FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

International Trade Day

May 18, 2020

FDA COVID-19 Response within Import Operations

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Division of Southeast Imports

Objective

- *Communicate FDA's response on critical import operations to protect public health during the COVID-19 pandemic*
- *Share FDA communications and resources*


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Menu
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FDA Takes Action to Address Coronavirus Disease 2019 (COVID-19)
FDA is working with U.S. Government partners, including CDC, and international partners to address the pandemic.

FDA communication COVID-19 strategies

FDA Informational Resources

Subscribe to receive updated **COVID-19-related information** from the FDA.

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CSMS messaging

- #42118616 - Reminder: Update on FDA's Import Operations During The Coronavirus Disease 2019 (COVID-19) Outbreak
- #42253103 - FDA Recommends Use of ITACS During COVID-19 Outbreak

FDA Import Trade Auxiliary Communication System (ITACS)

- ITACS accounts can be requested via the FDA Unified Registration and Listing System (FURLS) at https://www.access.fda.gov/oaa
- Instructions included within the ITACS Account Management Presentation at https://www.fda.gov/industry/import-systems/itacs to request an account.
- ITACS basic functionality can be accessed at https://itacs.fda.gov.

FDA communication COVID-19 strategies

#42590577 - Filing Entries of Hand Sanitizers for FDA

Hand sanitizers are drugs regulated by the FDA and are generally considered as over-the-counter (OTC) drug products.

Hand sanitizer entries should not be disclaim.

Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs

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#42272898- Information for Filing Personal Protective Equipment and Medical Devices During COVID-19

- Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA)
- Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

FDA communication COVID-19 strategies

#42272898- Information for Filing Personal Protective Equipment and Medical Devices During COVID-19…continued

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

FDA To Temporarily Conduct Remote Importer Inspections Under FSVP Due to COVID-19

- https://www.fda.gov/food/cfsan-constituent-updates/fda-temporarily-conduct-remote-importer-inspections-under-fsvp-due-covid-19
- Inspection protocol questions may be sent to FDAImportsInquiry@fda.hhs.gov

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- Press Announcements

https://www.fda.gov/news-events/fda-newsroom/press-announcements

FDA Resources

- COVID19FDAIMPORTINQUIRIES@fda.hhs.gov

  COVID-19 inquiries associated to the CSMS instructions and product code assistance.

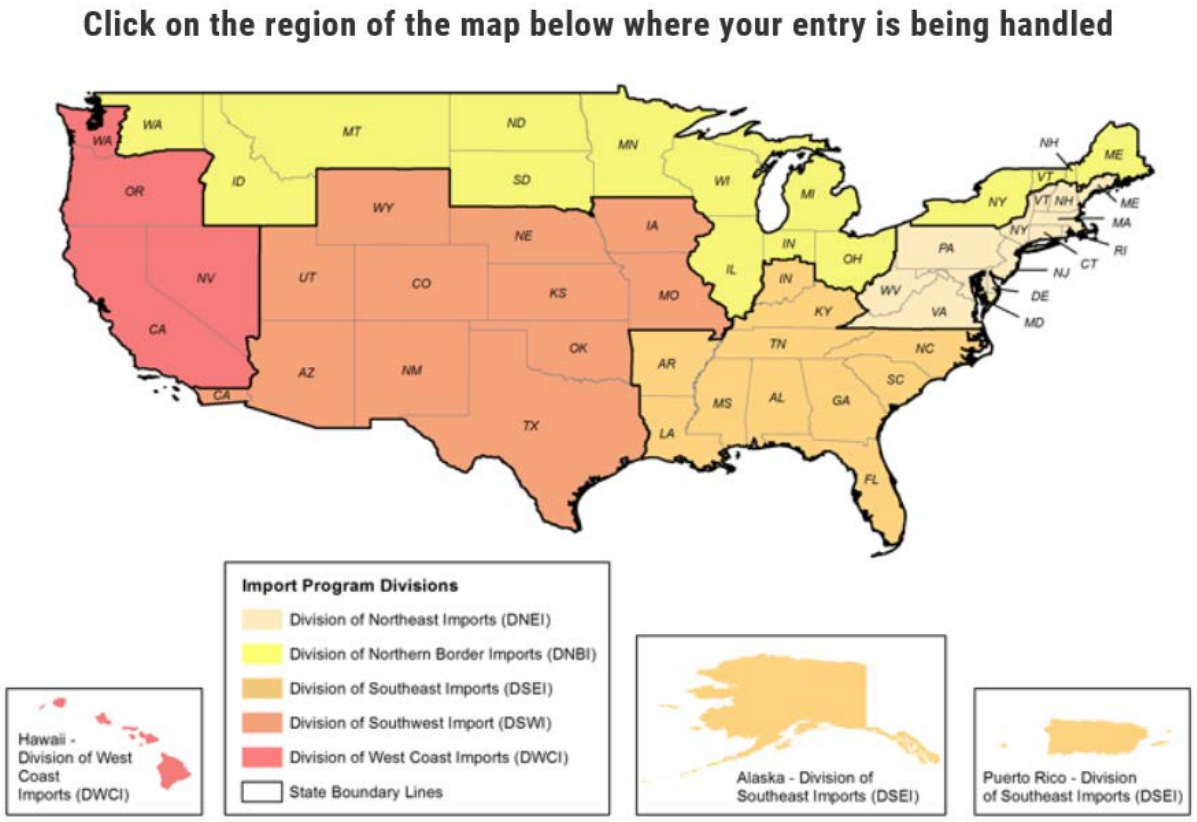
- FDAImportsInquiry@fda.hhs.gov; General Import questions

- DFDT main number 866-521-2297; Prior Notice processing

FDA Resources

"FDA Import Offices and Ports of Entry"

link: https://www.fda.gov/forindustry/importprogram/ucm319216.htm; Specific Import Entry inquiries



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