The ongoing spread of the novel coronavirus has prompted the U.S. Food and Drug Administration (FDA) to postpone most foreign inspections of manufacturing facilities. On March 10, 2020, the FDA provided an update on the status of FDA inspections outside of the U.S. in response to the COVID-19 outbreak where it noted that it will immediately postpone most foreign inspections until April 2020. Additionally, the FDA canceled all foreign travel by agency officials and said it is limiting domestic travel to “mission critical only” through April. Last month, FDA stopped conducting inspections in China.

In its update, FDA stated that when it is not temporarily able to physically inspect foreign produced FDA-regulated products or manufacturers, it will employ additional measures to ensure the safety of products imported to the U.S., which include denying entry of unsafe products into the country, physical examinations and/or product sampling at borders, reviewing a company’s previous compliance history, and using information sharing from foreign governments as part of mutual recognition and confidentiality agreements.

The FDA also noted that it will continue to partner 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 who may be unfamiliar with regulatory requirements or repeat offenders trying to circumvent the law.

FDA mentioned that it will continue to assess and calibrate its approach as needed to help advance federal response efforts in the fight against COVID-19. We will continue to monitor any developments.

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