November 2021

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In this issue

Global E-Commerce of Foods Addressed at New Era of Smarter Food Safety Summit

Regulatory authorities around the globe are grappling with how to ensure the safety of food purchased direct to consumers using e-commerce technology, noted Mark Abdoo, the FDA's Associate Commissioner of Global Policy and Strategy, as he opened the October 21 international panel of regulators during the FDA's virtual New Era of Smarter Food Safety Summit.

The rapidly growing food e-commerce market, already accounting for $100 billion in sales, includes online grocery shopping and delivery; hot meal delivery; packaged meal ingredient delivery; and online orders for staple and exotic food items shipped from warehouses and vendors located anywhere and everywhere.

Associate Commissioner Mark Abdoo

Regulators have systems for ensuring the safety of foods sold in traditional brick-and-mortar grocery stores and restaurants. Now they must consider whether additional steps are needed for e-commerce.

Food e-commerce is a "topic that crosses borders," Abdoo said. "Given today's interconnected supply chains, the U.S. can't achieve [its] food safety goals alone."

The international panel included officials from regulatory authorities in Brazil, Japan, Germany, and the United Kingdom. While each country has unique needs and perspectives that color their overall approach to regulation, they did share similar perspectives and what they had to say highlighted the complexity of what they all face:

• **Playing field:** The e-commerce sector is very easy to enter, hence the upsurge of vendors. Technology businesses, who often lack interest in food safety, are entering the food world. Thus, it is important to hold virtual marketplaces and online service providers accountable, in addition to vendors.

• **Old school:** While traditional supply chains have been rearranged, current regulations are based on the traditional food paradigm. Global regulators are working, albeit separately, toward updated approaches for e-commerce.

• **Structure:** Regulatory surveillance structures vary by country. In some, the federal authority leads, with state support. In others, state and local authorities have the greater onsite responsibility, looking to the federal authority to coordinate.

• **Scope:** It's not just foodstuffs. Dietary supplements (often the responsibility of food regulators) are popular e-commerce purchases, and are more likely to have unsafe claims and formulations.

• **Last mile:** The critical need for appropriate and protective packaging and adherence to safe food delivery temperatures poses challenges, as these issues expand the scope of who needs oversight, and bumps up against what is currently practical for the delivery sector.

• **Cooperation:** Cooperation and discussion is needed with other regulatory authorities, institutions, industry groups, consumer rights groups, and judiciary authorities.

• **Outreach:** Outreach, education, and training is important for industry, health agencies, and e-commerce platform providers.

The challenges regulators face are due, in part, to the lack of international standards and controls for food (and supplements, and pharmaceuticals, etc.) sold via e-commerce.

Fabio Miranda da Rocha, a senior Public Health Officer in the Food Inspection Department of the Brazilian Health Regulatory Agency, noted that his agency would be able to better manage oversight of e-commerce if international standards existed to allow for rapid information exchange since "online sales happen faster than authorities can communicate about it."

[*A Federal Register docket was opened for the Summit to collect comments from the public, industry, and global colleagues. It closed on November 20, 2021. Read what people had to say here.*]

OGPS Secures Support for a WHO Global Working Group on Informal Markets

Informal markets — where vendors congregate to sell a wide variety of products from market stalls, push carts and small retail shops — are the primary source for locally produced food, crafts, clothing and other products in low- and middle-income countries.

In areas that lack access to an approved pharmacy or medical facility, some vendors also sell medicines, meeting a market demand for convenient and accessible medicines. Often they provide the medications on an as-needed basis and are sold by

the pill or in small amounts that are devoid of any packaging, an approach that would be illegal in pharmacies or in formal markets with packaging restrictions.

These markets tend to be loosely regulated by local authorities and are not overseen by national regulatory authorities. Such lack of oversight, combined with limited pharmacy knowledge, and a potentially questionable supply chain, raises the risk that people in these markets are buying substandard and/or falsified medications.

The FDA's Office of Global Policy and Strategy (OGPS) has taken an interest in this issue ever since it was initially raised in the National Academies for Sciences, Engineering, and Medicine's 2020 report entitled, "Stronger Food and Drug Regulatory Systems Abroad" (commissioned by the FDA). After conducting additional research, OGPS developed a proposal that informal markets be one of the 2022-23 prioritized activities for the World Health Organization's Member State Mechanism on Substandard and Falsified Medical Products (MSM).

In late October, at its 10th meeting, the MSM — a global forum that convenes, coordinates, decides, and organizes activities addressing substandard and falsified medical products — accepted the FDA's prioritized new activity. Member countries now have until early December to review the MSM's full 2022-23 work plan — and come up with projects under the prioritized activities, including the one on informal markets. In the meantime an informal markets working group has been established and more than 10 countries have asked to join. A chair has yet to be selected.

The 2020 National Academies report highlighted Tanzania's successful approach to informal markets – an accreditation program for informal sellers established by the Tanzania Medicines and Medical Devices Authority in 2003. By the time the 2020 report was issued, Tanzania had accredited over 9,000 drug dispensing outlets. To gain accreditation, store owners and dispensing staff are required to complete training in health, communication and patient counseling, as well as local pharmacy laws, good

dispensing practices, and rational use of medicines. As an incentive to participate, shop owners are authorized to sell a limited list of restricted medicines and are eligible for business improvement loans. The program has improved access to medicines and the quality and appropriate use of these products. As a result, there has been a substantial increase in the number of people who adhere to malaria treatment guidelines.

There are a variety of potential projects for the informal markets working group to pursue, including a study to determine underlying causes of impacts of various intervention methods, a survey of member states on the prevalence of such markets, a tool kit to help regulatory authorities address medical product distribution through information markets, and the development of an awareness/education campaign for consumers.

OGPS International Policy Analyst Russell Campbell, who oversees the FDA's MSM work, said he expects the working group to take approximately five years to address the issues outlined in the OGPS proposal.

African Medicines Agency to Become a Reality

After years of discussion, Africa is getting an African Medicines Agency. Instead of acting as a stand-alone regulatory body, like the FDA, it will coordinate the activities of national and regional regulators as well as support local manufacturing and pharmacy, and act against substandard and falsified medicines.

The Treaty for the Establishment of the African Medicines Agency (AMA) entered into force on November 5. The AMA will operate as a special agency under the African Union, a 55-member-state continental union dedicated to achieving greater unity, cohesion, and solidarity across the continent.

The idea for the AMA was first discussed in 2010 at the 60th session of the World Health Organization Regional Committee for Africa. But African leaders didn't formally act on these discussions until the 32nd Ordinary Session of the Assembly in Addis Ababa, Ethiopia when they signed the AMA treaty.

To date, 16 African Union member states (Algeria, Benin, Burkina Faso, Cameroon, Chad, Gabon, Ghana, Guinea, Mali, Mauritius, Namibia, Niger, Rwanda, Seychelles, Sierra Leone, and Zimbabwe) have completed all of these steps. Another member state, Morocco, has ratified the treaty but has yet to deposit their instrument of ratification with the Commission. Eleven other states have signed the treaty: Burundi, Cote d'Ivoire, Egypt, Madagascar, Republic of Congo, Saharawi Arab Democratic Republic, Senegal, Tanzania, Togo, Tunisia, and Uganda.

Thirteen countries are said to be interested in hosting the AMA's headquarters. A site decision is expected to be made in February 2022 at the AU Summit. After that, formal AMA structures need to be set up and money raised to support the AMA's activities.

The AMA builds on the efforts of the African Medicines Regulatory Harmonization, established in 2009 by the Africa Union Development Agency - the New Partnership for Africa's Development (AUDA-NEPAD) to achieve regulatory harmonization among the AU member states. AUDA-NEPAD has been a strong advocate for the AMA. On its website, it states that once the AMA is fully operational the new agency will:

- Support the growth of local pharmaceutical production and play a critical role in catalyzing regional trade.
- Evaluate medical products for the treatment of priority diseases as determined by the African Union.

- Regularly inspect, coordinate and share information about products that are authorized for marketing.
- Coordinate joint reviews of clinical trial applications for vaccines and assessment of "highly complex" product dossiers such as biosimilars.
- Coordinate joint inspections of Active Pharmaceutical Ingredients (API) manufacturing sites.
- Collaborate with Regional Economic Communities and National Medicines Regulatory Authorities in the identification of substandard and falsified medical products.
- Facilitate information sharing across countries and develop common standards and regulations and in turn be responsible for harmonizing legislation.

Michel Sidibé, a former executive director of the Joint United Nations Programme on HIV and AIDS (UNAIDS) and former Minister of Health in Mali, was appointed by the AU in April as a special envoy to help secure the 15 countries needed for the establishment of the AMA.

He has been quoted as saying that he seeks U.S. partnership and collaboration to help standardize and harmonize AMA regulations in accordance with international norms and to strengthen Africa's network of laboratory systems.

In August, FDA senior officials and staff met with Jessica Lapenn, U.S. Ambassador to the African Union and U.S. Permanent Representative to the United Nations Economic Commission for Africa, to discuss future plans for working with the AMA once it was operational.

"The U.S. government and U.S. private sector are very much looking forward to collaboration with AMA," Lapenn was quoted as saying at a recent media briefing sponsored by the Africa Centres for Disease Control, which until now has been the lone public health agency under the African Union.

Additional Resources

African Union press release

AMA treaty infographic

COFEPRIS Becomes Latest ICH Member

Mexico’s Federal Commission for the Protection against Sanitary Risk (COFEPRIS) has become a member of the International Council on Harmonization (ICH), a nonprofit group that brings regulatory authorities and the pharmaceutical industry together to harmonize the scientific and technical aspects of drug registration.

COFEPRIS, a decentralized agency of Mexico’s Department of Health, regulates pharmaceutical products, medical devices, biological products, pesticides and fertilizer, food, cosmetics, and tobacco.

ICH member countries approved Mexico's nomination without objection at the organization’s plenary meeting, COFEPRIS said in a November 17 press release.

FDA Global ✓
@FDA_Global

@FDA_Global congratulates COFEPRIS on becoming a member of the International Council on Harmonization, an int'l nonprofit that brings regulatory authorities & the pharma industry together to harmonize the scientific & technical aspects of drug registration.

> **COFEPRIS** ✓ @COFEPRIS · Nov 17
>
> 🇲🇽México, primer país hispanohablante miembro de @ICH_news máximo foro regulatorio de productos farmacéuticos.
>
> Con ello, Cofepris es considerada autoridad reguladora de alto nivel de exigencia de acuerdo con la OMS 🌎.
>
> 👉 bit.ly/3CoElm0

Twitter exchange between @FDA_Global and Cofepris

Mexico is the fourth country in the Americas to become an ICH member, joining Canada, Brazil, and the United States, and is ICH's first Spanish-speaking nation.

In his speech before the virtual assembly, the head of Cofepris, Alejandro Svarch Pérez, highlighted the role of Cofepris in protecting the health of the more than 129 million people who live and transit in the country, as well as its neighbors in Central America and the Caribbean.

"It is our priority to align our processes with international best practices to facilitate access to medicines, especially for our most vulnerable population. We work to provide safe, effective and quality medicines in our country, and we are sure that harmonization is a crucial element for the proper functioning of health systems," said Svarch Pérez.

Becoming a member of ICH is a key step in strengthening the regulation of pharmaceuticals and clinical research throughout the region, which will facilitate earlier and more equitable access to innovative therapies, he added.

FDA Collaborates with Health Canada and the UK's MHRA on Good Machine Learning Practice

The FDA, Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice.

These guiding principles will help promote safe, effective, and high-quality medical devices that use artificial intelligence and machine learning, they said in an October 27 statement.

Artificial intelligence and machine learning technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. They use software algorithms to learn from real-world use and in some situations may use this information to improve product performance. But they also present unique considerations due to their complexity and the iterative and data-driven nature of their development.

“With artificial intelligence and machine learning progressing so rapidly, the three regulatory agencies see a global opportunity to help foster good machine learning practice by providing guiding principles that we believe will support the development and maturation of good machine learning practice,” said Bakul Patel, director of the FDA’s Digital Health Center of Excellence in the Center for Devices and Radiological Health.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	**Good Software Engineering and Security Practices are Implemented**
Clinical Study Participants and Data Sets are Representative of the Intended Population	**Training Data Sets are Independent of Test Sets**
Selected Reference Datasets are Based Upon Best Available Methods	**Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device**
Focus is Placed on the Performance of the Human-AI Team	**Testing Demonstrates Device Performance during Clinically Relevant Conditions**
Users are Provided Essential Information Clearly	**Deployed Models are Monitored for Performance and Re-training Risks are Managed**

Since many digital health care tools operate in the cloud, outside physical or country boundaries, the FDA believes it is important that regulatory expectations for these products be harmonized globally and that regulators work together as much as possible on a common set of industry standards and best practices.

The 10 principles are intended to identify areas where alignment in efforts related to research, building educational tools and resources, regulatory policies, regulatory guidelines, international harmonization, and consensus standards could be developed by the International Medical Device Regulators Forum (IMDRF), international standards organizations, and other collaborative bodies to advance the maturation of GMLP.

IMDRF is a voluntary group of medical device regulators from around the world that work together to accelerate international medical device harmonization and convergence. The FDA helped introduce a new paradigm within IMDRF for an internationally harmonized approach to Software as a Medical Device, which includes mobile medical applications. Currently, the agency participates in the IMDRF's Artificial Intelligence Medical Devices working group, which seeks to achieve a harmonized approach to the management of artificial intelligence and machine learning-enabled medical devices.

The FDA has established a public docket (FDA-2019-N-1185) at Regulations.gov to solicit feedback on the guiding principles.

FDA, HHS, and Colombian Government Hold Dialogue on Device Harmonization and Vaccine Development

Medical device harmonization and vaccine development were the primary topics of a working group meeting between U.S. public health officials and public health officials from the Colombian government on October 24-26 in Bogotá, Colombia.

The FDA's Latin America Office (LAO) Director Katherine Serrano represented the FDA as part of the U.S. Department of Health and Human Services delegation. The three-day meeting was held in conjunction with the Ninth High-Level Dialogue between the two countries, kicked off by U.S. Secretary of State Anthony Blinken and Colombia Vice President and Foreign Minister Marta Lucía Ramírez.

The working group made significant headway in advancing medical device harmonization — encouraging Colombia to adopt internationally recognized medical device quality system standards.

According to Serrano, the FDA has been an ardent supporter of international regulatory convergence, in the hope that it will facilitate more efficient development, manufacture, and marketing of medical devices worldwide. For Colombia, convergence will help lay the groundwork for participating in international programs, including the Medical Device Single Audit Program (MDSAP), which allows an MDSAP-recognized auditing organization to conduct a single regulatory audit of a medical device manufacturer that can satisfy the relevant requirements of the regulatory authorities participating in the program. MDSAP's current participants include Australia, Canada, Brazil, Japan, and the U.S.

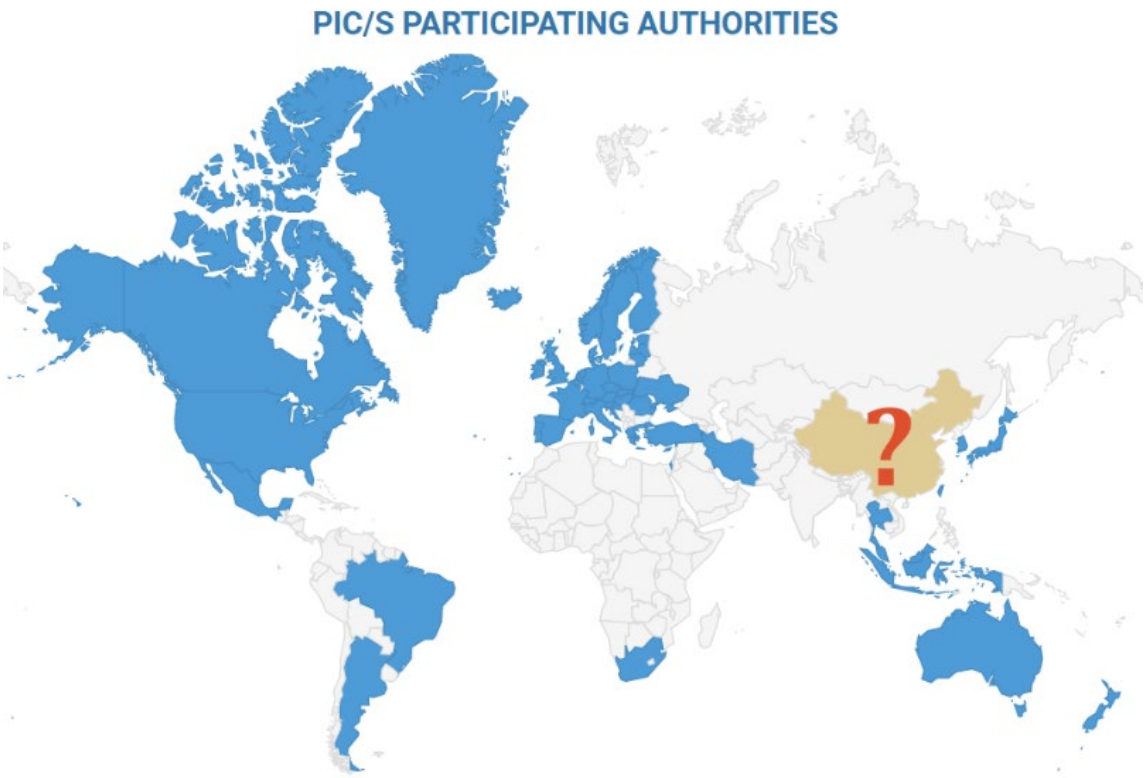
Vaccine Capacity Building

At the working group meeting, Colombia requested support and training from the FDA on vaccine regulation and capacity building to help the country build sustainable solutions to the public health challenges revealed by the pandemic. Colombia previously manufactured vaccines against rabies and yellow fever (among others), with enough capacity to supply the region, but production stagnated in recent decades. Both Colombia's government and its pharmaceutical sector are now taking steps to future-proof the country's — and thus Latin America's — vaccine production ability.

China's NMPA Begins Process of Joining Global Inspectional Group

China's primary regulatory agency for pharmaceuticals, medical devices, and cosmetics, the National Medical Products Administration, or NMPA, has begun the process of becoming a full member of an informal group of global regulatory authorities who work toward harmonizing inspection procedures.

That informal global group is known as the Pharmaceutical Inspection Co-operation Scheme, or PIC/S, founded in 1995 to lead in the international development, implementation, and maintenance of harmonized Good Manufacturing Practice standards and quality systems that regulatory authorities adhere to when inspecting manufacturing facilities that make medical products.



The NMPA was created in 2018 following a reorganization of the China Food and Drug Administration, which had participated in PIC/S-related activities for several years but had never sought formal membership. Since its reorganization, the NMPA has put more emphasis on international harmonization efforts, including harmonizing its own systems to international standards. In 2019, it met with PIC/S about a possible membership, and that led to its September 2021 pre-accession request. Pre-accession is a preliminary process designed to help applicants better understand the relevant requirements of the PIC/S before applying for full membership, or what PIC/S calls being a “participating authority.”

The pre-accession period can take up to two years. During this time, PIC/S will perform a gap analysis to identify whether the applicant fulfills all of the organization’s requirements for membership. If PIC/S decides to invite the NMPA to apply for membership, the Chinese authority would become the organization’s 55th member.

FDA’s Global Messaging Nearly Doubles

Whenever the FDA issues announcements of interest to the international community, the Office of Global Policy and Strategy (OGPS) sends an email alert to the 22,000 addresses in its international listserv, which includes embassies based in Washington, D.C., in addition to the thousands of individuals who subscribe to this free service.

These alerts, known as a Dear International Colleague Letter (DICL), have been issued by OGPS, and its predecessor, the Office of International Programs, for nearly two decades.

The number of DICLs has been on the rise in recent years, as other FDA offices have come to recognize their communications value and as the OGPS' Communications Team has devoted more time to working with other FDA offices on international messaging.

In fiscal year 2021, OGPS issued a record number of DICLs, nearly double the 38 DICLs in fiscal year 2020 (clearly an anomaly year) and 20% higher than the 48 DICLs issued in FY 2019.

	Q-1	**Q-2**	**Q-3**	**Q-4**	
DICLs	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Jul-Sept**	**Total**
FY2017	7	14	10	10	41
FY2018	10	13	9	15	47
FY2019	8	5	19	16	48
FY2020	8	10	6	14	38
FY2021	19	13	17	11	60

The 60 DICLs issued in FY 2021 covered a variety of topics, including information about upcoming webinars, food safety actions, and new drug and device regulations. But what helped to drive the recent increase and made FY 2021 unique was the FDA's extensive messaging on its COVID-19 activities, including its groundbreaking decisions about COVID-19 vaccines.

Nalubola Engages Croatian Stakeholders

On October 12, Europe Office Director Ritu Nalubola presented information on the New Era for Smarter Food Safety at the Conference on Food Safety and Quality, in Opatija, Croatia.

Dialogue Concludes with Two Signed MOUs

The FDA's India Office was part of a U.S. delegation of public health officials who participated in the 4th U.S.-India Health Dialogue in New Delhi on September 27-28.

The event provided an opportunity for the U.S. officials to discuss multiple ongoing collaborations with their Indian counterparts, including epidemiological research and surveillance, vaccine development, One Health, zoonotic and vector-borne diseases, food and drug regulations, health systems, and health policies.

INO Director Sarah McMullen shared information about the FDA's ongoing collaboration on efforts to enhance medical products and food safety with its Government of India counterparts. The FDA also held a sideline meeting regarding medical products with the Central Drugs Standard Control Organisation, India's national regulatory body for pharmaceuticals and medical devices.

The U.S. delegation was led by Patricia Lacina, Charge D'Affairs of the U.S. Embassy New Delhi, and Loyce Pace, director of the Department of Health and Human Services (HHS) Office of Global Affairs.

Two Memoranda of Understandings were signed on the last day: one between the India's Ministry of Health & Family Welfare and HHS that called for cooperation in health and biomedical sciences; another, between the Indian Council of Medical Research and the U.S. National Institute of Allergy and Infectious Diseases, regarding cooperation on the International Centre for Excellence in Research.

In concluding remarks, Union Health Minister, Shri Mansukh Mandaviya, cited ongoing collaboration between the two countries on many pressing health issues, including antimicrobial resistance, HIV/AIDS, and climate change and human health, as well as the importance of engagement with the FDA to better understand the PREDICT Model, a risk-based management tool to enhance the safety of U.S. imports.

"Both India and the U.S. are global partners, and we also need to work collaboratively in reforming the global health architecture, whose fault lines have become amply visible during the current pandemic," Mandaviya said. "I also note with satisfaction the increased convergence between the regulators of both countries and look forward for further tangible outputs and combined working on this issue at global fora."

STAFF NEWS

Foreign Office Network Launched

FDA staff who have worked in an FDA foreign office now have the opportunity to join the Foreign Office Alumni Network.

The new Network is part of the FDA Alumni Association, which is dedicated to helping current and future FDA alumni stay in touch with each other and the issues of the day, and support the agency's public health mission by providing a venue for sharing the collective wisdom of the FDA's "brain trust."

Both current and former FDA foreign office staff, including locally employed staff, qualify for membership. Those who join will receive the Association's newsletter, access to targeted events, and be added to a members-only listserv.

Associate Commissioner for Global Policy and Strategy Mark Abdoo sent an email to qualifying staff on November 16, alerting them to the membership opportunity which, he said, would allow them to reflect on and share their unique experiences.

"Living and working abroad…and serving as a U.S. diplomat, is a special opportunity to truly experience another culture, to meet and get to know foreign counterparts, and to develop new contacts and friendships," he said.

"At the end of a foreign tour, it is hard for staff to say goodbye to a once-in-a-lifetime experience and to the many new friends and colleagues they met at post."

Over time, the new network could fulfill a mentorship function — helping to develop the next generation of foreign office employees and encouraging the recruitment and retention of foreign office staff, Abdoo added.

The Foreign Office Alumni Network was spearheaded by Leigh Verbois, former director of OGPS' China Office, and former director of the Office of Global Operations, who now works in the Center for Drug Evaluation and Research as the director of the Office of Drug Security, Integrity, and Response.

Those who have questions about the network may contact Leigh.Verbois@fda.hhs.gov.

TRANSITIONS

Thomas Siebertz has been selected as a consumer safety officer with the China Office. He will specialize in human and animal food.

He joins OGPS from the Office of Regulatory Affairs' Office of Human and Animal Food Operations, where he was part of HAF-East 1, located in Stoneham, Massachusetts.

Siebertz has been an FDA consumer safety officer since 2014, conducting inspections of food, cosmetic, and dietary supplement firms both domestically and internationally. He also has experience with the Center for Food Safety and Applied Nutrition as an international policy analyst where he worked on the Systems Recognition program.

He holds a Master of Public Health degree in environmental health science from New York Medical College and a bachelor's degree in food science from Kansas State University. Siebertz is an adjunct faculty of food science at Bay Path University in Longmeadow, Massachusetts.

Grant Jones has been selected as a consumer safety officer with the China Office, specializing in human and animal food.

He joins OGPS from the Memphis Resident Post in Jackson, Mississippi where he conducted food inspections for the Office of Regulatory Affairs (ORA).

Jones has been an FDA consumer safety officer since 2016. FDA service is a family tradition: Jones' father is an FDA investigator for ORA's Office of Pharmaceutical Quality Operations Division 2. As a result, Jones had the unique opportunity to assist in a follow-up inspection where the senior Jones was lead investigator.

He holds a bachelor's degree in chemistry from Mississippi College, and is currently studying Christian theology.

Charles E. Idjagboro has been selected as a consumer safety officer specializing in human and animal food and will be stationed with the China Office.

He joins OGPS from the Center for Food Safety and Applied Nutrition where he was a Retail Food Policy Team representative since 2017.

Idjagboro also spent five years as a consumer safety officer with the Office of Regulatory Affairs Baltimore District, where he led and conducted domestic and foreign inspections.

He has provided technical expertise to new hires and senior management regarding compliance inspections of FDA regulated foods including conventional, acidified, juice, seafood, and dietary supplements.

Idjagboro holds a Master of Public Health degree in epidemiology from the University of Maryland Baltimore School of Medicine, and a Bachelor of Science Degree in zoology from the University of Benin, Benin City, Edo State, Nigeria.

Micah Augusma was selected as an ORISE fellow for the OGPS immediate office to provide support on research and analysis projects. He completed an undergraduate degree in medical anthropology from the University of Iowa in 2019.

During his undergraduate studies Augusma was actively involved in student government where he served as the student government director of health and safety.

In this role he collaborated with university officials to develop health programming and mental health resources for students.

In Spring 2021, Micah graduated from Emory University's Rollins School of Public Health where he received a Master of Public Health in global health with a concentration in infectious disease. While at Emory he served as a graduate research assistant for the CDC's Office of Science where he conducted qualitative data implementation, qualitative data analysis, and improvements in regulatory compliance systems.

Augusma also conducted research on global sanitation systems through the Center for Global Safe Water, Sanitation, and Hygiene at Emory. In 2020, he helped the Center and World Vision Zambia develop a novel sanitation data collection tool used to provide context on sanitation in the rural areas of Zambia. Aside from WASH topics (i.e., water,

sanitation, and hygiene), his other global health interests include vector-borne diseases, global health security, and global health diplomacy.

Kukhwa "Kristie" Oh was selected as an ORISE fellow for the OGPS immediate office to provide support on research and analysis projects.

She is a pharmacist by training who is keen to work on global health policy development in OGPS. Prior to attending pharmacy school, she graduated from Chung-Ang University in South Korea with a bachelor's degree in music, specializing in classical piano.

Before going to Germany to study for her doctorate, she had the opportunity to go on a mission trip to Mongolia with a medical team.

The experience opened her eyes to see how powerful access to medicine was, and how it can positively impact the rural community. After the mission trip, she changed her career goals and came to America to study biochemistry at Mercer University and eventually graduated from Notre Dame of Maryland University with a Pharm.D.

While serving as the chapter President of the APhA-ASP- American Pharmacists Association Academy of Student Pharmacists, she initiated the women's health operation and spearheaded an initiative that collected over 200 feminine care packages for Paul's Place in Baltimore.

Dear International Colleague

Following are the most recent Dear International Colleague Letters:

Pharmaceutical Quality Symposium 2021: Innovations in a Changing World

Drug Export Certificates – CPPs – to be issued electronically

FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines

FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age (IDICL)

Coronavirus (COVID-19) Update: FDA Updates Test Policies to Help to Ensure Accuracy and Reliability of Tests and Increase Access to At-Home Tests

FDA expands eligibility for COVID-19 Vaccine boosters

UPCOMING EVENTS

UPCOMING EVENTS

December 1 World AIDS Day

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