GUIDANCE ON IMPORTS OF MEDICAL DEVICES & PPE DURING COVID-19

The U.S. Food and Drug Administration (FDA) developed guides and information needed for importing Personal Protective Equipment (PPE) and medical devices during the COVID-19 outbreak.

The FDA has taken critical steps to respond while maintaining safe and secure access to the needed resources. The FDA has done this through two different mechanisms:

- Emergency Use Authorization (EAU) – Allows FDA to strengthen the nation's public health protections against chemical, biological, radiological and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures (MCM) needed during public health emergencies. This includes PPE, diagnostic tests, and other devices.
- Establishment of enforcement for guidance – Policy documents for COVID-19 and the EUA intended to remain in effect for the duration of this public health emergency. This guidance is for testing and policies related to face masks and respirators.

GUIDANCE DOCUMENTS FOR INDUSTRY

Below is a listing of guidance documents that have been issued for specific products related to COVID-19, which reference applicable product codes and policy:

Face Masks and Respirators
Diagnostic Tests
Non-Invasive Remote Monitoring Devices
Gowns, Other Apparel and Gloves
Ventilators and Respiratory Devices
Sterilizers, Disinfectant Devices and Air Purifiers

A full list of all guidance documents related to COVID-19 is also available on FDA's website. Questions regarding these instructions, product code assistance for these products, or to resolve entry issues can be submitted to FDA at: 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov. Step-by-Step instructions on how to register and list can be found here.

COVID-19 PRODUCT IMPORT INSTRUCTIONS

The FDA, through a U.S. Customs' Cargo Systems Messaging Service (CSMS #42168200), provided instructions to the import community regarding the submission of entry information for PPE and certain other medical devices. The CSMS provided the following instructions to help facilitate the import process for products related to the COVID-19 public health emergency that fall into one of the following three categories:

Non-FDA regulated general-purpose personal protective equipment (masks, respirators, gloves, etc.)

PPE for general purpose or industrial use (products that are not intended for use to prevent disease or illness) is not regulated by the FDA and no information is required to be submitted to the FDA.

Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA)

When entering these goods into the U.S. an Intended Use Code of 940.000: *Compassionate Use/Emergency Use Device*, and an appropriate FDA product code should be submitted to FDA.

Below is a list of EUA authorized product codes:

- Diagnostic tests: 83QKP, 83QKO, 83QJR
- Masks/Respirators: 80NZJ

A full list of EUA currently in place for the COVID-19 emergency is available on FDA's website.

Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

When importing the goods into the U.S., the appropriate Intended Use Code 081.006: *Enforcement discretion per final guidance*, and an appropriate FDA product code should be submitted to the FDA.

FDA GUIDANCE ON KN95 MASKS

KN95 masks are an equivalent Chinese-alternative to the scarce N95 mask. The FDA has advised that they are using the CDC Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies information to expand access, which includes similar masks from multiple countries, including China's KN95 mask. The CDC guidance identifies the specific respirators approved under the standards of other countries that are similar to the N95 masks.

Although the FDA does not confirm the performance of the masks that are not coverned under the EUA, however, they do not object to importation of these other country approved masks during this emergency.

HAND SANITIZERS, ANTIBACTERIAL "SOAPS"

Hand sanitizer is an FDA regulated over-the-counter drug requiring transmission of the registration of the manufacturer and the drug listing number. Questions regarding hand sanitizers can be submitted to COVID-19-Hand-Sanitizers@fda.hhs.gov.

The FDA considers most hand soaps or bath soaps cosmetics and does not require any drug reporting. However, antibacterial, disinfectant or similar claims fall under the jurisdiction of the FDA as a drug and requires the manufacturer to be registered, and the drug listing number.

SURFACE DISINFECTANTS

Surface disinfectants are regulated by the Environmental Protection Agency (EPA). Importers must determine whether the product is regulated as a pesticide under the guidance document published by the EPA. If the goods are considered to be a pesticide; prior notice will need to be filed with the EPA. If the goods are not regulated as a pesticide then they may be subject to EPA TSCA reporting requirements.

ENTRY OF FRAUDULENT COVID-19 PRODUCTS

The FDA, along with their partners at U.S. Customs and Border Protection (CBP), is taking all available steps to identify and deny entry of products that claim to cure, treat or prevent COVID-19, or are test kits for in-home testing for COVID-19.

As indicated in FDA's Consumer Update, there are currently no vaccines to prevent or drugs to treat COVID-19 approved by the FDA. The FDA also alerted the American public that, at this time, the FDA has not authorized any test that is available to purchase for at-home testing for COVID-19.

ADDITIONAL INFORMATION

More information from the FDA in regards to COVID-19 is available at the link below.
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions