FAQ: Import of COVID-19-Related Goods

- ***What is the U.S. Food & Drug Administration's (FDA's) Emergency Use Authorization?***
  The Emergency Use Authorization (EUA) authority allows "FDA to help strengthen the nation's public health protections against [chemical, biological, radiological and nuclear] threats by facilitating the availability and use of [medical countermeasures] needed during public health emergencies."

  The FDA has given the special designation of Emergency Use Authorization (EUA) to specific medical products and devices. When importing such products, entry information should be submitted to FDA; however, reduced FDA information is required for review.

  At the time of entry, importers should transmit the Intended Use Code of *940.000: Compassionate Use/Emergency Use Device* along with an appropriate FDA product code. Using this Intended Use Code, the Affirmations of Compliance for medical devices (e.g., Registration, Listing, and Premarket numbers) are optional in ACE.

  A full list of products with EUAs in place can be found on FDA's Emergency Use Authorization page.

  Additional information: CSMS 42168200

- ***Which products are authorized for emergency use pursuant to an Emergency Use Authorization (EUA)?***
  Firms who have applied for and received approval for specific products under an EUA are entitled to report reduced FDA information, using Intended Use Code 940.000 (Compassionate Use/Emergency Use) and an appropriate FDA product code specific to the pre-approved product.

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

  • Diagnostic tests: 83Q--KP, 83O--TG, 83Q--KO, 83Q--JR
  • Masks/Respirators: 83N--ZJ

  A list of current EUA information, including products and firms, are available on FDA's Emergency Use Authorization webpage.

  Additional information: CSMS 42168200

- ***Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance…***
  Below is a listing of guidance documents that have been issued for specific products related to COVID-19, which references applicable product codes and policy for those products:

  • Face Masks and Respirators
  • Ventilators and Accessories and Other Respiratory Devices
  • Non-Invasive Remote Monitoring Devices
  • Diagnostic Tests
  • Gowns, Other Apparel, and Gloves *(guidance document not published as of 3/31, but will be available on this page)*
  • Sterilizers, Disinfectant Devices, and Air Purifiers

If a product is mentioned in one of the currently published Coronavirus Disease (COVID-19) guidance documents and meets the requirements as set forth, it would temporarily qualify for special discretionary handling by the FDA. Under these conditions, the requirement for the transmission of affirmation of compliance codes (AOC), such as manufacturer registration and device listing is optional.

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. Importers should check the FDA website frequently as it will be updated on a regular basis.

Additional information: COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders

- ***Guidance regarding the import of hand sanitizer and antibacterial soaps:***

Hand sanitizer is an FDA-regulated over-the-counter drug requiring transmission of the registration of the manufacturer and the drug listing number. We have verified with the FDA that they have not made any exceptions to reporting requirements at this time. Most hand sanitizers are alcohol-based but there are other types available, and it should be verified if it is not clear on the CBP or PGA documents.

Not all soap is created equal. Typical hand, bath, or dish soaps are considered cosmetics and would not require any drug reporting. If the product makes an antibacterial, disinfectant, or makes a similar claim, it falls under the jurisdiction of the FDA as a drug requiring the manufacturer to be registered and a drug listing number (DLS or formerly NDC number).

The Center for Drug Evaluation and Research (CDER) has created the COVID-19-Hand-Sanitizers@fda.hhs.gov *email address for hand sanitizer questions during the outbreak.*

Additional information published by the FDA:

FDA Issues Final Rule on Safety and Effectiveness of Consumer Hand Sanitizers

FDA Issues Final Rule on Safety and Effectiveness of Antibacterial Soaps

Is it a Cosmetic, a Drug, or Both? (Or is it Soap?)

- ***Guidance regarding surface disinfectants:***

Cleaning products marketed as surface disinfectants are not subject to the FDA, but they are regulated by the U.S. Environmental Protection Agency (EPA). It's important to determine whether it is regulated as a pesticide under the guidance document published by the EPA (Determining if a Cleaning Product Is a Pesticide Under FIFRA). If the goods are considered to be a pesticide, a prior notice will need to be filed with the EPA. If the products are not regulated as a pesticide, then they may be subject to EPA TSCA reporting requirements.

- ***Guidance regarding other FDA-regulated devices:***

Goods which do not fall under either a EUA or a guidance document must be processed with full FDA information. The filer is encouraged to ensure that all affirmation of compliance (AOC) codes are accurate and complete in order to expedite release by FDA. Filers should also check FDA's COVID-19 Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders regularly to ensure that they are up-to-date on the most recent COVID-19 publications by the FDA. The FDA has also indicated that they will update the trade via CSMS messages as more information becomes available.

- ***Guidance regarding personal protective equipment (PPE), such as masks, respirators, gloves, etc.:***

The FDA does not regulate PPE products intended for general purpose or industrial use—products not intended for use in preventing disease or illness; therefore, entry information for these products should not be transmitted to the FDA.

At the time of entry for these products, Importers should transmit entry information to U.S. Customs and Border Protection (CBP) using an appropriate HTS code with no FD Flag, or using an appropriate HTS code with an FD1 flag and then file a 'disclaim' for FDA.

Additional information: CSMS 42168200

- ***How is the FDA handling imported products claiming to cure, treat, or prevent COVID-19?***

Fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness and might be dangerous to U.S. consumers. The FDA is particularly concerned that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications.

Earlier this month, FDA and the Federal Trade Commission (FTC) warned seven firms for selling fraudulent products with claims to prevent, treat, mitigate, diagnose, or cure COVID-19. The FDA and FTC will continue to monitor social media, online marketplaces, and incoming complaints to help ensure that the companies do not continue to sell fraudulent products under a different company name or on another website.

On March 20, 2020, the FDA alerted the American public that, at this time, the FDA has not authorized any test that is available to purchase for at-home testing for COVID-19. The only IVD test kits authorized to be imported are products that have an Emergency Use Authorization (EUA). Approved EUAs are found on FDA's Emergency Use Authorization page.

Additional information: Beware of Fraudulent Coronavirus Tests, Vaccines, and Treatments

- ***Additional Information:***

Those parties interested or concerned with the importation of COVID-19 related medical devices are encouraged to check FDA's online resources frequently as they are being updated on a regular basis. Additional information from the FDA in regard to COVID-19 is available on FDA's Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions.