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Professional Perspective

PPE Imports During Covid-19

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Personal protective equipment shortages have posed a tremendous challenge to the U.S. health-care system. The increased spread of the novel coronavirus (Covid-19) pandemic left hospitals and medical facilities with depleted PPE supplies to protect health-care workers and other medical first responders while treating Covid-19 patients.

Additionally, there is an increase in demand for similar protective gear from the general population who are following the Centers for Disease Control and Prevention's recommendation to wear "cloth face coverings [not surgical masks or N-95 respirators] in public settings where other social distancing measures are difficult to maintain (e.g., grocery stores and pharmacies) especially in areas of significant community-based transmission."

In response to the clear need to fulfill the demand of PPE and other protective gear, U.S. Customs and Border Protection and the U.S. Food and Drug Administration worked to relax import barriers to return PPE inventory back to normal. This article outlines what PPE is, which U.S. government agencies regulate importations of PPE, the process of importing PPE into the U.S., as well as recent actions taken by CBP and the FDA. Due to rapid change in policy relating to PPE, importers should consult with a custom and international trade attorney to avoid import delays.

What is PPE?

Personal protective equipment is used by health-care personnel (HCP) to protect themselves, patients, and others when providing care. PPE helps protect HCP from potentially infectious patients and materials, toxic medications, and other potentially dangerous substances used in healthcare delivery.

PPE items include protective clothing (gowns), helmets, gloves, face shields, goggles, face masks, respirators, and other equipment designed to protect the wearer from injury or help prevent the wearer from exposure to infection or illness. CDC's National Institute for Occupational Safety and Health maintains a database of that includes most of the current PPE standards in more detail.

Agency Regulation

The importation of PPE for health-care use must comply with both CBP and FDA regulatory requirements.

CBP

CBP is charged with keeping terrorists and their weapons out of the U.S. while facilitating lawful international travel and trade. To facilitate legitimate importations of PPE, CBP took the following immediate steps.

It launched a Covid-19 updates and announcements webpage. Information includes Federal Register Notices and Cargo Systems Messaging Service communications related to Covid-19, and links to partner government agencies' Covid-19 response websites. The page is updated regularly to reflect the most current information available.

In an effort to coordinate inquiries regarding the import of medical supplies and personal protective equipment, CBP's Pharmaceuticals, Health and Chemical Center of Excellence and Expertise established the Covid-19 Cargo Resolution Team.

Assigned staff will coordinate with the ports and other government agencies to ensure that legitimate shipments are not unnecessarily delayed. To assist CBP in expediting the release of Covid-19 relief materials, importers are urged to send CBP as much data about imported shipment as possible, including:

- Shipment information: manifest or air waybill numbers, tracking numbers, entry numbers, mode of transport information
- Conveyance information: carrier name, mode of transportation, flight number, vessel/voyage number, port of arrival, port of entry

- Cargo description: complete description of the goods being shipped
- Country information: country of manufacture, country of export
- Parties involved: names and locations of manufacturers, shippers, importers, and consignees

FDA

FDA regulates the importation of medical device products in the U.S. The agency is responsible for regulating medical devices used to diagnose, prevent, and treat Covid-19. Such medical devices are cleared by the FDA and include diagnostic tests, ventilators, and PPE.

FDA took the following immediate steps:

- Launched a medical devices website to communicate rapid changing policy.
- Issued an emergency use authorization for numerous medical devices, including PPE. On March 24, 2020, the FDA issued EUA for importing non-NIOSH-approved N95 respirators. Under this EUA, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea, and Mexico, which have similar standards to NIOSH. At the time, FDA did not list KN95 respirators (Chinese standard) because of concerns about fraudulent products listed as KN95s. However, the FDA issued a new EUA on April 3, 2020, which includes a Chinese KN95 respirator due to the increase in demand.
- Issued an enforcement guidance document for face masks and respirators (effective for the duration of the pandemic), clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and filtering facepiece respirators (including N95 respirators) for use by health care professionals in health-care settings. The guidance applies to KN95 respirators also and explains, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN95 respirators, if they are on the Centers for Disease Control and Prevention list of respirator alternatives during the Covid-19 pandemic. The FDA may request additional information on a case-by-case basis to make a final admissibility decision. Manufacturers and other stakeholders may submit a request to the FDA in order to have their products added to the EUA.

PPE Import Process

The following guidance was provided by CBP and the FDA for importers to use when importing PPE related to the Covid-19 public health emergency. When the information outlined below is provided at the time of importation, it will assist both CBP and FDA in expediting the import process. This information was published, in part, by CBP in CSMS #42168200 and updated April 6, 2020 via CSMS #42272898.

There are three categories of PPE products:

Non-FDA-Regulated General Purpose PPE

Personal protective equipment for general purpose or industrial use, such as masks, respirators, gloves, etc. used in construction and other industrial applications (that is, products that are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease) is not regulated by FDA, and all the other requirements of the FD&C Act do not apply to manufacturers, importers, and distributors of these products.

When evaluating whether these products are intended for a medical purpose, among other considerations, the FDA will consider whether they are labeled or otherwise intended for use by a health care professional, labeled or otherwise for use in a health-care facility or environment, and include any drugs, biologics, or anti-microbial/anti-viral agents.

For these types of products, entry information should not be transmitted to the FDA. At the time of entry for these products, importers should transmit entry information to CBP using an appropriate Harmonized Tariff Schedule of the United States code with no FDA Flag; or entering "disclaim" for the FDA.

The World Customs Organization issued a guidance document, "HS classification reference for Covid-19 medical supplies," to provide six categories of medical supplies and the correlating HTS up until the sixth digit (HTS's are universal worldwide up until the 6th digit).

However, as indicated in the guidance document, the HTS's provided do not have legal status as an importer of record is required to declare a 10-digit HTS to CBP upon importation. The Crash Course In The Harmonized Tariff Schedule Of The United States describes the meticulous process of identifying an appropriate classification.

> **Practitioner Tip**: consult with a customs and international trade attorney, review CBP Cross Rulings for classification of similar products, and declare the secondary Section 301 tariff or exclusion for import from China, if applicable. No importer wants to take on potential liability for misclassifying a product to CBP and potentially paying an incorrect amount of customs duties.

Authorized Products for Emergency Use via EUA

A full list of emergency use authorizations currently in place for the Covid-19 emergency is also available on the FDA's website. Check this site regularly for current information on products authorized by an EUA. Products entered under an EUA are strictly for use in a health-care setting by health-care personnel.

When importing such products, entry information should be submitted to the FDA; however reduced FDA information is required for review. At the time of entry, importers should transmit an Intended Use Code of 940.000: *Compassionate Use/Emergency Use Device*, and an appropriate FDA product code. Under this Intended Use Code, the (typically required) Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional in ACE.

Below is a list of products and the appropriate product codes that are currently authorized by an EUA:

1. Diagnostic tests: 83QKP, 83QKO, 83QJR

2. Masks/respirators: 80NZJ

3. Ventilators: See ventilator EUA for product codes

On April 3, 2020, the FDA, in response to the evolving public health emergency and mass need for filtering facepiece respirators (FFR or respirator), FDA concluded that FFR manufactured in China and not NIOSH-approved (where data exists that supports the respirators' authenticity, are appropriate to protect the public health or safety). Under this EUA, authorized respirators listed in Appendix A are authorized for use in health-care settings by health-care personnel.

> **Practitioner Tip:** Prior to importing non-NIOSH-approved respirator from China, a request must be submitted to the FDA to add the product and manufacturer information to Appendix A. Only then will the product be considered an authorized respirator under this EUA and permitted to be imported.

A disposable, non-NIOSH-approved respirator, manufactured in China that meets one of the following criteria for authentication is eligible for authorization under this EUA:

- "It is manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA
- It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA
- It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA."

The following are Conditions of Authorizations Per EUA for Importers (a similar list for manufacturers may be found here):

- 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.

FDA-Regulated But Not EUA-Authorized

When importing such devices regulated by the FDA as a medical device and not authorized by an EUA, but where an enforcement discretion policy has been published in guidance, the entry information should be submitted to FDA as follows:

- At the time of entry, importers should transmit Intended Use Code 081.006: *enforcement discretion per final guidance*, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional in ACE.

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 for those products:

1. Clinical Electronic ThermometersGowns, Other Apparel, and Gloves
2. Sterilizers, Disinfectant Devices and Air Purifiers
3. Face Masks and Respirators
4. Non-Invasive Remote Monitoring Devices
5. Ventilators and Accessories and Other Respiratory Devices

General FDA Import Requirements

CBP and the FDA regulate the importation of medical devices into the U.S. The FDA categorizes medical devices into three different classes, pursuant to 21 C.F.R.Parts 862-892—based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.

- Class I items are subjected to the lowest level of scrutiny because they present a low level of risk.
- Class II devices require a Premarket Notification (510(k)) because they exhibit a moderate level of risk.
- "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 C.F.R. 807.92(a)(3)) that is not subject to PMA."

  Practitioner Tip: Search FDA's 510(k) database for non-510(k) exempt devices:

  A specific manufacturer's gowns, and surgical masks can be identified by searching using the 3-letter product codes that FDA has assigned to those products:

  For gowns (FYA, FYB, FYC)

  for surgical masks (FXX, OUK, OXZ)

- 21 C.F.R. §807 states the requirements that meet a 510(k) submission. After properly submitting the 510(k), you should receive an FDA letter informing you that the device is substantially equivalent to a legally marketed device. Then you may commercially distribute the device in the U.S.
- Class III devices are used to support or sustain life, and are held to the most stringent level of regulatory controls: requiring a premarket approval (PMA).

Further, medical devices must fall within FDA regulations prior to the importation.

- The Product Code is assigned to the medical device according to the classification of the device. The Product Code assigned to a device is based upon the medical device product classification designated under FDA regulation 21 C.F.R.Parts 862-892. The product code assists CBP officers, FDA officials, importers, and etc. in accurately identifying the class in which the medical device falls under and in tracking the medical device.

Lastly, all firms are required to register their establishments, identify a U.S. Agent (if foreign), and individually list their medical devices on their registration and the manufacturer must also list the importer on its own facility registration before importing into the U.S.

Practitioner Tips:

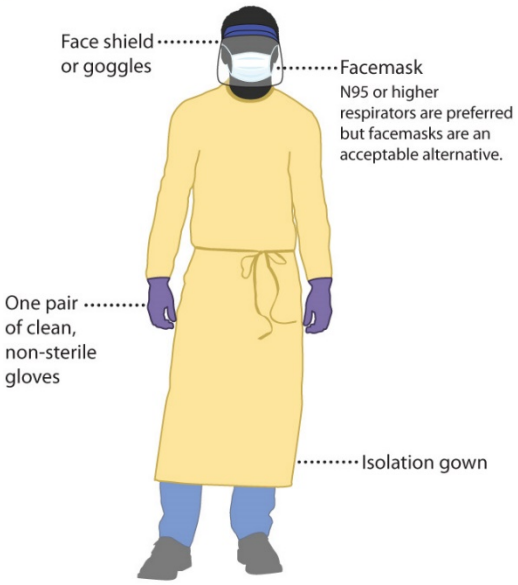
- Consult with a customs and international trade law attorney prior to importation to avoid delays
- Work with Experienced Customs Brokers
- If you experience delays act fast and contact a customs and international trade law attorney to effectively communicate with CBP to get your legitimate goods released asap.
- FDA Recommends Use of ITACS During Covid-19 Outbreak
- Take appropriate steps to verify authenticity of these products and suppliers.
- Review FDA guidance document: FDA FAQS on Shortages of Surgical Masks and Gowns, prior to purchasing from an overseas supplier.

Avoid price gouging, it is regulated by each state and not federally. In most states, price gouging during a time of emergency is considered a violation of unfair or deceptive trade practices law. Most of these laws provide for civil penalties, as enforced by the state attorney general, while some state laws also enforce criminal penalties for price gouging violations.

COVID-19 Personal Protective Equipment (PPE) for Healthcare Personnel

Preferred PPE – Use N95 or Higher Respirator

Acceptable Alternative PPE – Use Facemask



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cdc.gov/COVID19