Based on the inspectional findings and a subsequent review of your product labels collected during the inspection, we have identified serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You can find the Act and FDA regulations through links on the FDA's home page at http://www.fda.gov.External Link Disclaimer

Unapproved New Drug

Your firm manufactures and distributes "BIO-MINT Nasal Spray," which is an unapproved new drug and is being marketed as a nonprescription, over-the-counter (OTC) drug product. Introduction or delivery for introduction of such product into interstate commerce is prohibited under sections 505(a) and 301(d) of the Act, 21 U.S.C. 331(d) and 355(a). This product is also misbranded under section 502(ee) of the Act, 21 U.S.C. 352(ee), and its introduction into interstate commerce is prohibited by section 301(a) of the Act, 21 U.S.C. 331(a). These violations are described in more detail below.

"BIO-MINT Nasal Spray" is a drug under section 201(g)(1)(B) of the 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 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 combination nasal decongestant, antihistamine, and antiseptic. [...] Adulterated Dietary Supplements

The inspection revealed serious violations of the FDA's regulations for Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, under Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111). These violations cause the products you manufacture to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions that do not meet CGMP requirements for dietary supplements. [...] Misbranded Dietary Supplements

The dietary supplement products discussed below are misbranded within the meaning of section

403 [21 U.S.C. § 343] of the Act and/or fail to comply with the regulations implementing the food labeling requirements of the Act, which are found in 21 CFR Part 101. [...]

12 Lupin Limited - 572345 - 09/10/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	6.23
Report id	754694
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Active Pharmaceutical Ingredient (API)/Adulterated

Click here to see the Original Article

Table 23: Places for report 754694

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Bandra	26.14163	70.58803
Americas	United States	United States	39.76	-98.5

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Lupin Limited Unit 1 (FEI 3002807511) at Unit 1, 198-202 New Ind Area No 2, Mandideep, Madhya Pradesh, from November 26 to December 4, 2018.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, 21 CFR parts 210 and 211, and significant deviations from CGMP for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drugs 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).

We reviewed your December 26, 2018, response in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following.

1. 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). [...] 2. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to

possess (21 CFR 211.100(a)).[...] 3. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)). [...]

13 LEC Custom Products, Inc. - 607838 - 09/24/2020 - 2020-10-06

Publication date	2020-10-06
Create date	2020-10-08
Score	5.41
Report id	756019
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

Click here to see the Original Article

Table 24: Places for report 756019

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Brampton	43.68341	-79.76633
Americas	United States	United States	39.76	-98.5

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, LEC Custom Products, Inc., 3004737602, at 7 Kenview Boulevard, Brampton, Ontario, from March 2 to 6, 2020.

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 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).

We reviewed your March 25, 2020, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to use equipment in the manufacture, processing, packing, or holding of drug products that is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance (21 CFR 211.63). [...] 2.

Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)). [...] 3. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).[...] 4. Your firm failed to establish a 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)). [...] 5. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. 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)). [...] 6. Your firm failed to establish an adequate quality unit and the responsibilities, and procedures applicable to the quality control unit were not in writing and fully followed (21 CFR 211.22(a)&(d)). [...]

14 TG United, Inc. - 577583 - 08/01/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	5.14
Report id	754681
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

Click here to see the Original Article

Table 25: Places for report 754681

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Brooksville	28.55554	-82.38991

Table 26: Drugs for report 754681

Medicine Name	Medicine Class	Action	ATC Code
triprolidine	Other antihistamines for systemic use	antihistamines for systemic use	R06AX07
phenylephrine, combinations	Sympathomimetics	nasal decongestants for systemic use	R01BA53
phenylephrine, combinations	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA55
diphenhydramine	Antihistamines for topical use	antipruritics, incl. antihistamines, anesthetics, etc.	D04AA32
diphenhydramine	Aminoalkyl ethers	antihistamines for systemic use	R06AA02
brompheniramine, combinations	Substituted alkylamines	antihistamines for systemic use	R06AB51
dextromethorphan, combinations	Other nervous system drugs	other nervous system drugs	N07XX59

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, TG United, Inc., FEI: 3005350897, at 16275 Aviation Loop Drive, from December 17, 2018, to February 15, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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).

Your firm manufactures HISTEX PD Drops, Triprolidine HCl, Diphenhydramine HCl, ED Chlorped Jr., Rynex PSE, Rynex PE, Ed Chlorped D, Poly-Hist PD Drops, Capron DM Liquid, and Rynex DM that are unapproved new drugs in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a). Introduction or delivery for introduction of such products into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d).

We reviewed your March 8, 2019, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. 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). [...] 2. Your firm failed to use equipment in the manufacture, processing, packing, or holding of drug products that is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance (21 CFR 211.63). [...] 3. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a). [...] 4. Your firm failed to 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)). [...]

15 Pakistan drug regulator recalls remdesivir, other drugs over glass contamination

Publication date 2020-10-24

Create date 2020-10-26

Score 3.31

Report id 779461

Category Analgesic, Antibiotic, Antiviral others, Antiparasitic, Anti-inflammatory medicine, Other

Quality Substandard

Source Unknown

Curation Manually curated

Incident or General Incident

Snippet: Pakistan drug regulator recalls remdesivir, other drugs over glass contamination SAMAA

Click here to see the Original Article

Table 27: Places for report 779461

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Islamabad	33.72148	73.04329
Southern Asia	Pakistan	Karachi	24.8608	67.0104
Southern Asia	Pakistan	Lahore	31.558	74.35071

Table 28: Drugs for report 779461

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
albendazole	Benzimidazole derivatives	antinematodal agents	P02CA03
diclofenac	Other dermatologicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic products, non-steroids	M01AB05

Table 28: Drugs for report 779461(continued)

Medicine Name	Medicine Class	Action	ATC Code
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03
ceftriaxone	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD04
			J05
metronidazole	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB17
metronidazole	Other chemotherapeutics	chemotherapeutics for topical use	D06BX01
metronidazole	Imidazole derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AF01
metronidazole	Imidazole derivatives	other antibacterials	J01XD01
metronidazole	Nitroimidazole derivatives	agents against amoebiasis and other protozoal diseases	P01AB01

Table 29: Other Stories

ID	Title	Link
779642	SAMAA - Pakistan drug regulator recalls remdesivir, other drugs over glass contamination	Link

Notes: The Drug Regulatory Authority of Pakistan has issued recall alerts for substantial and adulterated drugs in the market. Glass particles were reportedly found in some of the drugs. [...] The drugs are: 1. Kanbact 500mg injection: antibiotic ceftriaxone used for various bacterial infections 2. Fenaclod injection: diclofenac sodium used as a painkiller 3. Oxiphin 1g injection: antibiotic ceftriaxone 4. Flazol infusion 500mg/100ml: antibiotic metronidazole used for stomach infections 5. Parapals Infusion 100ml 6. Medisol Compound Sodium Lactate IV infusion 500ml: solution for IV drips 7. Zental suspension: albendazole for worm infections 8. Redzi 100mg solution for injection: antiviral remdesivir being used in COVID-19 treatment 9. Water for injection b#wfi-237 [...]

16 Deva Holding AS - Cerkezkoy Subesi - 577493 - 08/06/2019 - 2020-10-05

Publication date 2020-10-05

Create date 2020-10-08

Score 2.76

Report id 754686

Category Analgesic, Antibiotic, Antiviral others, Antiparasitic, Anti-inflammatory medicine, Other

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

Click here to see the Original Article

Table 30: Places for report 754686

Region Name	Country	Location	Latitude	Longitude
Western Asia	Turkey	Küçükçekmece	41.06947	28.76983
Americas	United States	United States	39.76	-98.5

Table 31: Drugs for report 754686

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB

Table 31: Drugs for report 754686(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Deva Holding AS – Cerkezkoy Subesi at Organize Fatih Bulvar Fatih Bulvar 32 Cerkezkoy, Tekirdag, 59500, Turkey, from February 4, 2019 to February 15, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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).

We reviewed your March 6, 2019 response 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 perform operations related to the manufacture, processing, and packing of penicillin in facilities separate from those used for other drug products for human use (21 CFR 211.42(d)). You manufacture drugs on two campuses: Cerkezkoy 1 (CK1) and Cerkezkoy 2 (CK2) which are approximately ¼ mile apart. CK1 manufactures various products, including penicillin, (b)(4), and non-beta-lactam drug products. You manufacture (b)(4) capsules for the U.S. market in the (b)(4) Building and penicillin drug products in an adjacent building on the CK2 campus. [...] Your firm failed to test non-penicillin drug products for the presence of penicillin when a reasonable possibility existed that the non-penicillin drug product had been exposed to cross-contamination with penicillin (21 CFR 211.176).

17 Let's Talk Health, Inc. - 576771 - 08/06/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	2.23
Report id	754682
Category	Nutritional supplement, Vitamin
Quality	Old News
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved New Drugs/Misbranded

Click here to see the Original Article

Table 32: Places for report 754682

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Chula Vista	32.64005	-117.0842

Table 33: Drugs for report 754682

Medicine Name	Medicine Class	Action	ATC Code
acetic acid	Organic acids	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AD02
acetic acid	Antiinfectives	antiinfectives	S02AA10
melatonin	Melatonin receptor agonists	hypnotics and sedatives	N05CH01
			A11
	Vitamins	i.v. solution additives	B05XC
folic acid	Folic acid and derivatives	vitamin b12 and folic acid	B03BB01
glutathione	Antidotes	all other therapeutic products	V03AB32

Notes: The United States Food and Drug Administration (FDA) inspected your facility located at 2411 Fenton St. Ste 102, Chula Vista, CA on February 6, 8, and 11, 2019. Based on the

inspection, a review of the product labels and promotional literature collected, and a review of your website and blog, we have identified serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You may find the Act and related regulations through links on FDA's home page at www.fda.gov.

We have received your written response dated March 4, 2019, concerning our investigator's observations noted on the FDA-483, Inspectional Observations, issued to you on February 11, 2019. Our comments regarding the adequacy of the actions you took to correct the objectionable conditions and practices observed during the inspection are detailed after the applicable violations, noted below.

Unapproved New Drugs and Misbranded Drugs

We reviewed your website at www.letstalkhealth.com in June 2019 and have determined that you take orders there for the products Cardio Advantage Plus, Urine-Eze, Re-Lev-It, Liposomal Symplex P, Liposomal Vitamin C, Melatonin, Liposomal B-Complex, Liposomal Curcumin, Liposomal Glutathione, and VariGone. We also reviewed your blog at blog/letstalkhealth.com in June 2019, which links to your website at www.letstalkhealth.com, and following the February 2019 inspection, we reviewed additional materials collected during the inspection, including your product labels and brochures that accompany the product.

The claims on your website, blog, product labels, and brochures establish that your Cardio Advantage Plus, Urine-Eze, Re-Lev-It, Liposomal Symplex P, Liposomal Vitamin C, Melatonin, Liposomal B-Complex, Liposomal Curcumin, Liposomal Glutathione, and VariGone are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment or prevention of disease. [...] Adulterated Dietary Supplements

Your dietary supplements products are adulterated within the meaning of section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] because they products have been prepared, packed, or held under conditions that do not meet Current Good Manufacturing Practice (CGMP) regulations for dietary supplements found in Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111). Additionally, even if the product labeling for your Cardio Advantage Plus, Urine-Eze. Re-Lev-It, Liposomal Symplex P, Liposomal Vitamin C, Melatonin, Liposomal B-Complex, Liposomal Curcumin, Liposomal Glutathione, and VariGone did not have therapeutic claims which make these products unapproved new drugs and/or misbranded drugs, these products would still be adulterated dietary supplements within the meaning of section 402(g)(1) of the Act because the products have been prepared, packed, or held under conditions that do not meet the CGMP regulations in 21 CFR Part 111.[...] Dietary Supplement Misbranding

Several of the dietary supplements you distribute are misbranded under section 403 of the Act [21 U.S.C. § 343], as described below. Additionally, even if your Cardio Advantage Plus were not an unapproved new drug and misbranded drug, it would be misbranded as a dietary supplement under section 403 of the Act, as described below:[...]

Annex

7.5 COVID-19 medicines

Medicine Quality Monitoring Globe

November 23, 2020

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

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

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

Filters applied for this report

Search ("tranilast" OR "interleukin-2" OR "INC424" OR "TNKase" OR "nitazoxanide" OR "LY3832479" OR "baloxavir" OR "interleukin-7" OR "Kineret" OR "ritonavir" OR "Crizanlizumab" OR "Apixaban" OR "cyclosporin" OR "losartan" OR "ATI-450" OR "nitrogen monoxide" OR "tirofiban" OR "Ebselen" OR "corbistadine" OR "atorvastatin" OR "Eicosapentaenoic" OR "nitrite" OR "Riamilovir" OR "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 "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 "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 "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 "alpha lipoic" OR "almitrine" OR "melphalan" OR "TMJ2" OR "dapagliflozin" OR "NBT-NM108" 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 "bemiparin" OR "T89" OR "Spironolactone" OR "fingolimod" OR "aspirin" OR "Remdesivir" OR "pyridostigmine" OR "Prolastin" OR "EC-18" OR "poractant" OR "isotretinoin" OR "telmisartan" OR "TJM2 TJM-2"

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 SOO1" OR "vazegepant" OR "REGN10933" OR "Propranolol" 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 "CASOOO1" OR "immunoglobulin" OR "nafamostat" OR "Crocetinate" OR "Diphenhydramine" OR "BIO 101" OR "AZD1656" OR "PTC299" OR "amodiaquine" 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 "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 "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 "Anti-IL-8" OR "dihydroartemisinin" OR "vitamin c" OR "25-hydroxyvitamin D3" 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 "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 (("Drug" OR "Plasma" OR "Treatment" OR "Medication") AND ("CV19" OR "新冠病毒" OR "武汉新型冠状病毒" OR "非典" OR "SARS" OR "CoV-2" OR "vi rút corona" OR "武汉肺炎" OR "COVID-19" OR "COVID" OR "新冠疫情" OR "新型冠状病毒肺炎" OR "SARS-CoV-2" OR "CV" OR "Coronavirus" OR "CV-19" OR "SRAS" OR "新型冠状病毒" OR "新冠"))

Start date	2020-10-01
End date	2020-10-31
Language	en
Report type	incident

Curation status	validated
Number of Reports	38

1 Medical scientists allege importation of substandard COVID-19 test kits

Publication date	2020-10-14
Create date	2020-10-15
Score	41.98
Report id	765842
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Medical scientists allege importation of substandard COVID-19 test kits Guardian

Click here to see the Original Article

Table 1: Places for report 765842

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Abuja	9.05785	7.49508

Table 2: Other Stories

ID	Title	Link
777374	How Council saved Nigeria from substandard COVID-19 test kits	Link
777191	Medical scientists allege importation of substandard COVID-19 test kits	Link

Notes: The Medical Laboratory Science Council of Nigeria (MLSCN) has claimed that substandard antibody test kits are being imported into the country. According to the body, it validated 33 test kits and systems for COVID-19 but all antigen and antibody test kits failed to meet the minimum acceptable criteria. The said the council received 43 brands of test kits for validation, while 33 were validated and 22 fulfilled the requirements of rapid test kits, none met the characteristics of sensitivity and specificity to qualify for deployment for purposes of testing in disease surveillance and routine diagnosis. [...] The Registrar and Chief Executive Officer of the council, Dr. Tosan Erhabor, told reporters yesterday in Abuja that the use of any non-validated Rapid/ PCR Test Kits for COVID-19 testing would attract sanctions from

the body. [...] Erhabor said the highest sensitivity of 60.4 per cent found in such kits was too low to be used for detecting SARS-CoV-2 infection. According to him, it is also far below the generally acceptable minimum in-vitro diagnostics (IVD) sensitivity and specificity of 95 per cent.

2 Pakistan drug regulator recalls remdesivir, other drugs over glass contamination

Publication date 2020-10-24

Create date 2020-10-26

Score 40.60

Report id 779461

Category Analgesic, Antibiotic, Antiviral others, Antiparasitic, Anti-inflammatory medicine, Other

Quality Substandard

Source Unknown

Curation Manually curated

Incident or General Incident

Snippet: Pakistan drug regulator recalls remdesivir, other drugs over glass contamination SAMAA

Click here to see the Original Article

Table 3: Places for report 779461

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Islamabad	33.72148	73.04329
Southern Asia	Pakistan	Karachi	24.8608	67.0104
Southern Asia	Pakistan	Lahore	31.558	74.35071

Table 4: Drugs for report 779461

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
albendazole	Benzimidazole derivatives	antinematodal agents	P02CA03
diclofenac	Other dermatologicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic products, non-steroids	M01AB05

Table 4: Drugs for report 779461(continued)

Medicine Name	Medicine Class	Action	ATC Code
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03
ceftriaxone	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD04
			J05
metronidazole	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB17
metronidazole	Other chemotherapeutics	chemotherapeutics for topical use	D06BX01
metronidazole	Imidazole derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AF01
metronidazole	Imidazole derivatives	other antibacterials	J01XD01
metronidazole	Nitroimidazole derivatives	agents against amoebiasis and other protozoal diseases	P01AB01

Table 5: Other Stories

ID	Title	Link
779642	SAMAA - Pakistan drug regulator recalls remdesivir, other drugs over glass contamination	Link

Notes: The Drug Regulatory Authority of Pakistan has issued recall alerts for substantial and adulterated drugs in the market. Glass particles were reportedly found in some of the drugs. [...] The drugs are: 1. Kanbact 500mg injection: antibiotic ceftriaxone used for various bacterial infections 2. Fenaclod injection: diclofenac sodium used as a painkiller 3. Oxiphin 1g injection: antibiotic ceftriaxone 4. Flazol infusion 500mg/100ml: antibiotic metronidazole used for stomach infections 5. Parapals Infusion 100ml 6. Medisol Compound Sodium Lactate IV infusion 500ml: solution for IV drips 7. Zental suspension: albendazole for worm infections 8. Redzi 100mg solution for injection: antiviral remdesivir being used in COVID-19 treatment 9. Water for injection b#wfi-237 [...]

3 Let's Talk Health, Inc. - 576771 - 08/06/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	34.77
Report id	754682
Category	Nutritional supplement, Vitamin
Quality	Old News
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved New Drugs/Misbranded

Click here to see the Original Article

Table 6: Places for report 754682

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Chula Vista	32.64005	-117.0842

Table 7: Drugs for report 754682

Medicine Name	Medicine Class	Action	ATC Code
acetic acid	Organic acids	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AD02
acetic acid	Antiinfectives	antiinfectives	S02AA10
melatonin	Melatonin receptor agonists	hypnotics and sedatives	N05CH01
			A11
	Vitamins	i.v. solution additives	B05XC
folic acid	Folic acid and derivatives	vitamin b12 and folic acid	B03BB01
glutathione	Antidotes	all other therapeutic products	V03AB32

Notes: The United States Food and Drug Administration (FDA) inspected your facility located at 2411 Fenton St. Ste 102, Chula Vista, CA on February 6, 8, and 11, 2019. Based on the

inspection, a review of the product labels and promotional literature collected, and a review of your website and blog, we have identified serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You may find the Act and related regulations through links on FDA's home page at www.fda.gov.

We have received your written response dated March 4, 2019, concerning our investigator's observations noted on the FDA-483, Inspectional Observations, issued to you on February 11, 2019. Our comments regarding the adequacy of the actions you took to correct the objectionable conditions and practices observed during the inspection are detailed after the applicable violations, noted below.

Unapproved New Drugs and Misbranded Drugs

We reviewed your website at www.letstalkhealth.com in June 2019 and have determined that you take orders there for the products Cardio Advantage Plus, Urine-Eze, Re-Lev-It, Liposomal Symplex P, Liposomal Vitamin C, Melatonin, Liposomal B-Complex, Liposomal Curcumin, Liposomal Glutathione, and VariGone. We also reviewed your blog at blog/letstalkhealth.com in June 2019, which links to your website at www.letstalkhealth.com, and following the February 2019 inspection, we reviewed additional materials collected during the inspection, including your product labels and brochures that accompany the product.

The claims on your website, blog, product labels, and brochures establish that your Cardio Advantage Plus, Urine-Eze, Re-Lev-It, Liposomal Symplex P, Liposomal Vitamin C, Melatonin, Liposomal B-Complex, Liposomal Curcumin, Liposomal Glutathione, and VariGone are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment or prevention of disease. [...] Adulterated Dietary Supplements

Your dietary supplements products are adulterated within the meaning of section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] because they products have been prepared, packed, or held under conditions that do not meet Current Good Manufacturing Practice (CGMP) regulations for dietary supplements found in Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111). Additionally, even if the product labeling for your Cardio Advantage Plus, Urine-Eze. Re-Lev-It, Liposomal Symplex P, Liposomal Vitamin C, Melatonin, Liposomal B-Complex, Liposomal Curcumin, Liposomal Glutathione, and VariGone did not have therapeutic claims which make these products unapproved new drugs and/or misbranded drugs, these products would still be adulterated dietary supplements within the meaning of section 402(g)(1) of the Act because the products have been prepared, packed, or held under conditions that do not meet the CGMP regulations in 21 CFR Part 111.[...] Dietary Supplement Misbranding

Several of the dietary supplements you distribute are misbranded under section 403 of the Act [21 U.S.C. § 343], as described below. Additionally, even if your Cardio Advantage Plus were not an unapproved new drug and misbranded drug, it would be misbranded as a dietary supplement under section 403 of the Act, as described below:[...]

4 Gujarat: Two booked for blackmarketing of Covid drug

Publication date	2020-10-05
Create date	2020-10-07
Score	24.22
Report id	755217
Category	Antiviral others
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Gujarat: Two booked for blackmarketing of Covid drug The Indian Express

Click here to see the Original Article

Table 8: Places for report 755217

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Rajkot	22.29161	70.79322

Notes: A wholesale medical seller and a medical representative (MR) were booked by the Rajkot city Crime Branch on Monday for the alleged blackmarketing of REMDAC 100 MG injections [remdesivir], used in the treatment of Covid-19, wherein the accused produced fake bills of the critical injections. According to police officials of Detection of Crime Branch, Rajkot city, the main accused Paresh Patel (35), a resident of Janakpur society at Sheri Sadhuvasvani road in Rajkot, who runs 'New Ideal Agencies', a wholesale medicine shop and other accused RajniKant Patel (29), a resident of Sanskar Avenue at bypass road in Rajkot, who works as a medical representative, were booked by the police.

While Paresh was detained, the other accused Rajnikant Patel is already lodged in Rajkot sub jail in another case of fraud lodged at DCB police station in Rajkot. "A few days ago, Dr Anand Chauhan of Anand Clinic in Rajkot had approached the police stating that the owner of New Ideal Agencies had given him a bill of 24 REMDAC injections worth Rs 46,473 but he had not purchased it. Upon the complaint, officials of Food and Drug Safety department visited the Anand clinic and probed the fake bill," said an officer at Rajkot DCB.

"The role of the wholesaler and MR came into light and a raid was conducted and the accused Paresh has been detained. The license of New Ideal agencies has been cancelled," the officer added.

5 El Paso man accused of offering fake coronavirus prevention treatment

Publication date	2020-10-09
Create date	2020-10-14
Score	20.56
Report id	760484
Category	Not applicable, Antiviral others
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: El Paso man accused of offering fake coronavirus prevention treatment KFOX El Paso

Click here to see the Original Article

Table 9: Places for report 760484

Region Name	Country	Location	Latitude	Longitude
Americas	United States	El Paso	31.75872	-106.48693

Table 10: Other Stories

ID	Title	Link
767199	El Paso man accused of offering fake coronavirus prevention treatment	Link

Notes: Federal authorities have obtained a civil injunction against 39-year-old El Paso resident Hugo Chico in an effort to combat alleged fraud related to the coronavirus (COVID-19) pandemic, according to federal officials.

The purpose of the civil injunction is to stop Chico's sale of fraudulent COVID-19 prevention treatments through his business and his Facebook webpage, "Centro de Medicina Fisica y Rehabilitacion."

According to court records, Chico allegedly met with undercover agents on Monday to sell, and administer, COVID-19 prevention treatments.

This action will ensure Chico, and any others working with him, stop advertising or performing any COVID-19 treatments. In so doing, the government is employing a federal statute that permits federal courts to issue injunctions to prevent harm to potential victims of fraudulent

schemes.

6 Fake coronavirus protection products discovered for sale in West Sussex

Publication date	2020-10-23
Create date	2020-10-26
Score	19.32
Report id	778246
Category	Medical devices for disease prevention
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Fake coronavirus protection products discovered for sale in West Sussex Chichester Observer

Click here to see the Original Article

Table 11: Places for report 778246

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	Burgess Hill	50.95843	-0.13287
Europe	United Kingdom	Chichester	50.83673	-0.78003
Europe	United Kingdom	Horsham	51.06314	-0.32757
Europe	United Kingdom	Crawley	51.11303	-0.18312

Table 12: Other Stories

ID	Title	Link
778247	Fake Coronavirus protection products found on sale by Trading Standards officers	Link
785248	Fake PPE found for sale in West Sussex	Link
781417	Trading standards catch covid fraudsters selling fake protection	Link

Notes: UV lights, cards worn around the neck to 'sterilise the air' and face coverings are just some of the misleading items found for sale, a Trading Standards spokesman said.

Basic face coverings claiming to be made to a 'KN95' standard were purchased by officers in 23 high street shops across the county including Chichester, Burgess Hill, Crawley and Horsham.

[...] Products which allegedly kill 99 per cent of viruses using UV lights have also been found online. [...] A card which claims to 'sterilise the air' around the user by emitting chlorine dioxide was also found for sale on UK online platforms by officers. [...] "All of these products were falsely labelled.

7 Ningbo Pulisi Daily Chemical Products Co., Ltd - 577795 - 08/13/2019 - 2020-10-05

Publication date 2020-10-05

Create date 2020-10-08

Score 18.54

Report id 754679

Category Medical devices for disease prevention

Quality Old News

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated/Misbranded

Click here to see the Original Article

Table 13: Places for report 754679

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	Yuyao	30.05	121.14944
Americas	United States	United States	39.76	-98.5

Table 14: Drugs for report 754679

Medicine Name	Medicine Class	Action	ATC Code
salicylic acid	Other antifungals for topical use	antifungals for topical use	D01AE12
salicylic acid	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC08
	Zinc	other mineral supplements	A12CB

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Ningbo Pulisi Daily Chemical Products Co., Ltd. at Fangjia Road Xiaocao'e Town, Yuyao City, Zhejiang Province, from February 25 to 28, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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, Ningbo Pulisi Daily Chemical Products Co., Ltd manufactures Foaming Acne Scrub that is misbranded under section 502(c) of the FD&C Act, 21 U.S.C. 352(c). You also manufacture AuraFresh instant Hand Sanitizer 1.8 oz (Berries, Original, Lavender, Fresh Citrus); AuraFresh Instant Hand Sanitizer 8 oz (Vitamin E and Aloe, Aloe Vera & Moisturizers); AuraFresh INSTANT Hand Sanitizer 2 x 2 oz (Aloe Vera, Vitamin E); HALSA SHAMPOO; SPA MYSTIQUE Skin Relief Oatmeal and SPA MYSTIQUE Skin Protection Soothing Relief that are misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x). Introduction of such products into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

We reviewed your March 10, 2019, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to perform, 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, and appropriate laboratory testing of each batch of drug product required to be free of objectionable microorganisms (21 CFR 211.165(a) and (b)). You released your over-the-counter (OTC) drug products without adequate testing, including identity testing for each active ingredient. For example, you did not test drug products Halsa Anti-Dandruff Shampoo and Oil Free Acne Wash for their labelled active ingredients zinc pyrithione and salicylic acid, respectively, prior to release. [...] 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)). [...] 3. Your firm failed to follow an adequate written testing program designed to assess the stability characteristics of drug products. (21 CFR 211.166(a)). [...] Misbranding Charges

Foaming Acne Scrub; AuraFresh instant Hand Sanitizer 1.8 oz (Berries, Original, Lavender, Fresh Citrus); AuraFresh Instant Hand Sanitizer 8 oz (Vitamin E and Aloe, Aloe Vera & Moisturizers); AuraFresh INSTANT Hand Sanitizer 2 x 2 oz (Aloe Vera, Vitamin E); HALSA SHAMPOO; SPA MYSTIQUE Skin Relief Oatmeal; and SPA MYSTIQUE Skin Protection Soothing Relief

8 Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines

Publication date	2020-10-02
Create date	2020-10-07
Score	17.21
Report id	750450
Category	Vaccine, Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines The Irrawaddy News Magazine

Click here to see the Original Article

Table 15: Places for report 750450

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

Table 16: Drugs for report 750450

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 17: Other Stories

ID	Title	Link
781680	Burma : Myanmar Health Agency warns that fake COVID-19 vaccines are in circulation - 2020-10-26	Link

Notes: Yangon — Myanmar's Food and Drug Administration (FDA) has warned the public against so-called COVID-19 vaccines being sold in the country. The government said it is taking steps to prevent the smuggling and sale of fake vaccines and pills, a director of the FDA,

who asked not to be named, told The Irrawaddy. ”Not only vaccines but also pills have been illegally smuggled into the country and are being sold online. Those medicines are illegal,” the director told The Irrawaddy. The Ministry of Health and Sports on Thursday said there has been no COVID-19 vaccine endorsed by the World Health Organization (WHO) and no supplier has completed the three-phase clinical trial process. On Facebook, retailers are selling COVID-19 tests for 20,000 kyats (US$15) and COVID-19 drugs, which they claim are made in China.[...] [Covid-19 treatment] [COVID-19 test kits, testing kits]

9 Sun Pharma Recalls Meformin for NDMA Contamination | St. Petersburg Injury Law News

Publication date	2020-10-05
Create date	2020-10-07
Score	17.17
Report id	755157
Category	Antidiabetic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Sun Pharma Recalls Meformin for NDMA Contamination | St. Petersburg Injury Law News Legal Examiner

Click here to see the Original Article

Table 18: Places for report 755157

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

Table 19: Drugs for report 755157

Medicine Name	Medicine Class	Action	ATC Code
valsartan	Angiotensin II antagonists, plain	angiotensin ii antagonists, plain	C09CA03
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02
ranitidine	H2-receptor antagonists	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BA02

Notes: Sun Pharma became the seventh and latest manufacturer to join the metformin recall parade after finding high levels of a potential cancer-causing contaminant NDMA.

The company announced in late September it was voluntarily recalling 1 lot of its metformin hydrochloride for extended-release (ER) oral suspension (Riomet ER), 500 mg per 5 mL to the consumer level. In the release the company stated the recalled lot lot contains 747 bottles

of the drug with an expiration date of October 2021.[...] According to the FDA, NDMA was initially found earlier this year in certain extended-release versions of metformin. Since that discovery there has been a growing list of recalled drugs discovered to have high levels of NDMA. The contaminant is also connected to global recalls of sartan-based heart pressure drugs and heartburn medication Zantac, in tested lots. [...] The FDA is attempting to identify the source of the NDMA impurity and says it is working closely with manufacturers of these recalled drugs. But thousands of consumers diagnosed with cancer are already pursuing valsartan and Zantac lawsuits. The suits allege they may have avoided a cancer diagnosis if other treatments had been used. At Saunders & Walker we expect to see similar lawsuits coming from users of metformin who have also been stricken with cancer.

10 Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs

Publication date 2020-10-07

Create date 2020-10-08

Score 15.68

Report id 757518

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

Quality Falsified

Source Airport

Curation Manually curated

Incident or General Incident

Snippet: Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs Fox Baltimore

Click here to see the Original Article

Table 20: Places for report 757518

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Philadelphia	40.00764	-75.13396
Americas	United States	Harrisburg	40.2737	-76.88442
Americas	United States	Pittsburgh International Airport	40.49608	-80.25547
Americas	United States	Washington	47.50012	-120.50147
Americas	United States	Baltimore	39.29038	-76.61219
Americas	United States	Wilmington	39.74595	-75.54659

Table 21: Other Stories

ID	Title	Link
757539	Customs and Border Patrol agents say they've seized nearly $2.5 million worth of counterfeit COVID-19 masks	Link
758311	Bogus Face Masks, COVID Tests Seized By Feds In MD: Patch PM	Link
758065	Scammers overseas flying in counterfeit COVID-19 products into Pittsburgh International Airport	Link

Table 21: Other Stories(continued)

ID	Title	Link
763963	Counterfeit COVID-19 tests, medications seized by customs officials	Link
758592	Nearly 59,000 'potentially dangerous' counterfeit COVID-19 face masks seized, feds say	Link
758593	U.S. Customs and Border Protection seizes thousands of fake COVID-19 facemasks, test kits, and medications	Link
758857	US Customs seizes nearly 60K counterfeit facemasks	Link
757843	Baltimore Customs Agents Seize Over 50K Counterfeit Face Masks	Link
759157	Feds Seize Counterfeit Masks, Unapproved Coronavirus Meds in DMV, Along East Coast	Link
757897	Counterfeit COVID-19 tests, medications seized by customs officials	Link
758668	Illegitimate Coronavirus Tests, Masks Seized: Baltimore Customs	Link
765354	Counterfeit masks, unapproved COVID-19 meds seized in Baltimore	Link
763576	Over 59,000 Counterfeit COVID-19 Facemasks, Test Kits Seized By Baltimore Customs	Link
758720	US customs seize 'astonishing' amount of counterfeit COVID-19 masks	Link
758471	Nearly 59,000 counterfeit masks, hundreds of fake COVID-19 tests seized at Mid-Atlantic ports, including Baltimore	Link
758483	Counterfeit masks, unapproved COVID-19 meds seized in Baltimore	Link
793058	Nearly 59,000 'potentially dangerous' counterfeit COVID-19 face masks seized, feds say	Link

Notes: The U.S. Customs and Border Protection officers throughout the Mid-Atlantic region are still seizing counterfeit or unapproved COVID-19 medications, facemasks and test kits that arrived in express consignment in the last 6 weeks.

Topping the seizures are 58,846 facemasks that violated trademark protections of numerous brands, including designer consumer brands, sports teams, vehicle manufacturers, cartoon characters and others. [...] Oftentimes, counterfeit products are manufactured in unregulated facilities with substandard materials that could potentially harm American consumers. [...] Since August 13, CBP officers at the Area Ports of Philadelphia, Baltimore and Washington, and the Ports of Harrisburg, Pa., Pittsburgh and Wilmington, Del., have seized: * 58,846 counterfeit facemasks during 21 seizures; * 916 tablets of COVID-related medications during two seizures; and * 134 COVID-19 test kits and antibody tests during six seizures

CBP is withholding specific details of individual seizures as many cases remain under investigation.

The products arrived from Finland, Hong Kong, Nigeria, Philippines, Poland, South Africa,

Spain, Thailand, United Arab Emirates, United Kingdom, and Vietnam.

The parcels were destined to addresses in Florida, North Carolina, Pennsylvania, and Virginia,

Read previous notifications of CBP's Baltimore Field Office COVID-related product seizures at:

CBP announces 11 COVID-related products seizure August 7; CBP announces 18 COVID-related product seizures on June 5; and CBP announces 18 COVID-related product seizures on May 11.

11 'Very small amounts can kill you': Local leaders and law enforcement take aim at deadly influx of fentanyl with new outreach initiative

Publication date	2020-10-21
Create date	2020-10-22
Score	15.33
Report id	776012
Category	Opioid, Anti-inflammatory medicine
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: 'Very small amounts can kill you': Local leaders and law enforcement take aim at deadly influx of fentanyl with new outreach initiative KHQ Right Now

Click here to see the Original Article

Table 22: Places for report 776012

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Spokane	47.65966	-117.42908
Americas	United States	Washington	37.13054	-113.50829

Table 23: Drugs for report 776012

Medicine Name	Medicine Class	Action	ATC Code
oxycodone	Natural opium alkaloids	opioids	N02AA05
acetylsalicylic acid	Other agents for local oral treatment	stomatological preparations	A01AD05
acetylsalicylic acid	Platelet aggregation inhibitors excl. heparin	antithrombotic agents	B01AC06
acetylsalicylic acid	Salicylic acid and derivatives	other analgesics and antipyretics	N02BA01

Table 24: Other Stories

ID	Title	Link
782220	'Very small amounts can kill you': Local leaders and law enforcement take aim at deadly influx of fentanyl with new outreach initiative	Link
777108	Eastern Washington residents warned of drug surge, fentanyl dangers	Link

Notes: Last year, according to the DEA, 71,000 people in the United States died as a result of drug overdoses.

"51 percent of the deaths can be attributed to fentanyl and other synthetic opioids," Weis said.

Counterfeit pills are being manufactured in mass quantities by drug cartels in Mexico and then trafficked throughout the country, with Spokane, Yakima and Tri-Cities serving as major distribution hubs. The manufacturing involves zero quality control and often chemicals purchased from overseas. In the last year, seizures of illegal drugs are up 187 percent, according to the DEA, resulting in tens of thousands of pills being taken off the street, however, that's just a small drop in a large bucket as many more pills are out there, often disguised as oxycontin or even baby aspirin, which means kids might not even know what they're taking. [...] In the past month or so, three Spokane Police officers have been sent to the ER after being exposed to fentanyl, with at least one requiring NARCAN.

12 Promise Pharmacy, LLC - 587148 - 07/29/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	14.75
Report id	754680
Category	Antibiotic, Anti-inflammatory medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Compounding Pharmacy/Adulterated Drug Products

Click here to see the Original Article

Table 25: Places for report 754680

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Palm Harbor	28.07807	-82.76371

Table 26: Drugs for report 754680

Medicine Name	Medicine Class	Action	ATC Code
prednisolone	Corticosteroids acting locally	intestinal antiinflammatory agents	A07EA01
prednisolone	Corticosteroids	agents for treatment of hemorrhoids and anal fissures for topical use	C05AA04
prednisolone	Corticosteroids, weak (group I)	corticosteroids, plain	D07AA03
prednisolone	Corticosteroids, weak, other combinations	corticosteroids, other combinations	D07XA02
prednisolone	Glucocorticoids	corticosteroids for systemic use, plain	H02AB06
prednisolone	Corticosteroids	decongestants and other nasal preparations for topical use	R01AD02
prednisolone	Corticosteroids, plain	antiinflammatory agents	S01BA04

Table 26: Drugs for report 754680(continued)

Medicine Name	Medicine Class	Action	ATC Code
prednisolone	Corticosteroids/ antiinfectives/ mydriatics in combination	antiinflammatory agents and antiinfectives in combination	S01CB02
gatifloxacin	Fluoroquinolones	quinolone antibacterials	J01MA16
gatifloxacin	Fluoroquinolones	antiinfectives	S01AE06

Notes: From October 15, 2018, to October 25, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Promise Pharmacy, LLC, located at 31818 US Highway 19 N, Palm Harbor, Florida 34684-3713. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. The investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 and an amended Form FDA 483 to your firm on October 25, 2018, and November 12, 2018, respectively. FDA acknowledges receipt of your facility's response on November 14, 2018, revised on November 19, 2018, as well as your subsequent correspondence. Additionally, we acknowledge your actions, on October 22, 2018, to voluntarily recall prednisolone and gatifloxacin ophthalmic solutions due to small particulates floating in the solutions, and on December 13, 2018, to voluntarily recall all non-hazardous drug products intended to be sterile within expiry due to lack of sterility assurance. We also acknowledge that you voluntarily ceased sterile operations in your non-hazardous cleanroom on November 14, 2018, and November 19, 2018, and resumed sterile operations in your non-hazardous cleanroom on January 2, 2019.

Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products Under the FDCA [...] B. Failure to Meet the Conditions of Section 503A [...] C. Violations of the FDCA [...]

13 FDA cracking down on fake COVID-19 products

Publication date 2020-10-30

Create date 2020-11-01

Score 14.29

Report id 786684

Category Medical devices for disease prevention, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Not applicable

Curation Manually curated

Incident or General Incident

Snippet: FDA cracking down on fake COVID-19 products WILX

Click here to see the Original Article

Table 27: Places for report 786684

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

Notes: The FDA says it's cracked down on more than 1,000 fraudulent or unproven COVID-19 products.

In a Tweet Thursday FDA Commissioner Stephen Hahn revealed the results of operation "Quack Hack." The goal was to proactively classify threats to consumers.

Hahn says the agency has sent 120 warning letters, 270 reports to virtual marketplaces, and 225 complaints to domain registrars.

The products targeted include bogus drugs, tests, and PPE. Operation Quack Hack launched in March. [...]

14 9:26 Sales of fake Covid-19 vaccine in Brazil reported

Publication date	2020-10-13
Create date	2020-10-14
Score	13.87
Report id	764662
Category	Vaccine
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: 9:26 Sales of fake Covid-19 vaccine in Brazil reported Prensa Latina

Click here to see the Original Article

Table 28: Places for report 764662

Region Name	Country	Location	Latitude	Longitude
Americas	Brazil	Niterói	-22.88333	-43.10361

Table 29: Drugs for report 764662

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 30: Other Stories

ID	Title	Link
765767	Fake Covid-19 Vaccine Sold in Brazil's city of Niterói, Regulatory Body Alerts	Link

Notes: Sales of fake Covid-19 vaccine in Brazil reportedBrasilia, Oct 13 (Prensa Latina) Brazil's National Health Surveillance Agency (ANVISA) denounced it has reports of the sale of a fake Covid-19 vaccine in the city of Niteroi, Rio de Janeiro state. According to the G1 news portal, the document mentions a company that negotiates the fake immunizer as if it were the vaccine developed by the University of Oxford (United Kingdom) and the Anglo-Swedish laboratory AstraZeneca. [...] The regulatory body reiterates that there is still no Covid-19 drug authorized for marketing in Brazil.

It details there are some potential drugs against the pathogen in the country, but exclusively for use in clinical studies. 'There is no permission for the marketing and distribution of these vaccines,' it reiterated.

15 COVID-19 Product Distributor Says Vendors Sold Faulty Masks

Publication date	2020-10-13
Create date	2020-10-14
Score	13.61
Report id	765212
Category	Medical devices for disease prevention
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: COVID-19 Product Distributor Says Vendors Sold Faulty Masks Law360

Click here to see the Original Article

Table 31: Places for report 765212

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

Table 32: Other Stories

ID	Title	Link
771565	COVID-19 Product Distributor Says Vendors Sold Faulty Masks	Link

Notes: Law360 (October 13, 2020, 7:57 PM EDT) – A distributor of personal protective equipment to safeguard against the coronavirus sued two mask importers in California federal court, saying that it received $210,000 of worthless and defective KN95 medical masks from China.

Pacific Medical Products LLC, which serves the Washington state medical and health care industry, says in a Friday complaint that California Coco Tree Inc., Seven Bubbles Inc. and Wei Zhou, the vendors' shared president, provided it with possibly counterfeit certification documents from the U.S. Food and Drug Administration and misrepresented the origin of the masks, which allegedly had faulty nose clips. [...] In April, Pacific Medical purchased 90,000 KN95 masks from the vendors after assurances that the two manufacturers for the shipment met FDA standards, backed by a copy of the FDA Medical Device Registration for their masks.

Yet when a hospital client received a portion of the mask shipment the following month, it

rejected 20,000, citing a discrepancy between the promised product with a sewn-in metal nose clip and the actual product with a glued-on nose clip that was easily removed, according to the complaint.

At the same time, the maker of another 40,000 masks purchased by Pacific Medical was added to a list of 65 Chinese manufacturers banned from exporting face masks by the FDA when a test run by the Centers for Disease Control and Prevention showed only a 47% filtration rate, Pacific Medical said. [...] The suit is one among a spate of mask-related suits filed since April. Several Chinese manufacturers are facing claims they sold misbranded and defective masks with false FDA certification documents. The Federal Trade Commission and state attorneys general have also lodged a bevy of price-gouging claims against online retailers.

16 Lantech Pharmaceuticals Limited - 580027 - 08/08/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	12.93
Report id	754687
Category	Medical devices for disease prevention
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Active Pharmaceutical Ingredient (API)/Adulterated

Click here to see the Original Article

Table 33: Places for report 754687

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Southern Asia	India	Hyderabad	17.38405	78.45636

Table 34: Drugs for report 754687

Medicine Name	Medicine Class	Action	ATC Code
valsartan	Angiotensin II antagonists, plain	angiotensin ii antagonists, plain	C09CA03
olmesartan medoxomil	Angiotensin II antagonists, plain	angiotensin ii antagonists, plain	C09CA08
telmisartan	Angiotensin II antagonists, plain	angiotensin ii antagonists, plain	C09CA07
lamivudine	Nucleoside and nucleotide reverse transcriptase inhibitors	direct acting antivirals	J05AF05

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Lantech Pharmaceuticals Limited, FEI 3012390454, at Sy. No. 78, 79, 80, & 145,

Chittivalasa, Pydibhimavaram, Ranastalam, Andra Pradesh, from March 6 to 15, 2019.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API 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).

We reviewed your April 5, 2019, response in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific deviations including, but not limited to, the following.

1. Failure of your quality unit to ensure that quality-related complaints are investigated and resolved. [...] 2. Failure to have adequate cleaning procedures to prevent contamination or carry-over of a material that would alter the quality of the API. [...] 3. Failure to control and monitor procedures to recover solvents to ensure that they meet appropriate standards before reuse. [...]

17 CBD Product Data Shouldn't Fly Under the Radar – InsideSources

Publication date	2020-10-20
Create date	2020-10-20
Score	11.01
Report id	773466
Category	Analgesic
Quality	Substandard or Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: CBD Product Data Shouldn't Fly Under the Radar – InsideSources InsideSources

Click here to see the Original Article

Table 35: Places for report 773466

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

Table 36: Drugs for report 773466

Medicine Name	Medicine Class	Action	ATC Code
cannabinoids	Other analgesics and antipyretics	other analgesics and antipyretics	N02BG10

Notes: As the coronavirus pandemic continues to impact our lives with high infection rates, a number of cannabis companies are toeing a precarious line with therapeutic declarations that their cannabidiol (CBD) products may help mitigate COVID symptoms, boost immunity against the virus and even cure COVID-19.

These predatory marketing schemes that are quite prevalent on the internet and in no small number of brick-and-mortar stores come with no viable proof and in fact, may be in direct contrast to the scientific evidence. [...] FDA staff tested and analyzed 147 CBD products for accurate labeling and contaminants as well as levels of Tetrahydrocannabinol (THC), which is the chemical responsible for the psychoactive effects of marijuana. THC has been linked to potential harmful side effects on infected coronavirus patients.

The vast majority of CBD products tested were found to be mislabeled or adulterated. More

than half contained either more or less CBD than advertised and in fact, nearly 40 products had more than 120 percent CBD than the level listed. [...] Moreover, nearly 20 products contained THC without disclosure. This means consumers could unknowingly ingest the substance (or unwittingly give THC to pets or children) which can negatively impact personal safety, driving ability, mental health, drug test results, and more — all unbeknownst to them. [...] Setting aside all of the recent findings regarding the mislabeling of CBD products, these CBD products do not comply with good manufacturing processes, and thus are not thoroughly tested for therapeutic value.

18 Medical supply chain shortages led to deadly consequences

Publication date	2020-10-06
Create date	2020-10-13
Score	10.53
Report id	758727
Category	Medical devices for disease prevention
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Medical supply chain shortages led to deadly consequences The Columbian

Click here to see the Original Article

Table 37: Places for report 758727

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

Table 38: Other Stories

ID	Title	Link
761652	US medical supply chains failed, COVID deaths followed	Link
760230	How safe is my N95 mask?	Link

Notes: Nurse Sandra Oldfield's patient didn't have the usual symptoms of COVID-19 — yet. But then he tested positive for the virus, and it was clear that Oldfield — a veteran, 53-year-old caregiver — had been exposed. [...] She and her colleagues said they had felt unsafe at work and had raised concerns with their managers. They needed N95 masks, powerful protection against contracting COVID-19. Kaiser Permanente had none for Sandra Oldfield. Instead, she was issued a less effective surgical mask, leaving her vulnerable to the deadly virus.

Many others were similarly vulnerable, and not just at this 169-bed hospital in Fresno. From the very moment the pandemic reached America's shores, the country was unprepared. Hospitals, nursing homes and other health care facilities didn't have the masks and equipment needed to protect their workers. Some got sick and spread the virus. Some died. [...] Amid the chaos, AP and "FRONTLINE" found counterfeit masks flooded the market, tracking some back to a factory in China. Dr. Philip Clapp at the University of North Carolina tested a handful of

different masks collected by the AP, including ones imported by a non-profit relief organization, others donated to frontline workers by major tech firms, and masks AP had handed out to its own staff.

"All of it was counterfeit, as defined by OSHA's definition of counterfeit or fraudulently labeled," said Clapp. Every mask. Some were less than 50% effective, about the same as a cotton T-shirt.

19 People make a beeline for fake Covid medicine, drugs controller intervenes

Publication date	2020-10-19
Create date	2020-10-20
Score	10.01
Report id	773000
Category	Respiratory diseases medicine
Quality	Falsified
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: People make a beeline for fake Covid medicine, drugs controller intervenes The New Indian Express

Click here to see the Original Article

Table 39: Places for report 773000

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Kozhikode	11.24802	75.7804

Table 40: Other Stories

ID	Title	Link
780054	People make a beeline for fake Covid medicine, drugs controller intervenes	Link

Notes: Thanks to an ENT physician's 'discovery' of nasal drops which can 'resist Covid' and a prominent vernacular daily reporting it, a medical store in Koyilandy here is making a quick buck. E Sukumaran, a Koyilandy-based senior ENT surgeon and former deputy director of health department, has claimed that nasal drops — the 'medication' has a 25 per cent glucose content — can eliminate the coronavirus from the throat itself. [...] Though scientists and the medical fraternity have outrightly rejected Sukumaran's claims, calling them highly unscientific and totally misleading, what happened in Koyilandy was that people thronged a drug store which started selling this glucose-based nasal drop. A 15 ml bottle was priced at '50 in the beginning. Later, the price was slashed to '30 and now it is being sold for '20. This medical store has special licence which allows it to sell drugs manufactured by mixing the components.

”People queue up in front of the medical store to buy the drug. Though many of them were aware that it doesn’t prevent Covid, they are convinced that it will not cause any side effects either. The drug store is the biggest beneficiary of this fake discovery,” said a health department source. However, the biggest threat posed by this drug is that it will give a false sense of Covid immunity to gullible people and instigate them to breach Covid protocol. This correspondent bought the bottle directly from the said store without prescription. Along with the drug, there was also a piece of advice on how to administer it: ”Two droplets in each nostril twice daily.”

Meanwhile, after coming to know of the ‘miracle discovery’ through TNIE, the state drugs controller has ordered a probe. Sujith Kumar K, Assistant Drugs Controller, Kozhikode, told TNIE that he had sent two of his officials to investigate the matter. According to him, he will see to it that the nasal drop is not sold without a doctor’s prescription. ”We cannot prevent the sale of glucose water if there is a prescription as it is being used for other purposes such as drip. But it cannot be sold as a remedy for Covid,” he said.

20 FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online

Publication date	2020-10-30
Create date	2020-11-01
Score	9.78
Report id	787356
Category	Vaccine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online CBS Pittsburgh

Click here to see the Original Article

Table 41: Places for report 787356

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pittsburgh	40.44062	-79.99589

Table 42: Drugs for report 787356

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Scammers are always searching for new ways to prey on people's misery.

The latest attempt has caught the attention of the Food and Drug Administration. The FDA has previously warned of unauthorized coronavirus tests that can be taken and processed at home.

Now, the FDA is warning consumers about bogus vaccines and treatments being sold online. [...] The FDA is working with dozens of retailers to remove misleading products from the internet and store shelves. Security has also been boosted at ports of entry to ensure that they do not come through U.S. borders.

21 Lilly Plant Making Covid Drug Is Flagged Again by FDA Inspectors

Publication date	2020-10-20
Create date	2020-10-22
Score	9.23
Report id	774525
Category	Not applicable
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Lilly Plant Making Covid Drug Is Flagged Again by FDA Inspectors BloombergQuint

Click here to see the Original Article

Table 43: Places for report 774525

Region Name	Country	Location	Latitude	Longitude
Americas	United States	New Jersey	40.16706	-74.49987

Notes: U.S. drug-safety inspectors have found continuing quality-control problems problems at a New Jersey plant Eli Lilly & Co. is using to help produce its Covid-19 antibody therapy, posing a potential obstacle to the company meeting its goal of producing 1 million doses by year-end. [...] The assessment was based on a four-week site inspection at the Branchburg, New Jersey, facility that ended on Aug. 21, the details of which haven't previously been reported. [...] FDA officials didn't test any products made at the facility, but the compliance officers said in the letter the incidents they described "leave room for significant potential impact on product quality." In one case described by FDA inspectors, a Lilly employee allegedly used the wrong material in a critical purification step. In another, after routine checks revealed a potential impurity in a drug product, an employee retested it to get a passing result, according to the documents, instead of attempting to figure out why there were signs of an impurity in the sample. Lilly managers downplayed quality missteps in a data-management system FDA has access to during inspections called TrackWise, according to inspection documents. Drugmakers use such workflow tracking systems to record the outcomes of quality checks during the manufacturing process.

22 Lucrative Fake Medicine Trade In ASEAN

Publication date	2020-10-31
Create date	2020-11-01
Score	8.46
Report id	787622
Category	Not applicable
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Lucrative Fake Medicine Trade In ASEAN The ASEAN Post

Click here to see the Original Article

Table 44: Places for report 787622

Region Name	Country	Location	Latitude	Longitude
		South Eastern Asia	6.83917	116.45508

Table 45: Other Stories

ID	Title	Link
806005	South East Asia : Fake medicines, one of ASEAN's biggest problems - 2020-11-16	Link

Notes: ASEAN's reputation as a hub for fake medicine is nothing to sneeze at.

Increasing amounts of falsified medicines are being produced in the region, in part as a result of legitimate, and illegitimate, pharmaceutical producers based in India and China having transferred or outsourced some manufacturing processes to Malaysia, Vietnam, Myanmar and Cambodia to avoid tougher regulations and enforcement – and to benefit from lower production costs – according to a 2019 report by the United Nations Office on Drugs and Crime (UNODC). [...] These counterfeit medicines range from falsified anti-cancer treatments to drugs for infertility and weight loss, and the issue is a greater threat in remote areas, where poor health systems may drive patients to rely on unregulated medicines providers. [...] In March 2020, crime control organisation Interpol coordinated a global operation targeting the online sale of illicit medicines and medical devices and seized more than 34,000 fake medical goods. Based on their report, the most counterfeited products are medicines (antivirals, herbal medicines and anti-malarial), medical equipment (face masks, disinfectants, fake coronavirus test kits, gloves

and ventilators), and sanitisers (substandard hand sanitisers, soaps and cleaning wipes).

Likewise, the UNODC has also stated that previous tests have shown that 47 percent of anti-malarial medicines tested in Southeast Asia were found to be fraudulent – but the true figure could be much higher.[...]

23 TG United, Inc. - 577583 - 08/01/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	7.85
Report id	754681
Category	Not applicable
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

Click here to see the Original Article

Table 46: Places for report 754681

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Brooksville	28.55554	-82.38991

Table 47: Drugs for report 754681

Medicine Name	Medicine Class	Action	ATC Code
triprolidine	Other antihistamines for systemic use	antihistamines for systemic use	R06AX07
phenylephrine, combinations	Sympathomimetics	nasal decongestants for systemic use	R01BA53
phenylephrine, combinations	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA55
diphenhydramine	Antihistamines for topical use	antipruritics, incl. antihistamines, anesthetics, etc.	D04AA32
diphenhydramine	Aminoalkyl ethers	antihistamines for systemic use	R06AA02
brompheniramine, combinations	Substituted alkylamines	antihistamines for systemic use	R06AB51
dextromethorphan, combinations	Other nervous system drugs	other nervous system drugs	N07XX59

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, TG United, Inc., FEI: 3005350897, at 16275 Aviation Loop Drive, from December 17, 2018, to February 15, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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).

Your firm manufactures HISTEX PD Drops, Triprolidine HCl, Diphenhydramine HCl, ED Chlorped Jr., Rynex PSE, Rynex PE, Ed Chlorped D, Poly-Hist PD Drops, Capron DM Liquid, and Rynex DM that are unapproved new drugs in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a). Introduction or delivery for introduction of such products into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d).

We reviewed your March 8, 2019, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. 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). [...] 2. Your firm failed to use equipment in the manufacture, processing, packing, or holding of drug products that is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance (21 CFR 211.63). [...] 3. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a). [...] 4. Your firm failed to 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)). [...]

24 Spectrum Laboratory Products, Inc. - 579958 - 07/31/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	7.24
Report id	754690
Category	Not applicable
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Active Pharmaceutical Ingredient (API)/Adulterated

Click here to see the Original Article

Table 48: Places for report 754690

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Gardena	33.88835	-118.30896
Americas	United States	United States	39.76	-98.5

Table 49: Drugs for report 754690

Medicine Name	Medicine Class	Action	ATC Code
progesterone	Pregnen (4) derivatives	progestogens	G03DA04
		potassium	A12B
	Potassium	potassium	A12BA
sodium bicarbonate	Salt solutions	irrigating solutions	B05CB04
sodium bicarbonate	Electrolyte solutions	i.v. solution additives	B05XA02
tobramycin	Other aminoglycosides	aminoglycoside antibacterials	J01GB01
tobramycin	Antibiotics	antiinfectives	S01AA12

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Spectrum Laboratory Products, Inc., FEI 2246824, at 755, 769, and 777 Jersey Avenue,

New Brunswick, New Jersey, from February 19, 2019 to March 12, 2019.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API 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).

Your firm repackages and relabels many drugs for commercial distribution in the United States. A review of FDA's drug listing database confirms that some of these drugs are not currently listed with FDA as required by section 510 of the FD&C Act, 21 U.S.C. 360(j)), which is prohibited under section 301(p) of the FD&C Act, 21 U.S.C. 331(p)). Failure to properly list a drug with the FDA will also render it misbranded under section 502(o) of the FD&C Act, 21 U.S.C. 352(o)).

In addition, your potassium bicarbonate, sodium bicarbonate, progesterone, ferric subsulfate solution and tobramycin sulfate API are misbranded under sections 502(a) of the FD&C Act, 21 U.S.C. 352(a).

We reviewed your April 1, 2019, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigator observed specific deviations including, but not limited to, the following.

1. Failure to transfer all quality or regulatory information received from the API manufacturer to your customers and to reference the original manufacturer on your certificates of analysis. [...]

25 FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it

Publication date	2020-10-01
Create date	2020-10-07
Score	6.85
Report id	749267
Category	Antiseptic
Quality	Substandard or Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA warns of methanol-tainted hand sanitizer — but can't force companies to recall it NBC News

Click here to see the Original Article

Table 50: Places for report 749267

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

Table 51: Other Stories

ID	Title	Link
749580	17 people died this year from methanol-tainted hand sanitizer: report	Link
749848	Methanol-tainted hand sanitizer has killed 17 this year: report	Link
756032	17 deaths related to methanol-spiked hand sanitizer but FDA limited in actions	Link
757349	People are going blind and dying from drinking hand sanitizer: CDC	Link
751488	Why can I still buy toxic hand sanitizer?	Link
750070	String of fatal poisonings from ingesting toxic hand sanitizer highlights limits of FDA powers	Link

Notes: A 44-year-old man in the Southwest, seeking medical treatment after his vision suddenly

deteriorated in late spring, admitted that he had been drinking hand sanitizer for a few days. Blood tests revealed he had been poisoned by methanol, an extremely toxic form of alcohol that is never supposed to be used in consumer products like hand sanitizer. Despite treatment, he was left permanently blind.

The case was part of a disturbing trend that toxicologists in New Mexico and Arizona caught wind of beginning in May. Dr. Steven Seifert, medical director of the New Mexico Poison and Drug Information Center, noticed that two adults had been hospitalized after drinking hand sanitizer made with methanol. In June, the center treated three more adults who had been poisoned by methanol, making it "absolutely clear that there was something circulating in our state," said Seifert, who notified New Mexico's Department of Public Health.

The coronavirus pandemic has triggered a huge spike in demand for hand sanitizer, and with it, a shortage of ethanol, which is typically used as the active ingredient in hand sanitizers. That may be leading to the use of a highly toxic substitute — methanol, or wood alcohol — in products that have been rushed onto store shelves in the United States. The FDA has counted 17 deaths from exposure to methanol-tainted sanitizer this year, and spokesman Jeremy Kahn says the agency has received an additional 2,000 reports of exposure or injuries.

It's a vivid example of the Food and Drug Administration's lack of authority to crack down on dangerous over-the-counter drugs, a category that includes hand sanitizers. The FDA has responded by issuing numerous alerts about the dangers of ingesting methanol-containing sanitizers and asking manufacturers to issue recalls. But the agency lacks authority to force recalls, and some manufacturers have delayed taking action, according to warnings issued by the FDA and a FairWarning review of the agency's database of hand sanitizers to avoid. [...] "I think consumers would be shocked to learn that the FDA doesn't have authority to pull those products," said Dr. Michael Carome, director of the Health Research Group at the advocacy organization Public Citizen, which has argued for giving the FDA the power to force recalls of prescription and over-the-counter drugs. (Hand sanitizer is classified as an over-the-counter drug.) [...] FDA officials declined comment on whether the agency should have recall authority over drugs. But in a written statement, they said that patient safety is its "top priority. The FDA continues to warn consumers and health care professionals not to use the nearly 200 entries currently on the agency's hand sanitizer list." According to the statement, "The agency has taken additional action to help prevent certain hand sanitizers from entering the United States by placing them on an import alert. " [...] The FDA has long had the power to order recalls of defective medical devices. It gained authority to force recalls of contaminated food under the Food Safety Modernization Act signed into law in 2011. A year later, the agency used the power for the first time to shut down a peanut butter factory linked to salmonella poisoning that sickened 41 people. [...] Most producers of methanol-containing sanitizers have agreed to recall their products after the FDA flagged them, according to a review of the FDA's database, but more brands continue to be added to the FDA's warning list, which included nearly 200 products as of Sept. 17. The agency does not have a breakdown of how many problem hand sanitizers are still for sale in the U.S. compared to how many have been voluntarily recalled.

26 Certain Dietary Supplements Linked to Acne Development

Publication date	2020-10-01
Create date	2020-10-07
Score	6.77
Report id	749417
Category	Nutritional supplement
Quality	Substandard
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Certain Dietary Supplements Linked to Acne Development Monthly Prescribing Reference

Click here to see the Original Article

Table 52: Places for report 749417

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

Notes: Research has indicated that approximately one-half of adults in the US use dietary supplements daily. Several of these agents, many of which contain ingredients that seem innocuous, have been found to be associated with causing or aggravating acne. To better understand this association, the study authors reviewed the most recent clinical findings surrounding supplement-induced acne. According to their findings, supplements that have been associated with acne are those containing vitamins B6/B12, iodine, whey protein, and "muscle building supplements" that could potentially be contaminated with anabolic-androgenic steroids (AAS). Several case reports and series have been published describing the onset of acne with use of these dietary supplements as well as its resolution after supplement discontinuation. Findings of the review also revealed that the mechanism of action of supplement-induced acne appears to be specific to the agent, and in many cases, is not completely known. [...] "With studies indicating that about half of US adults report using dietary supplements, it is important that dermatologists directly ask acne patients about their supplement use and educate them on the potential risks of even seemingly innocuous dietary supplements," the authors concluded. "It is also important that physicians not rely on a written medication history, but instead verbally elicit this information, given that written questionnaires often do not adequately address full nutritional supplement use," they added.

27 Amneal Sued Over Alleged Carcinogen In Diabetes Medication

Publication date	2020-10-07
Create date	2020-10-08
Score	6.70
Report id	757820
Category	Antidiabetic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Amneal Sued Over Alleged Carcinogen In Diabetes Medication Bloomberg Law

Click here to see the Original Article

Notes: Amneal Pharmaceuticals Inc. has been accused of allowing its generic diabetes drug Metformin to be contaminated with a likely carcinogen during its manufacturing process, according to a class action complaint filed Wednesday in New Jersey federal court.

28 Mr Frags, LLC - 611295 - 10/19/2020 - 2020-10-27

Publication date	2020-10-27
Create date	2020-10-28
Score	6.62
Report id	782899
Category	Veterinary medicines
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved Chloroquine Phosphate Product

Click here to see the Original Article

Table 53: Places for report 782899

Region Name	Country	Location	Latitude	Longitude
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 website at the internet address https://mrfrags.com/ in October 2020. The FDA has observed that your website offers chloroquine phosphate for sale in the United States. We also reviewed the labels on these products. Based on our review, these products are adulterated. The introduction or delivery for introduction into interstate commerce of any food or drug that is adulterated is a prohibited act. (Section 301(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 331(a)].) [...]

29 Alarming Drug Overdoses Hit RivCo, Mexican Drug Cartels Blamed

Publication date	2020-10-18
Create date	2020-10-22
Score	6.11
Report id	775673
Category	Analgesic, Opioid
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Alarming Drug Overdoses Hit RivCo, Mexican Drug Cartels Blamed Banning, CA Patch

Click here to see the Original Article

Table 54: Places for report 775673

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Riverside	33.95335	-117.39616

Table 55: Drugs for report 775673

Medicine Name	Medicine Class	Action	ATC Code
oxycodone and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ17
oxycodone	Natural opium alkaloids	opioids	N02AA05

Notes: Officials continue to warn about a troubling and dangerous trend that has hit Riverside County: counterfeit pills manufactured by Mexican drug cartels. Known as M30s, the pills (and sometimes powders) are often marketed as Percocet or oxycodone, but may contain fentanyl, a synthetic opioid that can cause death even in small doses.

30 Anderson Co. coroner warns of street drug use dangers after several recent deaths

Publication date	2020-10-02
Create date	2020-10-07
Score	5.63
Report id	750943
Category	Opioid
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Anderson Co. coroner warns of street drug use dangers after several recent deaths WSPA 7News

Click here to see the Original Article

Table 56: Places for report 750943

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Anderson	34.50344	-82.65013

Table 57: Drugs for report 750943

Medicine Name	Medicine Class	Action	ATC Code
oxycodone	Natural opium alkaloids	opioids	N02AA05
		opioids	N02A
cocaine	Esters of benzoic acid	anesthetics, local	N01BC01
cocaine	Anesthetics, local	throat preparations	R02AD03
cocaine	Local anesthetics	local anesthetics	S01HA01
cocaine	Analgesics and anesthetics	other otologicals	S02DA02
fentanyl	Opioid anesthetics	anesthetics, general	N01AH01
fentanyl	Phenylpiperidine derivatives	opioids	N02AB03

Table 58: Other Stories

ID	Title	Link
751297	'Alarming': Anderson County coroner sends out warning after rash of fentanyl-related deaths	Link

Notes: This photo provided by the U.S. Attorneys Office for Utah and introduced as evidence in a 2019 trial shows fentanyl-laced fake oxycodone pills collected during an investigation. In a resumption of a brutal trend, nearly 71,000 Americans died of drug overdoses in 2019 according to the Centers for Disease Control and Prevention, a new record high that predates the COVID-19 crisis. The numbers were driven by fentanyl and similar synthetic opioids, which accounted for 36,500 overdose deaths. (U.S. Attorneys Office for Utah via AP) ANDERSON COUNTY, S.C. (WSPA) – Anderson County Coroner Greg Shore is sending a warning that street level drugs may be deadlier than some think. He advised that his office is currently investigating several incidents in which victims have died of illicit drug use over the last several days. Shore said in the course of the investigations, the drug Fentanyl seems to be a common denominator to the individual deaths and he is concerned that persons with an addiction problem may be obtaining street level Fentanyl that is more than just Fentanyl. "Fentanyl in itself is a deadly drug that can and does result in death. However, the most recent deaths are alarming based on the fact that they are so close together and over a short time period," he said in a news release on Friday. He said that the Anderson County community may have some street level Fentanyl being distributed that may also contain Carfentanil. This combination is even deadlier than the Fentanyl alone, according to the coroner. "Carfentanil is typically utilized for anaesthetizing large animals, such as elephants. Carfentanil, a synthetic Opioid, is a white powdery substance that looks like it could be Cocaine or Heroin. Drug dealers mix it with Heroin to presumably make the Heroin stronger," Shore said. Deaths involving illicitly manufactured Fentanyl and other synthetic Opioids are on the rise, and have been since 2018, he advised. Street drugs such as Heroin, Cocaine and Methamphetamines are being laced with Fentanyl as are other counterfeit drugs made to look like the real ones, like Xanax. Fentanyl works in the brain to block pain and is in the same class of drugs such as Morphine or Hydrocodone but is about 50-100 times more potent. Just 2 milligrams of Fentanyl can kill a person. Fentanyl blocks Opioid receptors and its most dangerous side effect, like other Opioids, is respiratory depression which can quickly lead to coma and death. Carfentanil is 10,000 times more potent than Morphine and 100 times more potent than Fentanyl. Shore wants to send a warning to people with an addiction disorder, that the street level Fentanyl, Cocaine and/or Heroin they are obtaining may be deadlier than they think, Shore said. He is encouraging individuals with an addiction disorder to seek help and to be aware that this drug has resulted in several deaths in Anderson County.

31 Counterfeit pills lead to spike in fentanyl deaths in Placer, Nevada counties

Publication date	2020-10-15
Create date	2020-10-16
Score	5.57
Report id	768415
Category	Opioid
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Counterfeit pills lead to spike in fentanyl deaths in Placer, Nevada counties KCRA Sacramento

Click here to see the Original Article

Table 59: Places for report 768415

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Placer	39.06343	-120.71766
Americas	United States	Nevada	39.25021	-116.75119

Table 60: Drugs for report 768415

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

Table 61: Other Stories

ID	Title	Link
769545	Accidental fentanyl-related overdose deaths on the rise in Nevada County	Link
769501	Town Hall on Oct. 22nd: Overdoses in Nevada County	Link

Notes: Placer and Nevada counties are seeing a spike in fentanyl overdoses. Both counties have recorded more fentanyl deaths this year compared to last year. Law enforcement agencies said the problem is compounded by the increase in counterfeit pills. "We've seen what we believe to be counterfeit pills that are being sold as though they are a legitimate pill, but actually contain very dangerous levels of fentanyl and other synthetic opiates," said Grass Valley police Chief Alex Gammelgard. [...] Lovett said this year, 10 people in Nevada County have died from fentanyl overdoses versus none last year. She said their patients are familiar with the counterfeit pills sometimes disguised as other drugs, like Percocet, and it is an issue hurting all age groups from 18 to 60 years old.

32 More than $1 million worth of counterfeit Viagra seized at US border

Publication date	2020-10-06
Create date	2020-10-07
Score	5.41
Report id	756371
Category	Erectile dysfunction medicine
Quality	Falsified
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: More than $1 million worth of counterfeit Viagra seized at US border WDBJ

Click here to see the Original Article

Table 62: Places for report 756371

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Knoxville	35.96064	-83.92074

Table 63: Drugs for report 756371

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

Table 64: Other Stories

ID	Title	Link
767528	More than $1 million worth of counterfeit Viagra seized at US border	Link
757075	15000 Viagra Pills Were Seized Before They Reached One Michigan Home	Link
756332	More than $1 million worth of counterfeit Viagra seized by US Customs and Border Protection	Link
757678	$1M worth of counterfeit Viagra pills headed to MI seized	Link

Table 64: Other Stories(continued)

ID	Title	Link
756151	$1M worth of counterfeit Viagra pills headed to Michigan seized at the border	Link
758211	US CBP Seized 15000 Viagra Pills Worth over $1M in Chicago	Link
783593	$1M worth of counterfeit Viagra pills headed to Michigan seized at the border	Link

Notes: KNOXVILLE, Tenn. (WVLT) - U.S. Custom and Border Protection officials seized 15,000 counterfeit Viagra tablets over the weekend.

Border Patrol officials said the misbranded pills valued at more than $1 million were shipped from Istanbul, Turkey to a home in Michigan.

"Our Officers are dedicated to identifying and intercepting these types of shipments that could potentially harm our communities," said Shane Campbell, Port Director-Chicago. "Consumers do not realize the risk they are taking when using prescription drugs from other countries. These non-regulated drugs could cause health concerns or even death."

The packages were marked as containing 100mg tablets of Viagra and boxes of honey mixed with Sildenafil. Officials said the products were counterfeit and not approved by the FDA, which violates the Federal Food, Drug and Cosmetic Act prohibiting the introduction of any food, drug or cosmetic that is adulterated or misbranded.

33 Overdoses linked to counterfeit opioid pills

Publication date	2020-10-03
Create date	2020-10-07
Score	5.17
Report id	752435
Category	Opioid
Quality	Falsified
Source	Unknown
Curation	Manually curated
Incident or General	Incident

Snippet: Overdoses linked to counterfeit opioid pills Chicago Daily Herald

Click here to see the Original Article

Table 65: Places for report 752435

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Illinois	40.00032	-89.25037

Table 66: Drugs for report 752435

Medicine Name	Medicine Class	Action	ATC Code
oxycodone and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ17
oxycodone	Natural opium alkaloids	opioids	N02AA05
		opioids	N02A

Table 67: Other Stories

ID	Title	Link
758652	Kane County Health Department Warning of Counterfeit Opioid Pills	Link
760218	Counterfeit Opioids Causing Overdoses, Deaths In Illinois: KCHD	Link
757681	Kane County Health Department Warns Residents of Deadly Counterfeit Opioid Pills	Link

Notes: Illinois has issued a warning about overdoses linked to counterfeit opioid pills bought on the street, DuPage County health authorities said Saturday.

The state alerted area health departments to multiple overdoses, including two deaths, over the past week. Officials did not specify where the overdoses occurred, but the cases involved young people, between the ages of 19 and 23 years old, who referred to the counterfeit pills as "M30," "Percocet," or oxycodone. Additional cases are under investigation.

"We continue to see an increase in fatal drug overdoses and suicides in our most vulnerable residents. Adding to our concerns is this new alert regarding counterfeit pills causing severe symptoms and loss of life in very young people," DuPage County Coroner Richard Jorgensen said in a statement. "I encourage individuals to connect with friends and family who are struggling and help connect them to the various local resources available. It could help save their lives."

The warning comes as the DuPage Narcan Program reports a sharp increase in the use of Narcan, an opiate overdose reversal medication, in the 19- to 23-year-old age group during September. As part of the program, first responders learn how to administer the revival drug to stop overdoses. [...]

34 100,000 substandard respirators acquired through PPE procurement | News

Publication date	2020-10-08
Create date	2020-10-09
Score	5.00
Report id	758487
Category	Medical devices for disease prevention
Quality	Substandard
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: 100,000 substandard respirators acquired through PPE procurement | News ERR News

Click here to see the Original Article

Table 68: Places for report 758487

Region Name	Country	Location	Latitude	Longitude
Europe	Estonia	Tallinn	59.43696	24.75353

Notes: 100,000 substandard respirators were acquired from China at the peak of the coronavirus emergency situation in spring. [...] The minister wrote: "All equipment in the contract concluded with Jiangxi Shunkang Pharmaceutical Group Co Ltd has arrived in Estonia. At the same time, 100,000 FFP3 respirators do not meet our requirements. By our assessment, we are dealing with lower-grade PPE. We have not paid our partner for this."

35 Everything Aquatic - 610530 - 10/06/2020 - 2020-10-27

Publication date	2020-10-27
Create date	2020-10-28
Score	4.55
Report id	782898
Category	Veterinary medicines
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved New Animal Drug Products

Click here to see the Original Article

Table 69: Places for report 782898

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Medford	42.32652	-122.87559

Notes: This is to advise you that in August and September 2020, the United States Food and Drug Administration (FDA) reviewed your website at the internet address, www.everythingaquatic.net. The FDA has observed that you offer for sale in the United States veterinary products1 for the use in aquarium species, including Chloroquine Phosphate products.2 The claims on your website establish that these products are drugs under Section 201(g) of the Federal Food, Drug and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals or because they are intended to affect the structure or function of the body of animals. Based on our review, as discussed below, these products are unapproved new animal drugs. An unapproved new animal drug is unsafe under section 512(a) of the FD&C Act [21 U.S.C. § 360b(a)] and adulterated under section 501(a)(5) of the FD&C Act [21 U.S.C. § 351(a)(5)]. [...]

36 Cash, cocaine and counterfeit Viagra seized over Columbus Day Weekend, Customs says

Publication date	2020-10-15
Create date	2020-10-16
Score	4.47
Report id	768254
Category	Erectile dysfunction medicine
Quality	Falsified
Source	Airport
Curation	Manually curated
Incident or General	Incident

Snippet: Cash, cocaine and counterfeit Viagra seized over Columbus Day Weekend, Customs says Miami Herald

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Table 70: Places for report 768254

Region Name	Country	Location	Latitude	Longitude
Americas	Puerto Rico	Puerto Rico	18.24829	-66.49989

Table 71: Drugs for report 768254

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

Table 72: Other Stories

ID	Title	Link
777397	Falsified Viagra seized by customs in Puerto Rico	Link

Notes: Ersatz Viagra, real cash and 3.8 kilos of real cocaine at two Puerto Rico airports didn't make it to their destination during Columbus Day Weekend, U.S. Customs and Border Protection said. [...] Also, Customs says it found 960 100 mg Viagra tablets of poor packaging and

quality that indicated the drugs were counterfeit. If sold as real without any form of health insurance, Customs says they would fetch $68,160.

37 Deva Holding AS - Cerkezkoy Subesi - 577493 - 08/06/2019 - 2020-10-05

Publication date	2020-10-05
Create date	2020-10-08
Score	2.44
Report id	754686
Category	Erectile dysfunction medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

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Table 73: Places for report 754686

Region Name	Country	Location	Latitude	Longitude
Western Asia	Turkey	Küçükçekmece	41.06947	28.76983
Americas	United States	United States	39.76	-98.5

Table 74: Drugs for report 754686

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB

Table 74: Drugs for report 754686(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	antiinfectives	S01AA

Notes: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Deva Holding AS – Cerkezkoy Subesi at Organize Fatih Bulvar Fatih Bulvar 32 Cerkezkoy, Tekirdag, 59500, Turkey, from February 4, 2019 to February 15, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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).

We reviewed your March 6, 2019 response 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 perform operations related to the manufacture, processing, and packing of penicillin in facilities separate from those used for other drug products for human use (21 CFR 211.42(d)). You manufacture drugs on two campuses: Cerkezkoy 1 (CK1) and Cerkezkoy 2 (CK2) which are approximately ¼ mile apart. CK1 manufactures various products, including penicillin, (b)(4), and non-beta-lactam drug products. You manufacture (b)(4) capsules for the U.S. market in the (b)(4) Building and penicillin drug products in an adjacent building on the CK2 campus. [...] Your firm failed to test non-penicillin drug products for the presence of penicillin when a reasonable possibility existed that the non-penicillin drug product had been exposed to cross-contamination with penicillin (21 CFR 211.176).

38 Essential Pharmaceutical Corp - 597677 - 09/03/2020 - 2020-10-06

Publication date	2020-10-06
Create date	2020-10-08
Score	2.21
Report id	756020
Category	Erectile dysfunction medicine
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved New Drugs/Misbranded

Click here to see the Original Article

Table 75: Places for report 756020

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Pomona	34.05529	-117.75228

Table 76: Drugs for report 756020

Medicine Name	Medicine Class	Action	ATC Code
	Cosmetics	all other non-therapeutic products	V07AT
	Antiseptics	throat preparations	R02AA
benzalkonium	Quaternary ammonium compounds	antiseptics and disinfectants	D08AJ01
benzalkonium	Medicated dressings with antiinfectives	medicated dressings	D09AA11
benzalkonium	Antiseptics	throat preparations	R02AA16
phenylephrine	Adrenergic and dopaminergic agents	cardiac stimulants excl. cardiac glycosides	C01CA06
phenylephrine	Sympathomimetics, plain	decongestants and other nasal preparations for topical use	R01AA04

Table 76: Drugs for report 756020(continued)

Medicine Name	Medicine Class	Action	ATC Code
phenylephrine	Sympathomimetics, combinations excl. corticosteroids	decongestants and other nasal preparations for topical use	R01AB01
phenylephrine	Sympathomimetics	nasal decongestants for systemic use	R01BA03
phenylephrine	Sympathomimetics excl. antiglaucoma preparations	mydriatics and cycloplegics	S01FB01
phenylephrine	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA05
			J07

Notes: The United States Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility, Essential Pharmaceutical Corp, located at 1906 W. Holt Ave, Pomona, CA, on October 8-10 and 17, 2019. Based on the inspectional findings and a subsequent review of your product labels collected during the inspection, we have identified serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You can find the Act and FDA regulations through links on the FDA's home page at http://www.fda.gov.External Link Disclaimer

Unapproved New Drug

Your firm manufactures and distributes "BIO-MINT Nasal Spray," which is an unapproved new drug and is being marketed as a nonprescription, over-the-counter (OTC) drug product. Introduction or delivery for introduction of such product into interstate commerce is prohibited under sections 505(a) and 301(d) of the Act, 21 U.S.C. 331(d) and 355(a). This product is also misbranded under section 502(ee) of the Act, 21 U.S.C. 352(ee), and its introduction into interstate commerce is prohibited by section 301(a) of the Act, 21 U.S.C. 331(a). These violations are described in more detail below.

"BIO-MINT Nasal Spray" is a drug under section 201(g)(1)(B) of the 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 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 combination nasal decongestant, antihistamine, and antiseptic. [...] Adulterated Dietary Supplements

The inspection revealed serious violations of the FDA's regulations for Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, under Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111). These violations cause the products you manufacture to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions that do not meet CGMP requirements for dietary supplements. [...] Misbranded Dietary Supplements

The dietary supplement products discussed below are misbranded within the meaning of section

403 [21 U.S.C. § 343] of the Act and/or fail to comply with the regulations implementing the food labeling requirements of the Act, which are found in 21 CFR Part 101. [...]