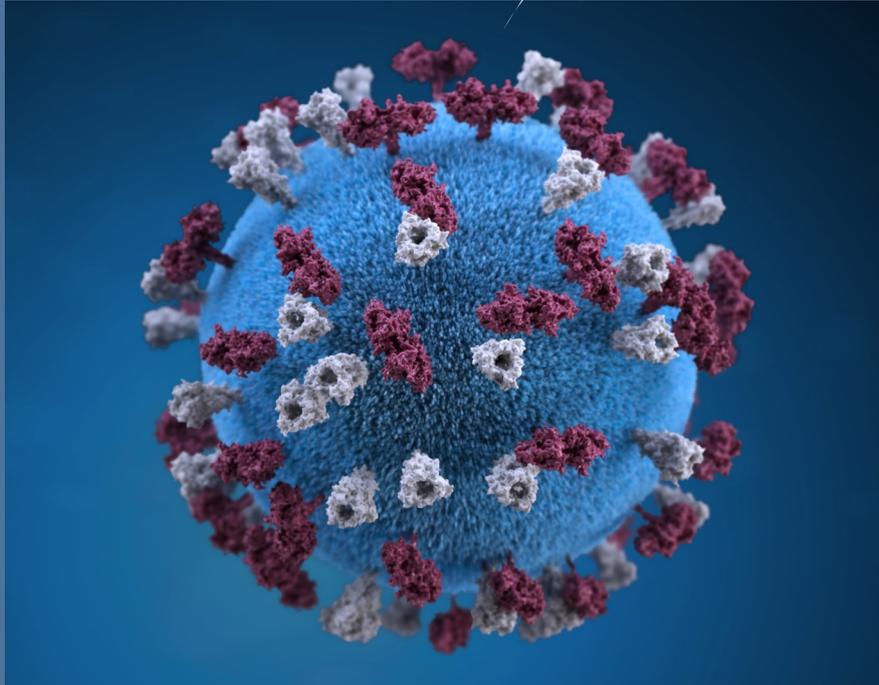




Bayne Law

Dedication | Diligence | Commitment

Navigating Importing PPE and Medical Devices Business Relief Strategies



COVID-19 ALERT UPDATE

Importing Personal Protective Equipment (PPE)

Ventilators and Other Respiratory Devices

Business Counsel for the Global Marketplace®

Navigating the Importing PPE and Medical Devices

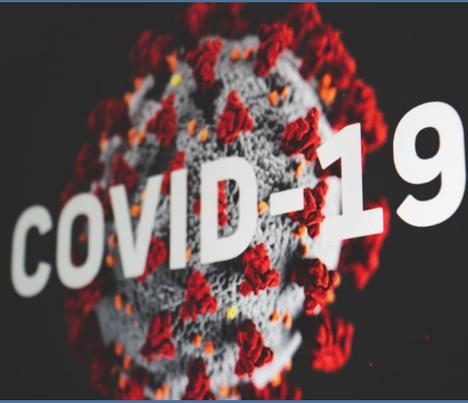
CBP INFORMATION FOR FILING PPE AND MEDICAL DEVICES

Product	Government Agencies Receive Entry Information	Information required	Notes
Non-FDA-regulated general purpose PPE (masks, respirators, gloves, etc.)	Importers should transmit entry information to CBP	Using an appropriate HTS code with no FD Flag; or using an appropriate HTS code with an FD1 flag and do a 'disclaim' for FDA.	FDA does not intend to object to the importation and use of respirators CDC recommended alternatives, without FDA compliance
Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA)	Entry information should be submitted to FDA	Reduced FDA information is required for review. Transmit an Intended Use Code of 940.000: Compassionate Use/ Emergency Use, and an appropriate FDA product code.	Requests for Emergency Use Authorization can be submitted to FDA.
Products regulated by FDA as a device, not authorized by an EUA	Entry information should be submitted to FDA.	Transmit an Intended Use Code of 081.006: Enforcement discretion per final guidance, and an appropriate FDA product code.	FDA issued a listing of guidance for specific products related to COVID-19, containing product codes.

To expedite the release of COVID-19 relief materials, CBP recommended include:

- i. shipment information, manifest or air waybill numbers, tracking numbers, entry numbers, mode of transport information
 - ii. Conveyance information: carrier name, mode of transportation, flight number, vessel/voyage number, port of arrival, port of entry
 - iii. Cargo description: complete description of the goods being shipped
 - iv. Country information: country of manufacture, country of export
 - v. Parties involved: names and locations of manufacturers, shippers, importers, and consignees
- CBP recommended to take advantage of the Automated Clearinghouse (ACH) for electronic payment to the greatest extent possible, transmit entry and entry summaries to the Automated Commercial Environment (ACE), update current account and point of contact information in the ACE portal to include email, submit supporting documentation or responses to CBP Requests for Information (CBPF28), etc.





COVID-19

AMERICAN BUSINESS LAWYERS

Our Commitment

BayneLaw is working diligently with our clients to help address all legal issues facing our valued clients during this crisis with respect to contract concerns, employment and labor law compliance and strategies, and other commercial matters impacted by the current economic effects of Covid-19 in the USA and globally. Please do not hesitate to let us know at any time of any issues we can help you with.

A Global Focus from the USA

Our clients come to us from throughout the United States of America and countries throughout the world, including Ireland, New Zealand, India, Canada, Australia, China, Europe, the Middle East and South America. We have a detailed understanding of state, federal and international business law, and we know how to effectively serve the interests of athletes, investors, entrepreneurs, professionals, small business owners and multinational enterprises.

National Critical Shortage of PPE

Committee on Oversight and Reform states that the national stockpile has been depleted. Most states apparently have limited if any PPE stockpile. U.S. and State agencies need to facilitate and expedite the importation of products into the U.S. market that address immediate, urgent public health needs.

Opportunities for Manufacturers & Suppliers of PPE

The CARES Act infuses nearly \$100 billion to address the supply chain breakdowns in medical products needed to combat the COVID-19 pandemic and creates new opportunities for entities that can manufacture or supply the desperately needed PPE and other kinds of medical products.

States Seizure and Nationalizing Private Property

Certain States have authorized State Police Departments and State Emergency Management agencies to take or use resources from private sources in order to address the continued pressing public health concern presented by COVID-19.

Such orders should state that compensation for such takings will be provided by various State Takings laws to remain lawful.

Report Price Gouging and Import Delay

Air cargo rates will be put under scrutiny if price gouging occurs, and we are suggesting that companies noting any commercially inappropriate up-charges advise their local congressional Representative and US Senators as well as report detailed concerns to the FTC and, when appropriate, the US Embassy in the off-shore jurisdiction.

For swift assistance contact a member of the BayneLaw Team or the attorney at the firm with whom you are in regular contact.

Regulations related to the rapidly evolving COVID-19 pandemic are subject to change. Consult your attorney for guidance specific to your current situation. Not Legal Advice.



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