U.S. Food and Drug Administration sent this bulletin at 10/17/2024 03:29 PM EDT

For best reading experience, view as a webpage.

October 2024

Global News | Briefs | Photo Album | Dear Int'l Colleague | Events

---

In this issue

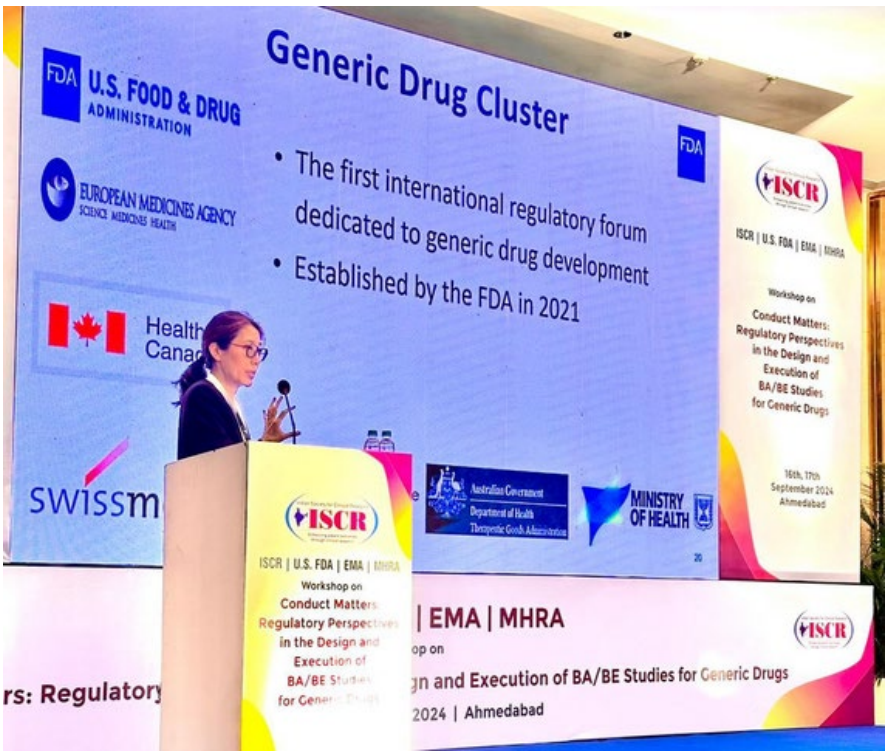
...and much more inside...

Global News

FDA to India: Adhering to Good Clinical Practice and Data Integrity in Generic Drug Studies Is Critically Important

To strengthen India's regulatory understanding of data integrity and human subject protection in the development of generic drugs and particularly complex generics, the FDA's India Office partnered with the Indian Society for Clinical Research and their regional chapters to put on the FDA Bioavailability (BA)/Bioequivalence (BE) Roadshow in mid-September. Fourteen FDA experts from the Offices of Generic Drugs, Translational Science, and Regulatory Affairs (now the Office of Inspections and Investigations) traveled to India to participate in the roadshow's meetings and workshops that took place over 10 days in three cities.

The event took place at a critical time, with data integrity issues threatening to disrupt the generics market in the United States and EU. Over the last three years, the FDA has issued changes to the therapeutic equivalence codes of 72 medicines, meaning they are no longer substitutable at the pharmacy level, while the EU has pulled 400 medications off the European market, all due to data integrity issues.



Presenting is Dr. Iilun Murphy, director of the FDA's Office of Generic Drugs.

BA/BE studies are generally necessary to demonstrate that generic drugs are substitutable for the branded drug, as part of the generic drug approval process. BA/BE studies may involve healthy human subjects or be patient-based outcomes studies, and also laboratory-based investigations. Ensuring Good Clinical Practice and data integrity are essential components of such studies.

The FDA estimates that India accounts for around 80% of the BA/BE studies for generic applications since research costs are lower in the country and there is a large pool of qualified professionals, including those in contract research organizations and pharmaceutical companies. And yet, the rapid rise of this industry has been marred by uneven compliance, with FDA investigators consistently finding an array of compliance issues in this sector. They include instances of data manipulation in lab-based studies, evidence of falsified data, and failure to conduct the clinical study in accordance with Good Clinical Practice — by providing inadequate informed consent, underreporting adverse events, ignoring conflicts of interest, and falsifying study participants.

FDA Commissioner Dr. Robert Califf repeatedly raised data integrity and human subject protection issues when he led an FDA delegation to India in September 2023.

“Not only is sound, ethical, clinical practice required by FDA regulations, it is our shared responsibility to research study participants and future beneficiaries of therapeutics that clinical studies be conducted in a way that ensures the integrity of the data and the protection of participants,” he said after the trip.

Last month’s roadshow was the FDA’s latest effort to address these issues. It began in New Delhi where the FDA exchanged practices and shared ideas with India's central regulator, the Central Drugs Standard Control Organisation. Though Indian regulators require BA/BE study data for some generic drugs in India, many generic products whose brand version was on the Indian market longer than four years are not required to do so. Manufacturers of these latter products conduct BA/BE studies if they want to export their drugs, but that leaves oversight of this sector largely up to foreign regulators like the FDA that require this data in generic drug applications.

After New Delhi, the FDA officials went on to the cities of Ahmedabad and Hyderabad where they conducted separate two-day workshops that included presentations by regulatory counterparts from the European Medicines Agency, Health Canada, and the U.K.'s Medicines and Healthcare products Regulatory Agency. While in Hyderabad, the FDA delegation met with company leaders from the Indian Pharmaceutical Alliance and the Indian Drug Manufacturers Association to discuss continuous improvement efforts in data quality and future planning. "Quality data and well-run studies are vital for generic and complex generic drug approvals,” they all agreed. More than 300 people — regulators, sponsors, contract research organizations, clinical scientists, trial experts, and more — participated over the course of the roadshow to discuss best practices and regulatory expectations.

In perhaps coincidental timing, immediately after the FDA's roadshow, India's government also publicly declared new rules better defining contract research organizations and their obligations, with new requirements for reporting to the central drug regulator CDSCO. This change, long requested by industry watchers, is intended to increase oversight of the clinical research sector, and a sign of hopeful change in this rapidly growing but currently underregulated industry in India.

FDA staff in India and at headquarters intend to continue to work with India to advance access to safe and effective generic medicines, while upholding rigorous standards for evidence generation and clinical research.

FDA Promotes Quality Management Maturity in India

Experts from the FDA's India Office (INO) and Center for Drug Evaluation and Research (CDER) recently promoted Quality Management Maturity — also known as QMM — at a conference in Bangalore, India, from September 18-20. The event, organized by the Parenteral Drug Association's (PDA) India chapter, brought together 200 representatives from a wide range of Indian medical product industries, including pharmaceuticals, biologics, vaccines, and cell gene therapy. Attendees included senior leaders such as chief quality officers, chief operations officers, chief human resource officers, supply chain heads, and vice-presidents.

QMM is the status a company attains by having consistent, reliable, and robust business processes to achieve quality objectives, promote continual improvement, and enhance supply chain resilience. Pharmaceutical companies that integrate business and manufacturing operations with quality practices and technological advancements can achieve higher levels of maturity. More importantly, adherence to mature quality management practices helps ensure the availability of quality medical products and reduces the likelihood that quality issues would contribute to drug shortages that negatively impact patients and consumers. In short, many global supply chain disruptions may have been caused by gaps in the maturity of existing quality systems.

Greg Smith, director of FDA's India Office, discussed the current landscape of pharmaceutical manufacturing in India and the ongoing efforts by the INO to enhance pharmaceutical quality. CDER has accepted industry volunteers to participate in its 2024 voluntary QMM Prototype Assessment Protocol Evaluation Program and plans to complete QMM assessments at nine manufacturing establishments this year.

The FDA routinely collects data using a wide range of quality surveillance systems and is therefore uniquely positioned to promote QMM practices. To that end, CDER is currently establishing its QMM Program with the goal of encouraging pharmaceutical manufacturing establishments to adopt quality management practices that go beyond current good manufacturing practice requirements. CDER has already accepted industry volunteers to participate in its 2024 voluntary QMM Prototype Assessment Protocol Evaluation Program and plans to complete QMM assessments at nine manufacturing establishments this year. The assessment protocol covers five practice areas: Management Commitment to Quality, Business Continuity, Advanced Pharmaceutical Quality System, Technical Excellence, and Employee Engagement and Empowerment.

The conference in Bangalore provided FDA presenters with a unique opportunity to both spark interest in CDER's emerging QMM program and encourage India's pharmaceutical manufacturers to adopt a robust quality culture. Greg Smith, director of the FDA's India Office, opened the session by discussing the current landscape of pharmaceutical manufacturing in India and the ongoing efforts by the INO to enhance pharmaceutical quality. Dr. Jennifer Huntington, from the FDA's Office of Pharmaceutical Quality (OPQ), followed by offering an in-

depth overview of the QMM program, highlighting significant milestones and outlining its five key practice areas.

Dr. Nandini Rakala, also with OPQ, presented on the business continuity practice area, explaining how having a robust business continuity plan helps to minimize the risks of product availability to patients and helps ensure a reliable market supply. In addition, Eric Twum of OPQ presented on knowledge management from a QMM perspective. Twum explained how an effective knowledge management strategy can help a company to eradicate inefficiencies, create a competitive market edge, and promote a quality culture within the organization. Following their presentations, the FDA speakers participated in a panel session to respond to audience questions.

Case studies and lessons learned were also discussed in depth, providing industry leaders and other stakeholders a platform for an in-country dialogue on charting a path forward. Participants identified action items, including creating an India-based cross-industry interest group on QMM and convening a follow-up meeting in 2025 for industry to present QMM case studies and experiments. India's production of quality pharmaceuticals is vital to the global supply chain, with manufacturers in India producing approximately 40% of the U.S. generic drug supply.

FDA Holds First-Ever Produce Safety Engagement with Colombia Fresh Produce Sector

Since the FDA first opened its Latin America Office in 2009, engaging with regional stakeholders on food safety issues has accounted for a significant portion of the staff's work portfolio.

After all, about 60% of the fresh fruit and 39% of the vegetables consumed by volume in the United States are imported, and 95% of the imported fresh fruit and 80% of the imported fresh vegetables come from Latin America.

One of the region's major importers of fresh herbs, fresh fruit, and coffee is Colombia, and yet the FDA never had the opportunity to meet with Colombia's fresh produce sector until late last month when agency officials co-sponsored two separate produce safety symposiums there. As part of the learning, they conducted an "Educational Farm Visit" (one type of FDA outreach to growers) at an organic basil farm; and toured the government-run Nataima Research Center, which focuses on foodborne pathogens.

Co-sponsoring the Symposium on the Safety of Fresh Agricultural Produce on September 24 in Bogotá and a similar event on September 26 in the town of El Espinal (in the heart of the country's fresh produce region), were the Colombian Agricultural and Livestock Institute (ICA),

which regulates Colombian fresh produce, and the Inter-American Institute for Cooperation on Agriculture (IICA), a nonprofit.

Left: FDA International Regulatory Analyst Gonzalo Ibanez speaks at the symposium held in the town of El Espinal. Right: Symposium attendees in Bogotá.

Updating and deepening what attendees already know about the FDA's requirements under the Food Safety Modernization Act of 2011 was the primary intent of the symposia, according to Gonzalo Ibanez, who is based in the FDA Latin America Office's post in Santiago, Chile. The topics included the Produce Safety Rule, the Foreign Supplier Verification Program, the Agricultural Water Rule, and the Food Traceability Rule. The latter rule, which goes into effect in January 2026, requires that companies that manufacture, process, pack, or hold certain kinds of food for consumption in the United States (including basil) comply with new recordkeeping requirements. Such recordkeeping is intended to help the FDA follow the movement of a food product and its ingredients throughout the supply chain so the agency can rapidly find the source of an outbreak of a foodborne illness or a food contamination event.

FDA and IICA officials also used the symposia to highlight their Growing Safe Produce web platform, which growers of fresh agricultural produce can access for supplementary training material to improve their understanding and subsequent implementation of the FDA's food safety requirements. The platform includes videos, interactive web applications, infographics, and posters.

A motivating factor for the timing of these on-the-ground meetings was the work the FDA has been doing with ICA as part of the Cyclospora Prevention, Response and Research Plan developed in 2021 by the Cyclospora Task Force (a collaboration between the FDA and the Centers for Disease Control and Prevention.) That plan emphasized three priority areas: improving prevention; enhancing response activities; and filling knowledge gaps in countries with a history of contamination with the cyclospora parasite, which can cause intestinal illness two days to two weeks after consuming contaminated produce. Fresh basil from Colombia has been linked to contamination events with cyclospora, and the FDA has been meeting with ICA since February 2024 to try to better understand the root causes of the contamination, informed by the FDA's sampling and testing traceback activities.

Officials from the FDA, ICA, and IICA visit the Nataima Research Center, as well as a basil farm.

Both symposia featured a video — recorded by Dr. Alexandre DaSilva, a parasitologist in the FDA's Senior Biomedical Research and Biomedical Product Assessment Service — which refers to the work being developed by the FDA regarding the parasite. Speakers also explained how, should there be a contamination event, imported fresh produce may be placed on Import Alert 99-35 (detention without physical examination) for the appearance of having been prepared, packed, or held under insanitary conditions — and also explained how firms can submit evidence to the FDA for removal from such an alert.

The Nataima Research Center in El Espinal is part of the Colombian Agricultural Research Corporation (AGROSAVIA), a government entity that strives to improve the productivity and competitiveness of national agriculture through science, technology, and innovation. During their visit to Nataima, the FDA team was briefed on the institute's research on the origin and prevention of fresh basil's contamination with foodborne pathogens, particularly cyclospora, and its studies on alternative approaches to the food safety management of basil production. Nataima researchers have sampled and tested water, soil, and basil and have met with growers to talk about controls for the parasite. No definitive source of contamination has been identified to date.

Educational Farm Visits have long been a part of the FDA's rollout of its Produce Safety Rule, allowing FDA staff to interact with growers and hear their perspective about their unique growing conditions, practices, and compliance challenges. During the visit to the basil farm in Colombia, the FDA delegation watched as drones sprayed the field with a spicy chili and distilled water mixture intended to serve as a pest deterrent in place of a pesticide. Workers carry coolers on their backs to the fields where they store their picked basil. Once full, the coolers are sent to a packing house where the basil is separated into plastic bags and stored in a box that is chilled to 10 °C. The farm also features a laboratory area where tests are conducted to detect pathogens.

Besides Ibanez, the other FDA official who traveled to Colombia was Crystal McKenna from the FDA's Center for Food Safety and Applied Nutrition (now the Human Foods Program.)

FDA Explores Food Traceability Practices in India Ahead of New Rule

The FDA's Food Traceability Rule is currently scheduled to go into effect less than 18 months from now, requiring both international and domestic companies that manufacture, process, pack, or hold certain kinds of food for consumption in the United States to comply with new recordkeeping requirements.

Such recordkeeping is intended to help the FDA follow the movement of a food product and its ingredients throughout the supply chain so the agency can rapidly find the source of an outbreak of a foodborne illness or a food contamination event.

But educating the estimated 62,000 international companies that are expected to be affected by the rule by its January 20, 2026, compliance date is a significant undertaking.

One of the food items subject to the rule, as identified on the FDA's Food Traceability List, is shrimp, and since India is the number one shrimp exporter to the United States, it offers a microcosm of what the FDA can expect as it prepares international stakeholders for the upcoming rule.

With that in mind, four FDA experts in traceability and international engagement recently traveled to Chennai, India, from August 14-27, to explore the current traceability practices of its aquacultured shrimp industry there.

FDA delegation from left to right: Anthony Rizkalla, Selma Pourzal, Pankaja Panda, and Chris Waldrop.

The FDA delegation was led by Pankaja Panda from the FDA's India Office. Chris Waldrop, Selma Pourzal, and Anthony Rizkalla from the Center for Food Safety and Applied Nutrition (now the Human Foods Program) were the other participants. During their time in Chennai, the group visited three shrimp aquaculture farms and three processing companies that export shrimp to the United States. At each stop, the group interviewed both owners and personnel to understand their current traceability practices, how their records are kept, and their current familiarity with the FDA's traceability rule.

Panda planned and implemented the trip, including identifying places to visit in only a few months. "I said, we are here to learn from you and study your traceability process from farm to firm," she said. "They were so gracious."

In addition to visiting the farms and facilities, the group met with officials from five Government of India food safety agencies — the Coastal Aquaculture Authority (CAA), Marine Products Exports Development Authority, Food Safety and Standards Authority of India, Export Inspection Council, and the Spices Board of India — to raise awareness about the rule and to

promote adoption and harmonization with FDA policy. The meeting was hosted by the CAA in Chennai and included over 80 participants in person and online.

Knowledge from this study will aid the FDA India Office as it conducts outreach and engagement with the local shrimp industry on the upcoming rule. It will also help the FDA address and clarify the industry's concerns or misconceptions; gain a better understanding of the realities that international industry, as a whole, faces as it complies with this rule; and how traceability practices may look like in certain food supply chains.

FDA a Key Voice at Dietary Supplement Workshops in China

In September, FDA officials presented at workshops on dietary supplement quality and safety in Shenzhen and Beijing, the first time a forum in China addressed the United States' regulatory, quality, and trade approaches to these products. Co-hosted by the U.S. Pharmacopeia (USP) and the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE), the workshops attracted nearly 300 attendees from across China's dietary supplement industry, contract research laboratories, and trade, academic, scientific, and regulatory sectors.

At the workshops, the FDA discussed the U.S. regulatory requirements relating to facility registration, new dietary ingredient notifications, current good manufacturing practices (cGMP), product labeling, and compliance and enforcement approaches.

FDA China Office staff attending the event. From left, Director Sara McMullen, Medical Research Scientist Lixia Wang, and International Relations Specialist Clinton Priestley.

"China is one of the most active regions in the global dietary supplement industry, serving as both a major producer and supplier of raw materials and a consumer market with enormous development potential," with nearly 1,700 licensed health food production enterprises at the end of 2023, according to the CCCMHPIE.

Due to an aging populace and modern lifestyle, the market for vitamins, sports nutrition and herbal and other specialized dietary supplements has expanded exponentially. In 2008, China's total global import and export value of dietary supplements was $720 million. Last year it was $10.76 billion, the CCMHPIE estimates, with more products coming into China than are exported — $6.74 billion in imports compared to $4.02 billion in exports. In the first half of 2024, the United States was China's top dietary supplement export market, to the amount of $320 million.

The FDA and USP officials both explained that quality standards are different for dietary supplements as compared to those for pharmaceuticals. Although pharmaceuticals are required by U.S. law to meet (as shown through laboratory analysis) specific quality standards set by the USP, such requirements don't apply to dietary supplements.

The USP, in its role as a standard-setting organization, has established quality standards for various dietary ingredients (and created a verification program specifically for dietary supplements). Many manufacturers voluntarily use these standards to ensure the quality of their products.

The FDA has found that imported dietary supplements can present specific challenges because the definition and scope of product categories can differ between countries. For example, many Chinese exporters may seek to market their products as dietary supplements in the United States; but in China, the same product may be classified as a food, drug, or Traditional Chinese Medicine.

"These workshops provided an important opportunity for the FDA to engage directly with Chinese dietary supplement firms and provide information to help them determine what FDA requirements apply to their products. The FDA is committed to working collaboratively with all of our stakeholders to help ensure that the U.S. marketplace has safe, well-manufactured, and accurately labeled dietary supplements," according to Dr. Haijing Hu, of the Office of Dietary Supplement Programs within the FDA's Center for Food Safety and Applied Nutrition (now the Human Foods Program).

Many participants were eager to learn about the FDA's process for New Dietary Ingredient Notification and the "when and how" of submitting a notification. The session on structure/function claims for a dietary supplement also drew a lot of interest. The audience benefited from, and were amused by, real-world examples of label claims translated from Traditional Chinese Medicines that would not be acceptable in the United States. The audience also benefited from examples of cGMP violations taken directly from FDA inspections at Chinese facilities.

Speakers from the FDA included Dr. Sarah McMullen, director of the FDA China Office, who gave opening remarks; and Dr. Haijing Hu, chief of the Regulatory Implementation Branch of the FDA's Office of Dietary Supplement Programs, who spoke in multiple sessions on cGMP and regulatory insight. Experts from the Foreign Commercial Service (FCS) within the U.S. Department of Commerce's International Trade Administration provided the U.S. trade perspective, and the USP provided technical insights on Dietary Supplements Compendium monographs, highlighting the level of effort required to develop quality specifications that are quantifiable and verifiable and how these standards can help manufacturers meet regulatory requirements.

Overall, the audiences at these workshops were highly interested and eager to engage with the FDA, USP, FCS, and CCCMPHIE subject matter experts. The FDA's China Office benefited as well, coming away with a better understanding of the dietary supplement landscape in China, and the office looks forward to further engagements on the topic, which it hopes will lead to greater compliance with FDA regulations.

New FDA Video on Importing Seafood

On September 24, the FDA released the video "Importing FDA-Regulated Products: Seafood" on YouTube. The video provides basic information for importers, foreign suppliers/exporters, and customs brokers on what steps to take to successfully import safe and compliant seafood products into the United States. (Spanish and Chinese language versions will be available soon.)

Importers need to know many things to navigate this process, including answers to such basic questions as what's in the product, how it is made, and how it is packaged, as well as the biological, physical, and chemical hazards associated with it. Also important is being familiar

with FDA seafood rules and regulations and verifying that the supplier is in compliance with them. These topics — and more — are addressed in the video.

The 16-minute seafood video is the third in a series that is intended to address a gap in the available information about the FDA's import admissibility process, as initially identified by the agency's India Office. At the time, information on this topic was only available through public websites or occasional webinars, industry trainings, and individual communications.

The first video, outlining the general FDA admissibility process for imports, has been viewed over 48,000 times on the YouTube platform since debuting in March 2022; while the second video, on importing human foods, has received over 25,000 views since its debut in September 2023.

Several FDA offices collaborated on the video project. The Office of Regulatory Affairs' (now the Office of Inspections and Investigations) Division of Import Operations provided subject matter experts, its Technical Assistance Branch worked with the Office of Global Policy and Strategy's (OGPS) Communications Team on the scripts, OGPS provided the funding, and the CDRH Studio provided technical production.

Additional expertise for the seafood video project was provided by the Division of Seafood Safety within the FDA's Center for Food Safety and Applied Nutrition (now the Human Foods Program). They plan to include this video on the FDA's public Seafood webpage, as well as in the seafood training courses that are targeted to importers.

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

Briefs

FDA Talks Quality, Partnerships, and International Harmonization at ICDRA

The 19th International Conference of Drug Regulatory Authorities (ICDRA) wraps up tomorrow in New Delhi, India.

Hosted by the World Health Organization (WHO) and India's Central Drugs Standard Control Organisation (CDSCO) and Ministry of Health and Family Welfare, this year's theme has been "Smart Regulation: Delivering Quality Assured Medical Products for All."

Held about every two to three years since 1980, the ICDRA provides regulatory authorities of WHO Member States with a forum to promote the exchange of information and collaborative approaches to issues of common concern. Representatives from 120 member states participated in this year's meeting, which is taking place from October 14-18.

The FDA delegation to ICDRA included Deputy Commissioner for Policy, Legislation, and International Affairs Kimberlee Trzeciak; Office of Global Operations Director Barr Weiner; CBER's Associate Director for Special Programs, Gopa Raychaudhuri; CDER's Director of the

Office of Manufacturing Quality, Captain Tara Gooen; and India Office Director Greg Smith, with the support of the India Office's policy, inspectorate, and operations staff.

In both formal remarks and small group meetings, the delegation used the conference to promote the importance of adopting a culture of quality, developing regulatory partnerships, and supporting regulatory harmonization as important touchstones for mitigating marketplace risks.

At the FDA, "our long-term vision is a global marketplace which consistently offers high-quality medical products…regardless of where they are manufactured or used," said Trzeciak, who delivered the keynote speech at the ICDRA's First Plenary, the official opening session of the conference on October 16.

"Inspecting our way to quality" isn't feasible, Trzeciak said. "No regulatory authority can do everything on its own. Every member of the supply chain plays a critical role in its success." Instead, what's critical is encouraging a culture of quality and developing partnerships that better position the FDA and its counterparts to mitigate the numerous risks that could impact access to high-quality medicines and vaccines, she explained.

In discussing international harmonization, Trzeciak highlighted the benefits of the new WHO-Listed Authority (WLA) process, which she brought up in both her plenary speech and during an ICDRA pre-conference panel on October 14. As she said in both sessions, the WLA process sets transparent, quantitative standards for identifying advanced performing regulatory authorities (designated as WLA reference authorities) and promotes reliance. This means that regulatory authorities that lack the resources or expertise to perform a function may confidently rely on WLAs for decisions and to guide competency building, which in turn furthers international harmonization, facilitates product access, and enables supply chain integrity, she said.

All three issues — quality, partnerships, and international harmonization — were featured during the FDA's trilateral meeting with the European Medicines Agency and CDSCO on October 17 that resulted in strengthened commitments to collaborate on advancing the expectation of "one high quality" for medical products.

While in India, Trzeciak and other FDA staff met with Dr. Yukiko Nakatani, WHO Assistant Director-General of Access to Medicines and Health Products, and her staff, the group that developed and implemented the WLA process. Discussions addressed the interrelationship of the WLA program and other WHO mechanisms to facilitate reliance and related matters —

including the work of the WHO's Member State Mechanism on Falsified and Substandard Medical Products.

IMDRF Makes Membership Strides

The International Medical Device Regulatory Forum saw a sharp increase this year in the number of regulatory authorities seeking to participate in the voluntary forum, whose goal is accelerating international medical device regulatory harmonization and convergence.

The forum was founded in 2011 when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan, and the United States (together known as the Management Committee) met in Ottawa with the World Health Organization. Since then, regulatory authorities from Russia, Singapore, and South Korea have been added to the Management Committee, along with the U.K. after Brexit.

Two other membership categories were created, Official Observers and Affiliate Members. Official Observers must be fully knowledgeable on IMDRF matters and so designated by the Management Committee for their perceived contribution or value to the IMDRF and Affiliate Members. There are only a limited number of those. Affiliate Members are those who would like to engage with IMDRF, but do not wish to become, or are not, Official Observers. They participate in the IMDRF by attending open meetings that typically feature a discussion on the latest medical device regulatory strategies and trends, and by using IMDRF documents in part or in whole as the basis for their own regulatory frameworks. Affiliate Members may also participate in open working groups.

This year, with the FDA as IMDRF Chairman, the number of affiliates jumped from seven to 22 members with seven regulatory authorities added during the IMDRF's March meeting in Washington, D.C. and eight during the September meeting held in Seattle. In addition, the Saudi Food and Drug Authority became an Official Observer, joining the WHO, Swissmedic, and Argentina's Administration of Drugs, Food and Medical Devices.

In remarks at the beginning of the Seattle meeting, FDA Commissioner Robert Califf said the IMDRF founders envisioned that "a broad-based and continually expanding membership was essential." To the founder's credit, they focused on that goal, he said. Not only has the membership grown, "but even more important has been the diversification of the membership."

Among the new affiliates approved by the Management Committee in September was the Central Drugs Standard Control Organisation, the central regulatory authority for India, the world's most populous nation and the world's fifth largest economy. Notably, IMDRF is the first international harmonization organization that CDSCO has joined.

In a statement, the Indian Ministry of Health and Welfare (MHW) said that CDSCO (which is organized under the Ministry) applied for affiliate membership to achieve global alignment in its medical device regulatory system, enhance the competitiveness of the domestic industry, and boost transnational prominence.

The membership "will strengthen the CDSCO's medical device regulatory system, helping meet emerging technical challenges that are increasingly diverse, to ensure protection of public health and safety, and continue to maintain the goal of international recognition for its medical device regulation," thus strengthening the "Brand India" in the global market, MHW said. India's medical device regulations are still being drafted.

Other new affiliates approved by the Management Committee in September included the Botswana Medicines Regulatory Authority; Costa Rica's Ministry of Health; the Dominican Republic's General Directorate of Medicines, Food and Health Products; Oman's Drug Safety Center, Medical Device Control Department; Paraguay's General Directorate of Health Surveillance; Peru's General Directorate of Medicines, Supplies, and Drugs; and Zimbabwe's Medicines Control Authority.

Approximately 300 people attended the IMDRF meeting in Seattle and over 900 participated virtually in the first two days of the public meeting.

In March, the Management Committee added El Salvador's Superintendence of Sanitary Regulation; the Ethiopian Food and Drug Authority; the Jordan Food and Drug Administration; Kenya's Pharmacy and Poisons Board; Mexico's Federal Commission for Protection against Sanitary Risks; Nigeria's National Agency for Food and Drug Administration and Control; and Tanzania's Medicines and Medical Devices Authority.

Chairmanship of the IMDRF will now go to Japan.

FDA's Human Foods Program Reorganization from an International Angle

On October 1, the FDA put in place the single largest reorganization in its modern history. The reorganization, which impacted 8,000 FDA employees, included a new model and name for the agency's food and field operations through the establishment of a unified Human Foods Program (HFP).

This new program was formed by merging all human foods functions, resources, and personnel from the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Food Policy and Response (OFPR), as well as from certain Office of Regulatory Affairs (ORA) functions, personnel, and resources.

The ORA became the Office of Inspections and Investigations (OII), which will continue to focus on three core activities: inspections, investigations, and import operations. The ORA's previous laboratory and regulatory science functions related to medical products and tobacco were placed within the Office of Chief Scientist, while those for human and animal foods were aligned to the HFP. Included in the OII are the FDA's dedicated food and drug foreign inspectorates — those U.S.-based staff who devote their time to inspections around the globe. (Their inspectional work continues to be supplemented by domestic inspectors doing periodic assignments overseas, plus inspectors located in the FDA's handful of foreign-based offices.)

The OII's Office of Import Operations still maintains first-line import compliance officers who, as previously, directly communicate with importers/brokers and coordinate complex decisions with product center and HFP compliance staff. (However, the ORA's domestic compliance functions were merged into the compliance functions of the HFP and the other product centers, to streamline operations and expedite decision-making.)

CFSAN's Office of International Engagement — which, most visibly over the years, has been involved with so many food safety efforts across all the FDA's foreign posts — keeps its name and most of its original remit, but is now organized under the HFP's Office of Policy and International Engagement.

In addition, the HFP's new Office of Integrated Food Safety System Partnerships (OIFSSP) will have some functions for day-to-day information sharing with international food safety regulatory partners, similar to its main domestic engagement with state, local, tribal, and territorial agencies. The OIFSSP was unified from specific functions of CFSAN, OFPR, and the ORA's Office of Partnerships and Operational Policy.

"We have created an enterprise-wide structure that will enhance collaboration between our field investigators and other subject matter experts throughout the agency and modernize and strengthen the entire agency to work more cohesively and collaboratively in accomplishing our

collective public health mission, FDA Commissioner Robert Califf, Deputy Commissioner for Human Foods Jim Jones and Associate Commissioner for Inspections and Investigations Mike Rogers said in a statement released on October 1.

Other changes of interest to international stakeholders:

- An Office of the Chief Medical Officer, led by Dr. Hilary Marston, has been established in the Office of the Commissioner to strengthen central coordination of activities that promote safe, effective, and innovative medical products for patients through agency-wide collaboration. Included in that office is the Office of Public Health Preparedness and Response to support medical countermeasure policy, emergency preparedness work, and medical product shortage coordination across the agency, functions that were previously performed in the Office of the Chief Scientist.
- Select resources previously in the ORA have been realigned to the Office of Global Policy and Strategy for international food trade policy support, i.e., work with the World Trade Organization's Committee on Sanitary and Phytosanitary Measures.

FDA's CVM Announced Funding for Animal and Veterinary Innovation Centers

The FDA's Center for Veterinary Medicine (CVM) announced four recipients of research funding to establish Animal and Veterinary Innovation Centers (AVIC).

The new innovation centers will enable CVM to better support global animal health and veterinary interventions and will concentrate on three areas of research: Highly Pathogenic Avian Influenza (HPAI), intentional genomic alterations (IGAs), and unmet veterinary medical needs in both minor and major species.

The funding recipients include:

- The University of Wisconsin-Madison, for work on HPAI and other emerging zoonotic disease threats that threaten both animals and humans. Specifically, the university will explore the development of genome-edited chickens to reduce susceptibility or provide resistance to HPAI and other avian viruses by genetically targeting pro-viral host factors, antiviral proteins, or viral genes.
- University of California at Davis, for work on IGAs in major livestock species to advance the use of gene editing technologies in food animals, while generating and sharing both phenotypic and bioinformatic data to support a science-based approach to the regulation of IGAs in food animals.
- Kansas State University, for work to develop models which reliably and consistently evaluate the efficacy of analgesics in food animals in support of new drug approvals.

This work supports pain relief in pigs, goats, and cattle for painful diseases or surgical pain.

- University of Arkansas, for work to determine the infectivity and formation of cyst-like *Histomonas meleagridis* (the causative agent of blackhead disease in turkeys) *in vitro* and *in vivo*; identify the cellular pathways mediating encystation in *H. meleagridis*; and screen and assess potent inhibitors against encystation of *H. meleagridis in vitro* and *in vivo*.

The AVIC research work is outlined by the goals in the FDA's Animal and Veterinary Innovation Agenda (AVIA).

FDA Attends XI Conference of the Pan American Network for Drug Regulatory Harmonization

Regulatory authorities from all over the Americas convened in Mexico City August 21-23 for the XI Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH) — which also marked the organization's 25th anniversary.

Organized under the auspices of the World Health Organization's regional entity, the Pan American Health Organization, PANDRH works toward the convergence and strengthening of medical product regulatory systems across the region.

Several FDA officials, including Michelle Rodriguez, director of the FDA's Latin America Office (LAO), Barr Weiner, director of the Office of Global Operations in the Office of Global Policy and Strategy, and LAO staff participated in the conference, where they renewed the agency's commitment to advancing convergence of drug and medical device regulations. In addition to the FDA, national regulatory authorities (NRAs) from 23 other countries attended the meeting.

Several FDA officials were invited to speak during the three-day meeting, including:

- LAO Director Rodriguez, who participated in the meeting's first panel discussion, on the role of the state as a promoter of regional innovation and the production of health technologies through its regulation. The panel discussed the use of the PANDRH Network as a forum for discussing pharmaceutical policies and about linking the network with other international forums. Rodriguez also highlighted the importance of participating in international initiatives and aligning with international standards and the concept of reliance amongst regulators.
- Joseph MacDougall, in the FDA's Office of Criminal Investigations, who was a panelist in a discussion on how to address online sales of medicines and medical devices. Participants concluded that NRAs should contribute to monitoring social networks, online commerce, and the deep/dark web and take the corresponding coordinated actions. The FDA has long warned that many online pharmacies are unsafe and sell dangerous, counterfeit, or expired drugs.
- Tala Fakhouri, in the Center for Drug Evaluation and Research's Office of Medical Policy, who participated in a panel on the impact of artificial intelligence on the regulation of health technologies. Regulators need to reach a consensus on key terms, definitions and concepts, the panel said, as well as work collaboratively and ensure that multidisciplinary teams will have the appropriate knowledge, skills, and resources to understand the risks and benefits of this technology.

The meeting's other panels and breakout sessions included such topics as production of vaccines, clinical trials, regulatory preparedness for pandemics, reliance mechanisms, postmarket surveillance, and professional development of human talent.

Co-hosting the meeting were Mexico's Ministry of Foreign Affairs; Mexico's Federal Commission for the Protection against Sanitary Risks, which regulates medical products; and the Pan American Health Organization.

Several staff from the FDA's Latin America Office, part of the Office of Global Policy and Strategy (OGPS), attended the event: Vesa Vuniqi (International Relations Specialist), Michelle Rodriguez (Director), and Patty Pineda (International Regulatory Analyst). They were joined by Barr Weiner, Director of the OGPS' Office of Global Operations, visiting Mexico from FDA headquarters.

FDA Continues Ongoing Oncology Partnership with Heath Canada

A small FDA delegation led by Dr. Richard Pazdur, director of the FDA's Oncology Center of Excellence (OCE), traveled to Ottawa September 3-6 to advance and support the agency's work on oncology drugs with Health Canada (HC).

For the OCE staff, the trip marked the first time they had engaged in person with HC officials even though the two agencies have been collaborating for nearly 15 years on ways to streamline the approval of oncology drugs, including launching Project Orbis with Australia's Therapeutic Goods Administration in 2019. That program provided a framework for companies to submit their oncology drug applications to all three regulators at the same time and seek concurrent review. As a result, cancer patients have received earlier access to promising therapies in countries that may otherwise experience significant delays in regulatory submissions. Since 2019, additional countries have also joined and become Project Orbis Partners.

In addition to Project Orbis, other topics discussed with HC during the Ottawa visit included multiregional clinical trials, accelerated approval, expanded access clinical trials, the review of oncology marketing applications, premarketing submissions, product development meetings, and opportunities for oncology review staff career development.

During the visit, the FDA's team met with various stakeholders and participated in a roundtable discussion at The Ottawa Hospital Cancer Centre, which is associated with the largest pragmatic cancer clinical trials program in the world.

Joining Dr. Pazdur on the trip were Dr. R. Angelo De Claro, OCE's associate director for global clinical sciences; Dianne Spillman, OCE global and regulatory outreach; and Sema Hashemi, OGPS senior policy advisor.

Photo Album: FDA Around the Globe

August 28: Suzhou Medical Device Conference

With more than 30% of the medical devices imported to the United States coming from China, and many of that country's device manufacturing facilities being located in Jiangsu Province (which includes the city of Suzhou), outreach to both industry and government officials there is an important goal for the FDA's China Office Director Sarah McMullen and device expert Scott Gonzalez.

Both attended the 2nd Suzhou Medical Device Industry Overseas Conference hosted by the Suzhou Association for Medical Device Industry. Gonzalez gave an update on the FDA's quality requirements and McMullen engaged with Jiangsu Provincial officials.

August 29: Embassy New Delhi Food Safety Video

To cap off Health Month at the U.S. Embassy in New Delhi, FDA India Office Director Greg Smith teamed up with Revant Himatsingka, the Indian influencer known as “Food Pharmer,” to debunk food safety myths, including whether it is okay to refrigerate hot food. Spoiler alert: Yes it is. The video was posted on the embassy’s social media platform X.

September 6: Swiss Medical Device Meeting

Thanks to an initiative by U.S. Ambassador to Switzerland Scott Miller, and Switzerland's State Secretary Helene Budliger Artieda, FDA Europe Office Director Katherine Serrano had a productive exchange on medical devices and pharmaceuticals with members of the Swiss Government and Parliament along with industry representatives. While in Switzerland, the FDA also met with regulatory counterparts in the Federal Office of Public Health and Swissmedic.

September 10: Exploring Opportunities in Costa Rica

An FDA delegation led by Associate Commissioner Mark Abdoo met with Costa Rica's Vice President and Minister of Health Dr. Mary Munive Angermüller and staff at the Presidential Palace in San Jose to explore opportunities for advancing regulatory harmonization, convergence, and reliance in Costa Rica, Central America, and the Caribbean. Similar themes were sounded later in the day when the delegation met with Costa Rica's Global Life-Centered Hub. Its 65+ members are drawn from industry, associations, academia, government, and

international organizations with an interest in biomedical research and telemedicine. Collaborative efforts like these are key to advancing and fostering innovation.

From left, International Policy Analyst Vesa Vuniqi from the Latin America Office, Latin America Office Director Michelle Rodriguez, Costa Rica's Vice President and Minister of Health Dr. Mary Munive Angermüller, FDA Associate Commissioner of Global Policy and Strategy Mark Abdoo, and OGPS' Office of Global Operations Director Barr Weiner.

September 11-13: Philippine Delegation Visits White Oak

The FDA's Center for Tobacco Products (CTP) hosted a delegation from the Philippine Food and Drug Administration (FDA-PH) at the White Oak Campus. FDA-PH is standing up their tobacco regulatory framework and has been meeting with regulatory counterparts to better understand how these authorities regulate tobacco. After hearing from CTP Director Brian King, the delegation participated in two days of briefings from CTP experts on the FDA's rulemaking process, compliance and enforcement, health communication and education, pathways to market for tobacco products, tobacco user fees, and more. On the third day of their visit, the delegation met with staff from OGPS and the FDA centers for drugs and food, followed by an FDA history tour.

September 21: FDA Speaks at New Delhi Conference

Roy Stephens, a regulatory specialist with the FDA India Office, spoke at technical sessions on Seafood Quality Assurance & Value at the World Food India conference in New Delhi. The technical sessions were sponsored by India's Marine Products Export Development Authority.


MINISTRY OF
FOOD PROCESSING
INDUSTRIES
GOVERNMENT OF INDIA
WORLD
FOOD INDIA
2024 19th to 22nd September
Processing for Prosperity
BHARAT MANDAPAM, NEW DELHI
INVEST INDIA
@worldfoodindia

September 26: CNO Speaks at Shanghai Medtec Conference

FDA's China Office spoke at Medtec China 2024, a medical device trade show in Shanghai that also featured a forum on such topics as regulation, quality, medical engineering integration, and active devices. As China is the No. 1 U.S. device importer, the FDA has been a longtime Medtec participant.

FDA China Office Director Sarah McMullen is the fourth person from the left.

China Office Director Sarah McMullen participated in a ceremony marking Medtec's 20th anniversary and also gave the opening remarks, while Regulatory Specialist Janete Guardia

spoke on the FDA's quality system regulations during a pre-conference forum. Approximately 400 people attended the Shanghai event.

September 30: ANVISA Visits White Oak for CC

The President-Director of the Brazilian Health Regulatory Authority (ANVISA), Dr. Antonio Barra Torres, and other ANVISA officials met with FDA Commissioner Robert Califf at FDA headquarters in White Oak, Maryland, to discuss areas of common interest. Before the meeting, the two leaders signed a confidentiality commitment that will facilitate cooperation between the two regulatory authorities.


FDA


International Programs
News, Speeches, and
Publications
From OGPS on FDA.gov:
CLICK
HERE
to
VISIT
• OGPS Statements
• OGPS Speeches
• OGPS Blogs
• OGPS Newsletters
• International Partner
News

Dear International Colleague

Recent communications from OGPS to our international stakeholders (list does not include twice-weekly FDA Roundup summaries), July 10 through September 25.

- World Health Assembly 2024: FDA's Takeaways (7/10/24)
- FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants (8/22/2024)
- FDA Releases Informational Video on Importing Seafood (9/25/2024)

Events

November 3	One Health Day
November 20-22	13th Meeting of the WHO's Member State Mechanism on Falsified and Substandard Medical Products, Geneva
December 1	World AIDS Day
December 9-11	National Regulatory Authorities of Regional Reference meeting in Washington

---

Read our Global Blog

Read thought-provoking pieces covering international topics in ***From A Global Perspective***.

Follow OGPS on X

Please follow **@FDA_Global**.

Subscribe to *Global Update*

Don't miss out on future issues of *Global Update* or other international news from OGPS. To sign up, click "Manage Subscriptions" in the below footer then follow the prompts and select the "International Programs" box.

Powered by