



FedEx Regulatory Alerts & Updates

Regulatory Alert Update: FDA Import Requirements for Personal Protective Equipment

April 8, 2020

BACKGROUND INFORMATION

The U.S. Food and Drug Administration (FDA) provided instruction to the import community via CSMS messages #42124872, #42168200 and #42272898 regarding the submission of FDA entry information for certain personal protective equipment (PPE) and other devices. Following the FDA's instructions will help facilitate the import process for products related to the coronavirus disease 2019 (COVID-19) public health emergency.

Note: The circumstances surrounding the COVID-19 public health emergency are very fluid and subject to rapid changes.

WHAT HAS CHANGED?

In CSMS message #42272898 issued on April 3, 2020, the FDA provided an updated list of products that are regulated by the FDA as devices which are not authorized by an Emergency Use Authorization (EUA), but where an enforcement discretion policy has been published in a guidance document.

The new product categories on the list include clinical thermometers, gowns and gloves, sterilizers, air purifiers, face masks, and respirators.

Qualifying products are designated by the FDA intended use code 081.006.

There is a link included in the References section below that leads to the full list of FDA guidance documents. Further information regarding which product codes fall within the scope of each guidance can be found there.

Q&A

Q1: How do I find my medical device's FDA product code?

A1: The FDA has a web page dedicated to product code classification which provides information about how to find a product code. A link to this site is provided in the References section.

Further questions regarding appropriate product coding or intended use can be submitted to FDA at COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

REFERENCES:

CSMS message #42272898:

https://content.govdelivery.com/bulletins/gd/USDHSCBP-2850882?wgt_ref=USDHSCBP_WIDGET_2

CSMS message #42124872:

https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt_ref=USDHSCBP_WIDGET_2%3Futm_source%3Dsearch.usa.gov&utm_medium=search.usa.gov&utm_term=undefined&utm_content=undefined&utm_campaign=%28not+set%29&gclid=undefined&dclid=undefined&GAID=102834089.1540533732

CSMS message #42168200:

<https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2836f88>

Link to all FDA COVID-19 guidance documents:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>

FDA Personal Protective Equipment (PPE) web page:

<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control>

FDA Product Code Finder web page:

<https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database>

Link to RegAlert 20-050 - FDA Import Requirements for Personal Protective Equipment:

https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert_20-050_FDA_Import_Requirements_for_Personal_Protectetive_Equipment.pdf