October 2021

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FDA Deactivates Decade-Long Import Alert

On September 21, the FDA deactivated a 10-year-old import alert that had stopped the entry of certain Japanese food products from areas around the damaged Fukushima Daiichi nuclear plant.

A magnitude 9 earthquake triggering an approximately 40-foot tsunami struck the Pacific Coast of Japan on March 11, 2011. The force of the tsunami destroyed a great deal of the infrastructure along portions of the Japanese coast, including the Fukushima nuclear plant, and damage to the plant released radiological contamination to the surrounding areas.

In the wake of the disaster, the Government of Japan determined that certain food products in affected prefectures (Japan's equivalent of a U.S. state) were not fit for human consumption, due to the public health risk associated with radionuclide contamination, and prohibited those food products from sale (both within Japan and for export).

The FDA responded by issuing Import Alert #99-33 (IA) "Detention Without Physical Examination of Products from Japan due to Radionuclide Contamination." The basis for the IA is section 801(a)(2) of the Federal Food, Drug, and Cosmetic Act, which states that FDA-regulated products are subject to refusal and will be refused admission into the United States if the products appear to be forbidden or restricted for sale in the country in which they were

produced or from which they were exported. The IA was designed to match Japan's restrictions at the prefecture level.

But after an extensive analysis of Japan's robust control measures that include decontamination, monitoring and enforcement; reviewing the results of 10 years of sampling food products from Japan; and determining a very low risk to American consumers from radioactive contaminated foods imported from Japan, the FDA decided that the IA was no longer necessary to protect public health and therefore should be deactivated, the agency said in a web posting.

"This decision has been long-awaited by people in the disaster-stricken areas, and it will be of great help in their recovery efforts," then Prime Minister Yoshihide Suga said on Twitter. "Japan greatly welcomes this decision."

Going forward, Japan's control measures and the FDA's standard surveillance and sampling measures will provide multiple levels of oversight, helping to ensure that food imported from Japan does not pose a food safety risk to U.S. consumers due to radionuclide contamination, the FDA said in the posting.

Also, the FDA will continue communicating and collaborating with the Government of Japan to monitor and ensure the safety of food products exported from Japan to the United States, as it has been doing since the days following the disaster.

The Office of Global Policy and Strategy played a major role in the Fukushima announcement. Sema Hashemi, now in OGPS' Office of Global Operations, was the FDA's primary contact with Japan for 10 years and led the FDA's Fukushima working group; Anne Kirchner in the Office of Trade, Mutual Recognition, and International Arrangements, handled the trade-related aspects of the announcement; and Karen Riley, on the OGPS Communications Team, oversaw the communications rollout.

FDA and the European Medicines Agency Establish Parallel Scientific Advice Pilot To Concurrently Consider Generic Drug Applications

The FDA and the European Medicines Agency (EMA) have established a pilot program to provide parallel scientific advice to applicants of the EMA's marketing authorization applications (MAAs) for hybrid products and abbreviated new drug applications (ANDAs) for complex generic drug products.

Successful collaboration may provide applicants with a deeper understanding of the basis of regulatory decisions, may optimize product development, and could avoid unnecessary replication of studies or unnecessary testing methodologies.

The Parallel Scientific Advice Pilot Program

The Parallel Scientific Advice (PSA) pilot program allows prospective applicants of ANDAs to FDA and MAAs to EMA to submit a request for a meeting with both agencies to discuss specific questions regarding the development of complex generic drug/hybrid products. The goal is for both agencies to concurrently communicate their views on scientific issues to companies as they develop complex generic and hybrid medicines.

Candidates for the Program

Applicants seeking approval of MAAs for hybrid products (submitted to the EMA) and ANDAs for complex generic drug products (submitted to the FDA) are candidates for the PSA.

How to Apply

To submit a meeting request to the PSA pilot program, send a justification letter ("Request for PSA") to both the European Medicines Agency and the Food and Drug Administration.

Additional Resources

- For more information about the PSA pilot program, contact FDA at preANDAHelp@fda.hhs.gov
- EMA: How Scientific Advice Works
- Global Generic Drug Affairs | FDA

MRAs with UK and EU Aid in COVID Response

The FDA's agreements to exchange drug facility inspections with the European Union and the United Kingdom have taken on greater importance during the COVID-19 pandemic.

Despite pausing domestic and foreign routine surveillance inspections in March 2020 to safeguard the health and well-being of our staff, our investigators continued to conduct mission-critical inspections both domestically and abroad and other activities to ensure FDA-related industries are meeting applicable FDA requirements. While the FDA resumed prioritized domestic routine inspections, foreign inspections continue to be conducted on a mission-critical basis.

In addition to conducting limited inspections, the FDA utilized other tools, including relying on inspectional reports from EU and UK authorities. These reports were made possible under the United States-European Union Mutual Recognition Agreement (MRA) and more recently the United States-United Kingdom MRA, established in response to the UK's exit from the EU – or Brexit.

Under the MRAs, the FDA may rely on the inspectional findings of EU member states, or the UK, for a European facility that may export to the U.S.; and an EU nation or the UK may rely on the FDA's inspectional findings for a U.S. facility that exports to a nation in the EU or the UK.

Initially, the MRAs were viewed as a more efficient, less redundant, way for the FDA, EU, and UK inspectorates to oversee pharmaceutical manufacturing sites;

but with the pandemic and its limits on travel and physical access, the program has offered additional benefits.

In fiscal year 2020, about 25% of the routine drug manufacturing inspections classified by the FDA came from assessments of reports from MRA-capable authorities in the EU and UK (183 of 745 sites), according to CDER's Office of Pharmaceutical Quality's latest report on the State of Pharmaceutical Quality. In pre-COVID FY 2019, 8% of all drug quality assurance inspections that year (109 of 1,367 sites) were EU assessments. Due to the COVID-19 pandemic, the FDA used capable partner reports along with other alternative tools to support regulatory decisions (e.g., pending application review, sampling at the border).

For the first time, the FDA decided to expand the MRA program to routinely include "third-country surveillance inspections", the OPQ report said. MRA assessments grew in 2020 since the FDA had access to information in reports from the EU and the UK for inspections that were performed outside their own countries, such as in India or China.

Now the FDA is poised to extend the positive benefits of the MRAs to the inspection of facilities that make veterinary drugs. The FDA's Center for Veterinary Medicine (CVM) has been laying the groundwork for including veterinary pharmaceuticals as part of the MRAs with the EU and the UK.

Just as the FDA did with human drugs, CVM has been sharing information with those governments, observing audits, and conducting evaluations of the

regulatory frameworks of EU member states and the U.K. — and they are doing the same with the United States.

This effort has now begun to pay off. On September 27, the FDA and the United Kingdom's Veterinary Medicines Directorate (VMD) announced they were expanding the scope of their MRA to include inspections of veterinary pharmaceuticals.

In a joint statement, FDA and VMD described the action as "an important step in ensuring the safety and quality of animal drug products and will enhance efficiencies for the U.S. and UK regulatory systems."

Resources to include at the end of the article:

Mutual Recognition Agreement (MRA) | FDA

FDA to Include Animal Drugs in EU Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections | FDA

Ensuring Patient Safety and Drug Manufacturing Quality Through Partnership with European Union Regulators | FDA

FDA and United Kingdom Announce Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections of Animal Drugs | FDA

The FSP on its First Anniversary

The FDA met with Mexico's two food regulatory authorities on August 20 to reflect on what they've accomplished to ensure the safety of food imported from Mexico since establishing the Food Safety Partnership (FSP) last year.

Deputy Commissioner for Food Policy and Response Frank Yiannas opened the FSP's first annual meeting for the FDA, followed by remarks from:

- Dr. Francisco Javier Trujillo Arriaga, director in chief of the National Service of Agro-Alimentary Health, Safety and Quality Quality (SENASICA)
- Dr. Alejandro Svarch Pérez, federal commissioner of the Federal Commission for the Protection of Sanitary Risks (Cofepris)

“The FDA plans to work closely with SENASICA and Cofepris on activities that will enhance communication and oversight and enable us to share our experience with new approaches,” said Yiannas. “This kind of collaboration is critical because of the high volume of food trade across our border."

About one-third of all imported food into the U.S. is from Mexico. Of that, 60% are fruits and vegetables.

The Food Safety Partnership, established on September 2020, expanded the scope of a previous partnership that focused only on produce safety. It now includes all FDA-regulated human foods that trade between the two countries.

The FDA and its Mexican counterparts are working on four strategic priorities:

- preventing foodborne illness (e.g., *Salmonella* in papaya and *Cyclospora* in produce);
- improving outbreak response;
- coordinating regulatory laboratories (e.g., whole genome sequencing of foodborne bacteria, viruses and other pathogens); and,
- providing food safety training opportunities for industry (e.g., produce safety and preventive controls for human foods).

Over the past year, FDA, SENASICA and Cofepris have facilitated outreach and training to the produce industry by providing content in multiple languages on the FDA's Produce Safety Rule. As a result, more than 300 papaya growers and most of the Mexican papaya industry have received training on papaya best practices, such as how to avoid *Salmonella* contamination.

Resources for you:

The Food Safety Partnership Between the U.S. and Mexico Reports Progress at First Annual Meeting | FDA

FDA - Mexico, Statement of Intent for a Collaborative Partnership on Food Safety | FDA

Foreign Supplier Verification Programs https://www.fda.gov/international-programs/cooperative-arrangements/fda-mexico-statement-intent-collaborative-partnership-food-safety

STAFF NEWS

Felix Marrero Receives Prestigious Investigator Award

Five years ago, FDA consumer safety officer Felix Marrero moved more than 6,000 miles from his home in Colorado to inspect medical device plants across China. Today he's recipient of the 2021 Patrick J. Pouzar Award for Investigator of the Year. How does an ordinary guy make an extraordinary difference?

He’s got decades of expertise in public health—as a food safety educator and inspector and as a medic in the U.S. Air Force.

Along the way he earns a bachelor’s degree in human nutrition and foods, and minors in global business and business administration from the University of Houston.

But *how* Felix uses his expertise after landing in China in 2016 wins him the Office of Regulatory Affairs award for going above and beyond to protect public health.

Felix with William Sutton, former FDA international analyst, and FDA Investigator Marijo Kambere, Ph.D.

Five days to inspect…

He travels from facility to facility, across vast provinces in China, to inspect companies manufacturing medical devices destined for the United States.

Some factories are small, just 400 square feet with an outhouse, others are huge campuses with multiple storied buildings, where 100s of employees manufacture a catalogue of medical devices.

At each plant, Felix typically takes five days to make sure life support equipment and protective paraphernalia intended for sale in the United States meet FDA

quality standards: orthopedic devices, radiological and X-ray equipment, syringes, surgical masks and gowns, for example.

To determine if medical devices sold by these companies work as they should, he compares hundreds of documents to data (numbers, measurements, dates, signatures). Do numbers add up? Does material in that surgical mask meet specifications? Did they design the device, or do they just sell it? Have they contracted with another company to have *them* make all or some of it?

Felix (left) and China Office colleague Roy Stephens.

Educate to regulate

Even before he steps into an FDA registered facility, however, Felix makes sure these companies currently manufacture and ship products to the United States. He wants to know if each one's import history matches what it claims to import, if previous inspections revealed problems or if any products were recalled or caused harm.

As he inspects plants and observes how employees manufacture medical devices, Felix humanizes FDA's mission and shares his vision with the company's staff.

"I believe I've got to educate to regulate," he said. "When managers can operationalize the intent of specific regulations, when they see how following them prevents their products from harming vulnerable people, they understand regulations in a different way," said Felix.

But persuading businesspeople focused on the bottom line to effect costly changes is no easy task. "I know they have to run a business and that it costs money to follow regulations. I've got to prove how following regulations is both a requirement *and* good business," said Felix.

Every facility is different

"Inspecting a plant for the first time is like stepping into a house I've never seen to meet someone I've never met," said Felix.

Greenery, vegetables, and even fruit trees often surround buildings (companies grow their own). Traditional Chinese aphorisms written on walls in plant entrances and throughout offices and conference rooms bestow prosperity and good fortune.

Yet, every facility displays something unexpected:

- Huge metal machinery on top of a high gloss porcelain tile floor, the kind of tiles you might see in a tastefully designed kitchen in the United States.

- Redwood office desks and chairs with carved images of the mythical Phoenix and dragon symbolizing yin and yang philosophy, the union of opposites.

- A 50-by-30-foot mountain scene hand painted in beige and black strokes on a foyer wall.

- A pond with rocks beneath a glass floor in an office, its water traveling through pumps and filters to nourish green plants surrounding the building.

- 5-by-4-foot paintings of mythical Chinese warriors clad in armor, their swords raised to protect the firm.

COVID-19

In December 2019 the coronavirus erupted in China shortly before becoming a pandemic and bringing medical systems around the world to their collective knees.

By February 2020, Felix's deceptively simple job became even more complicated, more difficult, and more dangerous. "Suddenly my family and I had less than 72 hours to evacuate from China and return to the United States. We had no choice but to leave everything behind except for the luggage we carried."

Back in the States, Felix contributed his insight to U.S. workgroups deciding what personal protective equipment (PPE), mainly masks, to allow into the country. Six months later, without his family this time, he returned to inspecting manufacturing plants in China.

Patrick J. Pouzar Award

Felix joins a long list of regulators dedicated to safeguarding U.S. imports and setting a gold standard for consumer protection world-wide.

During the early part of the 20th century, chemist Harvey Wiley was the first U.S. government employee to provoke public opinion (and his superiors in the agriculture department) in order to lead the fight against companies marketing mislabeled and contaminated food. Many FDA employees followed, including Patrick J. Pouzar, for whom ORA's award is named. This FDA inspector died in a plane crash as he returned from inspecting fruit-growing regions in Chile.

In 2008, FDA's first foreign offices opened in China and India to ensure the safety and effectiveness of food, drugs, and other FDA-regulated goods entering the United States. Today, Felix advocates for U.S. public safety as one of the faces of FDA in China. "I ensure companies do what's right, what's safe, what's necessary for public health," he said.

Receiving this award tells him all the hard work has paid off, "that quality and commitment mean something, and that is so affirming and encouraging," said Felix. "I'm truly honored. And getting so many heartfelt emails from former and current colleagues was amazing," said Felix, who also received a congratulatory letter from the Chargé d'Affaires at the U.S. Embassy in Beijing, China.

He hasn’t seen his wife and two young children in almost a year. At home in the United States, they too are sacrificing during this scary time of COVID-19 so that he can do this important job. “This award,” said Felix, “is also for them.”

Rieras Selected to Lead Trade Office

Joseph Rieras has been selected as the director of the Office of Trade, Mutual Recognition, and International Arrangements (OTMRIA).

“He will oversee and lead a broad range of significant, wide-ranging and complex activities related to the FDA’s trade environment; spearhead the FDA’s negotiation, conclusion, and implementation of mutual recognition agreements; and supervise the FDA’s work to establish international arrangements, including confidentiality commitments," said Associate Commissioner Mark Abdoo, who had been acting in the role since 2019, when the new office was established.

Rieras first joined OTMRIA as a senior public health advisor in 2019, serving as FDA’s lead for trade negotiations; advising the Office of the Commissioner and the Office of Chief Counsel on complicated and high-profile issues; and training, mentoring, and guiding OTMRIA trade staff.

Rieras earned his law degree from Howard University School of Law and began his career in the international trade group of a major Washington D.C. law firm. Later, he joined the Office of the United States Trade Representative (USTR), working in the General Counsel's Office.

As an associate general counsel at USTR, Rieras represented the United States in litigation at the World Trade Organization; handled trade-related regulatory policy and legal matters; and was lead counsel for trade agreement negotiations. He also served as a USTR legal advisor based in Geneva, Switzerland.

"I'm truly honored and pleased to have been selected as the new director for OTMRIA. This dynamic office serves an important role within FDA, as it is responsible for a wide range of international activities that contribute to the agency's mission to advance public health," said Rieras. "I look forward to collaborating with colleagues as we continue to enhance OTMRIA's profile and role."

Argentina Expands Role in International Device Regulators Group

The Office of Global Policy and Strategy's Latin America Office serves as the lead for FDA's on-site presence in the 44 countries and territories that span Latin America, Central America, the Caribbean, and Mexico.

Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) has been selected as an Official Observer at meetings of the International Medical Device Regulators Forum (IMDRF).

Established in 2011, the IMDRF is a voluntary organization of device regulators, working to accelerate medical device regulatory convergence. Members seek to promote efficient and effective regulatory approaches that are both responsive to rapidly evolving technologies and yet protective of public health and safety, the IMDRF says in its mission statement.

Official Observers attend forum meetings but don't vote. To qualify, a regulator must receive unanimous approval from the 10 regulatory authorities that make up the IMDRF's Management Committee: the U.S., Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, and South Korea.

ANMAT is the IMDRF's third Official Observer, joining the World Health Organization and the United Kingdom's Medicines and Healthcare products Regulatory Agency.

Before taking on its new role, Argentina had participated in IMDRF working groups and will continue to help develop technical documents and support regulatory convergence.

ANMAT's work with the IMDRF is only one example of its efforts to work towards global regulatory harmonization. ANMAT became the first health authority in Latin America to acquire affiliate membership in the Medical Device Single Audit Program (MDSAP). The MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

Katie Serrano, director of FDA's Latin America Office (LAO), congratulated ANMAT for becoming an Official Observer and for the work it has been doing to establish itself as a leader in the region by implementing internationally agreed standards and taking a global approach to regulating medical devices.

"LAO considers ANMAT a strong partner and looks forward to strengthening collaborations in regulatory convergence to achieve our common health goal in ensuring that safe and effective medical devices are available to patients," Serrano said.

Serrano's office coordinates and strengthens regulatory systems both regionally - through the Pan American Health Organization (PAHO), the World Health Organization's regional health agency for the Americas - as well as with a select group of PAHO-recognized regulatory agencies. ANMAT is one of these select regulatory agencies.

Additional Resources

Latin America Office

International Medical Device Regulators Forum (IMDRF)

Medical Device Single Audit Program (MDSAP)

National Administration of Drugs, Foods and Medical Devices (ANMAT)

Medicines and Healthcare products Regulatory Agency (MHRA) - GOV.UK

LAO Concludes Agricultural Webinars

The Inter-American Institute for Cooperation on Agriculture (IICA), in collaboration with the Latin America Office (LAO) and the Center for Food Safety and Applied Nutrition has completed a series of 11 food safety webinars which began in April.

The webinars focused on the Food Safety and Modernization Act (FSMA) of 2011 and its Produce Safety Rule.

The act transformed food safety by shifting the focus from responding to foodborne illness to preventing it. The rule established mandatory, science-based, minimum standards for safely growing, harvesting, packing, and holding fruits and vegetables for human consumption. While the rule was finalized in 2015, compliance was staggered to give stakeholders ample time to learn about the rule before they had to comply with it.

LAO has played a significant role in disseminating information and supporting training programs on both the act and the rule.

The food safety webinars also focused on FDA's New Era of Smarter Food Safety, labelling requirements, and outbreak response, featured six FDA officials as speakers and included more than 4,000 participants from 32 countries.

International Latin America Office presenters included Regulatory Analyst Gonzalo Ibañez and International Relations Specialists Jason Cornell and Rita Vera. "An excellent venue for stakeholders to connect…better understand the Produce Safety Rule and use resources…to support compliance," said Vera. Recordings of the events are available in Spanish and English on the Intern-American Institute's website.

Webinar 1: *Cyclospora Cayetanensis* Update

Webinar 2: Food Labeling Requirements and Updates to the Nutrition Facts Label (Part 1)

Webinar 3: Comfrut (the largest frozen fruit company in Chile): Food Safety Program in the Supply Chain of the Berries Industry in Chile

Webinar 4: What to Expect During a Regulatory Inspection of the Produce Safety Rule

Webinar 5: Good Practices in Agricultural Water: Learning Experiences from Chile and Mexico

Webinar 6: PSA Grower Training: Meeting the FSMA-PSR Requirement

Webinar 7: Dole Tropical Products and FSMA Implementation

Webinar 8: FDA Food Labeling Requirements and Updates to the Nutrition Facts Label (Part 2)

Webinar 9: Biological Soil Amendments: Experiences and Recommendations for Management and Treatment

Webinar 10: Traceability and Food Safety Culture in the New Era of Smarter Food Safety Participated in the Webinar

Webinar 11: Produce Safety Rule and Intentional Adulteration Rule: Addressing the Risks, Threats, and Vulnerabilities of the Food Supply

Additional Resources

Produce Safety Rule | Inter-American Institute for Cooperation on Agriculture

Food Safety Modernization Act (FSMA)

Final rule on produce safety

OGPS Sponsors Dialogue on Good Regulatory Practices

On September 15, the Office of Global Policy and Strategy sponsored a virtual dialogue on Good Regulatory Practices (GRPs) for our colleagues around the world.

Associate Commissioner for Global Policy and Strategy Mark Abdoo kicked off the event with opening remarks. The other presenters included:

- Associate Commissioner for Policy Lauren Roth, who talked about how FDA advances public health, despite shifting administration priorities, through consistent regulatory practices;
- Jarilyn Dupont, director of regulatory policy, who talked about FDA's approaches to transparency and information quality; and,
- Ravi Bharwani, principal policy advisor in the OGPS Immediate Office, who discussed the importance of Good Regulatory Practices for regulatory cooperation and international trade.

FDA believes that regulations and regulatory frameworks that are modern, transparent, predictable, and rooted in a thorough understanding of science and risk, best position us to protect and promote public health.

These Good Regulatory Practices help ensure quality regulations. Regulators who follow these practices consult with relevant departments and agencies, rely on high-quality scientific data and information, and solicit stakeholder and public comments.

GRP principles facilitate regulatory cooperation. Built into the obligations of World Trade Organization Member States, these principles have been incorporated into modern free trade agreements, protocols, and other arrangements.

USDA and FDA Discuss Food Safety in China

The Office of Global Policy and Strategy and the U.S. Department of Agriculture hosted a joint symposium in China, on August 26, to discuss food safety issues.

Approximately 50 people representing more than 20 offices assigned to the U.S. Embassy Beijing attended the event. It was moderated by Roy Stephens, a supervisory consumer safety officer in FDA’s China Office.

(left to right): USDA/APHIS Regional Manager (Acting) Office of North Asia & Pacific Region Silvia Kreindel; USDA/FAS Senior Agricultural Attaché Office of Agricultural Affairs Adam Branson; USDA/FAS Director of Agricultural Trade Office Lashonda McLeod; CNO Director Vanessa Shaw-Dore; USDA/FSIS Director of Beijing's International Liaison Office Ronnie Dunn.

Additional Resources

China Office

USDA Foreign Agricultural Service

USDA Food Safety and Inspection Service

USDA Animal and Plant Health Inspection Service

ESTH - U.S. Embassy & Consulates in China

Asia/Pacific Office | HHS.gov

TRANSITIONS

Yvins Dezan is serving as consumer safety officer for pharmaceuticals on a 60-day detail to the India office. He previously served as an investigator in ORA's Office of Pharmaceutical Quality Operations.

Dezan has been an FDA safety officer since 2016 and has spent more than 16 years inspecting pharmaceutical manufacturers producing sterile, non-sterile, and radiopharmaceutical products.

He holds Master of Science degrees in pharmaceutical biology from Rutgers University and in pharmaceutical engineering from the New Jersey Institute of Technology. Dezan is also an ASQ-Certified Quality Auditor and an IPEC-Registered EXiPACT Auditor (International Pharmaceutical Excipients Council of the Americas).

Nancy Espinal is serving a 60-day detail as consumer safety officer for pharmaceuticals in the India Office. This is Espinal's second detail to this office; her first was in 2019 for 40 days.

Espinal earned a a master's in regulatory science from Johns Hopkins University and a bachelor's in biochemistry from Chestnut Hill College. She comes from the Office of Medical Products and Tobacco Operations, part of the Office of Regulatory Affairs.

Jake Lane joined the India Office as a consumer safety officer, inspecting foreign facilities to help ensure the safety and quality of food. He comes from Minneapolis, where he had been working as an investigator for the FDA since 2015.

Lane served in the Army from 2005 - 2009, stationed at Fort Hood, Texas, and deployed to Iraq in 2006 and 2008. He earned a bachelor's degree in philosophy and biology from the University of Minnesota. Lane also attended a legal studies program at Hamline University.

Dear International Colleague

The Dear International Colleague Letter includes FDA announcements relevant to international interests and is sent to approximately 20,000 subscribers—both Washington D.C. embassies and international stakeholders. Following are the most recent:

FDA Approves First COVID-19 Vaccine

FDA Hosts New Era of Smarter Food Safety Summit on E-Commerce

One Week Away: Generic Drug Development Conference

FDA Issues Draft Guidance on Donor Eligibility and Manufacturing of Cellular Therapies for Animals

FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations

Enhanced Drug Distribution Security in 2023 Under the DSCSA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct

FDA Issues Guidance for Voluntarily Reducing Sodium in Processed/Packaged Foods

UPCOMING EVENTS

October

October 15 Global Handwashing Day

October 16 World Food Day

October 19-21 New Era of Smarter Food Safety Summit

October 25-27 Pharmaceutical Quality Symposium 2021

October 27-28 China International Food Safety & Quality Conference

November

November 18-24 World Antimicrobial Awareness Week

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