U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF POLICY, LEGISLATION, AND INTERNATIONAL AFFAIRS
OFFICE OF GLOBAL POLICY AND STRATEGY

Global Monthly Update

Office of Global Policy and Strategy

March 2020

OGPS Reaches One Year Mark

Later this month is the one-year anniversary of our office. On March 31, 2019, FDA reorganized the Commissioner's Office to increase efficiencies, better meet the demands of our work environment, and enhance collaboration efforts across commodities and policy areas.

This reorganization included the realignment of operations within the Global Regulatory Operations and Policy (OGROP) directorate, then under Acting Deputy Commissioner Mark Abdoo, into new offices. The Office of Regulatory Affairs, then part of OGROP, became a free-standing office and OGROP's Office of International Programs became our Office of Global Policy and Strategy, with the addition of OGROP's trade work and its Immediate Office. Thus enhanced, OGPS, led by Associate Commissioner Abdoo, was placed under the Office of Policy, Planning and Legislative Affairs, which became the Office of Policy, Legislation and International Affairs (OPLIA).

In turn, OGPS itself was structured into three sub-offices, based around our key focus areas: partnerships and multilateral diplomacy (Office of Global Diplomacy and Partnerships (OGDP)), operations and maintenance of our foreign posts and any associated policy work (Office of Global Operations (OGO)), and development of formal inter-governmental arrangements and issues related to the importation of FDA-regulated products (Office of Trade, Mutual Recognition and International Arrangements (OTMRIA)). This new structure is intended to enhance the breadth of OGPS's international policy, diplomacy, and compliance work in the U.S. and within our foreign posts.

The early stages or the reorganization required the usual operational changes: the need to redo our website pages, migrate SharePoint, and establish new SF50s among other things. In addition, steps were taken to help promote our new OGPS brand including the establishment of the new @FDA_Global Twitter handle and this new internal newsletter.

Now, Associate Commissioner Abdoo is ready for the office to embark on more ambitious work and will soon unveil a 5-year strategic plan for the office that will allow us to leverage our resources and strengthen our programs to achieve our mission.

Although the initial drafting of the plan fell to the Office of Planning and Evaluation, led by Kate Hughes, and the contracting firm Booz Allen Hamilton Inc., nearly everyone in the office had the chance to provide feedback at various brainstorming sessions. Mr. Abdoo has indicated that the plan is intended to be a living document, to be updated yearly.

OTMRIA Represents the FDA at the WTO's TBT Committee Meeting

Regulatory cooperation within the medical devices sector was one of the topics at the World Trade Organization's Technical Barriers to Trade (TBT) Committee meeting February 25-27 in Geneva.

The WTO's TBT Agreement was established to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, the WTO's TBT Agreement recognizes WTO member's right to implement measures to achieve legitimate policy objectives such as the protection of human health and safety or protection of the environment. The TBT Agreement established the TBT Committee, and WTO Members designate their own representatives to participate in the discussion of specific trade concerns, including laws, regulations and procedures which may affect trade.

The TBT Committee typically holds three formal meetings per year, which are sometimes preceded by workshops or thematic sessions followed by a regular meeting. "It is a highly-effective forum in which delegations from different WTO Member states can meet and openly discuss regulatory issues that may affect trade," said OTMRIA's Senior Advisor, Joseph Rieras. who attended the February meeting along with Jade Pham, Associate Director of Global Regulatory Affairs in the Inner Office.

Regulatory cooperation within the medical device sector was one of the examples discussed during the TBT's thematic session on good regulatory practice. One of the presenters was Melissa Torres, Associate Director for International Affairs in FDA's Center for Devices and Radiological Health, who offered two examples of cooperation: the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world that works towards medical device regulatory harmonization and the Medical Device Single Audit Program (MDSAP), which allows an MDSAP recognized third party auditor to conduct a single regulatory audit of a medical device manufacturer.

This single audit will then satisfy the relevant requirements of the five regulatory authorities participating in the program -- the FDA; Health Canada; Therapeutic Goods Administration of Australia; Japan's Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency; and Brazil's Agência Nacional de Vigilância Sanitária.

A separate TBT thematic session was devoted to case studies of practical examples of how members arrive at the acceptance of conformity assessment results. Torres presented at that as well, providing more details on the MDSAP's conformity assessment program.

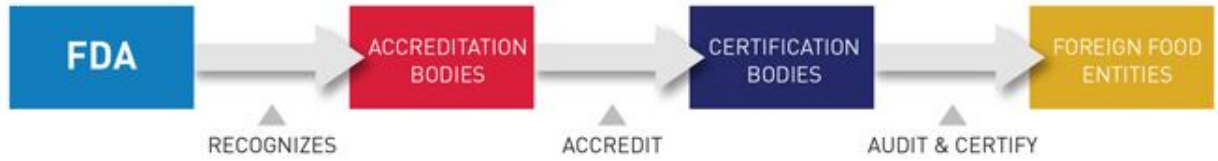
A total of 64 specific trade concerns, including 12 new topics, were taken up during the regular session of the TBT Committee that followed the thematic meetings.

Costco Becomes First VQIP Participant

The FDA has approved Costco Wholesale Corporation (Costco) as the first participant in the FDA's Voluntary Qualified Importer Program (VQIP) under the FDA Food Safety Modernization Act (FSMA). Part of our Imported Food Strategy, this voluntary, fee-based program provides expedited review and import entry of foods into the United States.

In becoming the first VQIP participant, Costco successfully demonstrated its ability to manage the safety and security of its supply chain. Having VQIP status will now allow Costco to utilize VQIP to import certain food products into the U.S. faster – avoiding unexpected delays at import entry.

Food importers who meet certain eligibility requirements may qualify to participate in the program. Eligibility criterion can be found in section III §C of the *Guidance for Industry*. The VQIP application portal is now open through May 31, 2020. VQIP supports the FDA *Strategy for the Safety of Imported Food* through the use of certified suppliers, which helps ensure that imported food meets U.S. food safety requirements.



Courtesy of FDA.

Abdoo/Valdez Discuss New OGPS- Sponsored Report at NASEM Dissemination Meeting

OGPS Associate Commissioner Mark Abdoo kicked off the dissemination meeting for the National Academies of Sciences, Engineering and Medicine's (NASEM) new report, *Stronger Food and Drug Regulatory Systems Abroad,* on March 11.

Noting that the meeting was occurring against the backdrop of the global Coronavirus outbreak “our efforts serve as a timely reminder of the need for global collaboration, stronger regulatory systems throughout the world, and greater support for public health initiatives,” Abdoo said.

FDA commissioned the NASEM report in 2018 to gauge how much progress had been made in regulatory system strengthening around the world since the release of NASEM’s earlier FDA-commissioned study, *Ensuring Safe and Medical Products Through Stronger Regulatory Systems Abroad*, released in 2012.

The dissemination meeting was held at NASEM’s ornate Washington-based headquarters near the State Department, but given the outbreak, most participants, including members of the NASEM expert panel of food and drug regulatory experts, attended the event via webcast.

Since the release of the 2012 report “our collective efforts have raised the global profile of the need to strengthen regulatory systems,” Mr. Abdoo said. “It is our hope that the current report will have even more impact.”

The latest report highlights some of FDA’s efforts in recent years to strengthen regulatory systems abroad including supporting global efforts to combat and report falsified and

substandard medicines; confronting the global burden of foodborne illnesses; and working with our global partners to improve and harmonize standards for medical products. Former OGDP Associate Commissioner Mary Lou Valdez followed up Abdoo's remarks with further detail on FDA's regulatory strengthening efforts and provided recommendations on how to best use the new report. Valdez is now Deputy Director of the Pan American Health Organization. Before she left FDA, Valdez reflected on the report's findings in one of OGPS's occasional thought pieces, From a *Global Perspective*.

Other topics discussed during the dissemination meeting included benchmarking regulatory success, facilitating donor and public involvement, and achieving political will and regulatory collaboration.

The meeting was recorded and will soon be available for viewing on NASEM's dedicated webpage for the event.

Transitions

Farewell to **Julio Salazar**, who returned to ORA, stationed in Texas, effective 3/15/2020.
Farewell to **Jay Jariwala**, who returned to CDER, effective 3/1/2020.
Farewell to **Glenn Quintanilla**, who returned to ORA, effective 3/15/2020.

Michele Berger is the new Senior Advisor in the Immediate Office. Michele will act as a bridge between OGPS, the Office of Enterprise Management Strategies (OEMS) and the Immediate Office of the Office of Policy, Legislation and International Affairs (OPLIA), liaising with OEMS and OPLIA on significant issues such as human capital management and acquisitions.

Michele brings a wealth of experience to OGPS. She previously acted as a Senior Advisor to the Deputy Commissioner for Global Regulatory Operations and Policy and has held senior positions in the Office of the Commissioner and the Office of Regulatory Affairs.

Amelia Tetterton is a Consumer Safety Officer on a 120-day detail to the Latin America Office. She comes from ORA's Office of Enforcement and Import Operations, Import Program Development Branch, where she focuses on constructing and implementing the import operations for a range of projects, with an emphasis on Food Safety Modernization Act (FSMA) initiatives. Amelia serves as a subject matter expert for FDA's Voluntary Qualified Importer Program (VQIP), with years of experience implementing this novel Agency program. She graduated from California State University, Los Angeles, with a Bachelor of Science Degree in Nutrition Sciences and has been with FDA for over 11 years.

Combined Efforts Tackle Impurities

FDA participated in an international workshop sponsored by the European Medicines Agency on Feb. 27-28 to review experience and knowledge about the toxic contamination of various medicines with nitrosamines. Experts from other fields, including food safety, environmental science and epidemiology, contributed to the discussion, addressing a wide range of topics including root causes, how to avoid contamination in product manufacturing, risks of exposure and other regulatory considerations.

(L-R) Brian Hasselbalch, Office of Product Quality, CDER; Efe Eworuke, Office of Safety and Epidemiology, CDER; Aisar Atrakchi, Officer of New Drugs, Sandy Kweder, Europe Office; CDER; David Keire, Office of Product Quality, CDER

Partnering with Indian Government and Industry on Seafood Safety

The FDA India Office (INO) continues its efforts to ensure the safety of U.S. seafood products imported from India. INO International Relations Specialist Chris Priddy, JD, and Food Safety Coordinator Dr. Pankaja Panda attended the 22nd International Seafood Show in Kochi, Kerala on Feb. 7-8. At the invitation of India's Marine Products Export Development Authority (MPEDA), Chris provided an overview of FDA's Seafood Hazard Analysis Critical Control Point (HACCP) and Food Safety Modernization Act (FSMA) regulatory requirements to over 150 seafood industry representatives, government officials, and academics attending the conference. Over the two-day series of meetings, Chris and Pankaja also engaged with conference participants on such topics as seafood supply chain traceability, sustainability and antibiotic usage.

Upcoming Activities

3/31 OGPS turns one-year old.

4/1 Europe Office staff will host a webinar on drug shortages

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