FDA STATEMENT

Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections

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Statement From:

Commissioner of Food and Drugs - Food and Drug Administration
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Español (/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-inspecciones-en-el-extranjero)

Today, we are providing an update on the status of U.S. Food and Drug Administration inspections outside of the U.S. in response to the COVID-19 outbreak. After careful consideration, the FDA is postponing most foreign inspections through April, effective immediately. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis.

The FDA based this decision on a number of factors, including State Department Level 4 travel advisories in which travel is prohibited for U.S. government employees, Centers for Disease Control and Prevention travel recommendations, access restrictions being imposed on foreign visitors by certain countries, guidance from the Office of Personnel Management and the importance of the health and safety of our employees. Another critical factor in taking this action is the confidence we have in our ability to maintain oversight over international manufacturers and imported products using alternative tools and methods.

We are aware of how this action may impact other FDA responsibilities, including product application reviews. We will be vigilant and monitor the situation very closely and will try to mitigate potential impacts from this outbreak in lockstep with the whole of the federal government. We stand ready to resume foreign inspections as soon as feasible.

When we are temporarily not able to physically inspect foreign produced FDA-regulated products or manufacturers, as an interim measure we employ additional tools to ensure the safety of products imported to the U.S., which have proved effective in the past. These include denying entry of unsafe products into the U.S., physical examinations and/or product sampling at our borders, reviewing a firm's previous compliance history, using information sharing from foreign governments as part of mutual recognition and confidentiality agreements and requesting records "in advance of or in lieu of" on-site drug inspections. For example, we began exercising this authority when we postponed on-the-ground inspections of

manufacturers of FDA-regulated products in China earlier in the outbreak. This is all part of the FDA's multi-pronged and risk-based approach to ensuring quality, as well as compliance, with applicable federal laws and regulations.

The FDA will continue working with U.S. Customs and Border Protection to target products intended for importation into the U.S. that violate applicable legal requirements for FDA-regulated products, which may come from a variety of sources, such as first-time importers unfamiliar with regulatory requirements or repeat offenders trying to skirt the law. The FDA has the ability through our risk-based import screening tool (PREDICT) to focus our examinations and sample collections based on heightened concerns of specific products being entered into U.S. commerce. The PREDICT screening continues to adjust risk scores as necessary throughout the COVID-19 outbreak. We are keeping a close eye out for indications of port shopping or cargo diversion and will continue our oversight of shipments through potentially higher-risk venues such as International Mail Facilities. We can refuse admission of products that fail sample testing or may violate other applicable legal requirements.

Americans can rest assured the FDA is diligently monitoring this outbreak and the impact to our operations. Our leadership team meets daily to talk about the myriad of urgent issues facing us as we actively facilitate efforts to diagnose, treat and prevent the disease; survey the medical product supply chain for potential shortages or disruptions and help to mitigate such impacts, as necessary; and leverage the full breadth of our public health tools, including enforcement tools to stop fraudulent COVID-19 activity.

As this remains a dynamic situation, we will continue to assess and calibrate our approach as needed to help advance federal response efforts in the fight against this outbreak.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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