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INO Coping with India's Rebounding Pandemic

As India has confronted a massive surge of COVID-19 cases throughout the country this past month, the Office of Global Policy and Strategy's [India Office](#) (INO) has been working tirelessly with the U.S. Embassy New Delhi to contribute to the humanitarian aid organized by the White House, promoting public health in the face of a crisis that has impacted the Embassy community and all of our staff personally. The FDA India Office is leading an interagency workgroup at post which is focused on ensuring that all U.S. government donated medical products are consistent with American and Government of India regulatory expectations and meets the functionality and implementation requirements for use within India. This "one-USG" Embassy working group continues to work together with our regulatory counterparts on the ground, and within the needs identified by the Indian Government, to make additional donation recommendations.

For its part in this effort, the FDA has assisted U.S. companies navigate the process in India of providing over a million N95 respirators, hundreds of thousands of rapid-testing kits, over a hundred thousand vials of the anti-viral drug remdesivir, oxygen cylinders, and raw materials for vaccine manufacture. This engagement, including facilitating Indian manufacturers' access to source materials from U.S. manufacturers, which has been helpful as India grapples with its response to COVID-19 surging across the country.



Image courtesy of <https://twitter.com/USAndIndia>

At the beginning of May, the U.S. began deploying [planeloads](#) of life-saving donated supplies to New Delhi. “We believe this important interagency work is a model for international collaboration and for future global missions for similar crisis situations,” said Bruce Ross, director of the OGPS' [Office of Global Operations](#), which oversees the foreign offices at the FDA.

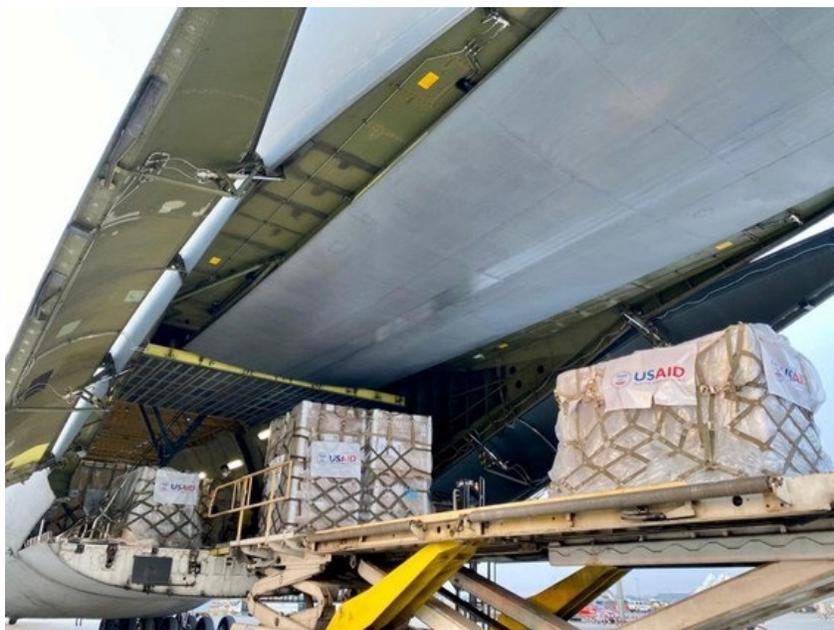


Image courtesy of <https://twitter.com/USAndIndia>

Throughout the pandemic, the INO worked closely – and continues to do so – with the Government of India to resolve COVID-19 export concerns. They helped to facilitate the release of critical medical products from export restrictions and assisted in providing information on Indian manufacturers of critical medical goods while the U.S. was experiencing its own COVID outbreak surges. The India Office also contributed to the FDA’s oversight of pharmaceutical and biological monitoring facilities by completing numerous remote interactive evaluations.

On April 28, the Department of State authorized the voluntary departure of family members of U.S. government employees in Mission India. Then on May 5, the Department of State authorized the voluntary departure of U.S. government non-emergency employees in Mission India. This has since been extended for an additional 30-days, through June 26, 2021. All INO staff and their families have opted for repatriation, except for the acting country director.

FDA’s Inspectional Roadmap Released for Both Domestic and Foreign Inspections

This month, the FDA released its [Resiliency Roadmap for FDA Inspectional Oversight](#), which covers inspectional activities during the COVID-19 pandemic and a detailed plan of moving toward a more consistent state of operations – including the agency’s related priorities going forward.



The report also outlines inspections that the agency was unable to complete during the past year due to travel restrictions or inability to ensure the safety of our workforce or the workforces the agency regulates.

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. These consist of inspections of: facilities for which there was a drug shortage, as well as inspections needed for the approval of novel drugs or drugs related to the potential treatment of COVID-19; support for pre-market and pre-license applications; and response to foodborne disease outbreaks or other food safety risks such as undeclared allergens.

For our foreign posts in [China](#) and [India](#), performing priority inspections is a large portion of the workplan, and despite not being able to conduct in-person inspections for

much of the past year, the FDA has been leveraging our other oversight tools as outlined in the Roadmap. The China Office resumed performing certain in-country inspections in October of 2020 and is continuing to perform inspections in accordance with the risk-based approach spelled out in the Roadmap.

Our consumer safety officers in China and India have also been reviewing records and conducting remote interactive evaluations to assess applications and determine the Current Good Manufacturing Process compliance of facilities, leveraging their in-country knowledge, as well as time-zone proximity to perform oversight of foreign drug and bioresearch monitoring facilities.

The Roadmap also delves into alternative methods for oversight of FDA-regulated products like leveraging information shared by trusted foreign regulatory partners through mutual recognition and confidentiality commitments. The [Office of Trade, Mutual Recognition, and International Arrangements](#), part of the [Office Global Policy and Strategy](#), assists the agency by entering into arrangements and sharing information with global counterparts.

The Roadmap plans for accomplishing postponed surveillance work based on base-/best-/worst-case scenarios, given the continued uncertainty of the ongoing pandemic. (*Resiliency Roadmap for FDA Inspectional Oversight*, p.15) These possible scenarios consider continued uncertainty related to potential surges of COVID-19 and will guide the FDA's inspectional operational strategies. Inspections considered critical to the FDA's mission will remain the primary focus.

Annual World Health Assembly Kicks Off

Ending the pandemic and preventing the next one and building together a healthier, safer and fairer world is the theme of this year's virtual World Health Assembly (WHA) which began on May 24 and runs through June 1.



The WHA is the governing body of the World Health Organization (WHO) which meets annually to discuss an agenda prepared by the WHO's [Executive Board](#). It is attended by delegations led by the health ministers from the WHO's 194 Member States. Topics on this year's agenda include:

- Global action on patient safety
- Global strategy and plan of action on public health, innovation and intellectual property
- Substandard and falsified medical products
- Standardization of medical devices nomenclature
- Immunization Agenda 2030
- Public health emergencies: preparedness and response

FDA Deputy Commissioner for Policy, Legislation, and International Affairs [Andi Fristedt](#) is representing the FDA as a member of the U.S. delegation led by the Health and Human Services (HHS) [Secretary Xavier Becerra](#). In addition, officials from other HHS operating divisions, the Department of State, the U.S. Agency for International Development, the Departments of Commerce and of Agriculture and the Office of the U.S. Trade Representative are included in the delegation.

The Office of Global Policy and Strategy works closely with the FDA Centers and Offices to prepare for the Assembly and serves as the lead and the coordination point for cross-cutting issues with the WHO and as the point of contact with the HHS Office of Global Affairs in developing, reviewing, and clearing U.S. Government policy positions for WHO governance forums, such as the WHA and the WHO Executive Board.

The WHA74 (the 74th World Health Assembly) annual meeting will be available for live streaming and recorded for those who want to [view it later](#).

Inaugural World Local Production Forum Expected to Expand Access

The Local Production and Assistance Unit (LPA), part of the [World Health Organization](#) (WHO) will host the inaugural World Local Production Forum (WLPF), *Enhancing access to medicines and other health technologies*, virtually on June 21-25. The Local Production and Assistance unit supports Member States in strengthening sustainable local production and technology transfer to improve access to quality-assured health products in a holistic and strategic manner in collaboration with governments, partners, and other stakeholders.

The WLPF will be a regular global forum for the global community – governments, strategic partners, non-governmental organizations, civil societies, technology experts, industry, and others – to stimulate engagement, dialogue and collaboration on addressing key challenges and bottlenecks in promoting local production and [technology transfer](#) to improve access and strengthen health security.



The Forum will be structured as a series of individual sessions focused on key themes most relevant to local production and technology transfer. On June 22, FDA Acting Commissioner [Janet Woodcock, M.D.](#), will participate as a panelist in a session entitled, "Regulatory systems: how agile can they be in pandemic times." Panelists will discuss:

Regulatory responses during public health emergencies: how do they support timely access?

Leveraging on the WHO Emergency Use Listing to improve access to health products.

What is the role of regional national regulatory authorities (NRA) harmonization in promoting local production?

Joining Dr. Woodcock on the panel will be representatives from the European Medicines Agency, Ghana Food and Drugs Authority, Jordan Food and Drug Administration, and the New Partnership for Africa's Development. There will be a Q&A at the conclusion of the session.

NMPA Issues 2020 Drug and Device Statistics

With the Chinese government reorganization in 2018, the National Medical Products Administration (NMPA) is now China's primary pharmaceutical and medical device regulatory agency. NMPA is organized under the State Administration for Market Regulation (SAMR), a ministry that covers company registration, product and consumer protection regulation, advertising, and standardization, among other areas. Previously, the China Food and Drug Administration – a stand-alone ministry – regulated food, medical products, and cosmetics; now it is a smaller, specialized product regulator under SAMR. The NMPA is responsible for most aspects of pre-market approval and many post-marketing activities for drugs and devices.

In late April, the NMPA released its *2020 Drug Regulatory Statistical Annual Report*, which provides information for the 2020 calendar year for both drugs and devices. Here's a summary of pertinent information:



Pharmaceutical manufacturers/distributors: In 2020, there were 7,960 businesses with valid pharmaceutical manufacturer licenses (including traditional Chinese medicine (TCM) finished and crude drugs, and medical oxygen producers). Of the total, there were 4,460 manufacturers of APIs and drug formulations, down 1.52% from 2019. There were 3,519 chemical drug manufacturers, 4,357 TCM manufacturers, 671 medical oxygen manufacturers, and 224 special control drug substance producers.

Drug registration: In 2020, the NMPA for imported drugs (including those from Hong Kong, Macao, and Taiwan) accepted 587 clinical trial applications (CTAs), 300 new drug applications (NDAs), 320 renewal registration applications, and 3,685 supplemental applications. For domestic drugs, it accepted: 1,099 CTAs; 1,076 NDAs; 1,520 supplemental applications; and 881 generic quality and clinical equivalence

(GQCE) evaluation applications. It also accepted 489 temporary drug import applications (for urgently-needed drugs that are in-process for a renewed registration certificate).

Drug Inspections, and administrative enforcements: In 2020, all levels of China's drug regulatory agencies conducted a total of 19,900 inspections of pharmaceutical manufacturers. Those inspections identified: 202 law breakers; 2,293 regulation violators; 3,262 completing corrections; and 284 that were investigated and prosecuted. All levels of drug regulatory agencies conducted a total of 3,042,500 inspections of pharmaceutical distributors. Of these, 47,500 inspections were of wholesalers and of those inspections, 5,855 were regulation violators, and 6,451 were completing corrections.

Medical Device Listing: In 2020, the NMPA approved a total of 15,208 medical devices as first-time listings with 13,636 as Class II devices, 1,020 as Class III devices, 552 as import devices (including those from Hong Kong, Macao, and Taiwan), and 14,618 devices as renewal listings. At the end of 2020, there were a total of 100,074 domestic Class I devices and 7,913 import Class I devices filed (including those from Hong Kong, Macao, and Taiwan).

Medical Devices Adverse Event Monitoring: The National Drug Adverse Drug Reaction (ADR) Monitoring Center received a total of 536,100 ADR reports related to medical devices, including 32,900 serious cases, and 218 death reports. The reports involved 88 types of products.

The Office of Global Policy and Strategy's (OGPS) China Office is the FDA's lead for keeping abreast of these statistics.

Transitions



Rita Vera has joined the Latin America Office as an international relations specialist based out of San Jose, Costa Rica, where she will focus on food commodities. She was previously an international policy analyst with the FDA's Center for Food Safety and Applied Nutrition (CFSAN) for five years. There, she led the Systems Recognition program. Vera has also worked as a public health liaison at the FDA's Center for Tobacco Products. She has interned with the World Health Organization and Legal Aid Cape Town.

Vera received her Juris Doctor from the University of Maryland Carey School of Law and her bachelor's degree in political science from St. Mary's College of Maryland.



Vesa Vuniqi has joined the Latin America Office as an international relations specialist based out of San Jose, Costa Rica, where she will focus on medical products. She was previously a senior biomedical engineer within the Office of Product Quality at the FDA's Center for Devices and Radiological Health, leading a team responsible for premarket and postmarket activities related to orthopedic medical devices.

Vuniqi has a bachelor's degree in chemistry and biological sciences and a master's degree in biomedical engineering from Wayne State University in Detroit.



Meisha Sampson has returned to OGPS headquarters after serving as a Supervisory Consumer Safety Officer in the China Office where she handled medical product inspection activities.

In her new role, she will serve as a management analyst within the OGPS Immediate Office.



Lane Christensen, Ph.D., has returned to the U.S. from the China Office where he served as an international program and policy analyst. He is currently working as a chemist in the Office of Pharmaceutical Quality (OPQ), part of the FDA's Center for Drug Evaluation and Research.

OPQ works to assure that quality medicines are available to the American public.

OGPS Acknowledges Public Service Recognition Week

Since 1985, the first week of May is set aside to pay tribute to government employees through the Public Service Recognition Week (PSRW) campaign. This year, from May 2-8, many employees throughout the country and abroad showed their support for [#IServeBecause](#) by posting messages and videos on social media.

Several OGPS staff participated in PSRW. From left to right: China Office Consumer Safety Officer Jonathan Chapman; former China Office Supervisory Consumer Safety

Officer Meisha Sampson; China Office Consumer Safety Officer Rachel Gomez; China Office Consumer Safety Officer Raicine Campbell; Latin America Office International Relations Specialist Jason Cornell; China Office Director Vanessa Shaw-Dore; and China Office Consumer Safety Officer Roy Stephens.



[2021 White House Proclamation](#)

[Watch the video from President Joe Biden](#)

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 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 Launching New Era of Smarter Food Safety Traceability Challenge

FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents

FDA Opens Industry Portal for FSVP Records Submission

Resiliency Roadmap for FDA Inspectional Oversight (5-5)

SBIA training

FDA Commits to Evidence-Based Actions on Two Tobacco Product Standards

15th Annual FDA Classic

LAO staff



The Serrano's (Mario and Katie); Vesa Vuniqi; Alberto and Patty Pineda; Michelle Rodriguez; Alejandro Cevallos; Nicki Conklin; Rita Vera

Headquarters staff



Pictured: (l-r) Heidi Marks, Communications Team; Paulette Dawes, Program Support Team; Anna Ferus, Global Engagements Team

Upcoming events

June 5	40th Anniversary of MMWR HIV.gov
June 7	World Food Safety Day United Nations
June 11-13	2021 G7 Summit - Cornwall Council
June 21-25	World Local Production Forum
June 27-July 1	DIA Global Annual Meeting 2021

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