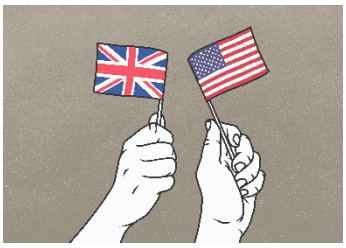
Global Monthly Update

May 2020

Negotiations Begin on Free Trade Agreement with the United Kingdom



On May 5, 2020, the United States and the United Kingdom formally launched the first round of negotiations for a comprehensive trade agreement between the two sides. Due to the ongoing global pandemic caused by COVID-19, the negotiations are taking place in a virtual format. FDA's Office of Trade, Mutual Recognition, and International Arrangements (OTMRIA) represents the FDA in these negotiations as part of an interagency U.S. delegation led by the Office of the U.S. Trade Representative.

The negotiations will hopefully produce a free trade agreement between the two countries that has "high standards in the digital and other services sectors, that will eliminate barriers to trade and that will incorporate best practices in all sectors," U.S. Trade Representative Robert Lighthizer said at the start of the talks. "If we are successful, benefit will flow to workers, farmers, and businessmen on both sides of the Atlantic."

There is almost $270 billion in two-way trade between the two countries and they are each other's largest source of foreign investment.

The U.S. and the UK are holding negotiating group sessions on a full range of typical trade agreement chapters. Both Joseph Rieras and Anne Kirchner in OTMRIA are participating, as is Jade Pham, now in the IO, who will soon move to OTMRIA. The group sessions of interest to FDA include Legal/Architecture chapters (e.g. preamble, general provisions, exceptions, etc.), Customs Administration and Trade Facilitation, Sanitary and Phytosanitary Measures, Technical Barriers to Trade, Sectoral Annexes, Good Regulatory Practices, and Dispute Settlement.

FDA/FTC Seek to Block COVID-19 Health Fraud With OGPS Assist

A number of bad actors have been trying to exploit or take advantage of fearful consumers during this COVID-19 pandemic by marketing unapproved products that fraudulently claim to mitigate, prevent, treat, diagnose or cure the disease. Many of these products are being sold online.

Both FDA and the Federal Trade Commission have responded by issuing warning letters (WLs) to marketers of COVID-related products which appear to violate the Federal Food, Drug, and Cosmetic Act and the anti-fraud provisions of the FTC Act, respectively. To date, FDA has issued more than 60 WLs notifying the marketers of the violations and providing directions and a time-frame for the company to inform FDA of its plans for corrective action. FDA then evaluates whether the company's corrections are adequate. One warning letter of note was issued to a seller of fraudulent chlorine dioxide products, equivalent to industrial bleach, frequently referred to as "Miracle Mineral Solution" or "MMS," as a treatment for COVID-19. After the seller refused to take corrective action, a federal court issued a preliminary injunction requiring the seller to immediately stop distributing its unapproved and potentially dangerous product.

Besides issuing warning letters, FDA is working with online marketplaces, domain name registrars, payment processors and social media websites, which has resulted in removal of products that fraudulently claim to mitigate, prevent, treat, diagnose or cure COVID-19 from their platforms. FDA also provides input to help keep violative products from reappearing under different names after a listing has been removed. At this time, the FDA has sent hundreds of abuse complaints to domain name registrars and online marketplaces, who in most instances, have voluntarily removed the identified postings.

Our India Office has assisted in efforts to combat fraudulent COVID-19 products. Among the first warning letters issued by FDA and the FTC to sellers of products fraudulently claiming to treat or prevent COVID-19 were warning letters issued to three Indian companies, Homeomart Indibuy, Dr. Dhole's Sushanti Homeopathy Clinic, and The GBS dba Alpha Arogya India Pvt Ltd. OGPS' India Office shared the warning letters with India's Central Drug Standard Control Organization and India's Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH). After examining the warning letters, the Drug Policy Section in the Ministry of AYUSH, New Delhi, issued its own warning letters to the implicated companies. On April 1, the Ministry of AYUSH issued an order to all Central and State/Union Territories Government Authorities "to take effective measures," which includes making a false claim a punishable offense.

FDA Voice Highlights ORA's Import Work During COVID-19

In an FDA Voice blog published on May 18, Associate Commissioner for Regulatory Affairs Judith McMeekin provided a COVID-19 supply chain update, discussing how her Office of Regulatory Affairs is helping to ensure that safe imported products are entering the U.S. during the pandemic.

As an added complication, many of the medical products health care workers and hospitals need to battle COVID-19 come from overseas, so ORA must work to ensure that products are moving as quickly as possible through the ports of entry, she said.

ORA is using the risk-ranking technology tool PREDICT on commercial shipments to release packages with accurate documentation and shipping contents in minutes rather than days while smaller, non-commercial shipments often enter through the U.S. international mail facilities and undergo their own screening process.

"FDA entry reviewers prioritize, and screen, items offered for import to verify that the shipment can be released into domestic commerce," McMeekin said. In instances where the shipper does not provide the appropriate documentation, the FDA must contact the shipper, the importer, the broker, or other parties involved, to ensure that we have complete documentation. This process can cause delays, at times creating frustration for the recipient.

During this screening process, ORA staff will find and block the entry of fraudulent products that falsely claim to prevent, diagnose, treat, or cure COVID-19. She gave an example of the sort of things they have found: fraudulent COVID-19 test kits at the international mail facilities that were declared as “water treatment,” which may lead users to incorrectly think they are protected from the virus when in fact they can unknowingly contract and spread it to others.

To minimize disruptions during the importing process, industry is being encouraged to use ORA’s special email inbox, COVID19FDAIMPORTINQUIRIES@fda.hhs.gov, for help in answering questions and resolving concerns.

Bruce Ross Brings Decades of Global Experience to New Role

Not many people can say they have lived and worked all over the world. However, Bruce Ross can. The new director of the Office of Global Operations (OGO). He began his detail in January as OGO director, overseeing FDA’s seven foreign posts, and officially accepted the permanent OGO position last month.

Ross comes to OGPS from FDA’s Office of Human and Animal Food Operations in the Office of Regulatory Affairs, where he was a Senior Advisor. His extensive experience began in 1995 with a three-year detail within the U.S. Agency for International Development (USAID) Regional Mission for Central Asia as CDC’s Deputy Director, based in Almaty, Kazakhstan. He went on to complete a two-year detail to the Carter Center’s Global 2000 Guinea Worm Eradication Program as the Resident Technical Advisor for South Sudan, based in Nairobi, Kenya.

Bruce Ross has served in Mexico City; Almaty, Kazakhstan; Kampala; Nairobi; New Delhi; Beijing; Bangkok; FDA headquarters

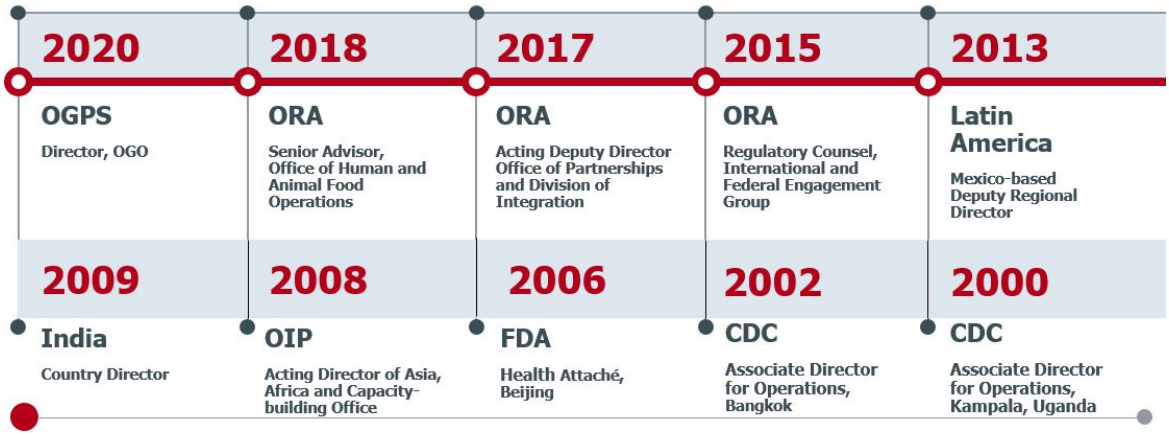
How will this depth of experience help inform how Ross oversees the work at FDA’s seven foreign posts?

“Having worked in a variety of countries and affiliated with different agencies, I have learned about their different bureaucratic procedures and how to work within them – translating one to/for the other and enabling public health programming (strengthening surveillance systems, HIV/AIDS, infectious diseases, and regulatory policy and practices) to integrate within a whole-of-government approach that meets the countries’ needs,” Ross said.

“This operational background and policy experience informs my leadership to bring an inclusive approach, an in-depth exposure to implementation processes and an understanding of how to meet the various needs in many cultural settings across the globe. "Bruce comes to OGPS from FDA’s Office of Human and Animal Food Operations in the Office of Regulatory Affairs, where he was a Senior Advisor. His extensive experience began in 1995 with a three-year detail within the U.S. Agency for International Development (USAID) Regional Mission for Central Asia as CDC’s Deputy Director, based in Almaty, Kazakhstan. He went on to complete a two-year detail to the Carter Center’s Global 2000 Guinea Worm Eradication Program as the Resident Technical Advisor for South Sudan, based in Nairobi, Kenya.

Ross holds an MPH from Boston University and a Master of Arts in International Development from American University. He received his BA in International Relations (Asian Studies) from San Francisco State University. Ross was also a professional chef, working in Chicago, San Francisco and Los Angeles in gourmet French and Italian food establishments for over seven years. Married for over 30 years, he and Suzanne have two grown daughters who joined international life beginning at ages 2 and 4; continuing through their high school graduations in Beijing and Delhi, definitely making them third-culture kids.

See more of the career trajectory for Ross below.



FDA and EFSA Strengthening Technical Cooperation on Food Safety

The European Food Safety Authority (EFSA) is an independent scientific agency responsible for risk assessment, independent risk communication and crisis management. On April 6-7, FDA, held virtual meetings with EFSA leadership and technical experts to continue their dialogue initiated during EFSA’s visit to FDA in Sept. 2019 – where both agreed to strengthen their collaboration on food safety.

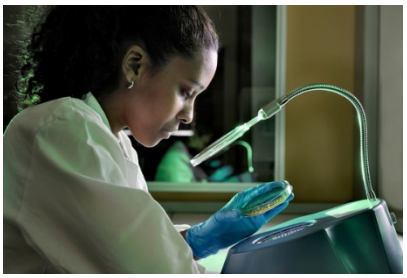
The latest meeting focused on COVID-19 and other significant updates, as well as the launching of a technical ‘cluster’ expert group on the use of whole genome sequencing for pathogen detection and outbreak investigations.

FDA presented its experience with the GenomeTrakr, the first distributed network of labs that use whole-genome sequencing for pathogen identification. The network currently includes 15 federal labs, 25 state health and university labs, 1 U.S. hospital lab, 2 other labs located in the U.S., and 21 labs located outside of the U.S.

The data, which are housed in public databases at the National Center for Biotechnology Information (NCBI), can be accessed by researchers and public health officials for real-time comparison and analysis that promises to speed foodborne illness outbreak investigations and reduce foodborne illnesses and deaths. The network is regularly sequencing over 9,000 isolates each month and all told has sequenced more than 462,000 isolates and closed more than 300 genomes.

Also discussed during the two-day meeting: the role of whole-genome sequencing in addressing antimicrobial resistance.

EFSA Releases Biotechnology-related Draft Opinions



Under the mandate of the European Commission, the EFSA has recently issued four draft opinions on different issues related to food safety and environmental risk assessments for products of gene drives, synthetic biology, and genome editing. The documents were published for public consultation with comment periods ending in late April to late May. The Europe Office, along with other U.S. agency officials, is monitoring these developments.

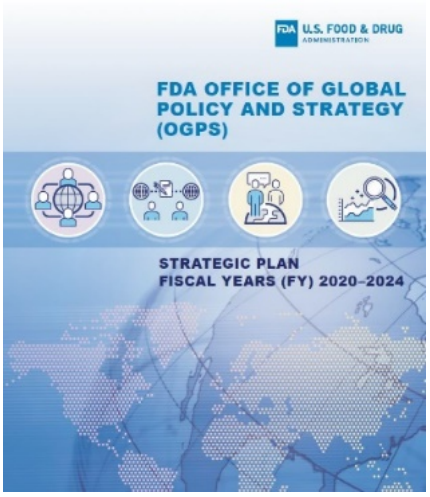
LAO Conducts Lead Trainer Reporting Webinar

The Latin America Office (LAO) hosted a webinar with the Inter-American Institute for the Cooperation on Agriculture (IICA) on May 19 to consider how to improve elements of an innovative training program designed to expand FDA's ability to ensure compliance with its Produce Safety Rule in Latin America.

The Produce Safety Alliance offers a variety of programs designed to train people who in turn can train others to become trainers, working with farmers on how to comply with the safety rule. A total of 80 people who had previously received training participated in the webinar to consider use of the PSA Trainer application program as well as challenges and creative solutions to successfully conduct PSA growers' trainings in Latin America. Since 2017, LAO has been collaborating with IICA to develop capacity for FSMA implementation.

Forty-five percent of the produce consumed in the U.S. is imported and nine of 10 top exporters of produce to the U.S. are from Latin America and the Caribbean. The webinar was jointly facilitated by LAO and IICA, was observed by the Trainer of Trainers who provided the Intensive programs and involved active participation of PSA Trainers and Lead Trainers from Mexico, Honduras, Guatemala, Dominican Republic, Costa Rica, Colombia, Ecuador, Peru, Chile, Argentina, and Brazil.

Next Steps for the OGPS Five-Year Strategic Plan



OGPS is preparing to roll-out its Strategic Plan for Fiscal Years (FY) 2020-2024 across FDA and to the general public, via a series of communications that are likely to include a blog and a Dear International Colleague letter. The report has also been posted on FDA's website. The plan identifies four complementary and connected strategic priority areas for our office: Organizational Excellence, Policy Coherence, Global Partnerships, and Information Collection and Dissemination. These four areas will guide our work and direct how we put our mission into practice. Next up: assessing progress towards successful implementation of the plan and its impacts on public health, particularly drug safety. This will require the development of new metrics and evaluation methods, both qualitative and quantitative, that are appropriate to the complex context in which the work of the office is performed. Read the report here.

WorkLife4You – Tips & Resources to Help You

This is a trying time and many of us are facing disruptions and uncertainty amid the continuing COVID-19 pandemic. Here are some resources to help you and your family navigate the challenges.

Visit www.worklife4you.com - the screen name is fda and the password is fda. This valuable resource provides on-demand webinars, articles and a personalized section to assist with your unique needs. This information is sponsored by OHCM's Work Life Programs Branch.

Upcoming Activities

June 2	Senate Finance Hearing on *COVID-19 and Beyond*: *Oversight of the FDA's Foreign Drug Manufacturing Inspection Process*. CDER Deputy Director Dr. Doug Throckmorton, Associate Commissioner for Global Policy and Strategy Mark Abdoo, and Associate Commissioner for Regulatory Affairs Judy McMeekin will testify.
June 9	Webinar – CURE ID
June 14	DIA 2020 Annual Meeting (virtual)
June 18	US-EU-EMA Bilateral Meeting (virtual)
June 19	World Sickle Cell Disease Day
June 27	National HIV Testing Day

The 14th Annual FDA Classic: "United We Walk, United We Run, United We Stand Against COVID-19," was well received with 5,343 participants. Thank you for joining your colleagues!

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