



The Bottom Line

APRIL 2020 | VOL. 31

THE FOOD AND DRUG ADMINISTRATION'S REACTION TO THE COVID-19 CRISIS IN THE UNITED STATES

Summary

Confirmation of shortages of medical supplies—combined with a growing panic in the United States—may lead companies to either try to help or capitalize on importing masks, hand sanitizer, and other medical supplies to the United States without being aware of the additional regulatory requirements.

Background

On December 31, China alerted the World Health Organization (WHO) to several cases of a pneumonia-like illness in the city of Wuhan. Within weeks, Wuhan was quarantined and gatherings for the upcoming Lunar New Year were canceled. Travelers returning to their home countries spread the virus outside of mainland China, including the west coast of the United States. By the beginning of March, the rate of new cases was beginning to outpace the availability of supplies to keep uninfected medical staff, first responders, and family members protected from the illness. As Chinese manufacturing ramps back up to full capacity, imports of personal protective equipment (PPE) will increase.

Current Status

Both the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have been balancing the urgent need to allow the efficient import of personal protective equipment with the equally urgent need to protect the United States from unsafe, misleading or dangerous products. Under normal circumstances, equipment designed to prevent the spread of disease in a medical environment, such as gloves, face masks, face shields, respirators, and hand sanitizer, are regulated by the Food and Drug Administration (FDA) to ensure that they meet minimum safety requirements. The FDA requires registration for anyone (manufacturer, importer or distributor) introducing regulated medical devices into the United States' market. The individual devices are inspected and assigned a device listing number. In order to process an import of these products, the Customs entry must include registration numbers for all the parties involved and the products being imported.

Face masks can be designed for either medical or nonmedical use. Masks designated for nonmedical use are required to meet standards set by the National Institute of Occupational Safety and Health (NIOSH). Manufacturers of masks that meet NIOSH standards are not required to register with the FDA, but the masks are required to be identified as not intended for medical use.

In order to facilitate the import of masks, the FDA has issued an Emergency Use Authorization (EUA) which makes the reporting of the registration information optional. This allows for the import of NIOSH-approved masks as medical devices. The EUA also covers non-NIOSH approved masks that have been validated to meet specific performance standards or have a marketing authorization from certain countries.

Impact

The EUA does not open the U.S. market to anyone and everyone looking to import masks. The best way to ensure approval of imports is to follow the procedures in place before the crisis – registration of the parties and products involved.

In addition to masks, the FDA is regulating COVID-19 test kits, hand sanitizer, potential vaccines, and possible treatments. The FDA has not authorized any test that is available for testing yourself at home, nor have they approved any product to prevent COVID-19. Fraudulent COVID-19 products can come in many forms, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines. The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products in order to keep us all safe.

RESOURCES:

[FDA Warning of Fraudulent Products \(FDA\)](#)
[CBP Seizes Fake Cleaning Products \(Breitbart\)](#)
[Bringing Face Masks to Market \(FDA Imports\)](#)