

OGPS | Office of Global Policy and Strategy

GLOBAL UPDATE

 U.S. FOOD & DRUG
ADMINISTRATION



July 2021

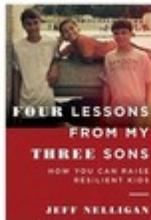
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GLOBAL NEWS

Fristedt Calls for Strengthening Local Production, Adoption of FDA-Backed Device Nomenclature at WHA

FDA Deputy Commissioner for Policy, Legislation, and International Affairs [Andri Fristedt](#) represented the FDA at the 74th World Health Assembly (WHA) on May 28 as a member of the U.S. delegation led by the Health and Human Services (HHS) [Secretary Xavier Becerra](#).

The WHA is the governing body of the World Health Organization (WHO). Delegations led by the health ministers from the WHO's 194 Member states participate in the WHA's annual meeting. The agenda is prepared by the WHO's [Executive Board](#).

In her remarks to the WHA, Fristedt said, "The COVID-19 pandemic has demonstrated the urgent need to strengthen global supply chains, including through enhanced sustainable and strategic regional and local production, strengthened regulatory systems to enable access to quality assured products, and facilitation of trade in key health products."

The United States cosponsored a [resolution](#) calling for strengthening local production of medicines and other health technologies to improve access, she said, adding that strong regulatory systems are a precursor for local production to contribute to greater access.

Although United States believes strongly in intellectual property protections, it supports a waiver of those protections for COVID-19 vaccines, in service of ending the pandemic, she said, explaining that "the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures."



Seventy-fourth World Health Assembly – 28 May 2021

Fristedt also addressed implementation of a harmonized nomenclature system for naming medical devices, that regulators, health care providers, and others use to exchange medical device information and support patient safety. Such a system can be useful in the exchange of post-market safety reports, supporting inventory control in hospitals, and for purchasing and supply chain management.

The FDA supports the free Global Medical Device Nomenclature system, under development since the 1990s, that is now being used by 70 national medical device regulators from across all WHO regions. In this nomenclature system, information in the form of a five-digit numeric GMDN Code is cross-referenced to a precisely defined Term Name and Definition. The European Union has chosen to adopt its own European Medical Devices Nomenclature instead and the WHO has proposed to adopt that version, once it is finalized by the EU. “We remain deeply concerned” by the WHO’s proposal, Fristedt said, noting that the EMDN is not harmonized with the GMDN system. To address that issue, she urged that the WHO complete the following actions before proceeding:

Comprehensively map the proposed new EMDN-based nomenclature system against the already widely used GMDN to identify and minimize the negative impacts of a duplicate system on Member States, medical device manufacturers, and other stakeholders.

Conduct a costing exercise so that Member States understand the resource requirements for WHO to host, maintain and update a system to ensure its continued value for member States and stakeholders.

Continue its cooperation with the [International Medical Device Regulators Forum \(IMDRF\)](#) towards developing a harmonized approach to nomenclature and to consult with regulatory authorities, medical device manufacturers, and other appropriate stakeholders.

Regulators Share a Common Goal in First-Ever Generic Drug Cluster

The FDA’s [Office of Generic Drugs](#) (OGD), part of the [Center for Drug Evaluation and Research](#) (CDER), is spearheading an effort to more closely align the way the world’s major regulatory agencies oversee generic drugs. To do that, OGD has established the Generic Drug Cluster, the first forum for regulators to routinely meet and discuss generic drug development globally.

Through the auspices of the cluster, regulators will have an opportunity to:

- Advance robust science-based approaches to generic drug regulation.
- Achieve a common understanding of each agency’s regulatory requirements for approval as well as current thinking on topics related to generic drug development.

- Seek opportunities to align on innovative bioequivalence approaches that support complex generic drug approvals.
- Confidentially share reports on safety issues to support the global safety of generic drugs.



Generic drugs are therapeutically equivalent to brand name drugs. Since they were established under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) they have grown to account for about 90% of prescriptions filled in the United States. The FDA is committed to helping facilitate access to lower-cost generic medicines by taking steps to enhance and streamline the development and approval process of high-quality generic drugs.

How did it start?

While the idea of a cluster is not new, the initiative to stand up a cluster dedicated to generic drug development is new — and is the innovative concept of Sarah Ibrahim, Ph.D., who became associate director of [Global Generic Drug Affairs](#) last year. Ibrahim worked closely with both CDER’s international staff and staff from the [Office of Global Policy and Strategy](#) who supported her efforts to understand the current global environment. Ibrahim credits her colleagues and is appreciative of their support. “It takes a village and the dedication and collaboration in OGD and the support of its leadership, truly exemplifies the organizational excellence. OGPS and CDER international [staff] were pioneers in helping me establish the cluster.”

“At the end of the day we are working to ensure patients have access to safe, affordable, and effective medications”

Sarah Ibrahim, Ph.D.



Who is involved?

The cluster is currently limited to government regulatory authorities and includes participants from the FDA; the European Medicines Agency; Health Canada; Medicines and Healthcare products Regulatory Agency of the United Kingdom; Swissmedic; and the Israeli Ministry of Health. The nature of the cluster, given the need for confidential information-sharing, is limited to regulatory agencies that the FDA has identified as partners with the appropriate confidentiality commitments in place.

In the future, observers from other regulatory authorities may participate in cluster activities – subject to the agreement of the FDA and all the founding regulatory agencies – provided they, too, have the appropriate confidentiality arrangements in place, Ibrahim says.

Why do it?

One of today’s challenges for FDA centers is around development programs for complex generics. These are generic drugs that could have a complex active ingredient; complex formulation; complex route of delivery; or a complex drug device combination. If generic regulation was more closely aligned, companies could operate more efficiently and at greater scale. This is especially important when it comes to complex generic drugs that might serve only a small number of patients in any given market. While the market might be prohibitively small in one country, it might be economically viable if sold in multiple markets with comparable regulatory requirements.

“As an agency, we value global collaboration and we recognize that with certain products such as complex generics that face a more complicated development process, access to multiple markets offers an incentive for companies to move forward with a development program,” Ibrahim said. Additionally, in part of the [Generic Drug User Fee](#)

[Amendments](#) (GDUFA) negotiations, industry repeatedly pointed out that there is no clear regulatory expectation for complex generics, making it a global unmet need.

For now, the variations in approach can be striking. For example, other regulators describe [complex generics as hybrid generics](#) and have distinct authorization and submission requirements.

Complex generics can greatly reduce health care costs. For instance, FDA approved the [first generic Advair Diskus](#) (a complex generic drug device combination product for asthma and COPD) in January of 2019. When it was introduced to the U.S. market, the out-of-pocket cost was reportedly half that of the brand product.

What is the end goal?

Regulatory agencies are unified by the mission of promoting the health of our citizens and ensuring that global quality and safety standards are met. Our path to harmonization of scientific and technical standards require an understanding of how generics are regulated across the world. Conducting a gap analysis is the first project for the cluster by determining how generic drugs are regulated across the globe.

The inaugural cluster session was held on June 15, with subsequent meetings to be held on an approximately quarterly basis. “At the end of the day we are working to ensure patients have access to safe, affordable, and effective medications,” said Ibrahim.

Inaugural Meeting of the Joint Sectoral Committee Commences

The United States-United Kingdom Mutual Recognition Joint Sectoral Committee (JSC) held its inaugural meeting on June 11, discussing next steps since the Mutual Recognition Agreement between the two nations went into effect early this year.

Before “Brexit” – the United Kingdom’s official exit from the European Union – the UK had been part of the EU’s mutual recognition agreement with the U.S., allowing foreign regulatory authorities to rely upon each other’s Good Manufacturing Practice (GMP) surveillance inspections of drug facilities.



After Britain signaled that it was leaving the EU, the U.S. began work on establishing a comparable MRA with the UK.

The US-UK Mutual Recognition Agreement (MRA) was signed on February 14, 2019, and entered into force on January 1, 2021, the day on which Britain left the EU.

Associate Commissioner Mark Abdo led the FDA delegation at the inaugural meeting of the Committee this month. A key objective of the first JSC meeting was to consider the addition of veterinary medicines into the scope of the MRA.

Also attending the meeting for the FDA were representatives from the [Center for Veterinary Medicine](#) (CVM), [Office of Regulatory Affairs](#) (ORA); and OGPS' [Office of Trade, Mutual Recognition and International Arrangements](#) (OTMRIA) and [Europe Office](#) (EO).

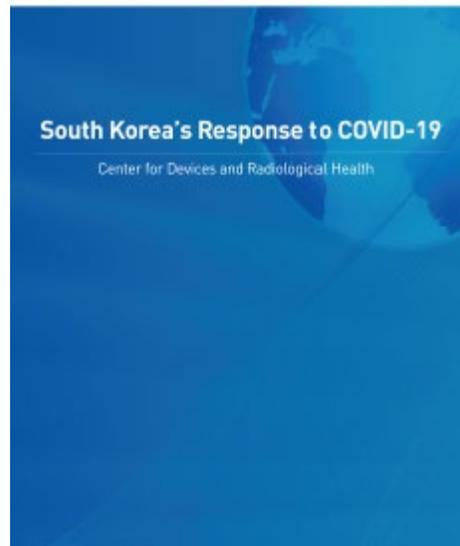
The UK delegation included representatives from the [Medicines and Healthcare products Regulatory Agency](#) and the [Veterinary Medicines Directorate](#).

The framework of the partnership is maintained by the [National Institute of Standards and Technology](#), which oversees inspectional collaborations involving telecommunications equipment and electromagnetic compatibility.

CDRH Releases Report on South Korea's COVID-19 Response

Just like public health experts around the world, officials in the FDA's Center for Devices and Radiological Health were impressed that South Korea was able to contain its COVID-19 outbreak two months after the first case of the disease was confirmed in early 2020, even though the nation was then the second most infected country after China. CDRH set out to determine why South Korea was able to accomplish this and learned that the nation's success was largely attributable to having a national testing strategy in place. These findings were published in a [25-page report](#) that CDRH released in late May.

In addition to the report, CDRH Director Jeffrey Shuren, M.D., J.D., and Timothy Stenzel, M.D., Ph.D., who directs the CDRH office that oversees diagnostic products, wrote a blog for the public health publication [Health Affairs](#) that summarizes the report's findings.



“Much of South Korea’s success in addressing the current pandemic has been attributed to lessons learned from their response to a deadly outbreak of Middle East Respiratory Syndrome (MERS) in 2015, including a national testing strategy,” the two wrote.

The CDRH officials identified five initiatives that contributed to South Korea’s successful testing strategy:

- Investing early in the commercial development of diagnostic tests for infectious diseases.
- Guaranteeing the purchase of minimum quantities of tests and reimbursing once the tests were authorized.
- Streamlining test validation studies
- Developing a centrally coordinated, nationwide testing program that relied upon a few dozen authorized tests commercially manufactured in high volumes, and
- Creating a network of testing sites.

The FDA recognizes different approaches may work for different countries, and the report does not make recommendations for what approaches could or should be adopted in the U.S. for emerging infectious diseases, the officials said.

STAFF NEWS

Reconvening Inspections in Mexico Makes an Immeasurable Impact

Last year in March, the FDA [announced](#) a temporary postponement of all domestic and foreign routine surveillance facility inspections, while continuing mission-critical inspections when possible. This precaution resulted in a hiatus of produce inspections in the Latin America region.

Due to ongoing foreign travel restrictions, consumer safety officers assigned to the [Office of Regulatory Affairs](#) (ORA) are still not able to conduct foreign inspections at this time. Thankfully, OGPS' [Latin America Office](#) (LAO) could dispatch Janete Oliveira, a CSO in Mexico City, who is fully trained in produce-related operations and has previous experience conducting produce inspections and outbreak investigations.

Oliveira was excited about being able to conduct the FDA's first onsite inspection in the Latin America region after more than a year. "It's been really nice to be able to go back to the field and perform these inspections – having my [LAO] leadership, OGPS leadership, and ORA leadership believe that I can put out some quality work without the need to wait until the next growing season."



LAO has resumed inspections in Mexico by targeting produce operations as a high priority commodity for the FDA in that country. LAO's Janete Oliveira performing a produce inspection of tomato greenhouses in June.

Prior to her deployment to LAO, Oliveira was a food specialist in the FDA Kansas City District Office (now Human and Animal Food West 2) where she worked on other food commodities in addition to many dietary supplement inspections, becoming one of their experts in this particular type of inspection.

Thus, it was fitting that she resumed inspections on May 24 by performing a high-priority compliance assignment of a dietary supplement firm. The next three inspections on Oliveira's task list were produce inspections. With over 45% of the produce consumed in the United States coming from Mexico, these are high-priority inspections which will hopefully derail any potential outbreaks.

Because growing season ends in September, Oliveira's work will take her all over the country of Mexico to inspect as many produce firms as she can. She created and implemented a COVID questionnaire in order to be as safe as possible and to gauge the COVID safety protocols of each facility before her visit. The document covers the wearing of masks and the number of staff who will be present during an inspection. It also helps assure the firms that she will be fully compliant with their own protocols.



One of the challenges a CSO faces in the field when performing produce inspections in remote areas is lack of an office set-up to review documents with management. During this inspection, Oliveira (first from right) reviewed documents on a round cement table and seats, where the harvesters usually eat their meals. The firm's management called the set up "Janete's rustic office!" Also, in this photo, a counterpart (first from the left) from the Mexican National Service of Agricultural Sanitation, Quality and Food Safety (SENASICA) observed the inspection as part of the FDA's collaboration with this agency under the Food Safety Partnership (FSP) agreement signed by the two agencies in 2020.

Born in Brazil, Oliveira became fluent in Spanish during college, which is useful as she conducts produce inspections in Spanish. She says firms are grateful to be able to explain documents and processes, and answer questions in their native language. “During a regulatory inspection, I tend to pull up the Spanish version of the [Produce Safety Rule](#) on my computer and they appreciate that because they can understand it.”

Oliveira says that throughout her 12-year career with the FDA one thing that she really admires about foreign companies is their willingness to go above and beyond to reach compliance because they realize that an outcome of an inspection may affect their livelihood. Consequently, they take learning the rules seriously. “Part of my job is an educator. Everything that they can learn from me, to them, is a plus.”



Lunch break on the farm: Oliveira enjoying an authentic “pollo con mole” (chicken with mole sauce), flavored with spices and chocolate.

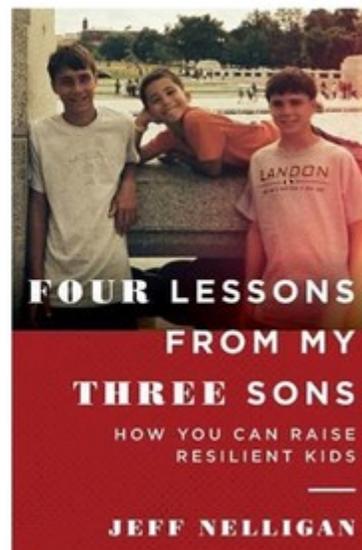
If there is time in between inspections, Oliveira says she will venture out and visit “some of the nicest places in Mexico where I never dreamed of going to before.” She loves to explore by eating authentic Mexican food, meeting different people, and absorbing the

culture. “I really engage, and I really appreciate that side of my job very much,” she said.

Being flexible and adaptable is important for this type of work, and Oliveira will continue to support ORA with other high-priority assignments while maintaining her own workload. The value of her in-country inspectional support is immeasurable as the FDA continues the [road to resiliency](#) in its planning for both domestic and international inspections, with the goal of ensuring a safe food supply in the U.S.

Nelligan Breaks Down Formula for Success

When he isn't championing the communications of OGPS' Immediate Office, Health Communication Officer Jeff Nelligan is fascinating the world with his proudest dad moments. He has authored five books; one of which breaks down his formula for raising a resilient and driven cadre. He was recently featured in an [NPR piece](#) on Father's Day.



Nelligan, a graduate of Williams College, is a U.S. Army Reserve/Army Guard veteran who worked many years on Capitol Hill and as a Schedule C appointee at the Department of State and at the Department of Health and Human Services. His drive and ambition come from his family. Nelligan's lineage includes a long line of victors who overcame adversity to find prosperity.

The maternal side of his family are the tangata whenus, which means “people of the land” in Māori, an Austronesian language primarily spoken in the North Island in New Zealand. The Māori people are the indigenous Polynesian people of mainland New Zealand. Nelligan's great-grandmother was Maori and left New Zealand when she was

fourteen years old. He is a member of the Huria *marae* (family) in Tauranga; his *Iwi* (tribe) is Ngāti Ranginui.

After years in Utah and Idaho, where she was sometimes referred to as the “Black Devil” because of her skin color and ancestry, she settled in Los Angeles where she found success running and owning a popular restaurant. Nelligan’s grandmother, like her mother, was also an “overcomer.” Although she was born nearly deaf, she became strong and confident, not allowing her deafness to become a hindrance. Indeed, she was an autodidact and became very well off financially playing rubber bridge. Nelligan’s mother, a political organizer, raised her three children with the cultural heritage passed down to her from previous generations.



A part of my good-natured approach to parenting was that I occasionally liked seeing one of my sons in a tight situation, even when it was nerve-wracking for me and utterly agonizing for him.

-Jeff Nelligan

The virtues of the Māori are clearly reflected in Nelligan’s three sons, and captured in the book, *Four Lessons from My Three Sons*. It provides simple and concise techniques proven to work. Here’s the proof:

His oldest son graduated from Williams College majoring in Mandarin. While there, he played four years of NCAA lacrosse; served as a Congressional staffer; and worked in Taipei in finance. He is currently a commissioned officer in the U.S. Navy with the U.S.S. Carl Vinson Carrier Strike Group in the Pacific.

Nelligan’s middle son graduated from the U.S. Naval Academy where he majored in math and played on the 2016 national champion U.S. Navy Club Lacrosse team. He is an engineering officer serving on a guided missile destroyer in the U.S. Navy, the U.S.S. Daniel Inouye, and is in the Pacific as well.

The youngest son is a senior cadet at the U.S. Military Academy at West Point, majoring in Arabic and French and will be commissioned an Infantry Officer. He is a

member of the Army West Point men's rugby team and was a congressional intern at the U.S. House of Representatives on the House Ways and Means committee.

While Nelligan's narrative is light-hearted, his parenting approaches are solid and practical. His methods are doable. His formula unique. He says that being grounded in four areas will help boys "reflexively make the correct decision in every situation encountered at home and school, within their peer groups and the world at large."

Resolute personal conduct

A confident worldview

Grinding resilience in adversity

Realistic ambition

The book also reveals the importance of identifying situations where parents can provide "practical and moral" on-the-spot instruction. Nelligan started seeking learning opportunities when his boys were very young. He then used these situations as subsequent examples of how they should behave when they were confronted with an identical or similar event. He framed these in an offbeat, funny manner. Later his sons referred to them as "sayings," which resonate with them to this day.

The rest you'll have to read for yourself.

BRIEFS

FDA Issues Letter to Industry Following Issues with Sterility

The FDA [issued a letter](#) to medical device manufacturers on June 2, to alert them to sterility issues with medical devices processed at [Steril Milano](#) S.R.L.'s ethylene oxide sterilization facilities in Italy.

Claudia Louati is the lead for OGPS' [Europe Office](#), which is monitoring and supporting outreach to relevant European Union competent authorities related to Steril Milano, following reports of falsifications and fraud at the company's ethylene oxide plants in

Monza and Reggiolo. FDA is investigating the extent of the impact on firms and devices in the U.S. market.

The FDA has been working with medical device manufacturers, international partners, and U.S. federal partners to investigate the scope of medical devices that may be impacted since it became aware that Steril Milano had falsified graphs and parameters of sterilization certificates for a variety of FDA-regulated products, dating back to 2016.

The FDA believes that 97 medical device manufacturers may be affected including those that make biopsy needles, catheters, intravascular administration sets, arthroscopes, syringes, and other medical devices.



The Steril Milano S.R.L. Reggiolo and Monza ethylene oxide sterilization facilities were closed in March 2021 and are no longer sterilizing medical devices.

Europe Office Supports Collaborative Work to Combat *Salmonella*

Europe Office (EO) Policy Advisor Alessandro Fiorelli is working closely with the Office of Regulatory Affairs (ORA) on a series of *Salmonella* international outbreaks linked to tahini as a source of contamination. Swedish authorities have recently notified the [Epidemic Intelligence Information System](#) (EPIS) network about the outbreak.



The FDA, together with the U.S. Centers for Disease Prevention (CDC), asked EO to reach out to the Swedish authorities following a suspected case identified in the United States, which is likely to be linked to the same outbreak.

Both the Swedish authorities (the Food Agency and the Public Health Authority of Sweden) and the FDA are interested in discussing findings and next steps to ensure the identification of firms that caused the Swedish outbreak, and that they are not exporting product to the U.S.

Beijing Embassy Recognizes CNO Staff

On June 3, the [U.S. Embassy Beijing](#) held their 2020 Mission Awards Ceremony, a celebration to recognize significant contributions to the U.S. Mission China. For the first time ever, locally employed staff *and* U.S. FDA direct hire staff (USDH) received recognition from the embassy for their achievements.

Members of OGPS' [China Office](#) (CNO) received two [Superior Honor Awards](#), which is presented to groups or individuals in recognition of a special act or service or sustained extraordinary performance covering a period of one year or longer. These awards are one of the highest awards presented at a Mission.



(L-R) Mandy Fu; Julia Wang; Vanessa Shaw-Dore; Nannan Zhang; Robert W. Forden, Chargé d'Affaires, a.i.; Emily Zheng; Latasha Robinson; Lixia Wang, M.D.; Nikki Sun.

For exceptional teamwork and innovation to ensure safe, effective, and adequate supply of medical personal protective equipment in the United States during the COVID-19 pandemic.

Felix Marrero – Medical Devices Consumer Safety Officer

Rachel Gomez – Food Consumer Safety Officer

Qian Wang – Locally Employed Staff

Lixia Wang – Locally Employed Staff

Meisha Sampson – Medical Products Supervisory Consumer Safety Officer

Latasha Robinson – Deputy Country Director

Vanessa Shaw-Dore – Country Director

For extraordinary contributions and outstanding service in upholding the FDA's public health mission during the China authorized departure of all FDA USDH staff.

Locally Employed Staff:

Zhe (Nikki) Sun

Huihan (Viki) Zhang

Hao (Emily) Zheng

Zimei (Mandy) Fu

Qian (Julia) Wang

Nannan Zhang

Lixia Wang, M.D.

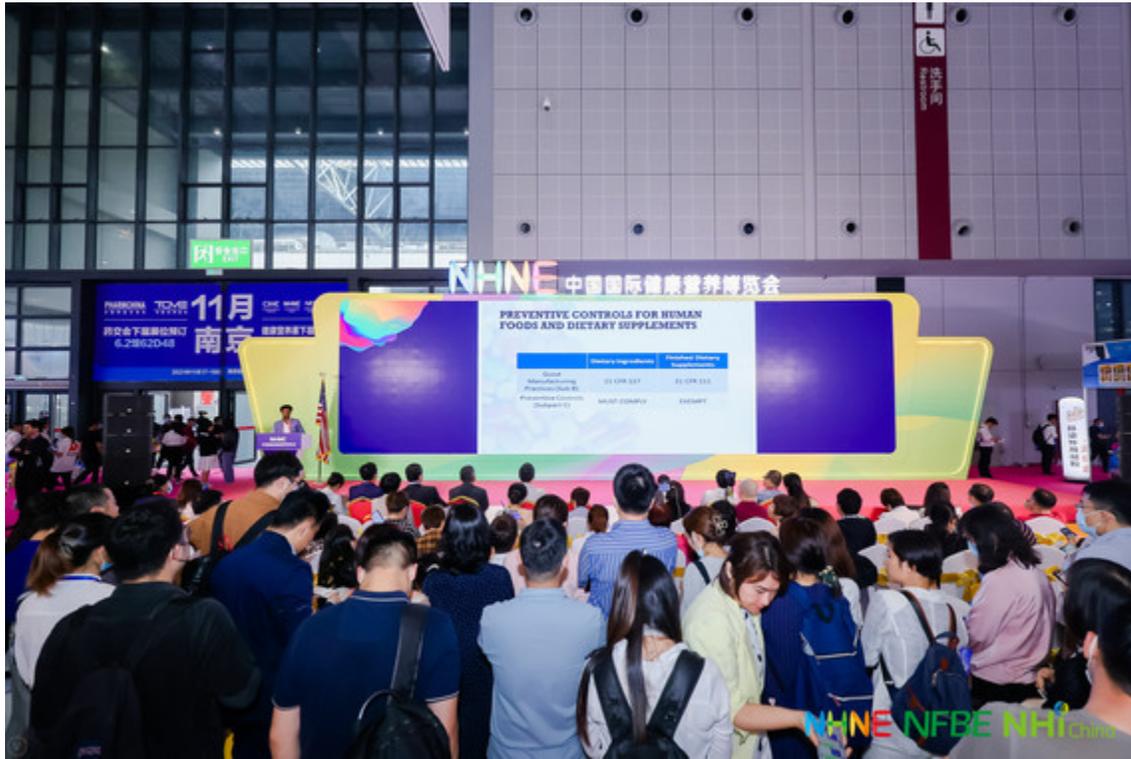
Additional awards presented to FDA personnel included the Meritorious Honor Award, issued for a special act, or sustained outstanding performance; and the Franklin Award, issued for individual achievements of importance to the U.S. Mission. An example of some of these awards include FDA staff assisting in the implementation of the recent US-China Phase 1 Trade Agreement, as well as continued safe and effective importation of medical products and foods. "The CNO was honored to be recognized for our contributions," said CNO Deputy Director Latasha Robinson.

CNO Staff Resumes Live Engagement

Although the pandemic continues to make travel within mainland China a challenge, staff in the OGPS [China Office](#) (CNO) have still managed to continue their outreach and engagement efforts with Chinese regulators and industry, traveling to various cities throughout China to participate in speaking engagements covering regulatory topics related to drugs, medical devices, and dietary supplements.

Deputy Country Director Latasha Robinson supported Mission China's [Foreign Commercial Service](#) (FCS), by participating in the [2021 Natural Health & Nutrition Expo](#) (NHNE) and USA Day in Shanghai, China. Robinson told companies considering exporting their dietary supplements to the U.S. that they must adhere to the same rules as U.S. manufacturers do, which are intended to ensure the safety of dietary ingredients and dietary supplements. These rules include Preventive Controls under the Food

Safety and Modernization Act and [Current Good Manufacturing Practice](#) in the Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.



Deputy Director Latasha Robinson (at the lectern) addresses the audience

Medical Device International Relations Specialist Scott Gonzalez participated in the 13th Annual China Medical Device International Regulators Forum in Shanghai, organized by the [Chinese Association for Medical Device Industry](#). Gonzalez presented updates on FDA medical device regulatory policy, including negotiations to reauthorize the [Medical Device User Fee Amendments](#), novel premarket pathways to market, and the FDA's new [Digital Health Center of Excellence](#), which was established in September 2020. The center is dedicated to the advancement of digital health technology, including mobile health devices, Software as a Medical Device (SaMD), wearables when used as a medical device, and technologies used to study medical products.



Medical Device International Relations Specialist Scott Gonzalez presenting updates

Country Director Shaw-Dore gave remarks at the opening plenary of the DIA China 2021 Annual Meeting that focused on FDA initiatives to strengthen regulatory science. Medical product supervisor Jonathan Chapman also attended the meeting to talk about *Pre-Approval and Pre-License Inspections*.



Country Director Vanessa Shaw-Dore and Julia Wang pictured with individuals at Yeehong University

Chapman also attended the Biologics Manufacturing & Quality Management Forum along with Program Coordinator for Medical Product Program Julia Wang and discussed the FDA's expectations for sterile drug manufacturing. The event was organized by China Pharmaceutical Association of Plant Engineering.



Jonathan Chapman speaking at the lectern

TRANSITIONS



Roy Stephens has been selected as the China Office's (CNO) Human and Animal Food Supervisory Consumer Safety Officer, replacing Jennifer Mathern, effective the week of July 5. He has been with the FDA for greater than nineteen years, mostly in Cincinnati, Ohio, serving in the consumer safety officer and supervisory consumer safety officer roles.

His background includes human food, animal feed, medical devices, drug, bioresearch monitoring, and import work, with actions resulting in seizures, injunctions, and prosecution. For the past two years, Stephens has been a food and feed consumer safety officer in the FDA China Office with recent results involving fraud detection and data integrity. In his new position, he looks forward to future interactions with government entities and the resulting opportunities to build coordination for food safety.



CDR Nicole Conklin has transitioned from the Latin America Office to the Policy Team (PPT) of OGPS' Office of Global Operations as an international policy analyst for the foods portfolio. She was previously an international relations specialist in San José, Costa Rica, where she was responsible for overseeing regional implementation efforts for the Food Safety Modernization Act.

She has collaborated with a variety of partners to design and conduct capacity development initiatives to enhance Produce Safety Rule training and information availability for Latin American growers, governments, and industry. As a result, over 4,000 growers received training.

CDR Conklin joined the FDA in 2013, as a consumer safety officer in ORA's Kansas City District conducting food manufacturing inspections and investigations. She was commissioned as an ensign in the U.S. Public Health Service while still a nursing student and served her first eight years as a clinical nurse with the Indian Health Service on the Winnebago Reservation in Nebraska.

CDR Conklin earned her Bachelor of Science in Nursing from Johns Hopkins University School of Nursing and is close to completing her Master of Public Health, Administration and Policy, from the University of Minnesota, Twin Cities.

Dear International Colleague

The Dear International Colleague Letter (DIDL) is a letter sent via email to a list-serve of about 20,000 subscribers – both D.C.-based embassies and international stakeholders.

The DICL is intended to inform these stakeholders of any FDA announcements that are relevant to an audience with international interests. Here are the most recent DICLs:

[FDA Marks World Food Safety Day 2021](#)

[Executive Order 14017 on America's Supply Chains](#)

[Regulatory Education for Industry \(REdI\) Annual Conference 2021](#)

Upcoming events

July 6 20th Anniversary of [COFEPRIS](#)

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