

COVID-19 Supply Chain and Trade Update

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Customs and Border Protection Updates

Requirements for Filing Entries of Hand Sanitizers for FDA

On May 5, 2020, Customs and Border Protection (CBP) [released clarifications](#) related to the import of hand sanitizers into the U.S. As hand sanitizers are drugs regulated by the Food and Drug Administration (FDA), entries of hand sanitizers must be filed with the FDA upon importation. Importers should note that the FDA's [Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#) and [Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#) do not affect the requirement to file entries of hand sanitizers with the FDA. For more information on the drug importation process, please see: <https://www.fda.gov/industry/regulated-products/human-drugs>.

Updated FAQs on PPE Exports

On April 27, 2020, CBP released [an updated FAQ list](#) of commonly asked questions related to the recent prohibition on the export of protective equipment (PPE) from the U.S. The FAQs address issues including exports to Canada; notifications of holds and hold releases; the submission process for a Letter of Attestation (LOA); and CBP mechanisms for identifying covered shipments. As reported in our [prior update](#), as of April 10, 2020 a new temporary rule released by the Federal Emergency Management Agency prohibits the export of PPE outside of the U.S., with certain exemptions [described here](#).

FAQs on the 90 Day Postponement of Certain Payments

As of April 20, 2020, the Secretary of the Treasury and CBP have postponed the deadline for payment of certain estimated duties, taxes, and fees for importers experiencing a significant financial hardship due to the COVID-19 pandemic for 90 days. On April 22, 2020, CBP [notified](#) the trade community of new FAQs related to this postponement, which are [available here](#). The FAQs reiterate that Chinese products subject to Section 301 duties are not eligible for the 90-day postponement.

New FDA Guidance on Submitting Labels

On May 8, 2020, CBP [published a notice](#) from the FDA requesting that importers submit product labeling along with regularly submitted

entry documents in a request for document production. The FDA stated that this will help expedite the admissibility process during the COVID-19 pandemic.

Labeling, along with other entry documents, should be submitted electronically via the FDA Import Trade Auxiliary Communication System (ITACS) at <https://itacs.fda.gov>. ITACS can be used for checking statuses, providing requested documentation and location of goods electronically, and checking the estimated laboratory analysis completion dates for lines which have been sampled. Additional information on ITACS, including FAQs, can be found on FDA's [ITACS for Industry webpage](#).

Directorate of Defense Trade Controls Updates

Reduction in Fees for Tier I and II DDTC Registrants

Due to the “the extraordinary impact of the COVID-19 pandemic on the national economy and Defense Industrial Base,” on May 1, 2020, the Department of State's Directorate of Defense Trade Controls (DDTC) [announced](#) that they are temporarily reducing registration fees. DDTC registrants in Tier I and Tier II whose original expiration date is between May 31, 2020 and April 30, 2021 will now have their registration cost reduced from \$2,250 (Tier I) or \$2,750 (Tier II) to \$500. New applicants who submit their registration application between May 1, 2020 and April 30, 2021 will also only be charged the \$500 fee. The fee structure for Tier III entities remains unchanged at this time. DDTC anticipates that this temporary reduction in fees for Tier I, Tier II, and new registrants will save covered industry over \$20 million over the course of the coming year.

Temporary Suspensions, Exceptions and Modifications to the ITAR

On May 1, 2020, DDTC [published in the Federal Register](#) a comprehensive list of temporary suspensions, modifications, and exceptions to requirements of the International Traffic in Arms Regulations (ITAR). The intention of these changes is to ensure continuity of operations during the COVID-19 pandemic. The changes include:

- As of February 29, 2020, a temporary extension of the registration renewal requirements for manufacturers, exporters, and brokers under ITAR Parts 122 and 129 for two months from the original date of expiration;
- As of March 13, 2020, a temporary extension of licenses covered by ITAR Parts 120 to 130 for six months from the original date of expiration, so long as there are no changes to the scope of the original license;
- As of March 13, 2020, a temporary suspension of ITAR Part 120.39(a)(2) to allow regular employees to work remotely rather than at a company's facilities, so long as the individual is not located in Russia or a country listed in ITAR Part 126.1
- As of March 13, 2020, a temporary exception to authorize regular employees who are working remotely in a country not currently authorized by a technical assistance agreement, manufacturing license agreement, or exemption to send, receive, or access any technical data authorized for export, reexport, or retransfer to their employer, so long as the individual is not located in Russia or a country listed in ITAR Part 126.1

DDTC Web Notice on COVID Measures

DDTC is now compiling all of its major COVID-19 updates from March to the present on its website under [News and Events](#). This includes updates related to registration/compliance, licensing, and management/contact information. Members of the trade community who rely on DDTC should check frequently for new updates.

World Customs Organization Publishes Guidance on Communicating During a Crisis

On April 24, 2020, the World Customs Organization (WCO) published “[COVID-19 Crisis: WCO Guidance on how to communicate during a crisis](#).” In ten steps, the publication lays out a road map to ensure that those in charge of communicating messages rely on accurate information; understand the objectives of the messages being sent; create trust through empathy; and are equipped to effectively plan and communicate to targeted audiences. WCO also has a [COVID-19 webpage](#) which tracks updates, information, and resources related to the pandemic.

Fraud and Counterfeit Goods Updates

Seizure of Counterfeit 3M Masks

On April 23, 2020, CBP officers at an Express Consignment Operations hub in Cincinnati seized 2,000 counterfeit face masks that were shipped to the U.S. from China and falsely marked as “3M Masks.” The quality of the masks was of a lower standard than those actually manufactured by 3M Company, which was the subject of an earlier [Executive Memorandum](#) which granted FEMA the authority to acquire as many 3M masks as required to respond to the pandemic. The counterfeit masks were seized for copyright violations. For more information, see the [CBP press release](#).

Operation Stolen Promise Combats COVID-19 Fraud

Immigration and Customs Enforcement’s (ICE) Homeland Security Investigations (HSI) launched Operation Stolen Promise on April 15, 2020 to combat COVID-19 related fraud and other criminal activity. The new unit targets global trade and supply chain fraud, cybercrime, and financial fraud. HSI works in tandem with CBP to seize shipments of mislabeled, fraudulent, unauthorized or prohibited COVID-19 test kits, homeopathic remedies, and PPE. As of May 5, 2020, the unit has seized \$3.2 million of illicit products, including 494 product seizures related to COVID-19. More information is [available here](#).

Foley Hoag has formed a firm-wide, multi-disciplinary [task force](#) dedicated to client matters related to the novel coronavirus (COVID-19). For more guidance on your COVID-19 issues, visit our [Resource Portal](#) or contact your Foley Hoag attorney.

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