U.S. FOOD & DRUG ADMINISTRATION

Global Monthly Update

Summer II 2020

New Era of Smarter Food Safety Blueprint Released

On July 13, 2020, FDA Commissioner Stephen Hahn, M.D., and Deputy Commissioner for Food Policy and Response Frank Yiannas, introduced the New Era of Smarter Food Safety Blueprint that defines the course the FDA will take over the next decade to create a more modern, technology-driven and cooperative approach to food safety.

The New Era supports increased use of partnerships and dialogues between governments, standards bodies, industry groups, and public health organizations to reach achievable goals that enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models and foster the development of stronger food safety cultures around the globe.

What is it?

This new approach to food safety will leverage leading-edge technology and digital tools to create a better-traceable and safer food system. The Blueprint also recognizes the need to address the underlying psychology of a food safety mindset as critical for all players along the production and delivery chain. Four core elements represent the foundational pillars of the New Era of Smarter Food Safety Blueprint, covering the range of technologies, analytics, business models, modernization and values that are its building blocks:

I. Tech-Enabled Traceability
II. Smarter Tools and Approaches for Prevention and Outbreak Response
III. New Business Models and Retail Modernization
IV. Food Safety Culture

The goal of the blueprint is to bend the curve of foodborne illness by reducing the number of illnesses. “Smarter Food Safety to me means always looking to the future. Our destination − safe food for our families, our children, and our animals − is unchanged, said Dr. Hahn.”

How has this evolved and where do we go from here?

Last year in April, the FDA announced the New Era of Smarter Food Safety initiative. Three months later, FDA’s Foods Program leadership took the first step, selecting experts within the agency to provide their insights on how to develop the initiative. To keep pace with continually evolving food production and safety practices and technologies, the FDA is looking at emphasizing technology-driven approaches and processes. With short- and long-term activities, the Blueprint is a living document intended to keep pace with new food technologies, methods of food production and delivery.

The Office of Global Policy and Strategy (OGPS), including directors from our offices around the globe, will meet virtually this month with staff in the Office of Food Policy and Response to discuss FDA’s global approach to the New Era Blueprint, and OGPS’s role in supporting global deliverables. OGPS is in the perfect position to do this: our staff already work with international regulatory partners and rely on strong partnerships with foreign governments and organizations to support the goals of the FDA.

Why is this important?

About 13 percent of all foods consumed by Americans originate from outside of the United States. That number jumps significantly if we consider some of our most basic foods: 53 percent of fresh fruits, 29 percent of vegetables and 93 percent of seafood! The safety of the global food supply chain is thus vitally important to Americans. With expanding implementation of Blueprint-supported modern technologies – like artificial intelligence, predictive modeling, digital tracking, sensor technologies and whole genome sequencing – to enhance food growing and production practices and decisions, Americans can have greater confidence in the safety of food from the U.S. and abroad.

Watch the video.

Webinar Reveals Why Pharmaceutical Quality is a Global Priority

The Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality (OPQ), CDER Small Business and Industry Assistance (SBIA) and the OGPS India and China offices recently hosted a first-of-its-kind, nighttime, online, interactive event to help further FDA's global commitment to pharmaceutical quality. The July 23 webinar kicked off at midnight EDT so it would take place during the working hours of many of our international stakeholders.

With a significant portion of the finished drugs and active pharmaceutical ingredients used in the U.S. coming from abroad, engaging international stakeholders is essential to furthering the FDA's overall commitment to pharmaceutical quality.

Since previous SBIA conferences have drawn a large number of attendees from China and India, OPQ's Adam Fisher decided to schedule an extended webinar that could best meet the schedules of stakeholders from those countries. The organizers were thrilled that SBIA was able to accommodate and deliver on this concept. After numerous discussions, it was unanimously decided that midnight to 5 a.m. EDT would be the best time for all parties involved.

Fisher coined the phrase "Midnight Madness" even though the webinar was advertised under the formal name of "A Pharmaceutical Quality Webinar for Global Stakeholders."

Attendance statistics showed 791 unique logins – however, this may be a conservative number as one login may in fact have supported multiple viewers.

CDER's Acting Center Director Patrizia Cavazzoni, M.D., and OPQ Director Michael Kopcha, Ph.D., RPh, provided the keynote addresses while other FDA experts presented on specific topics of interest to an international audience. Two OGPS staffers, Lane Christensen, Ph.D., international program and policy analyst with the OGPS China Office (CNO), and Chris Middendorf, international relations specialist for pharmaceuticals in the India Office (INO), were among the speakers.

Christensen's webinar topic was FDA's International Mission and the Global Manufacturing Landscape. He explained CNO's mission and why its presence is important in China. Workload for the office is up due to COVID-19, he said. In China alone, the total of drug facilities registered "has more than doubled" from the inventory registered at the beginning of the year, which Christensen attributes in large part to world-wide interest in the manufacturing of alcohol-based hand sanitizers.

INO's Chris Middendorf, who recently moved from the CNO to our office in New Delhi, discussed FDA's International Office and the Pharmaceutical Quality Mission. "Because we are in-country, we have a close relationship with our stakeholders," he said. India has the largest number of FDA-registered drug manufacturing facilities outside of the United States and is one of the largest exporters of drug products to this country. FDA has strong collaborations with the Government of India, stakeholders and industry, helping to ensure a safe and reliable supply chain.

In February, Middendorf said, the Government of India and the FDA joined in establishing a Memorandum of Understanding on the safety of medical products. Included in the agreement are information-sharing, observing each other's inspections, collaborations with other entities (between agencies, state and local authorities, industry and other non-government organizations) and meetings/other engagements.

Other webinar topics included Quality Management Maturity: FDA Vision & Expectations, Major Issues and Facilities in Drug Master Files, and Pharmaceutical Quality Policies: What You Need to Know, among others. The entire webinar can be viewed in segments, here.

FDA's Actions to Protect the Public from Unsafe Hand Sanitizers

The FDA has been actively working to protect the American public from the dangers of certain alcohol-based hand sanitizers and OGPS has been playing an important role in these efforts.

> Hand hygiene has been an important part of the U.S. response to the COVID-19 pandemic. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent alcohol (also referred to as ethanol or ethyl alcohol).

Unfortunately, FDA has seen a sharp increase in hand sanitizer products that do not meet quality standards. Some contain dangerous substances while others are sub-potent. One example are products labeled to contain ethanol but actually contain unacceptable amounts of methanol (also known as wood alcohol) that can be toxic when absorbed through the skin and life-threatening when ingested.

Staff in our foreign offices have helped investigate the source of these products in the supply chain. Our Latin America Office staff worked closely with regulatory agency officials in Mexico to identify the source of methanol in hand sanitizer products and to take measures to promptly

alert the public. Since June, the FDA has compiled a list of over 160 hand sanitizers that consumers should not use.

On August 18, OGPS assisted in organizing a teleconference with international regulators, to discuss the ongoing problem. The teleconference was moderated by Bruce Ross, director of our Office of Global Operations. Other participants included Dr. Theresa Michele, director of the Office of Nonprescription Drugs in CDER's Office of New Drugs; Francis Godwin in the Office of Manufacturing Quality, which is part of CDER's Office of Compliance; and Leigh Verbois, director of the Office of Drug Security, Integrity and Response, which is also part of CDER's Office of Compliance. As Ross said in opening remarks, the FDA decided to hold the briefing to further amplify FDA's concerns and engage with regulators to better understand how the effects of the COVID-19 public health emergency are impacting international hand sanitizer product quality and supply chains. Vashti Klein on the OGPS Communications Team was responsible for facilitating the successful teleconference.

Australia's Plain Packaging Tobacco Measures Reaffirmed by WTO

On June 10, the World Trade Organization (WTO) reaffirmed its decision that Australia's plain packaging measures for tobacco products and packaging were consistent with WTO rules. In doing so, the WTO rejected appeals from the Dominican Republic and Honduras.

WTO members must ensure that their technical regulations are not more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. The WTO ruled that Australia's measures make a meaningful contribution to Australia's legitimate objective of reducing the use of, and exposure to, tobacco products. Further, the public health consequences of not fulfilling this legitimate objective are particularly grave; and the complainants did not demonstrate that proposed alternative measures would be less-trade restrictive or would make an equivalent contribution to Australia's legitimate objectives.

In 2012, Australia became the first country in the world to require plain packaging for tobacco products, directing that brand images, display logos and promotional text be removed from cigarette packages and to instead display required text and graphic health warnings. Australia introduced these measures to reduce the appeal of tobacco products, make health warnings more effective, and remove misleading information on packaging. The plain packaging measures formed part of Australia's tobacco control scheme, which included taxation measures and educational campaigns.

Transitions

Farewell

William “Bill” Sutton, assistant country director for the China office, retired from the federal government on August 15 after 37 years of public service. His FDA career began in 1983 with the Center for Devices and Radiological Health’s (CDRH) Office of Device Evaluation (now part of the Office of Product Evaluation and Quality). He worked first in a series of administrative positions there before joining the Office of Health Industry Programs, now the Office of Communication and Education and the mandated industry and international assistance program in the Division of Small Manufacturers Assistance, now the Division of Industry and Consumer Education (DICE), where he spent over twenty years.

During his tenure in DICE, Bill focused on educating industry on the center’s total product lifecycle of regulatory programs for medical devices and radiation-emitting electronic products. He also served as deputy division director of DICE where he led the division in the strategic development of regulatory education on medical devices spanning premarket and postmarket policy. Sutton took on advanced responsibilities, including chair of FDA’s Third-Party Recognition Board (TPRB), which administered both the Accredited Persons (AP) for 510(k) review and AP for Inspection programs.

In 2016, Bill joined the Office of International Programs, now the Office of Global Policy and Strategy, to work in the China Office. In this role, he served as a liaison between China and FDA in facilitating the distribution of safe and effective medical devices into the United States. Since the COVID-19 pandemic began, Bill took on a significantly increased role, due to the large volume of personal protective equipment and Class I medical devices being exported from China into the U.S.

Welcome

Anabela Marçal is the new European Medicines Agency (EMA) Liaison Official to the FDA. Her work involves supporting scientific and regulatory collaboration between the EMA and the FDA, in the context of their confidentiality arrangements. Marçal has held various positions during her 20 year tenure at the EMA, including Head of Committees and Inspections, responsible for coordination of Good Manufacturing Practices, Good Clinical Practice, Good Laboratory Practice and Pharmacovigilance Inspections for the EMA; and Head of Community Procedures, responsible for the handling of European reviews initiated on the basis of new information on quality, safety or efficacy of authorized medicinal products that might lead to regulatory actions such as a suspension of a marketing authorization.

Although she is currently working remotely in Europe, Marçal will soon relocate to the White Oak campus of the FDA in Silver Spring, Md. Marçal obtained her degree in pharmacy at the University of Lisbon and received a professional certification in hospital pharmacy. She started her career at the Portuguese National Medicines Agency (INFARMED) before moving to the United Kingdom to join the EMA in 1999. In 2019, she relocated with EMA to Amsterdam.

Discussion on Food Safety Elevates Understanding

On July 8, Europe Office (EO) Director Ritu Nalubola and EO Policy Analyst Alessandro Fiorelli held webinars at the request of both the Portuguese Economic and Food Safety Authority (ASAE) and Directorate General for Food and Veterinary Issues (DGAV), to discuss issues of common interest in food safety and nutrition. Topics of discussion included the FDA Food Safety Modernization Act (FSMA), New Era of Smarter Food Safety, FDA regulatory system on dietary supplements, International Cooperation on Food Safety and the FDA's Nutrition Innovation Strategy.

Export Listing Changed for Dairy and Infant Formula

On June 24, the U.S. Department of Agriculture's Agricultural Marketing Service announced it was eliminating plant audits for dairy and infant formula companies seeking to export to China. The change, which was effective July 1, occurred as a result of the January 1, 2020, Economic and Trade Agreement between the United States and China, in which China agreed to recognize the U.S. dairy-safety system as providing at least the same level of protection as China's dairy-safety system.

To be eligible to ship dairy products to China, U.S. dairy companies must be registered with the General Administration of Customs of the People's Republic of China (GACC). GACC registers facilities that are named on lists that are provided to GACC by FDA. Industry may apply for inclusion on these lists via the Export Listing Module (ELM). With the change in plant audit requirements, facilities wanting to be listed as eligible to export dairy and infant formula products to China no longer need to provide FDA (and FDA will no longer provide to China) confirmation that a third-party auditor has found the firm compliant with the relevant standards, laws, and regulations of China for dairy and infant formula firms.

However, FDA reminds companies intending to export dairy and infant formula products to China that the agency will include them on export lists only if the facility is in substantial compliance with applicable FDA regulations.

HHS Revises Duration of Overseas Appointments

Initially, the duration of an overseas assignment was 24 months. Eligible employees who were endorsed and approved by the Chief of Mission at the Foreign Post, their Center/Office of origin, current Foreign Post Supervisor and OGPS Senior Management could renew their tour in one-year and two-year increments for a period not to exceed 6 years in a single location, or 12 years of continuous service overseas.

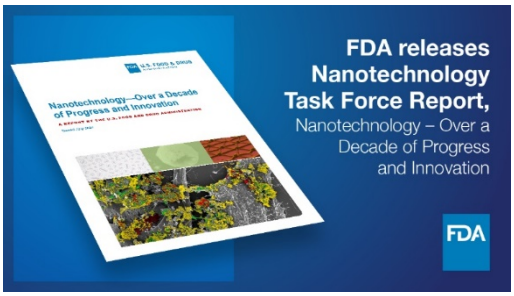
That's now changed. Effective July 17, 2020, the HHS Instruction 301-1, Overseas Employment section on Overseas Tour of Duty Appointments and Assignments has has made two revisions of note:

1. The length of standard HHS overseas tours of duty is changed to 24 or 36 months, at the discretion of the Operating Division or Staff Division.
2. The maximum 12 year consecutive assignment limit on overseas assignment is abolished.

The maximum length an employee can serve in a single country remains at 6 years.

FDA seeks to hire inspectors and senior technical experts with specialties in a given area (foods, drugs, medical devices, etc.), and a variety of skills and experience. To learn more about living and working abroad for FDA, check out this video.

Report Highlights Nanotechnology Efforts



The FDA's work in the field of nanotechnology helps build regulatory science knowledge and supports science-based regulation of products containing nanomaterial to advance public health. The FDA does not have a legal definition for nanotechnology. However, when scientists talk about nanotechnology, they typically mean the manipulation of material of extremely small dimensions, usually between 1 and 100 nanometers.

For nearly 15 years, the FDA has sought to achieve responsible nanotech development and international cooperation. Much of this work has been done through the Nanotechnology Task Force, which includes members from every Center and Office. Over the years FDA has hosted public meetings and issued industry guidance to clarify our regulatory approach that strives to ensure the safety of nanotechnology products while supporting innovation. The *Nanotechnology*

Taskforce Report, released on July 30, 2020, highlights the important efforts of the agency-wide taskforce since its last report was released in 2007.

Horizon-scanning and information exchanges with domestic and international partners can enable the FDA to enhance scientific expertise and develop the tools necessary to ensure safe use of nanotechnology and to support innovation. This has included providing global leadership through active bilateral/multilateral engagements and working with international organizations and academia to enhance understanding of science and risk-based factors for nanotech product safety and regulatory alignment.

The next generation of nanotechnology-enabled products may involve convergence with modern molecular techniques, or 3D printing of devices containing nanofeatures and nanomaterials. These would potentially result in increasing complexity and diversity of products and their uses.

As a member of the *National Nanotechnology Initiative*, the FDA has engaged with scientists in federal agencies and international partners (the European Union, India and others) regarding consensus-based standards, regulatory science and policy development.

FDA and Trade Featured at SBA International Technology Forum

A U.S. Small Business Administration International Technology Forum on August 11 brought together trade and technology experts to discuss how to navigate the new US-Mexico-Canada Trade Agreement (USMCA).

Joseph Rieras, JD, senior advisor in the Office of Trade, Mutual Recognition, and International Arrangements (OTMRIA) was a featured speaker, discussing FDA's role in trade policy and how USMCA affects FDA and regulated industries. During his talk, Rieras highlighted:

- OTMRIA's work, general trade policy framework and why FDA cares about trade and trade policy
- General points about USMCA
- USMCA's regulatory chapters and provisions that are relevant to FDA-regulated products, including medical devices

The World Trade Organization's agreement on Technical Barriers to Trade is used by countries to "regulate markets, protect their consumers, or preserve their natural resources, but they also can be used to discriminate against imports in order to protect domestic industries," Rieras said. He gave a brief overview of comprehensive trade agreements, and U.S. trade policy functions, explaining how trade agreements may be bilateral or multilateral; that is, between two countries or more than two countries. Lastly, Rieras explained emergency use authorizations, export restrictions on personal protective equipment and how the possible expiration of the USMCA will be handled. For more information about USMCA, check out our blog.

INO Staff Support Embassy Efforts During COVID-19 Lockdown

This story previously appeared in its entirety in an internal publication via the Office of Regulatory Affairs.
A special thanks to Janete Guardia and our staff in the India Office for this submission.

"Hello, US Embassy New Delhi. This is [state your name]. How can I assist you?" This was the greeting embassy personnel used when on call to assist Americans citizens that were contacting the U.S. Embassy in New Delhi wanting to return to the U.S. after the Government of India declared a nationwide lockdown and stay-at-home orders on midnight, March 22, due to the COVID-19 pandemic.

Many Americans were left stranded and wondering how to return home. The announcement created a huge influx of calls to the embassy.

Prior to the lockdown, on March 16, the embassy had authorized 100% telework for all embassy and consulate personnel – to support social distancing while still continuing the Mission's services by working from home.

All consular work was placed on limited service and many consular officers evacuated under Authorized Departure, leaving the consular office with limited staff. This impacted consulate's ability to respond to the incoming volume of concerns and questions from U.S. citizens about returning to the U.S., which ramped up after all commercial incoming and outgoing flights in India were suspended on March 22, causing thousands of Americans throughout the country to be stranded.

An all hands-on-deck approach was needed from those remaining at post to assist with repatriation efforts. OGPS's India Office (INO) responded with gusto and volunteered hundreds of hours to help repatriate 6,170 American citizens and legal permanent residents of the U.S. over a period of seven weeks. The FDA employees assisted with late night airport runs, 12-hour shift consular calls, switchboard operations and other repatriation efforts in the office.

We are thankful and proud to have the support of INO management who encouraged us to assist with the mission's task force. Sarah McMullen, deputy director of INO would send us messages of thanks and support over WhatsApp for the INO Task Force for, "assisting with airport runs and those who manned the phones over several weeks to help Americans get home."

On April 7, Ambassador to India Kenneth Ian Juster wrote, "…In addition to supporting repatriation flights, one of our key activities at the Mission is working to ensure that critical pharmaceuticals and medical supplies continue to be produced in India and flow, in part, to the United States and other countries…our colleagues in the Department of Health and Human Services, the Centers for Disease Control and Prevention, the Food and Drug Administration,

and USAID continue to do vital work supporting India's efforts to understand COVID-19 and combat its spread."

On April 14, our efforts were also acknowledged by the Secretary of State Michael R. Pompeo, made clear his appreciation for the Mission, "…success in assisting large numbers of American citizens in getting home, supporting the sourcing of key pharmaceuticals and medical supplies, assisting firms critical to the U.S. economy with their back-office operations in India, and supporting India's efforts to combat COVID-19."

In summary, the lockdown extended through May 31, and while we continued to social distance and missed our daily INO interactions at the embassy, we remained virtually engaged with each other throughout the days and weeks while teleworking.

Katie Serrano Receives Accolades from Chargé d'Affaires

The U.S. Charge d'Affaires in Bolivia Bruce Williamson formally commended Katie Serrano, director of our Latin America Office, last month for organizing a live webcast to discuss the FDA's collaborations with Latin America countries to address the COVID-19 pandemic.

"Ms. Serrano's dedication to the panel, both in time and in expertise on the topic, was vital to the success of the critical public engagement," Williamson wrote on behalf of the U.S. Embassy in Bolivia in a July 23 letter to OGPS Associate Commissioner Mark Abdoo and Office of Global Operations Director Bruce Ross. Williamson went on to describe how HHS Secretary Alex Azar expressed a desire to reengage with Bolivia to improve global health security, epidemic responses, vaccine programs, and migrant health.

More than 4,300 people viewed the broadcast.

Dear International Colleague

The *Dear International Colleague Letter* (DICL) is a letter sent via email to a list-serve of about 20,000 subscribers – both DC-based embassies and international stakeholders. The DICL is intended to inform subscribers of any FDA and OGPS announcements about the agency's international and regulatory activities. Our Communications Team has issued 28 letters, including the following DICLs issued since our last newsletter in late July:

July 29, 2020 – Food Safety and the Coronavirus Disease

July 29, 2020 – FDA Amends Its Export Listing Procedures for Dairy and Infant Formula Firms Exporting to China

July 30, 2020 – FDA Announces New Protocol for the Development and Registration of Treatments for Preharvest Agricultural Water

August 6, 2020 – FDA Announces Approval of Lampit for Treatment of Chagas Disease in Pediatric Patients

August 17, 2020 – Dangers of Certain Alcohol-Based Hand Sanitizers

August 31, 2020 – Import Screening Pilot Unleashes the Power of Data and Leverages Artificial Intelligence

September 2, 2020 – FDA is switching to a new email subscription service provider