



Global Update February 2021



FDA Places Hand Sanitizers from Mexico on Import Alert

FDA has placed all alcohol-based hand sanitizers made in Mexico on countrywide [import alert #62-08](#) to help stop products that appear to be in violation of manufacturing requirements from entering the U.S. The import alert titled "Detention Without Physical Examination of Alcohol-Based Hand Sanitizers Manufactured in Mexico" is the first time that FDA has ever issued a countrywide import alert for any category of drug product.

Over the course of the COVID-19 pandemic, the FDA has seen a sharp increase in [hand sanitizer products](#) from Mexico that were labeled as containing ethanol (also known as ethyl alcohol) or isopropanol (also called isopropyl alcohol or 2-propanol) but that tested positive for methanol and/or 1-propanol contamination. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the skin and life-threatening when ingested. Methanol and 1-propanol are not acceptable ingredients in hand sanitizers or other drugs.

Under the import alert, imports of these hand sanitizers from Mexican manufacturers are subject to heightened FDA scrutiny. Mexican manufacturers of ethanol- or isopropanol-based hand sanitizers may petition the FDA to be added to the Green List of Import Alert #62-08 by providing adequate evidence and documentation that the facility is in full compliance with current good manufacturing practices requirements. (Products from manufacturers on the Green List are *not* subject to heightened scrutiny). The instructions to submit a petition are provided within the alert; petitions are reviewed by the FDA and the agency makes Green List decisions on a case-by-case basis.

As part of the FDA's actions to protect consumers, the agency has also issued 15 [warning letters](#) since July 2020 for the distribution of hand sanitizer with undeclared methanol, inappropriate ethanol content, misleading claims erroneously stating FDA approval, and violative manufacturing practices. The FDA continues to proactively work with Mexican government authorities, manufacturers and retailers to ensure potentially dangerous or violative products are not distributed to consumers.



"Consumer use of hand sanitizers has increased significantly during the coronavirus pandemic, especially when soap and water are not accessible, and the availability of poor-quality products with dangerous and unacceptable ingredients will not be tolerated," said Judy McMeekin, Pharm.D., FDA Associate Commissioner for Regulatory Affairs. "Today's actions are necessary to protect the safe supply of alcohol-based hand sanitizers. We will continue to work with our stakeholders to ensure the availability of safe products and to communicate vital information with the health and safety of U.S. consumers in mind."

Since July 2020, our [Latin America Office](#) (LAO), in coordination with the [Center for Drug Evaluation and Research](#) (CDER), has been collaborating with Mexico's [Federal Commission for the Protection from Sanitary Risks](#) (COFEPRIS, for its initials in Spanish) to share information about CDER's efforts toward identifying this problem, providing information on laboratory methodologies for testing hand sanitizers, and to help COFEPRIS as it conducted in-country evaluations of manufacturers of hand sanitizers and of active ingredients. LAO's collaboration has provided critical information for CDER as it seeks to trace back the source of contamination. As a result of our interactions, COFEPRIS began a country-wide sampling program and investigational activities which resulted in the publication of a consumer alert informing the Mexican public about the risks of using hand sanitizers contaminated with methanol.

LAO also notified COFEPRIS of any U.S. import refusals of hand sanitizer shipments that could be re-exported to Mexico.

This has allowed COFEPRIS to coordinate the detention, seizure, and sampling of hand sanitizer products re-entering Mexico—thereby preventing the distribution of the products in Mexico, as well as the possibility that the products might be re-offered for import into the U.S. through another port.

Those who have been exposed to hand sanitizer contaminated with methanol and are experiencing symptoms should contact their local poison control center and seek immediate medical treatment for potential reversal of the toxic effects of methanol poisoning.

CBP, FDA Seize Counterfeit, Unauthorized E-Cigarettes from China

On January 13, U.S. Customs and Border Protection officers at the Dallas Fort Worth International Airport, in an ongoing joint operation with FDA, seized 33,681 units of e-cigarettes, coming in from China. The units have a Manufacturer's Suggested Retail Price of \$719,453. These products did not meet the [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act) requirements, as amended by the [Family Smoking Prevention and Tobacco Control Act](#) (Tobacco Control Act).



In December 2020, CBP seized 42 separate shipments arriving from China destined to various Texas counties. The shipments included individual disposable flavored e-cigarette cartridges resembling the Puff Bar brand, including Puff XXL and Puff Flow. Tobacco products including e-cigarettes [imported or offered for import](#) into the U.S. must comply with all [applicable U.S. laws](#).

“The FDA continues to prioritize enforcement against e-cigarette products, specifically those most appealing and accessible to youth,” said Mitch Zeller, J.D., director of the FDA’s Center for Tobacco Products. “We are very concerned about how popular these products are with youth. This seizure makes clear to tobacco product manufacturers, retailers and importers that the FDA is keeping a close watch on the marketplace and will hold accountable those companies that violate tobacco laws and regulations.”

In July 2020, the FDA [issued a warning letter](#) to Cool Clouds Distribution Inc. (doing business as Puff Bar), to remove their flavored disposable e-cigarettes and youth-appealing e-liquid products from the market because they do not have the required premarket authorization.

Pet Food Recalled for Potentially Fatal Levels of Aflatoxin

An ongoing recall of pet food containing a potentially fatal toxin may have implications for pet owners outside of the United States.

On December 30, Midwestern Pet Foods Inc. announced a recall of certain lots of Sportmix pet food products after FDA was alerted about reports of at least 28 dogs that died and eight that were ill after consuming the recalled pet food. Multiple product samples were tested by the Missouri Department of Agriculture and found to contain very high levels of aflatoxins. Aflatoxins are toxins produced by the mold *Aspergillus flavus* and, at high levels, can cause illness and death in pets. The toxins can be present even if there is no visible mold. Symptoms in pets may include sluggishness, loss of appetite, vomiting, jaundice), and/or diarrhea.

Midwestern Pet Foods expanded the recall on January 11 to include additional products that contain corn and were made in their Oklahoma manufacturing plant. These include Sportmix, Pro Pac and Nunn pet foods and Splash Fat Cat fish foods that were made in the company's Oklahoma plant and that expire on or before July 9, 2022.



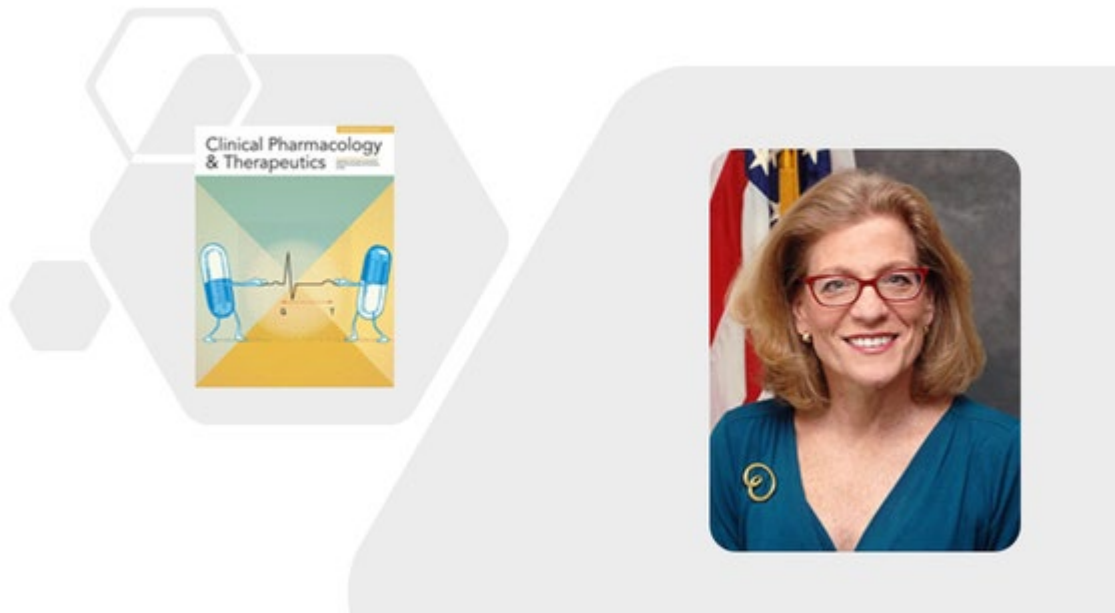
Initially it was thought that the affected products were distributed to online retailers and stores across the United States. But on January 25, FDA added a list of 35 countries where the recalled product may have been exported. The countries are: Bahrain, Barbados, Chile, Costa Rica, Curacao, Cyprus, Czech Republic, Ecuador, El Salvador, French Polynesia, Ghana, Guatemala, Honduras, Hong Kong, Iceland, Indonesia, Ireland, Israel, Korea, Kuwait, Lebanon, Lithuania, Malaysia, Mexico, New Zealand, Nicaragua, Panama, Peru, Singapore, Taiwan, Trinidad, Ukraine, UAE, Uruguay, and

Vietnam. To get the word out to FDA's international colleagues, OGPS sent an alert to all foreign embassies in Washington that same day.

As of January 21, FDA had been made aware of more than 110 dogs that have died and more than 210 that are sick after eating certain pet food manufactured by Midwestern Pet Foods.

Kweder Awarded

For the first time ever, the Editorial Team of [Clinical Pharmacology and Therapeutics \(CPT\)](#) will be presenting an award at the annual meeting of the [American Society for Clinical Pharmacology and Therapeutics \(ASCPT\)](#), their sponsoring society. The team chose to recognize a paper co-authored by Europe Office Deputy Director Sandra Kweder, M.D., entitled, *A Comparison of EMA and FDA Decisions for New Drug Marketing Applications 2014–2016: Concordance, Discordance, and Why*. In a congratulatory letter to Dr. Kweder, the journal's editor-in-chief Piet van der Graaf, PharmD, Ph.D., said that after careful review and discussion of the journal's many outstanding 2020 papers "it was clear to our team" that Dr. Kweder's study best represented the type of research CPT strives to publish, those that are timely, influential and carefully researched."



The study was the first time that the two agencies had worked together to systematically compare their decisions. Dr. Kweder and her co-authors from the European Medicines Agency examined the 107 new drug applications that received a regulatory outcome from both agencies during the 2014-2016 period, as well as individual applications with

differing outcomes in terms of marketing approval, type of approval and approved indication. The authors found a high concordance (91-98%) in decisions on marketing approvals. When decisions diverged, they occurred due to differences in conclusions about efficacy based on review of the same data or differing clinical data submitted to support the application.

The FDA and the EMA have been committed to achieving global alignment of regulatory standards for drug development. Dr. Kweder's study suggests that their ongoing efforts to collaborate on regulatory science may indeed be contributing to greater global harmonization, at least in such areas as clinical pharmacology and translational science.

Due to the ongoing pandemic, the award will not be presented in person. However, the ASCPT meeting will be held virtually and Dr. Kweder has been invited to attend. Please join us in congratulating Sandy!

Start 2021 “Write”: Introducing the OGPS Editorial Style Guide

Which British university lends its name to the serial comma...and what's a serial comma? What is the difference between an “em dash” and an “en dash”? What is the difference between affect and effect?

Remembering all the stylistic rules for making your writing experience easier and more polished can be a challenge. The new *OGPS Editorial Style Guide* (or *The Guide*, for short) has been designed to help all of us produce clearer, more precise, and more consistent communications.

The Guide has segments on routine grammar and stylistic concerns, frequently-encountered punctuation mistakes, and commonly misused words (such as who/whom and insure/ensure/assure, plus plenty of others). Special to OGPS, we have included a section on government and international words, both general and specific to our global experience. There's even an appendix with tips on plain language and 508 compliance.



Did you know that there are many style guides available to writers? Our new Guide generally defers to The Associated Press Stylebook, which is also embraced by the Department of Health and Human Services. But style guides are intended for specific audiences — meaning there is often more than one way to approach a situation (such as for the Oxford comma...you'll have to read *The Guide* to find out, or read a true NBC news [story](#) about its importance). Yet many rules are the same across all the style guides. Beyond our high school grammar books, you may have used the very popular *Chicago Manual of Style* (for book or academic publishing) or the *Government Printing Office Style Manual* (geared toward department-level printing). The rules of style can change over time and can sometimes be based on the needs or expectations of an organization or audience. Some elements of style here in the United States may be different than how they are applied in foreign countries — we understand that; do what your in-country audience expects when writing for them.

We intend for the *OGPS Editorial Style Guide* to be a living document that will change over time, with additions, corrections, and updates. Its purpose is to make our writing duties easier and our documents better.

Serrano Recognized as a Woman in Science

According to the United Nations Educational, Scientific and Cultural Organization, less than 30% of the world's researchers are women. One of the ways to address this gap, is to inspire young researchers. In 2015, the United Nations General Assembly adopted resolution [A/RES/70/212](#) declaring February 11 as the International Day of Women and Girls in Science.

Today, the Day is recognized throughout the world with programs and initiatives honoring women's significant achievements in science and working towards achieving equal access for women and girls in science education, careers, and leadership.



Last year, OGPS [@FDA Global](#) [acknowledged](#) the achievements of [Ritu Nalubola](#), Ph.D., director of FDA's Europe Office, who has led both nanotechnology policy activities and efforts to modernize the regulatory system for biotechnology products at FDA. This year, we celebrate the work of Katherine "Katie" Serrano, director of the Latin America Office.

The theme for this year's celebration of the Day is women scientists at the forefront of the fight against COVID-19. Serrano is a biomedical engineer whose specialty is in vitro diagnostics (IVDs), an important focus area given the intense interest in tests for COVID-19.

"The topic of encouraging women in science is one that is very dear to me," Serrano said. Her maternal grandmother pursued a degree in mathematics from St. Cloud State University (now Minnesota State University – St. Cloud) during WWII at a time when this was very unusual for women. Serrano said her grandmother would share stories about how great it was to be at the university then because with men away fighting the war, women were encouraged to take courses, even courses in math and science.

Serrano's mother, who works for a medical device company in Minnesota, has a degree in metallurgical engineering from Michigan Tech University and has her own stories about how "weird" it was for a woman to choose that technical subject. Serrano's family history of strong, science-minded women helped support her own pursuit of biomedical engineering and eventually, her career with FDA.



Serrano, pictured in red, at a meeting with SENASICA

Serrano has over 15 years of experience in the medical device field, with nine years spent in the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health's Office of In Vitro Diagnostics and Radiological Health (CDRH).

She began her FDA career as part of the 2008 inaugural class of FDA fellows and has worked as a scientific reviewer, as chief of the Diabetes Diagnostic Devices Branch, and as deputy director of FDA's Division of Chemistry and Toxicology Devices. While at CDRH, she served as the technical and policy lead for the agency's efforts related to [Laboratory Developed Tests](#). From 2009 to 2017, she participated as one of the "Nifty Fifty," part of the annual [USA Science and Engineering Festival](#). During the festival, STEM professionals present exhibits and TED-style speaker symposiums to encourage young people to consider careers in science and engineering.

Before working at the FDA, Serrano worked in regulatory affairs for Boston Scientific Corp. and as a biomedical engineer at the National Institutes of Health, supporting new programs focused on cutting edge technologies in the field of bioengineering.

Serrano received a Bachelor of Science degree in Biomedical Engineering and a Bachelor of Arts degree in Spanish from the University of Minnesota, Twin Cities. She credits learning and becoming fluent in a foreign language as beneficial to her career.

#WomenInScience

Transitions



Tonia Bernard has been selected as a consumer safety officer (CSO) for the China Office. Prior to her current role, Bernard was a CSO stationed in New Jersey. Before joining the FDA, she served as a program coordinator/medical case manager, overseeing \$178,000 in federal funds administered by District of Columbia, Department of Health HIV/AIDS, Hepatitis, STD and TB Administration (HAHSTA).

Tonia has 15 years of hospital pharmacy drug compounding experience at various hospitals in the Baltimore, Maryland area, including: John Hopkins Bayview Medical Center, Peninsula Regional Medical Center, and the Greater Baltimore Medical Center. Tonia holds a Master of Public Health in environmental science from Fort Valley State University and a Bachelor of Science in exercise science from University of Maryland Eastern Shore.

From a Global Perspective Features International History and EFSA

OGPS issued two thought pieces on international topics in the last month under our occasional series known as From A Global Perspective.

The [first article](#), “Global Considerations and Engagements: How FDA’s Global Work is Advancing Public Health,” written by Anna Abram, past deputy commissioner for policy, legislation, and international affairs; and Mark Abdoo, associate commissioner for global policy and strategy, traces the history of the FDA’s international work since World War II and how the FDA’s current ability to respond effectively on the global stage has been shaped by our emphasis on engagement, harmonization and knowledge-sharing.



The [second article](#), “Strengthening Scientific Cooperation Between FDA and the European Food Safety Authority,” written by Ritu Nalubola, director of the FDA’s Europe Office, and Steve Musser, deputy director of scientific operations in the Center for Food Safety and Applied Nutrition, highlights the scientific cooperation between the two agencies that began in 2007 and was greatly enhanced by a 2019 leadership meeting to define new opportunities for convergence on science policy and collaboration. Touching upon a selection of current cooperative efforts, including addressing the challenges of food safety risk communication, the blog then takes a closer look at the FDA and EFSA working group for whole genome sequencing and the use of this technology for outbreak tracing and risk characterization, by mining data in the GenomeTrakr network.

Dear International Colleague

The Dear International Colleague Letter (DIDL) is a letter sent via email to a list-serve of about 20,000 subscribers – both DC-based embassies and international stakeholders.

The DICL is intended to inform these stakeholders of any FDA announcements that are relevant to an audience with international interests. Here are the most recent DICLs:

Guidance on Testing for Methanol in Hand Sanitizers

International Food Safety and Nutrition Update - January 25, 2021

OTC Monograph Reform in the CARES Act: Safety Orders

Pet Food Recalled for Potentially Fatal Levels of Aflatoxin

FDA Places Hand Sanitizers from Mexico on Import Alert

Upcoming events

February 4 [World Cancer Day](#)

February 11 [International Day of Women and Girls in Science](#)

March 15-19 [DIA Europe](#)

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