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insights

TYPES NOT MAPPED YET April 16, 2020 | TTR not mapped yet | Robert A. Shapiro

Importing face masks and personal protective equipment during COVID-19

The Coronavirus Disease (COVID-19) pandemic has driven a demand for Personal Protective Equipment (PPE) by both health care professionals (HCP) and the general public. The Food and Drug Administration (FDA) has published several Emergency Use Authorizations (EUA) and enforcement guidance in an effort to increase the availability of face masks, respirators and similar PPE. In this article, we address the general regulatory environment and challenges associated with the importation of face masks, respirators and similar PPE into the United States during the COVID-19 public health emergency.[1] U.S. Customs and Border Protection (CBP) has also published guidance to address how customs entries for PPE should be prepared. This is an area of rapid change. Importers are encouraged to monitor this space for additional information.

FDA response to COVID-19

Devices covered

PPE falls under the definition of a "medical device" under Section 201(h) of the Federal Food, Drug, and Cosmetic Act and is regulated by the Food and Drug Administration (FDA) when it is "intended for use…in the cure, mitigation, treatment, or prevention of disease…." The FDA will examine various factors in determining whether the PPE is a medical device, including whether:

- The items are labeled or otherwise intended for use by a health care professional (HCP)
- The items are labeled or otherwise for use in a healthcare facility or environment; and
- The items include any drugs, biologics or anti-microbial/anti-viral agents.

Items not intended for medical purposes are not medical devices. Furthermore, FDA "does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared masks or respirators, are available."

Regulatory changes during the COVID-19 pandemic

Since February 29, 2020, the FDA has issued 23 guidance memoranda for industry and/or FDA staff about the alteration of enforcement or regulatory requirements in light of the COVID-19 crisis. The FDA has issued Emergency Use Authorizations (EUAs) to allow certain otherwise unauthorized respirators to be used in healthcare settings by HCPs. The EUAs include authorization to use certain National Institute of Occupational Safety and Health (NIOSH)-approved disposable respirators (FFRs, PAPRs, and reusable respirators); expired or decontaminated respirators; and certain non-NIOSH-approved respirators, including certain respirators from China, in healthcare settings by HCP, during the COVID-19 emergency, without the need to adhere to certain pre-market approval requirements. Each EUA has different requirements and identifies specific lists of respirators that are authorized for use in healthcare settings by HCP. The EUAs provide mechanisms to expeditiously add additional devices to the authorized list, but also impose certain labeling and reporting requirements.

Based on the information published by the FDA, the following factors are important for determining the standard applicable to imported face masks, respirators and similar PPE:

Face masks, respirators and similar PPE intended for use in healthcare settings by HCP

- NIOSH-approved non-powered respirators that are listed on NIOSH Certified Equipment list (CEL) for non-powered air purifying respirators with particulate protection are authorized respirators under the EUA when labeled consistently with the labeling approved by NIOSH:
  - All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
  - No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.
  - Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.
  - Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.
- Non-NIOSH-approved respirators intended for use in a healthcare setting by HCPs:
  - Does the respirator meet the standards or product classification of the EUA or Exhibit 1 to the EUA? If not, consider having the items added to Exhibit 1.
  - Importers must assure:
    - All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
    - No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.
    - That they notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.
    - They maintain all records associated with this EUA until the end of this public health emergency.
- Non-NIOSH-approved respirators from China:
  - Is the respirator listed in Appendix A to the EUA? If not, consider having it added to Appendix A.
  - Importers must assure:
    - All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
    - No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.
    - Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.
    - Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.
- If the item is not intended for use in a healthcare setting by HCPs:
  - Clearly indicate that the items are not intended for use in a healthcare setting or by an HCP. Consider including such marking on the packaging as well as the commercial documents.
  - Avoid any claim regarding the efficacy of the item for the prevention of disease.
  - Avoid any claim that the item includes anti-microbial/anti-viral agents.

Entry of FDA goods

CBP provides guidance on the proper entry of the above types of PPE in Cargo Systems Messaging Service (CSMS) #42272898 (April 5, 2020). Generally, for products that do not constitute a medical device and are not

regulated by FDA, the importer should enter goods as usual and disclaim FDA on the entry. However, for medical devices, including medical devices covered by an enforcement discretion policy or EUA, an Intended Use Code and FDA product code are required.

Classification and duty under the Harmonized Tariff Schedule of the United States (HTSUS)

Given the high demand for PPE, importers are transforming production activities to increase PPE imports into the United States. Many importers are finding themselves producing new (possibly unfamiliar) items. When bringing new items into the United States, it is critical to ensure that the products are properly classified under the HTSUS. In CSMS #42231420, CBP provided a helpful reference guide for importers on the general HTSUS classifications for an assortment of medical devices needed for the pandemic.

Importers must still pay any applicable rate of duty under the HTSUS on PPE being imported into the United States. For PPE from China, importers will also pay additional Section 301 duties pursuant to *Notice of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation,* 83 Fed. Reg. 40823 (August 23, 2018). However, the Office of the U.S. Trade Representative (USTR) has already started to announce exclusions (such as those on March 17, and March 31) from the Section 301 duties applying to certain of these items. Not all products will qualify for an exclusion–the product details must fit the description provided in the applicable Federal Register Notice and the importer must claim the exclusion and Section 301 exclusion HTSUS classifications on the entry.

In addition to the exclusions it has granted, USTR is also asking for comments on whether additional actions should be taken with respect to the Section 301 duties on Chinese goods.

Some nations have opted to make certain PPE duty-free in the fight against coronavirus. *See, e.g.*, Bangladesh, Philippines.

Risks of improperly importing PPE

Importers must remember that their obligations to comply with CBP and FDA regulations do not cease despite the national emergency that this pandemic has created.

Failure to properly import FDA-regulated medical devices could result in detention or seizure of the shipment (see 21 C.F.R. § 800.55), civil penalties of up to $15,000 per violation, or even criminal prosecution. See 21 U.S.C. § 333. These are **in addition** to penalties that CBP may impose, under 19 U.S.C. § 1592, for violations of relevant CBP statutes and regulations on the entry of goods, which could be as high as the domestic value of the imported merchandise for fraudulent behavior, and in addition to delays in clearing the goods through U.S. customs.

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