

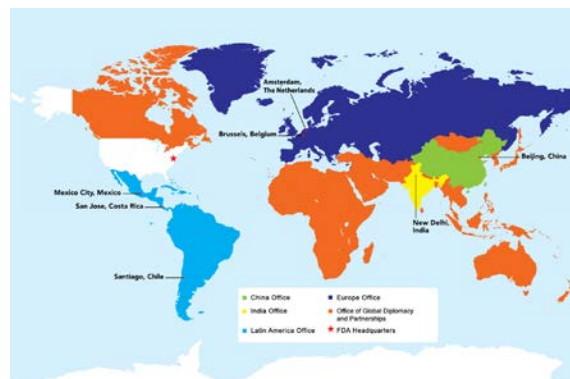


U.S. FOOD & DRUG ADMINISTRATION

Global Monthly Update

Office of Global Policy and Strategy

Summer 2020



Editor's Note:

We have combined June and July content for a special Summer 2020 issue. Our following Monthly Update will be for August.

FDA and the EU Strengthen Partnership at Bilateral



The European Union (EU) has long been one of the U.S. Food and Drug Administration's most important collaborators in tackling public health challenges and working with our counterparts across the Atlantic is a top priority for the agency. To advance this partnership, FDA hosted a [bilateral meeting](#) with the European Commission (EC) and the European Medicines Agency (EMA), on June 18-19, 2020, to discuss regulatory cooperation in medical products areas, including issues related to COVID-19. It was originally planned to take place at the White Oak Campus but had to occur virtually due to pandemic-related travel restrictions.

The bilateral rotates between the U.S. and Europe every two years and aims to strengthen overall collaborations regarding medical products by sharing priorities,

reviewing progress of ongoing activities, and identifying additional areas for regulatory cooperation.

“The robust relationship with our European colleagues is vital during global public health crises,” said FDA Commissioner Dr. Stephen Hahn, who joined EMA’s Executive Director, Professor Guido Rasi, and Dr. Andrzej Rys, director of Health Systems, Medical Products and Innovation, at the European Commission, in kicking off the meeting. “Now, our many years of working together have prepared us to jointly confront the COVID-19 pandemic. We will continue to partner closely with our European colleagues during this pandemic and on any future situations where collaboration is essential,” Dr. Hahn said.

FDA’s work with its European regulatory counterparts, built over more than a decade, has paved the way for a multitude of active collaborations on many scientific and regulatory fronts in addressing the COVID-19 response.



Signing confidentiality commitments in 2003 allowed the EMA and the FDA to collaborate and share data and enabled the creation of several standing technical work groups called clusters that focus on a specific topic or therapeutic area. These groups cover a wide range of topics, from oncology to patient engagement and vaccines, and they now often include other regulatory authorities (e.g., Japan, Canada, Australia). Since the start of the pandemic, many of these groups have shifted their work priorities to focus on COVID-19.

In addition, FDA and the EMA, along with the European Commission (EC), have been actively engaged in supporting information exchange and regulatory alignment through large COVID-19 virtual workshops held under the auspices of the International Coalition of Medicines Regulatory Agencies (ICMRA). ICMRA includes 28 regulatory authorities globally and is currently chaired by the EMA. For example, in March, as vaccine candidates began to be identified, the FDA and the EMA jointly chaired the first [global regulators meeting](#) to discuss regulatory strategies to facilitate the development of SARS-CoV-2 vaccines. Subsequent ICMRA workshops that are focused on COVID-19 therapeutic development, observational studies, and real-world data as well as policy approaches are helping to support mutual awareness and consideration of potential guidance alignment.

“As two prominent and advanced regulatory systems, FDA and EU have a unique opportunity to not only work toward policy convergence and regulatory harmonization but also to provide global leadership by sharing our expertise with fellow regulators and promoting global collaboration,” said Anna Abram, FDA Deputy Commissioner for Policy, Legislation, and International Affairs.

Besides ongoing efforts related to therapeutics and vaccines for COVID-19, the the June bilateral meeting also addressed mutual reliance agreements, medical devices, (which recently returned to the EC's health portfolio) and the use of diverse digital sources to collect real-world data.

This year's meeting was organized by the OGPS Europe Office, which serves as the lead for the FDA's on-site presence in Europe with offices in Brussels and White Oak and an EO official embedded at the EMA's office in Amsterdam. The EO covers the European Union and individual countries that are not EU members, such as Switzerland and Norway and facilitates progress on many joint European-U.S. projects spanning the full spectrum of FDA-regulated products.

To inform the public about this year's bilateral meeting, the EO worked with the OGPS Communications Team on an international [press release](#) and real-time Tweets featuring comments by Dr. Hahn and Deputy Commissioner Abram. In addition, Deputy Commissioner Abram penned an [FDA Voices](#) article with OGPS Associate Commissioner Mark Abdo, published June 25, that highlighted FDA's collaborative work with the European Union on COVID-19 related issues.

FDA Commissioner Discusses Partnerships During Brussels Forum



On June 24, FDA Commissioner Stephen Hahn, M.D., participated in a virtual conversation with Axios Health Care Editor Sam Baker during The German Marshall Fund's [Brussels Forum](#), exploring the agency's work with the European Union (EU), and the European Medicines Agency (EMA) in meeting public health needs throughout the COVID-19 pandemic.

The Brussels Forum is a high-level meeting of influential North American and European political, corporate, and intellectual leaders put on annually by The German Marshall Fund of the United States -- a non-partisan American public policy and grant-making institution dedicated to promoting better understanding and cooperation between North America and Europe on transatlantic and global issues.

Papaya Industry Letter Addresses Prevention



The OGPS Latin America Office (LAO) continues to play a significant role in support of the cooperative effort by FDA, Mexican government and papaya industry in seeking to prevent recurring outbreaks of Salmonella associated with imported papayas. The LAO serves as the lead for FDA's on-site presence in the 34 countries and territories that span Latin America—from South and Central America, to the Caribbean and Mexico—and is poised to monitor and report on the safety of FDA-regulated goods that are produced in the Latin American region for export to the United States.

Since 2011, eight outbreaks, causing more than 100 hospitalizations and two deaths in the United States, have been tied to the consumption of imported fresh papayas. In a [letter](#) to all sectors of the papaya industry late last year, FDA issued a “Call to Action” to take four discrete steps, which included encouraging industry to “examine the use and monitoring of water used to grow, spray (pesticides, fungicides), move, rinse or wax crops to identify and minimize risks from potential hazards.”

Mexico is the largest supplier of papayas to the U.S., and with the 2020 growing season upon us, FDA issued a second "Call to Action" [letter](#) in June urging industry to follow the latest best practices and proactively work to keep papayas free of contamination. Recommendations included “adopting traceability best practices and technologies to help ensure quick and easy access to key data elements from farm to fork.”

Requirements under the [FDA Food Safety Modernization Act](#) (FSMA) of 2011 focus on preventing foodborne illnesses and minimizing the presence of potentially dangerous contamination that could cause serious adverse health consequences. LAO staff have worked to advance the implementation of FSMA's Produce Safety Rule, which requires that farms wanting to sell produce in the U.S., have at least one supervisor or responsible party who has successfully completed FSMA food safety training.

Since 2017, the LAO has collaborated with industry counterparts to conduct trainings that aim to help growers meet the minimum standards for safe growing, harvesting, packing, and holding of fresh produce.

Hughes Selected to Lead the Office of Diplomacy and Partnerships



Kathryn (Kate) Hughes, Ph.D., has been selected for a 120-day detail as director of the Office of Global Diplomacy and Partnerships (OGDP) in the Office of Global Policy and Strategy (OGPS). Kate had been serving as a supervisory international policy analyst for the OGDP Planning and Evaluation Team. She is an analytical chemist by training, having received her doctorate degree in analytical chemistry from the University of Michigan-Ann Arbor in 2005 and her bachelor's degree in chemistry from Carleton College in Northfield, Minn.

Following graduate school, Kate accepted a postdoctoral fellowship at the American Chemical Society's Office of Legislative and Government Affairs, and later moved to the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM). There she spent nine years managing numerous consensus studies and workshops covering a range of topics at the intersection of science, technology, and domestic and international policy. These included developing materials to support chemical safety and security in laboratories around the world; assessing approaches to monitor for and measure biological aerosols, analysis of science and technology advancements relevant to the Chemical Weapons and Biological and Toxin Weapons Conventions; and supporting the U.S. National Committee to the International Union of Pure and Applied Chemistry.

In 2016, Kate joined the FDA as a staff fellow in the Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, later becoming a chemist and lead for the Science Informatics Team in that Office. Kate transitioned to OGPS in July of 2019 on a detail as team lead for PET and became the permanent team lead in April of this year.

Transitions

Farewell



Tania Teixeira reunites with her European Medicines Agency office effective July 15. She was embedded with the Europe Office, based at White Oak, working on various projects related to drugs. Tania started her career in the pharmaceutical industry and joined EMA in 2004. She held positions as a Head of Service for Referrals, dealing with emerging concerns which require a harmonized position across the European Union.

Tania holds a Doctorate in Pharmaceutical Sciences, and a post-graduate degree in Regulation and Evaluation of Medicines and Health Products from the Faculty of Pharmacy, University of Lisbon. She will be replaced by Anabela Marcal.

Welcome



Kristan Callahan moves to the Office of Trade, Mutual Recognition, and International Arrangements as a public health advisor. She previously served as an international relations specialist in the India Office, where she focused on matters related to medical devices and bioresearch monitoring issues. Kristan earned her juris doctorate degree from American University Washington College of Law, and a Bachelor of Arts degree from New York University, Gallatin School of Individualized Studies.



Chris Middendorf has been selected as an international relations specialist for pharmaceuticals in the India Office after completing a detail there. Previously he was a drug specialist in FDA's China Office (CNO). Chris joined FDA in 2000 through the Presidential Management Intern program (PMI now PMF) as a program analyst in the Office of the Commissioner. Chris has also worked at the Center for Biologics Evaluation and Research (CBER) as a consumer safety officer where he was promoted to branch chief in CBER's Office of Consumer Affairs.

In 2008, Chris became a public affairs specialist at the Center for Devices and Radiological Health before accepting a position with the CNO as a consumer safety officer. He has an MS in Animal Science from Auburn University and a BS in Biology from the University of Cincinnati.



Dr. Jacquin (Jackie) Jones joins the India Office as the international relations specialist for BIMO/Medical Devices. She began working at the Center for Drug Evaluation and Research (CDER) as a regulatory health project manager in the Office of Hematology and Oncology Products in 2014. Previously she worked on policy and standards development projects as a policy lead and project manager in the Office of Policy of Pharmaceutical Quality and as a consumer safety officer in FDA's Compounding Program in CDER's Office of Compliance.

Dr. Jones holds a Doctor of Health Sciences degree with a Global Health concentration from Nova Southeastern University, a Master of Science in Nursing Informatics from the University of Maryland, Baltimore, and a Bachelor of Science in Nursing from Liberty University, Lynchburg, Va.



Jason Cornell will transfer from the Latin America Office, Embassy San José, Costa Rica to Embassy Santiago in Chile. He is currently an international relations specialist, focusing on matters related to whole genome sequencing, human and animal foods, imports/exports, outbreaks, and trade issues. Jason will continue his work in these policy areas while also adding responsibilities related to supporting FDA's policy and trade interests.

Prior to joining OGPS, Jason was a supervisory consumer safety officer, managing Import Operations for the Division of West Coast Imports and Division of Northern Border Imports at seven ports of entry and one International Mail facility from Portland, OR. Before starting his career at FDA, he worked as an engineering supervisor at United Parcel Service where he worked in project management and facility management.

Jason earned his master's degree in human geography from Western Washington University (WWU), focusing his research on institutional and educational bias in multidisciplinary science projects. He was also a researcher at the WWU's Resiliency Institute specializing in emergency food distribution in Washington State as well as collaborating to design and help teach the course, The Art and Science of Cheese Making.

No, It's Not Midnight Madness. It's Drug Quality

Two offices from the Center for Drug Evaluation and Research (CDER) are partnering with our India Office (INO) and our China Office (CNO) in hosting a first-of-its-kind, nighttime, [interactive webinar](#) that falls within the working day for international stakeholders. That means midnight for those on EDT. The topic of the July 23 webinar is pharmaceutical quality, addressed in three consecutive sessions: Pharmaceutical Manufacturing Assessment; Expectations for Pharmaceutical Quality; and the Present and Future of Pharmaceutical Quality. The webinar is intended for foreign manufacturing professionals (drug product and API), foreign regulators, and/or regulatory affairs professionals (innovator and generic or biosimilar) and to help them navigate the wealth of information offered by FDA and to aid in understanding human drug product regulation. The two CDER co-sponsors are the Small Business and Industry Assistance office and the Office of Pharmaceutical Quality.



CDER's Acting Center Director [Patrizia Cavazzoni, M.D.](#), along with CDER OPQ Director [Michael Kopcha, PhD, RPh](#), will provide the keynote addresses. Other presenters include Lane Christensen, an international program and policy analyst in CNO,

and Chris Middendorf, an international relations specialist for pharmaceuticals in India. Find your broadcast time with [The World Clock](#).

CVM Moves Away from Paper Applications



FDA's Center for Veterinary Medicine (CVM) launched a new [online system](#) enabling manufacturers of animal food, drug and devices to apply for export certificates electronically for the first time. Previously, manufacturers of CVM-regulated products were required to submit a paper application via mail. The new portal and electronic process will reduce the amount of time it takes for a manufacturer to apply for, track and receive export certificates.

FDA anticipates that the CVM Export Certification Application and Tracking System (CVM eCATS) will help facilitate exports by:

- 1) assisting industry in fulfilling importing country requirements for certification by CVM of CVM-regulated animal products and
- 2) providing a tool for foreign governments to verify the authenticity of export certificates provided to them by industry.

CVM will continue to accept hard copy applications, however, strongly encourages industry to use the new system to apply for export certificates for faster processing and issuance of these documents.

FDA Leadership Provide Insight on Foreign Inspections



Associate Commissioner Mark Abdoo was one of three FDA officials who testified during the U.S. Senate Finance Committee hearing on [COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process](#) on June 2. Other FDA participants at the hearing were [Judith McMeekin](#), PharmD, associate commissioner for Regulatory Affairs, Office of Regulatory Affairs, and [Douglas Throckmorton](#), M.D., deputy director for Regulatory Programs, Center for Drug Evaluation and Research.

Also testifying was [Mary Denigan-Macauley](#), director of Health Care at the United States Government Accountability Office. Mr. Abdoo and Dr. McMeekin appeared in person while Dr. Throckmorton and Dr. Denigan-Macauley appeared virtually, as did many of the Senators. Topics discussed included foreign inspections and surveillance during the COVID-19 pandemic, as well as the globalization of pharmaceutical manufacturing.

Change to Export Certificates Leverages Technology



FDA began issuing the [updated certificates](#) on June 29, adding a unique QR code to improve the functionality and appearance of two types of export certificates issued for human food products exported from the United States. The code has been added to the "Certificate to a Foreign Government" and "Certificate of Exportability." The code will allow easier verification of the authenticity of these certificates for security and ease of use.

Using QR codes will expedite verification compared to the previous system, which required a user to create an account, contact FDA to activate the account, and log in to verify the authenticity of certificates. Anyone who receives a certificate from a U.S. exporter can scan the QR code and see a copy of the certificate as issued by the FDA through the new system. FDA will honor and accept any certificates issued with the previous format, through their expiration dates.

OGPS Experts Take a Close Look at the USMCA Trade Pact



Yes, FDA is a public health agency but that doesn't preclude the importance of trade agreements for FDA and for public health. We recently explored why the United States – Mexico-Canada Agreement (USMCA), is important to FDA in our blog, [From A Global Perspective](#). The blog, which was issued on July 1, the day the USMCA went into force, was co-authored by Anne Kirchner and Joseph Rieras, both senior advisors in the Office of Trade, Mutual Recognition, and International Arrangements.

As they explain, the USMCA strengthens obligations for sanitary and phytosanitary measures for food and feed, including protection of FDA's right to conduct overseas inspections. It also includes sector-specific chapters on medical devices, pharmaceuticals and cosmetics; technical barriers to trade (technical regulations essential to assuring that products meet FDA requirements such as labeling and packaging, transparency, standards-related measures, and conformity assessment), protection of intellectual property and good regulatory practices.

Do you have a Global Perspective? FDA staff are encouraged to contribute ideas or blogs. Send your ideas to Karen.Riley@fda.hhs.gov

Upcoming Activities

July 23 [Pharmaceutical Quality for Global Stakeholders](#)

July 28 [World Hepatitis Day](#)

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