IMPORTING & EXPORTING PPE'S

DISCLAIMER: THE CONTENT OF THIS WEBINAR IS FOR INFORMATIONAL PURPOSES ONLY. THE MATERIAL SHOULD NOT BE CONSIDERED LEGAL ADVICE OR LEGALLY BINDING.

COVID-19 SUPPLY SHORTAGE

- The effect of COVID-19 has left a severe shortage of PPE for both medical and industrial professions.
- FDA is aware that as the COVID-19 continues to expand globally, the supply chain for equipment is stressed due to the demand exceeding available supplies.

Masks

Gloves

Hand Sanitizer

Respirators

WHAT IS PPE?

- Personal Protection Equipment (PPE) refers to equipment designed to protect an individual from the spread of infection or illness.
  - Examples: Masks, Gloves, Gowns, etc.

- PPE is used in many industries. Particularly those with high risk of exposing the eyes, ears, skin and/or and lungs to damaging environments.

REGULATORY AUTHORITIES

- PPE standards are regulated by the National Institute for Occupational Safety and Health, a part of CDC, the Occupational Safety and Health Administration, and the US Food & Drug Administration.
- The Federal Emergency Management Agency is involved with exports of PPE also.

NIOSH (CDC) | OSHA | FDA | FEMA

CONTINGENCY PLANS

FDA, NIOSH, and OSHA, are working together to institute strategies to help during the shortages.

Each category of PPEs have a specific contingency plan. PPE allowances may vary by commodity.

Keep in mind the contingency plans can change as the effects of the virus evolve.

EMERGENCY USAGE AUTHORIZATION

- The Emergency Usage Authorization (EUA) under FDAs authority incorporates the use of FDAs Medical Countermeasures (MCM) framework to prepare and respond to chemical, biological, radiological, nuclear, and infectious disease threats and/or potential threats.
  - Under the EUA, FDA may allow the use of products by medical professionals that have not been previously approved.
  - CDC maintains a certified equipment list of all EUA approved items.

STANDARD FDA IMPORT REQUIREMENTS

- For FDA, non-radiation, medical devices, imported for use in medical facilities, usually require the following (masks/gloves/gowns):

- Requirements differ based on end use and commodity.
- FDA regulates most items used in a medical facility as a device not limited to items related to medicine or treatments (even the plastic bags given to hold personal items must have a device listing).

IMPORTING MASKS & RESPIRATORS

If importing masks, what do you need to know?

- You will need to provide the following details about the masks:
  - Intended use? Medical/Non-Medical? Surgical mask that provides a liquid barrier protection?
  - Manufacturer and type (if medical use)
  - Determine whether the manufacturer is on the approved list of NIOSH or Non-NIOSH approved.

- FDA relaxed the import registration requirements of face masks and respirators.
  - NOTE - **Masks for industrial use MUST NOT make any medical claim. The mask or the packaging cannot have the FDA logo or insinuate in any way that it is approved by the FDA. If those claims are made on the packaging, then the product is subject to FDA and processed accordingly.**

- FDA is allowing medical professionals to use masks of similar standards, from certain countries with specific reporting details such as:
  - Manufacturer, model number (s), marketing authorization certification number, performance standards met, applicable documents.

IMPORTING SANITIZERS

If importing hand sanitizers or alcohol wipes, what do you need to know?

- You will need to provide the following details about the product:
  - Confirm if alcohol based. If alcohol based, provide the content of alcohol.
  - Provide manufacturer information.
  - Confirm if they are microbials.

- The manufacturer is required to be registered with FDA.
- FDA drug importing rules apply.
- Alcohol or Benzalkonium chloride-based products are considered drugs under FDA.

IMPORTING COVID TEST KITS

- If importing COVID-19 test kits, what do you need to know?
  - Complete manufacturer information is required.
  - Foreign suppliers must be covered by the EUA or meet full FDA medical device registration and listing requirements.
  - There are no exceptions for these test kits currently.

OTHER FDA DEVICES

- For imports of other devices regulated by FDA for medical use, must meet medical device importing rules. (gowns, gloves, thermometers, etc.)

- For imports of masks, gloves and respirators for **Non-medical Industries, disclaim FDA.**

For surface disinfectors, other medical devices or pharmaceuticals please contact compliance@jas.com for more information.

GRANTED EXCLUSIONS

- Certain medical products have been granted exclusions from section 301 China tariffs, not all items are excluded.
    - Importers should review tariff rates thoroughly and expect to pay the appropriate column 1 duty rate plus the China tariff.
    - Surgical masks and gloves are examples of exclusions.
    - The exclusion process is currently open until June 25, 2020.

CSMS MESSAGE UPDATE

U.S. Customs and Border Protection

Cargo Systems Messaging Service

CSMS #42448725 - Information for Filing Personal Protective Equipment and Medical Devices During COVID-19

The U.S. Food and Drug Administration is providing an update to CSMS messages 42124872 and 42168200 for instructions to the import community regarding the submission of entry information for personal protective equipment and certain other devices. Following the instructions below will help facilitate the import process for all; especially for products related to the Coronavirus Disease-2019 (COVID-19) public health emergency. It is in the best interest of the U.S. to facilitate and expedite the importation of products into the U.S. market that address immediate, urgent public health needs.

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:

- Telethermographic Systems
- Remote Ophthalmic Assessment and Monitoring Devices
- Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices
- Infusion Pumps and Accessories
- Digital Health Devices for Treating Psychiatric Disorders
- Clinical Electronic Thermometers
- Gowns, Other Apparel, and Gloves
- Sterilizers, Disinfectant Devices and Air Purifiers
- Face Masks and Respirators
- Non-Invasive Remote Monitoring Devices
- Ventilators and Accessories and Other Respiratory Devices
- Diagnostic Tests

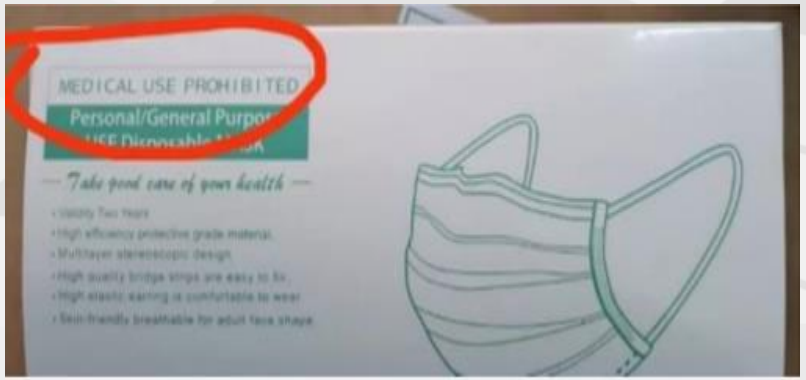
A full list of all guidance documents related to COVID-19 is also available on FDA's website. For guidance applicable to medical devices, you may filter by the medical device product area and display all entries. Please check this site, as well as Information for Filing Personal Protective Equipment and Medical Devices During COVID-19, regularly for current information on these and other product areas.

EXPORTING FROM CHINA

- Why are there new requirements for exporting PPE from China?
  - Quality control and counterfeit masks
  - Country requirements – N95/KN95/FFP2
- What does the foreign factory need to do?
  - Manufacturer registration
  - Declaration with required information
  - Registration certificate of China's medical device product
  - License to export PPE
  - Meet quality standards of the importing country
  - All shipments of medical PPE are subject to compulsory inspection by China customs prior to exporting any of these 11 products:
    - Medical Masks, Medical Protective Gowns, Thermometers, Ventilators, Medical Surgical Caps, Medical Goggles, Medical Gloves, Medical Shoe Covers, ICU Monitors, Medical Disinfect Tissue and Medical Disinfectant.

EXPORTING FROM CHINA

- China government is applying stricter rules on masks.
- Requirements:
  - Supplier must be on approved list
  - Provide medical device product license
  - Provide medical device registration certificate
  - For non-surgical masks – package labeling should indicate non-medical or non-surgical

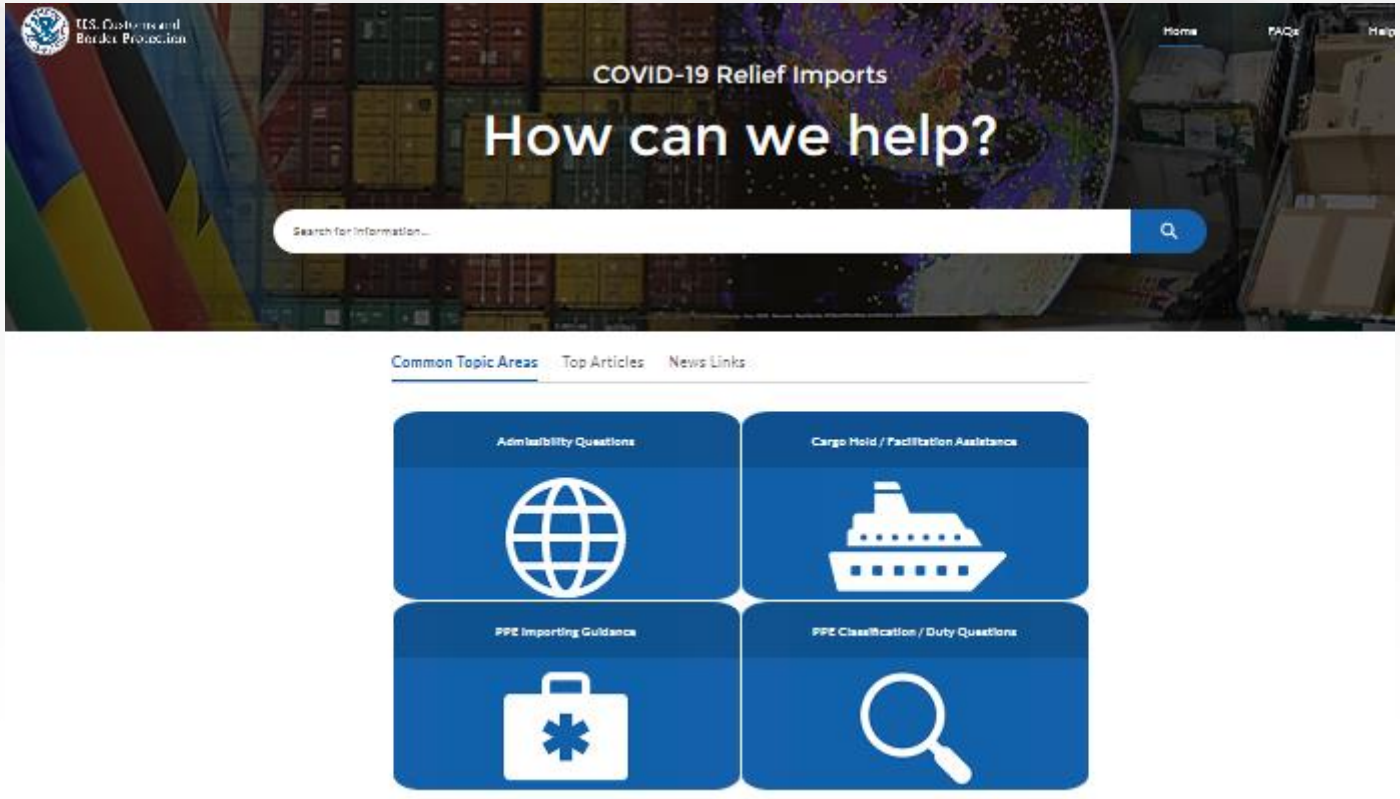


Correct

Wrong

CBP COVID-19 WEB PORTAL

- CBP has created a web portal containing helpful hints and FAQs. Topics can be searched, or one of the four groups can be selected to browse pointers base by subject. ***export version coming soon***



https://imports.cbp.gov/

EXPORTING PPE'S

On April 3, 2020, the President published a Memorandum and Temporary Final Rule to ban the export of scarce or threatened PPE materials that are to remain in the US for use in responding to COVID-19.

EXPORTS RESTRICTED ITEMS

There are five named items restricted for export:

- N-95 Filtering Facepiece Respirators*
- Other Filtering Facepiece Respirators*
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges
- PPE surgical masks
- PPE gloves or surgical gloves

*See Memorandum for complete descriptions of items.

FEMA AND CBP

- FEMA has been appointed to review medical goods prior to export.
- CBP will work with FEMA to hold medical supply goods until FEMA provides instructions for holding or releasing the goods.
- If the goods are determined to be scarce, there is a possibility the goods will be purchased and reallocated for domestic use.

EXEMPTIONS

- The below shipment types are exempt:
  - Exports to Canada or Mexico;
  - Exports to US Government entities such as US military bases overseas;
  - Exports by US Government agencies;
  - Exports by US charities;
  - Exports by critical infrastructure industries for the protection of their workers;
  - Express or mail parcels that do not meet the commercial quantity definition above;
  - In-transit shipments

RESOURCE WEBSITES

Approved EUA Items/Companies

- Masks & Respirators
- Particulate Respirations

CDCs PPE Strategy

FDAs Emergency Use Authorization's page

Memorandum

Temporary Final Rule

Information for Filing PPE & Medical Devices

90-DAY DUTY POSTPONEMENT

- CBP announced a 90-calendar day postponement deadline for Importers experiencing a financial hardship of certain duties, taxes and fees.
- Applies to entries in March 2020 and April 2020 only.
- Does not apply to ADD/CVD duties or Section 201, 232, 301 duties.
- Reference Links
  - Criteria Required for Importers
  - FAQ's

UPDATES

- For further COVID-19 updates, please be sure to visit our website at https://www.jas.com/compliance-solutions.

QUESTIONS?

THANK YOU!