Global Update - November 2023
Newsletter of the FDA's Office of Global Policy and Strategy

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Global News

FDA and Guam Partner to Strengthen Import Practices Across the Pacific Island Territories

On the island of Guam, 95% of the items are imported — including essential food and medical products, cosmetics and dietary supplements, and tobacco products. Being accessible from a number of Asian-Pacific ports, this U.S. territory in the western Pacific Ocean, at the boundary of the Philippine Sea, has garnered increased interest by the U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) as a possible shipping crossroads for the transshipment of fraudulent, misbranded, and adulterated products.

Transshipment may happen when cargo can't reach its destination through a direct route, so the cargo is transferred at an intermediate port from one vessel to another, including sometimes with a period of storage ashore, while in transit to its final port of discharge. As a consequence, sometimes packaging is modified to make it falsely appear that the intermediate port is the actual point of origin for the products.

To gain a better understanding of what products are moving through Guam's ports, the FDA and the government of Guam signed a Partnership Agreement (MOU 225-23-006) on October 18, 2023. It formalizes a mutual commitment between the three agencies to coordinate oversight activities related to such products.

Aerial view of Apra Harbor on Guam. Image courtesy U.S. Navy from 2006.

Keeping unsafe medical products out of the supply chains also advances the objectives of the Health Care Fraud and Abuse Control Program, or HCFAC, which is administered by the Department of Health and Human Services jointly with the U.S. Attorney General. The FDA has received funding for its Guam initiative under the HCFAC.

This three-year Partnership Agreement will allow the FDA and Guam's agencies to more deeply engage in exploratory and foundation-building activities to improve intelligence regarding imported fraudulent and noncompliant commodities potentially entering through Guam to the U.S. Territory Pacific Islands (Guam, Commonwealth of Northern Mariana Islands, and American Samoa), or those continuing on to Hawaii and the U.S. mainland. This also includes activities regarding refused import shipments (from mainland or Hawaiian ports) that may end up, fraudulently, in commerce in the islands instead of being returned to their foreign country of origin. Other key goals include determining the public health and HCFAC impact of activities undertaken per the FDA-Guam partnership and the feasibility of establishing a sustainable FDA regulatory presence in Guam for supporting the Pacific Territories.

"Enhancing our imports engagement will help to ensure products entering and passing through this region are safe. Our Partnership Agreement positions us to respond to import challenges more efficiently and helps ensure that we keep fulfilling our shared mission to protect and promote health and safety," FDA Commissioner Robert M. Califf, M.D., said.

The FDA has continuously been present on the island since June 2022, with temporary staff engaging with local customs and health authorities. Planned expansions in Guam for 2024 include hiring a long-term supervisor as well as continued temporary staffing from ORA's Offices of Import Operations, Regulatory Science, and Criminal Investigations stationed in Guam to support the Guam initiative and jointly further the wide-ranging partnership objectives as outlined in the MOU. Going forward, the FDA also plans to expand its presence in the other U.S. Pacific Territory Islands.

WHO's Member State Mechanism Looks Ahead to the Future

The World Health Organization's Member State Mechanism on Substandard and Falsified Medical Products adopted its first forward-looking strategic plan during its plenary in Geneva earlier this month.

The Mechanism, established in 2012, is a unique governance forum that brings together the 194 Member States of the WHO to develop strategies for mitigating the public health risk and harm caused by substandard or falsified medical products.

Participants at the Member State Mechanism Plenary meeting. Paul Huleatt, front and center. The FDA's Mark Abdoo, front row, second from left.

Over the years, the work plan of the Mechanism has been “quite open-ended,” said Paul Huleatt, the outgoing chairman of the Mechanism’s Steering Committee, who discussed the need for a strategic plan in an interview with OGPS in late January. “As a result, the ‘actions’ of the mechanism, though planned on a two-year cycle, also tend to be open-ended, meaning that successful completion (or otherwise) isn’t always linked to the planning cycle and some actions roll over to the next cycle,” he said.

“Having clear time frames for measuring progress and success in completing tasks is useful, especially when they feed into bigger pieces of work that are ongoing or at least extend beyond the biennial cycle,” said Huleatt, who is also First Secretary and Strategic Partnerships and Program Implementation Lead at the Program Implementation and Regulatory Strengthening Section in the International Regulatory Branch of the Therapeutic Goods Administration, within Australia’s Department of Health.

The Mechanism’s Strategic Plan, adopted on November 17, was developed in part by the FDA’s Office of Global Policy and Strategy, one of two vice-chairs of the Mechanism from the Americas region. It sets forth 12 forward-looking goals and lists proposed actions for achieving each goal including: improving engagement by Member States, raising the mechanism’s profile, establishing regional meetings, focusing on regulatory systems strengthening to address substandard and falsified medical products, prioritizing building national and regional testing capacity, ensuring a multisectoral approach to raise awareness about the sale of substandard and falsified medical products via the internet and/or through informal markets and improving the quality and consistency of

data reported to the WHO's Global Surveillance and Monitoring System for such products.

In addition, the Mechanism is considering how to better react in a more agile way to emerging issues when not in session. A new work group has been set up to address this issue, to be chaired by the Steering Committee's new chairman, Dr. Emile Bienvenu, Director-General of the Rwanda Food and Drugs Authority.

China's National Medical Products Administration Becomes an Official Applicant to PIC/S

China's drug regulator, the National Medical Products Administration (NMPA), has submitted a formal application to become a full member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), an international organization focused on the international harmonization of inspection procedures.

Source: Getty Images.

The NMPA submitted a formal application to PIC/S in late September 2023, and PIC/S confirmed the MMPA's status as an official applicant early this month.

PIC/S is a multilateral and informal cooperative arrangement between participating regulatory authorities that have oversight of good manufacturing

practices (GMP) for human and animal pharmaceutical products. Membership is open to any authority that has a comparable GMP inspection system; there are currently 56 participating authorities from across the globe, including the FDA. This arrangement aims to achieve the international harmonization of inspection procedures by developing common GMP standards and providing inspectors with training opportunities.

The NMPA initiated their plan to join PIC/S in early 2017, and after years of internal preparation and discussion with PIC/S the regulatory authority submitted its application for pre-accession in September 2021. The NMPA finished the two-year pre-accession procedure, paving the way for them to apply for and become an official applicant. Their new status allows the NMPA to take the final steps required to become a full member. This typically includes completing a detailed application package and translating supporting documents into English for PIC/S review. In addition, applicants may make some adjustments in their inspection practices to meet PIC/S' membership criteria. Before membership is finalized, time is also given to in-country manufacturers to make adjustments based on the PIC/S Good Manufacturing Practice Guide. The maximum deadline to successfully complete an accession process is six years.

In a November 9, 2023, press release announcing its new PIC/S status, the NMPA said they plan to strengthen their communication and cooperation with PIC/S and will continue to improve the country's drug inspection system, standards, and quality management, and will encourage further training and development of its inspectorate.

When a regulator participates in PIC/S, industry typically benefits since membership may facilitate exports or enhanced market access and can also mean fewer duplicate inspections, which can lower costs. In fact, the FDA China Office reports that pharmaceutical stakeholders in China are pleased that NMPA is pursuing full membership.

OGPS Observes 15th Anniversary of its Foreign Offices by Reflecting on Its History

On November 19, 2008, the FDA expanded its physical presence beyond the borders of the United States with the opening of the first FDA foreign office — in Beijing, China.

“Today, FDA has become a global organization,” Dr. Murray “Mac” Lumpkin, FDA Deputy Commissioner for International and Special Programs, said in an email message to FDA staff on that day.

Other foreign offices were opened soon afterward, beginning with a post in New Delhi, India, in the same month.

To mark the 15th anniversary of the FDA’s foreign offices — and of the agency’s evolving global vantage point — OGPS published an interview with Susan Winckler, CEO of the Reagan-Udall Foundation for the Food and Drug Administration, who was FDA chief of staff from 2007-2009. In 2007, Winckler led the FDA’s medical product negotiation with China’s then-State Food and Drug Administration, resulting in the Product Safety Memorandum of Agreement to enhance the safety of food, drugs, medical devices, and animal feed traded between the two countries. Under this legally binding agreement, both nations agreed to notify one another as soon as they discover a circumstance — such as a product recall — that could endanger public health.

As Reagan-Udall’s CEO, Winckler facilitated the Operational Evaluation of the FDA’s Human Foods Program and the subsequent evaluation and report submitted to FDA Commissioner Robert Califf on December 6, 2022. In her OGPS interview, Winckler looked back on her international work as chief of staff and how that experience influenced her work on Reagan-Udall’s evaluation of the FDA’s human foods program.

FDA Releases Informational Video on Importing Human Food

On September 29, the FDA released a YouTube video titled "Importing FDA-Regulated Products: Human Foods" that provides basic information for importers, foreign suppliers/exporters, and customs brokers on the steps they need to take to successfully import safe and compliant food into the United States. So far, the English-language video has received over 7,000 views. Spanish and Chinese versions were released on November 22.

Importers need to know many things to successfully import food products into the United States, including answers to such basic questions as what's in the product, how is it made, and how it is packaged, as well as the biological, physical, and chemical hazards associated with it. Also important is being familiar with the FDA's rules and regulations regarding food as well as verifying that the supplier is in compliance with them. These topics — and more — are addressed in the video.

The human foods video is the second in a series of planned YouTube videos on importing FDA-regulated products. The first video, outlining the general FDA admissibility process for imports, debuted in March 2022, and now has over 30,000 views. These numbers don't capture views inside China, where these videos must be watched on a separate, Chinese-sanctioned platform.

The videos are intended to address a gap in the available information about the FDA's import admissibility process, as initially identified by the Office of Global Policy and Strategy's (OGPS) India Office. At the time, information on this topic

was only available through public websites or occasional webinars, industry trainings, and individual communications.

Stay Tuned! Videos on other commodities are in the works…

Briefs

FDA and EMA Partner for Metastatic Breast Cancer Discussion Panel

The FDA's Oncology Center of Excellence (OCE) recently collaborated with the European Medicines Agency (EMA) in hosting a historic panel discussion, "Conversations on Cancer: Living with Metastatic Breast Cancer. "

"We are very interested in exploring similarities and differences that may exist both in drug regulation, treatments, and perceptions of diseases. We also hope today's conversation will be the first of many joint conversations on cancer by the FDA and EMA," said Dr. Richard Pazdur, the FDA's OCE director and medical oncologist.

The event marked the first international collaboration with the FDA and EMA highlighting the experiences of U.S. and European metastatic breast cancer patients, including four panelists currently living with the disease.

"EMA is dedicated to incorporating patient perspective. Today's discussion represents a significant step in this direction, a prime example of our commitment to engaging with patients and the broader community," said Caroline Voltz, Team Leader for EMA's Oncology and Drug Therapies Office.

OCE's Conversations on Cancer series was initiated to serve as an interface between societal issues and the science of oncology, as well as drug regulation.

Previous Conversations have included discussions of cancer clinical trial and health care access in Native American, LGBTQ+, Latinx, Asian American, Pacific Islander, and African American communities; the important role of oncology nursing; lung cancer in nonsmokers; and dialogue between the HIV and oncology communities. OCE believes that patient perspectives are crucial in determining what is working, what could be better, and how to help others survive this deadly disease.

The joint FDA-EMA event included a discussion on the differences and challenges that cancer experts face in making treatments available to patients. The four participating patients focused on current barriers to receiving high-quality, equitable, accessible, and affordable medical care in both the United States and Europe.

“We haven’t got a [global] system that is collecting data nor the real-world evidence of even older drugs and how they are working. It’s hugely upsetting because patients are dying, unable to access necessary drugs – what is the point of creating a drug if patients cannot access them? There are also different regulatory approval layers in [the] U.S. and Europe as barriers,” said Jo Taylor, founder of MET UP UK, the only metastatic breast cancer patient advocacy group in the U.K.

Globally, almost 30% of breast cancer patients are diagnosed with advanced-stage or metastatic disease.

The October 19 panel was hosted on YouTube and recorded with subtitles. Attendees were able to post comments and questions to OCE’s X account, formerly known as Twitter.

FDA Approves First Vaccine to Prevent Disease Caused by Chikungunya Virus

The world’s first vaccine to prevent disease caused by the potentially debilitating chikungunya virus has been approved by the FDA.

Ixchiq, manufactured by the French company Valneva SE, is approved for individuals 18 years of age and older who are at increased risk of exposure to the virus, which is primarily transmitted through the bite of an infected mosquito.

“Infection with chikungunya virus can lead to severe disease and prolonged health problems, particularly for older adults and individuals with underlying medical conditions,” said Dr. Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research “[The] approval addresses an unmet medical need and is an important advancement in the prevention of a potentially debilitating disease with limited treatment options.”

Chikungunya – which comes from a word meaning “to become contorted” in the Kimakonde language spoken in parts of east Africa – was first detected in Tanzania in 1952, triggering the first documented outbreaks in cities in Thailand and India some 15 years later.

According to the World Health Organization, chikungunya is an emerging global health threat with at least 5 million cases of chikungunya virus infection reported during the past 15 years. The highest risk of infection is in tropical and subtropical regions of Africa, Southeast Asia, and parts of the Americas where

chikungunya virus-carrying mosquitos are endemic. However, the virus has spread to new geographical areas, causing a rise in global prevalence of the disease.

Image of an adult Aedes aegypti mosquito, feeding. Courtesy the Centers for Disease Control and Prevention.

In February, the Pan American Health Organization (PAHO) issued an epidemiologic alert about elevated chikungunya activity in the Americas, urging countries to prepare their health care systems for the medical management of it and other mosquito-borne diseases. PAHO reported that cases were up sharply in 2022 compared to the previous year, with 13 countries reporting chikungunya infections.

Ixchiq is a live, weakened version of the virus, administered as a single dose by injection into the muscle. The safety of the vaccine was determined through two clinical studies involving about 3,500 adults in North America. Common side effects included headache, fatigue, muscle pain, joint pain, fever, nausea, and tenderness where the needle went in the skin. Severe reactions that prevented daily activity or required medical intervention occurred in 1.6% of vaccine recipients. Two people who received the vaccine had to be hospitalized.

The vaccine was approved using the Accelerated Approval pathway. Accelerated approval allows the FDA to approve certain products for serious or life-threatening conditions based on evidence of a product's effectiveness that is reasonably likely to predict clinical benefit. In the FDA evaluation of Ixchiq for accelerated approval, evidence of effectiveness is based on immune response data in clinical trial participants. As a condition for approval for Ixchiq, the

agency is requiring that confirmatory clinical studies be conducted to verify clinical benefit.

Ixchiq was granted Fast Track and Breakthrough Therapy designations, and the application was granted Priority Review. The FDA also awarded the manufacturer of Ixchiq a tropical disease priority review voucher, under a provision included in the Food and Drug Administration Amendments Act of 2007. This provision aims to encourage the development of new drugs and biological products for the prevention and treatment of certain tropical diseases.

Additional Resouces:

- Ixchiq (Chikungunya Vaccine, Live)

CDRH and LAO Experts Share Insight on Medical Device Regulation at Latin America Regional Meeting

For more than a decade, regulators and industry across the Americas have been committed to strengthening the regulatory capacity of the region's medical device national regulatory authorities, with the support of the Pan American Health Organization (PAHO).

One avenue for strengthening capacity has been the region's annual meeting on device regulation, held this year in El Salvador on October 11-13, which was co-hosted by PAHO and El Salvador's National Directorate of Medicines and the Salvadoran Social Security Institute.

The hybrid XI Regional Meeting on Medical Devices Regulation drew participants from 22 countries across the region. FDA subject matter experts from the Center for Devices and Radiological Health (CDRH) and the agency's Latin America Office (LAO) presented remotely. The meeting offered open sessions for promoting dialogue between regulators and stakeholders, and closed sessions for regulators only. Attendees included regulators, industry, academia, and members of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (a private sector group that has unified the 17 largest industry bodies for the medical technology sector in the region to provide hemispheric industry consensus recommendations for regulatory convergence priorities).

Image courtesy of PAHO.

At the open session, Ethny Obas, a lead consumer safety officer with CDRH, presented on the electronic issuance of export certificates, or e-certs, and provided clarification on the new process that will be implemented next year. Such certificates, issued by the FDA, attest to the marketing status of a medical device in the United States, as well as the compliance status of the device manufacturer with current good manufacturing practice regulations. Devices that can be legally marketed in the United States may be exported anywhere in the world without prior FDA notification or approval of exportation. However, having an export certificate is required by many device regulatory authorities in Latin America (and elsewhere) for companies to legally sell their product in their territories. Those export certificates will be going electronic, meaning no more paper as of January 2, 2024.

Focusing on regulatory issues, Erin Cutts, a regulatory policy analyst with CDRH, presented on the use of Real-World Evidence (RWE), which provides an understanding of device performance in actual clinical settings to inform regulatory benefit/risk decision-making. The evidence derived from the analysis of data related to patient health status and/or delivery of health care may be collected from a variety of sources. Use of RWE includes the ability to collect outcomes not always feasible in traditional trials, as well as the reduction of the time and cost to answer important questions.

CDRH has taken several concrete steps to promote RWE adoption and use for regulatory purposes and to optimize the infrastructure needed to develop RWE. Cutts described how CDRH has published guidance and examples of RWE being used in regulatory decision making and underscored its international value. Real-world data from any country can be collected to answer questions about clinical practice and outcomes applicable to all countries. Regulatory convergence on how to approach real-world data collection and the uses of RWE help patients across the globe have access to safe, effective, high-quality, and innovative medical devices.

Regulatory reliance was also a hot topic. The World Health Organization defines the concept in its Annex 10 Good Reliance Practices guideline document as:

"The act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another national regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible, and accountable regarding the decisions taken, even when it relies on the decisions and information of others."

Vesa Vuniqi, an international relations specialist with the LAO, talked about the FDA's public databases and the marketing, compliance, and safety information that is available to support the implementation of reliance mechanisms in Latin America. These include CDRH's numerous public medical device databases — on 510(k) premarket notifications, premarket approvals, and many other product-oriented data collections — as well as the public FDA Data Dashboard highlighting information on manufacturers and inspections, compliance actions, and recalls. At the regulators-only session, Vuniqi addressed the FDA's own activities related to reliance, as well as the benefits of adopting reliance mechanisms and opportunities for the countries in the region. She also talked in detail about postmarket surveillance and the regulatory approach to recalls; this was of interest for the Latin America regulators since several of them rely on the FDA's recall information.

For the closed session, Cutts presented updates on the activities of the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world aiming to accelerate international medical device regulatory harmonization and convergence. Brazil, Canada, and the United States are currently the only IMDRF members from the Americas. Argentina is an official observer, and Chile and Cuba are affiliate members who can participate in the IMDRF by attending open meetings and using IMDRF documents in part or in whole as the basis for their own regulatory framework. During her presentation, Cutts also provided valuable input during the discussions about the Latin America regulators participation in the IMDRF working groups.

BONUS PHOTO ALBUM:

Joseph Rieras [first on the right], director of OGPS' Office of Trade and Global Partnerships, participated in the closing session of the U.S. Trade and Development Agency's Workshop on Regulatory Convergence for Healthcare Products in East/Central Africa. The session's topic was Private Sector Recommendations on How to Advance Regulatory Convergence and Reliance for Medical Devices. The workshop drew participants from five African Regulatory Authorities and more than 100 pharmaceutical and medical device companies over the course of the two-day program in Nairobi, Kenya, earlier this month.

An FDA delegation led by Deputy Commissioner Kimberlee Trzeciak met with members of the European Parliament's Subcommittee on Public Health at FDA headquarters in Maryland on October 30. Topics discussed included nutrition, food labeling, and drug shortages.

Staff News

FDA India Office Presents at World Spice Congress 2023

FDA India Office (INO) Director Dr. Sarah McMullen gave a presentation on the FDA's approach to spice safety during a technical session at the 14th World Spice Congress (WSC) on September 15-17 in Mumbai. Also participating in the panel were speakers from Canada and Azerbaijan. Canada also emphasized many of the same regulatory concepts, and both countries underscored the importance of prevention when it comes to food safety. Speakers from Bangladesh, Indonesia, Iran, Turkey, and the United Arab Emirates participated in an earlier session to give their perspective on the spice industry and global opportunities.

Clockwise from top left: Sarah McMullen and Pankaja Panda from the FDA India Office. McMullen with session participants, WSC Chair and co-Chair, and the Secretary of the Spices Board. Panda with Spices Board officials from northeast India. McMullen and Panda with the CODEX Chairman and the Director, Chairman, and Secretary of the Spices Board.

The Government of India's Spices Board organized the biannual event, which provides an opportunity for spice-interested industry, policymakers, regulatory authorities, trade associations, government officials, and technical experts from key G20 countries as well as other countries to interact with each other and exchange information related to the international trade of Indian spices. This year's meeting drew 1,300 delegates and some 156 exhibitors seeking to showcase their spice products and spice-related equipment.

The Spices Board is part of GOI's Ministry of Commerce & Industry.

Dr. McMullen and Dr. Pankaja Panda, the INO's senior technical advisor for foods who also attended the meeting, have made it a point to better understand the landscape, operations, and concerns of the Indian spice industry while communicating and advocating for the FDA's regulatory expectations. Last year, they visited the Spices Board's Spice Park and various farms in Kerala, India. This past June, the INO facilitated regional training in the states of Kerala and Assam on Good Agricultural Practices and Good Manufacturing Practices, targeting the unique needs of growers and producers of spices, herbs, and medicinal plants. Spices from India are a significant export to the United States.

Staff on the Move - October & November 2023

Incoming

Ioana Ulea has joined the FDA Europe Office in Brussels as a policy advisor focusing on the analysis of EU medical product policy developments. She has experience in the medical device regulatory affairs sector, providing expert guidance and strategic insights to various medical device manufacturers of proton therapy and clinical imaging devices. Her expertise extends to diverse facets of medical device operations encompassing premarket submissions, clinical trials, quality management system audits, and vigilance activities. Ioana has both undergraduate and advanced degrees in law.

Tracy Portelli joined the FDA China Office in November as a consumer safety officer (CSO) for foods and will make the move to China in early 2024. She comes to OGPS from the New York District Office, where she had been a CSO in the Human and Animal Foods Division since joining the agency in 2015. While there, Tracy completed a detail as a supervisory CSO and was a part of the division's mentoring program for newly hired CSOs. She holds a master's degree in public health and an undergraduate degree in biology.

Departing

Jonathan Chapman, the former international relations specialist for drug products in the FDA China Office, has transitioned to a new role in the FDA's Center for Drug Evaluation and Research's Office of Compliance as senior

policy advisor with the Office of Manufacturing Quality's Manufacturing Quality Guidance and Policy Staff. During his time in the China Office, Jonathan traveled all over China conducting inspections of drug facilities, giving technical presentations to industry and academia, and representing the FDA at meetings with medical product regulatory counterparts.

Latasha Robinson, the former deputy director of the FDA China Office, has transitioned to her new role with the FDA Center for Food Safety and Applied Nutrition (CFSAN) as the center's chief critical foods officer. This is a bit of a homecoming since Latasha spent the first 10 years of her FDA career with CFSAN. Risk management of critical foods will ultimately become an integral part of a new Nutrition Center of Excellence within the FDA's proposed Human Foods Program reorganization.

Dear International Colleague

Recent communications from OGPS to our international stakeholders (list does not include twice-weekly FDA Roundup summaries), September 27 through November 17.

- Global Efforts to Address Plastic Pollution: An FDA Perspective
- FDA Proposes Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests
- FDA Releases Informational Video on Importing Human Foods
- India's Unique Opportunity and Important Responsibility as the Pharmacy to the World
- FDA Approves First Vaccine to Prevent Disease Caused by Chikungunya Virus
- Looking Back at the Founding of the FDA Foreign Offices

Events

December 1 World Aids Day

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