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## June 2022

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## Global News

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### FDA and OECD Tackle Illicit Products with a Whole-of-Governments Approach

The FDA and the [Organisation of Economic Co-Operation and Development](#) (OECD) have launched an initiative to encourage the wide-scale adoption of a “whole-of-governments” approach to combating illicit medical products.

The initiative began when Kerry Mannion of the FDA’s Office of Criminal Investigations (OCI) reached out to the FDA’s Europe Office (EO) with an idea for promoting the whole-of-governments concept across the globe. Mannion, who sits on the OECD Task Force on Countering Illicit Trade, suggested that the EO and OECD jointly host a series of meetings to raise awareness of the concept.

The first meeting, held virtually on May 24, focused on a successful whole-of-governments case study that OCI worked on — Operation Lascar — to not only illustrate the concept but also suggest what is possible. The event drew government counterparts from 17 nations.

“With increasingly sophisticated criminal networks, the threat posed by the illicit pharmaceutical trade has become too complex to be adequately addressed by a singular stakeholder. This growing threat now warrants a whole-of-governments approach, utilizing coordinated efforts by multiple countries and their arsenal of authorities that crosscut multiple sectors of government,” said Ritu Nalubola, EO director, and Piotr Stryszowski, senior project manager of the OECD task force, in a letter of invitation to the May 24 event.

Operation Lascar, with the United Kingdom, was the FDA’s first bilateral initiative focused on the [movement of illicit FDA-regulated products](#). It started in 2017 in response to illicit FDA-regulated products being shipped to the U.S. from and through the U.K.



*Images from Operation Lascar. Top row: example of transshipped product in the U.K. made ready to ship to the U.S. Bottom row: (left) how one such player advertised themselves; (right) what they really looked like.*

At the time, many of the illicit medications (including counterfeit products), were intended to treat serious and life-threatening conditions, such as various forms of cancer, and required strict temperature controls to be administered safely. Further, the underlying distribution model had changed from direct-to-consumer sales to one which sought to penetrate the FDA-regulated pharmaceutical supply chain with targeted sales to physicians. In turn, these products were being administered to unsuspecting patients who were unaware these products were being obtained from unauthorized foreign sources and being shipped and stored outside of approved conditions.

Since 2017, the FDA has partnered with the U.K. to conduct five international enforcement operations, three of which occurred in the U.K, with various U.K. and U.S. counterpart agencies. Although participation has varied, the latest initiative involved the FDA's Office of Criminal Investigations (OCI) within the Office of Regulatory Affairs partnered with the U.S. Customs and Border Protection, the U.S. Patent and Trademark Office, the U.S. Embassy in London, and the United Kingdom's Revenue and Customs, Border Force, and Intellectual Property Office to execute Operation Lascar V.



*Logos for current Lascar participants. (Images courtesy each organization.)*

As of April 2022, the bilateral enforcement teams have identified more than 3,000 violative shipments of illicit medicines intended for the U.S. Operation Lascar has been responsible for the initiation of more than 80 new OCI criminal investigations, and numerous shipments have also been identified linked to ongoing OCI investigations including several associated with Interpol Notice or fugitive investigations.

The initiative produced some nontangible benefits as well. The FDA decided to post a special agent in the U.S. Embassy in London, representatives from the U.K.'s Border Force and Her Majesty's Revenue and Customs attended OCI's Special Agent Training Program, and OCI has participated in a range of bilateral and multilateral initiatives.

As Operation Lascar evolved, U.S. and U.K. partners identified a variety of regulatory gaps that currently make a whole-of-governments approach more challenging. “Criminals are smart and know how to abuse the government’s gaps. As a result, the FDA is working with our U.S. and U.K. counterparts to establish a bilateral work group focused on this issue with the intent of developing viable and effective courses of action to combat this form of illicit trade,” said Mannion, who is Special Agent in Charge of OCI’s Headquarters Operations.



For example, tax authorities may not be able to easily exchange information with customs or the police and some nations take different approaches to illicit goods that may make it more difficult to identify the criminal operators. Potential gaps in the legal framework and how it applies to, or is effectively enforced with respect to, shipments of illicit products destined for third countries also remains a challenge.

Identifying such regulatory and legal weaknesses will be one of the topics at the second panel discussion on July 6 with governmental counterparts. Also, on the agenda will be how to broaden the coalition, and potential prioritization and technological challenges, complementary to work in this area by multilateral forums, such as the OECD and the World Health Organization.

The two nonpublic meetings are intended to lay the groundwork for a two-day symposium on the whole-of-governments approach to illicit products, scheduled for September 15-16 in Paris. Representatives from the public and private sectors and multinational organizations will be invited to speak to discuss current trends, opportunities to identify and leverage best practices and capabilities, free trade zones, potential regulatory enhancements, and the need for model legislation to address illicit exported and transshipped products.

The OECD, an intergovernmental organization with 38 member countries, was founded in 1961 to stimulate economic progress and world trade. The OECD task force has been studying illicit trade of all product types for over 15 years. While quantification is difficult, the task force estimates that counterfeit products alone account for about \$460 billion in global trade every year.

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## CNO Adds Clarity to Food Facility Registration Process

When walking through a grocery store, have you ever stopped to think about the myriad foodstuffs on sale there, produced by thousands of companies located all over the world, and how challenging it is for the FDA to keep track of all those companies and their production facilities? It's mind-boggling. Like many offices within the FDA, the agency's China Office (CNO) must deal with this formidable task on a routine basis for the many foods imported from China to the U.S.



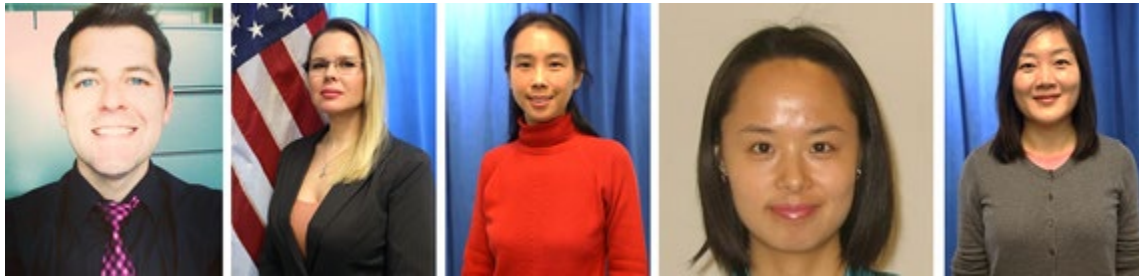
Just like domestic U.S. companies, food facilities around the world that manufacture, pack, or hold food intended for consumption within the U.S. are required to register their location(s), product type(s), and contact information with the FDA. This process, known as Food Facility Registration (FFR), is a statutory requirement under the FDA Food Safety and Modernization Act (FSMA).

Every two years, a food facility must renew their FFR by verifying information and providing updates as needed. In China alone, renewals can amount to over 10,000 companies.

The FDA uses renewals to determine which companies are actively in business, what their product line is, and where they are located. This information helps the FDA plan inspections more efficiently and conduct traceback efforts in the event of a product recall or disease outbreak.

To help companies submit their FFR's to the agency, the FDA maintains an online portal — [FDA Industry Systems](#). Although this is a free, no-cost process, it can be challenging for small, overseas business owners who are interfacing with a data system in a foreign language. As a result, there have been a number of erroneous registrations.

Recognizing this problem, the CNO staff coordinated the translation of the agency's multiple guidance/help documents on the FFR into simplified Chinese. The documents touch on the FSMA Biennial FFR renewal process and the agency's requirements for a unique facility identifier (DUNS number).



The project was the joint effort of Clinton Priestley, CNO's international relations specialist for foods; Rachel Gomez, a former CNO consumer safety officer who is now acting FFR program manager with CFSAN's Office of Compliance; and three members of the CNO's Locally Employed Staff (LES), Medical Research Scientist Lixia Wang, Interpreter Zimei (Mandy) Fu, and Program Coordinator Nannan Zhangee. The LES are hired by the local U.S. Embassy and assigned to the FDA to work in support of agency activities. The translations were posted on the FDA's website in May.

Food Facility User Guides can be accessed from the FDA's webpage for [Online Registration of Food Facilities](#). Specific guides with the new Chinese translations include the following (look for the green button on each webpage):

- [Step-by-Step Instructions](#)
- [Biennial Registration Renewal](#)
- [Update Registration](#)
- [Additional Capabilities](#)

- [Retrieve Registration PIN](#)
- [FDA Industry Systems: Create New Account Quick Start Guide](#)

The CNO team also provided the simplified Chinese translation of Dun & Bradstreet's related guide:

- [Import Safety Lookup Portal D-U-N-S® \(DUNS\) Number Quick User Guide](#) (translation begins on page 22 of the PDF)
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## **Headway Made toward Clinical Trial Inclusion of Pregnant/Breastfeeding Individuals**

Several years ago, when the Europe Office's Lt. Cmdr. Shannon Thor, Pharm.D., and Sandra Kweder, M.D., began working with a broader team to promote the inclusion of pregnant/breastfeeding individuals in clinical trials, developing a standard international guideline on this topic was a long-term goal.

Now the team — which includes experts from CDER and CBER and officials from the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) — has reached a significant milestone toward achieving that goal. In May, the ICH Assembly (short for the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) agreed to take up the development of the guideline: Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials.

The ICH is an international nonprofit organization for bringing together regulatory authorities with the pharmaceutical industry to discuss scientific and technical aspects of drug development and registration. Development of an ICH guideline on this topic is important because the organization has significant influence and global reach with many regulatory authorities and regulated industry. Adopting an ICH guideline can lead to systemic change in research practices and regulatory standards regarding these populations.





*Inclusion of pregnant and breastfeeding individuals in clinical trials ultimately lead to improved prescribing information, which these populations and their health care providers use when making health care decisions.*

“I have no doubt that this milestone is the result of our strategizing together with EMA and MHRA and raising awareness and action across regions through workshops, publications, blogs, conference presentations, and standing up a technical working group,” Lt. Cmdr. Thor commented.

The FDA’s previous activities supporting the inclusion of pregnant/breastfeeding individuals in clinical trials were highlighted in a July 2021 [FDA Voices article](#).

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## **FDA, German Regulators Hold Fruitful Talks**

Officials from the FDA met in Berlin on May 9 with the German Federal Institute for Risk Assessment — Bundesinstitut für Risikobewertung or BfR — to officially launch the implementation of the Memorandum of Understanding (MOU) signed by the two agencies last year. The [MOU to Share Information and Facilitate Collaborative Research Projects](#) was signed in late August 2021. Since that signing, staff from the FDA’s Europe Office (EO), the Center for Food Safety and Applied Nutrition (CFSAN), and the Office of Food Policy and Response have been working with the BfR to identify common areas of interest and determine the scope of specific workstreams.



*FDA officials recently held productive talks in Berlin with representatives from counterpart agency the German Federal Institute for Risk Assessment. The meeting was held to launch the MOU signed by the two agencies last year.*

Considered to be the FDA's "sister agency" in Germany, the BfR is a scientifically independent institution within the Federal Ministry of Food and Agriculture in Germany. The BfR advises both the German federal government and states on questions of food, chemicals, and product safety, while conducting independent research on topics closely linked to the agency's assessment tasks.

Most of the meeting was devoted to two topics: foodborne outbreaks – including the use and enhancement of BfR's open-source visual traceback tool Food Chain Lab and potential ways to share data and algorithms; and whole genome sequencing technology, including the U.S.-based [GenomeTrakr](#), the first distributed global network of public health and university laboratories to utilize whole genome sequencing for pathogen identification. In addition, the two agencies discussed the BfR's upcoming public meetings on tattoo inks and new risk assessment methodologies.

As a result of the meeting, the FDA and BfR have agreed to set up joint technical working groups to continue exploring how they might work together on traceability and whole genome sequencing. The FDA delegation, led by Steve Musser, CFSAN's deputy director for scientific operations, and Ritu Nalubola, director of the Europe Office, also included technical experts from the EO, CFSAN, and the Office of Food Policy and Response.

## Briefs

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### **Brazilian Health Regulatory Agency Meets with FDA to Discuss Medical Product Issues**



On May 18, the FDA Principal Deputy Commissioner Janet Woodcock, M.D., and other FDA officials met with a delegation from the [Brazilian Health Regulatory Agency](#) (ANVISA) led by Director-President Antonio Barra, M.D., to discuss issues of mutual interest related to drugs, biologics, and medical devices.

[Agência Nacional de Vigilância Sanitária](#) (Anvisa) is the most mature regulatory system in Latin America. It issues market authorizations for medical devices and

pharmaceuticals, exercises post-marketing surveillance to ensure manufacturers comply with Brazilian requirements, and is an active participant in international regulatory convergence initiatives.

The FDA maintains a close collaborative relationship with ANVISA, which was only heightened over the past two years during the coronavirus pandemic, Dr. Woodcock told the Brazilian delegation.

The FDA and ANVISA have a signed Statement of Cooperation and a Confidentiality Commitment in place that allow the two agencies to exchange inspection reports and discuss drug applications. Throughout the pandemic, these arrangements allowed the two regulators to share regulatory approaches to decision-making regarding medical products used to treat and prevent COVID-19.

ANVISA is also one of the seven regulatory agencies that participate with the FDA in [Project Orbis](#), which provides the partnering agencies with a framework for concurrent submission and review of oncology drugs.

At the meeting, officials discussed strategies to address drug shortages and the medical product supply chain, the potential for future collaboration related to drugs for rare diseases, plans for the exchange of nonpublic information, monitoring medical products sold on the internet, and Brazil's progress in developing a Unique Device Identification System for medical devices.



The meeting was facilitated in a hybrid fashion, with some participating in person at the FDA's headquarters in White Oak, Maryland, and others participating virtually.

Joining Dr. Woodcock from the FDA were Mark Abdo, associate commissioner for global policy and strategy; Dr. Peter Marks, director of the Center for Biologics Evaluation and Research; Theresa Mullin, associate director for strategic initiatives in the Center for Drug Evaluation and Research; and Melissa Torres, associate director for international affairs in the Center for Devices and Radiological Health.

Joining Dr. Barra were Leonardo Dutra, head of Anvisa's International Affairs Office; Karin Mendes, head of the Anvisa Cabinet; Renato Stancato, head of the Science and Technology Section of the Brazilian Embassy in Washington; and Samia Melo, advisor to Dr. Barra.

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## **FDA Europe Office Staff Meets Counterparts in Croatia**

The FDA Europe Office (EO) met with their regulatory counterparts in Croatia from April 19-22 to explore potential technical cooperation in common areas of interest and discuss international priorities such as risk assessment, medical devices, and digital health.

Europe Office Director Ritu Nalubola, Ph.D., Policy Advisor on Medical Products Claudia Louati, and Food Policy Advisor Alessandro Fiorelli participated in the talks in Zagreb with officials from Croatia's Public Health Institute, the Agency for Medicinal Products and Medical Devices (HALMED), the Agency for Agriculture and Food, the Ministry of Agriculture, the State Inspectorate, and the Ministry of Health.



*FDA Europe Office staff members with their Croatian regulatory counterparts.*

After meeting with six different ministries and agencies, EO staff members came away with a better understanding of the various organizations and their respective roles in the broader EU food safety and medical product systems. That included a clarification of the division of competencies between HALMED and the Ministry of Health and Ministry of Agriculture on medical devices as well as veterinary medicines “which was important in the context of the [Mutual Recognition Agreement](#) on veterinary medicines,” said Louati.

The U.S.-Croatian dialogue with the Ministry of Agriculture and Ministry of Health also focused on “New Era of Smarter Food Safety,” biotechnology, nutrition policies, systems recognition, and the implementation of the [EU’s Official Control Regulation](#).

The FDA staff presented on several key initiatives, including the [GenomeTrakr](#) platform, nutrition labeling, cannabidiol (CBD), and e-commerce. Attendees from the two nations discovered they had common interests in agricultural biotechnology and new breeding techniques. Going forward, both nations agreed to continue to share information on issues of mutual concern.

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## India Office Spices Things Up

Throughout history, spices have been an important source of trade and income for India. To learn more about the spice industry and how it is regulated, Sarah McMullen, director of the India Office, and Pankaja Panda, INO's food safety coordinator, visited the "Spices Park" in Puttady, Kerala on April 27.

Spices Park is a 10-acre growing, processing, warehousing, and e-auction location for cardamom and black pepper operated by the Spices Board of India. Part of the Government of India's Ministry of Commerce and Industry, the Spices Board is the leading organization for the market development, regulation, and global promotion of Indian spices.



*The verdant hills of the Idukki District support the growing of many spices. Here, INO Director Dr. Sarah McMullen stands in front of the surprisingly tall cardamom plants at the Spices Park farm. A close-up of the base of a plant reveals the ripening seed pods on trailing stems.*

The Park is located in the botanically diverse Idukki District of Kerala. Getting to the Park requires driving four hours on winding roads up into the hills from Kochi, Kerala's main port city and home to the Spices Board headquarters. The hills provide cool and misty weather conditions good for growing cardamom and pepper. While cardamom plants grow tall and lush, their seed pods, which are dried and sold as spice, grow from the base of the plant. Pepper, on the other hand, is harvested from berries that grow on vines among the many trees. Its dried berries make up the ubiquitous black seasoning loved the world over.

McMullen and Panda were hosted by Ms. Vijishna, assistant director in charge of the Spices Park, and Mr. Vijayraj, an officer from the Spices Board. During

the visit, the two INO officials observed a cardamom auction in progress and saw how the pods are assessed by graders, with the best quality pods (based on color and size) fetching much higher prices. They also toured cold storage facilities where cardamom is held until farmers can secure a higher price for their harvest.



*Left: Cardamom being staged for grading and auction. Right: Vijayraj, McMullen, Vijishna, and Panda visit the fragrant cardamom storage warehouse at the Spices Park.*

The aroma was just amazing, noted McMullen. It was as if you were in an aromatic vaporizer — “good for your cough or cold,” said Mr. Vijayraj.

The Idukki region is also known for producing turmeric, bay leaf, and cocoa. On their drive up to Puttady, McMullen and Panda saw cocoa trees with immature pods still a few months away from harvest. They got to taste the inside of a raw cocoa pod, thanks to their enterprising driver who removed a pod from a tree for the ladies to taste. “It was sweet and sour at the same time, nothing like chocolate tastes!” noted Panda.



*A fresh-picked cocoa pod reveals large pulp-covered seeds. To obtain the beloved chocolate flavor, the seeds need to undergo a drying and fermentation process to become “cocoa beans.” The cacao tree is an Amazon rainforest native, which has been introduced around the world to other equatorial growing zones.*



McMullen's and Panda's visit to the Spices Park piqued their interest to visit the area again during pepper and cocoa season. To see the plant-to-package process provided them useful insight into the beginning of the cardamom supply chain. The fragrance of this "queen of spices" and the lush green hills were a reminder of the rich diversity of India's geography that gives rise to so many of the spices that have become staples in kitchens worldwide.

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## FDA Recognizes India Office's Public Service



Nearly 40 years ago, Congress designated the first week of May as Public Service Recognition Week to salute the contributions of public servants who serve our nation at all levels. During this year's observance, Commissioner Califf acknowledged the entire team in OGPS' India Office (INO) for "[doing the needful](#)" during India's tumultuous second wave of the pandemic.

In the spring of 2021, as the Delta variant emerged, a rapid surge of COVID-19 cases hit India. The INO, as part of the U.S. Embassy Mission, immediately stepped in to lead the interagency COVID-19 specification task force charged with determining the needs and specifications of items intended for donation — including medical devices, oxygen, oxygen storage/transport/delivery devices, and other pharmaceuticals.

The INO played a key role in ensuring urgently needed supplies were reaching those in need as fast as possible. Employees worked well beyond regular work hours and beyond the scope of their normal regulatory work to identify medical product and oxygen suppliers; answer questions about storage, transport, and other critical specifications; and reach out to Government of India counterparts for regulatory information.

The INO also leveraged the agency's considerable expertise back in the U.S. to respond to supply chain inquiries, such as the availability of antifungal medications to combat secondary infections associated with COVID-19 steroid therapy. All the while, these same employees were concerned for the safety of their family and friends in India, with some directly suffering from COVID-19. The tireless dedication and commitment of INO helped to save lives during the global public health crisis.

INO staff were also recognized by the State Department, with a Meritorious Honor Award in December 2021. "This hard work and commitment during the second wave of the COVID-19 pandemic was instrumental in providing emergency supplies to an overtaxed health system and allowing healthcare workers to effectively manage cases and provide lifesaving treatment," said Chief of Mission Patricia A. Lacina.

## **"Doing the needful."**

When people in India use that expression, they mean they trust someone to pitch in to perform a task, to do "what is necessary," without instruction.

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## **OGPS Alumnus Shares FDA Insights with Private Sector**



Chris Middendorf, a former FDA employee and OGPS alumnus who worked as an international relations specialist in the FDA's India Office and a consumer safety officer in the China Office (both positions focusing on drugs), recently wrote an article titled "FDA 'high-risk' foreign inspections: Post-COVID-19 responses to GMP challenges." The piece is featured in *Regulatory Focus*, an online news journal produced by the [Regulatory Affairs Professional Society](#).

Middendorf and coauthor Lowell M. Zeta, J.D., summarize the agency's policies, as well as industry considerations and recommendations to manufacturers in advance of their next FDA inspection. The article also examines the FDA's return to inspections put on hold during the COVID-19 pandemic, delineating the agency's oversight of drug and biological products during the pandemic and its future plans.

Middendorf, now director of regulatory affairs in the pharmaceuticals and biotechnology practice at the law firm Hogan Lovells, also gave a recent presentation to Chinese firms on what to expect when normal inspection operations for the FDA resume. He worked at the FDA for more than 20 years, conducting hundreds of inspections in the U.S. and internationally.

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## Staff on the Move

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### Promotions



## **Natalie Mickelsen, D.V.M.**

Dr. Natalie Mickelsen has accepted the position of Deputy Country Director of the India Office, after briefly acting in that position. She previously served in the India Office (INO) as a supervisory consumer safety officer since October 2019, overseeing the INO's bioresearch monitoring, drug, and food consumer safety officers. In this role, she supervised the initiation of foreign remote regulatory assessments and the restarting of inspections in India during the COVID-19 pandemic. Previously, she worked six years as a consumer safety officer conducting food, Good Laboratory Practices, and bioresearch monitoring inspections, with two of these years being in INO.

Prior to joining the FDA in 2013, Dr. Mickelsen was a veterinarian in mixed animal private practice, shelter medicine, and emergency medicine. She also conducted field and laboratory research on Chronic Wasting Disease at the U.S. Geological Survey's National Wildlife Health Center and researched Lyme Disease and West Nile Virus at the University of Kentucky. Dr. Mickelsen served in the U.S. Peace Corps in Malawi as an environmental volunteer, working with the country's Forestry and Fisheries Departments on sustainable development.

Dr. Mickelsen holds a Doctor of Veterinary Medicine from the University of Wisconsin School of Veterinary Medicine, a Master of Public Health from the University of Minnesota, and a Bachelor of Science in biology and environmental studies minor from the University of Kentucky. She is a Diplomate of the American College of Veterinary Preventive Medicine and is Certified in Public Health.

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## **Lt. Cmdr. Shannon Thor, Pharm.D.**

Lt. Cmdr. Shannon Thor, has been chosen as the Deputy Director of the FDA Europe Office (EO), located in Brussels. Lt. Cmdr. Thor, a pharmacist and officer in the U.S. Public Health Service Commissioned Corps, has served for more than eight years at the FDA. As an international policy analyst in the EO, she was responsible for providing leadership and

technical expertise on international public health initiatives and U.S.-European Union relations. Her previous FDA experience included policy advisor roles in the Office of Health and Constituent Affairs and in the Office of New Drugs.

Prior to joining the FDA, Lt. Cmdr. Thor served as an officer in the U.S. Navy, where she supervised pharmacy operations and directed medication safety programs at military medical facilities across the globe. She earned her Doctor of Pharmacy degree from the University of Illinois at Chicago, her Master of Science in pharmacy policy and regulation from the University of Florida, and her Bachelor of Science degree from the University of Illinois at Urbana-Champaign.

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### **Intra-office Transitions**



## **Jonathan Chapman**

Jonathan Chapman, former supervisory consumer safety officer for medical products in the China Office (CNO) has transitioned to the role of international regulatory specialist (IRS) covering CNO's drug portfolio.

Chapman joined OGPS in 2017, and moved to Beijing in 2018, serving as a drug investigator on the medical products team performing complex inspections throughout mainland

China. Chapman has been gaining expertise needed to move to the policy role

since May 2021 when CNO's medical products supervisor and drug international relations specialist both departed.

Chapman first transitioned to the SCSO role and then assumed some policy duties, because the IRS position remained vacant. While performing these activities, which included writing policy papers and speaking to industry, he became increasingly interested in that role. So, in early 2022, he applied for and was offered the drug IRS position, which he as now assumed.

In his new role, Chapman plans to continue to engage with the FDA's regulatory counterparts in China; research and report on China policies that may have immediate and/or long-term impacts on the global and/or U.S. pharmaceutical market; engage and perform educational outreach to the pharmaceutical industry in China; and continue to work with other U.S. agencies at the U.S. Embassy in Beijing on topics of mutual interest.

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## Incoming



### **Phil Nguyen, M.D.**

Dr. Phuc (Phil) Nguyen is on a detail with the Office of Global Operations' Immediate Office, assisting with the India Office's bioresearch monitoring, i.e., work that involves monitoring the conduct and reporting of the FDA-regulated research to ensure the quality and integrity of data submitted to the agency. Nguyen will provide technical expertise and reporting, liaise with the FDA's medical product centers and facilitate engagements and information sharing with the FDA staff, industry, and counterpart regulators. He will spend some of his detail in India, helping with outreach to the Government of India and to the many clinical research organizations there.

Dr. Nguyen comes to OGPS from CDER, where he is a physician for the FDA's Biomedical Research Monitoring Program. Before joining the FDA, Dr. Nguyen's experience spanned working in the nonprofit sector on regulatory systems strengthening, supply chains, and pharmaceutical quality standards with multilateral organizations. A former assistant professor at the Georgetown University School of Medicine, Dr. Nguyen holds a medical doctorate from Tufts

University, and a bachelor's in molecular and cell biology, cum laude, from Harvard University.

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## **Vanessa Noelte**

Vanessa Noelte joins OGPS as LAO's new international relations specialist at the Mexico City post.

Noelte previously worked on the Regulatory Cooperation and Partnerships Team within the International Affairs Staff of the Center for Food Safety and Applied Nutrition (CFSAN), functioning as the international produce safety strategic coordinator and international expert. In

that role, Noelte served as the project manager for the Mexico-FDA Food Safety Partnership Steering Committee and Executive Committee and led an interagency collaborative forum with international produce safety collaborators, including USDA and relevant academics.

She previously worked with CFSAN's Office of Nutrition and Food Labeling where she developed a medical food database for the FDA and worked on enforcement of nutrition labeling and nutrient claims, as well as standards of identity.

Noelte has a Master of Public Health in health policy from the Yale School of Public Health with a focus in food policy and nutrition. She graduated from Yale University with an undergraduate degree in the history of public health, with a focus on the Spanish language and pre-med.

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## Gregory Smith

Gregory Smith joins the India Office as an international relations specialist, focusing on drug products.

In his most recent role in CDER, Smith was the director of the Office of Executive Programs' Special Projects Staff. There he supervised a cross-functional/multi-disciplinary staff working on complex and mission-critical scientific, regulatory, legislative, and operational issues. The scope of topics ranged from user-fee negotiation, supply chain assessment, legislative implementation, organization-wide governance, and portfolio management. During the peak months of the COVID-19 pandemic, he managed CDER's external engagement with multilateral organizations and other federal agencies to create collaborative partnerships addressing supply chain issues involving domestic and foreign manufacturing, donation requests, and the assessment and acquisition of active pharmaceutical ingredients.

Smith originally joined the FDA in 2011 as a project manager in the Center for Veterinary Medicine's Office of New Animal Drug Evaluation. In that role, he was the primary liaison on the drug approval process for sponsors, review teams, and other internal and external stakeholders to ensure optimal time to project completion. Prior to the FDA, he managed clinical trials, risk evaluation and mitigation strategies, postmarketing, and surveillance initiatives for a global contract research organization. He was also a founding manager of an in-patient clinical pharmacology center where he supervised the processes associated with patient education, enrollment, and retention of patients in first-in-human clinical trials.

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## Dear International Colleague



Recent communications from OGPS to our international stakeholders, mid-April to mid-June.

- [Generic Drugs Forum 2022: The Current State of Generic Drugs](#)
- [CDER SBIA Quality Management Maturity Workshop](#)
- [FDA Takes Steps to Limit Lead in Juice to Further Reduce Exposure to Toxic Elements in Foods](#)
- [FDA Proposes Rules Prohibiting Menthol Cigarettes and Flavored Cigars](#)
- [FDA Announces Tentative Advisory Committee Meeting Schedule Regarding COVID-19 Vaccines](#)
- [FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products](#)
- [US-Canada ICH Consultation](#)
- [FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals](#)
- [FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products](#)
- [FDA Encourages Importation of Safe Infant Formula and Other Flexibilities to Further Increase Availability](#)
- [Coronavirus \(COVID-19\) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years](#)
- [FDA Flexibilities to Yield Millions of Cans of Additional Infant Formula in Coming Months to Increase Supply Available to U.S. Consumers](#)
- [Update on Importation of Specialized Medical Infant Formula](#)
- [Update on Importation of Infant Formula](#)

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# Events

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June 19-23	DIA Global Annual Meeting 2022
June 20-24	European Food Safety Agency's One Conference
July 6	Second meeting of the FDA and OECD's Task Force on Countering Illicit Trade Whole-of-Governments program
July 11-15	World Trade Organization Technical Barriers to Trade committee meeting
September 15-16	Third meeting of the FDA/OECD Whole-of-Governments program

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