March 27, 2020

MEMBER ALERT

Hi @@first_name@@,

We are happy to report that the President has signed the CARES Act which provides relief individuals and businesses for COVID-19. Additionally, Canada has extended the time for importers to pay customs duties and GST. See CBSA Customs Notice 20-11 that extends the deadline for payment to June 30, 2020. AAEI is still working with Congress to get duty deferral for U.S. importers.

On the regulatory front, AAEI has compiled a global overview document with the restrictions for air passengers, ports, imports, exports, etc. We worked with our international trade association partners to get the most comprehensive document possible. AAEI will roll out the document next week.

FDA PPE Guidance

FDA has provided updated product import instruction in CSMS #421168200 Information for Filing Personal Protective Equipment and Medical Devices During COVID-19. FDA has stated that ***"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."

FDA has shared the following summary of guidance with AAEI for U.S. importers:

- **Non-FDA-regulated general purpose personal protective equipment (masks, respirators, gloves, etc.)**
    - Personal protective equipment for general purpose or industrial use (that is, products that are not intended for use to prevent disease or illness) is not regulated by FDA.
    - For these types of products, entry information should not be transmitted to FDA. At the time of entry for these products, Importers should transmit entry information to US 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 do a 'disclaim' for FDA.
- **Products authorized for emergency use pursuant to an** Emergency Use Authorization **(EUA)**
    - 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 an Intended Use Code of 940.000: Compassionate Use/Emergency Use Device, 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 list of products and the appropriate product codes that are currently authorized by an EUA:
        - Diagnostic tests: 83QKP, 83QKO, 83QJR
        - Masks/Respirators: 80NZJ

A full list of Emergency Use Authorizations currently in place for the COVID-19 emergency is also available on FDA's website. Please check this site regularly for current information on products authorized by an EUA.

Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

- When importing such devices, entry information should be submitted to FDA.

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:

- Face Masks and Respirators
- Ventilators and Accessories and Other Respiratory Devices
- Non-Invasive Remote Monitoring Devices
- Diagnostic Tests

A full list of all guidance documents related to COVID-19 is also available on FDA's website. Please check this site regularly for current information on these and other product areas. This message will be updated to specifically include additional guidance as it becomes available.

All questions regarding these instructions, product code assistance for these products, or to resolve entry issues can be submitted to FDA at: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov or 301-796-0356.

- Step-by-Step instructions on how to register and list can be found on our website at: https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.
- For additional assistance with completing initial registration, firms should contact the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.
- For assistance with paying the annual registration user fee, firms can reach out to the User Fee Helpdesk at userfees@fda.gov.
- For further information regarding entry submission requirements in the Automated Commercial Environment (ACE) system, see the FDA Supplemental Guide for ACE at https://www.cbp.gov/sites/default/files/assets/documents/2020-Mar/FDA%20Supplemental%20Guide%20Release%202.5.1%202018%200410.pdf.

As usual, FDA may request additional information on a case-by-case basis for making its final admissibility decision.

Finally, we have closed Week 2 of the COVID-19 Survey and compile results, and we will advise when the Week 3 Survey is open.

Thank you to our Champion Strategic Alliance Partner:

FTZC™ (Foreign-Trade Zone Corporation)

@@unsubscribe_url@@

About This Email

You have received this email, because you are registered for your organization as a member of AAEI. If you believe you received this message in error, please let us know at helpdesk@aaei.org.

This email was sent to '@@email@@' from AAEI. If you wish to stop receiving email from us, you can simply remove yourself by visiting: Unsubscribe

American Association of Exporters and Importers
1717 K St. N.W. Suite 1120
Washington, DC 20006

This email was sent to '@@email@@' from AAEI. If you wish to stop receiving email from us, you can simply remove yourself by visiting: Unsubscribe

American Association of Exporters and Importers
1717 K St. N.W. Suite 1120
Washington, DC 20006