

CSMS #42118616 - Reminder: Update on FDA's Import Operations During The Coronavirus Disease 2019 (COVID-19) Outbreak

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Cargo Systems Messaging Service

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FDA's Import Operations currently remain functional and operational. Activities including FDA Prior Notice review, FDA entry processing, FDA sampling/examination of high risk shipments, FSVP inspections, filer assessments, and compliance activities are all ongoing.

While most import operations are not currently experiencing delays, the import community should expect delays in the receipt of hard copy notices. FDA will have a lessened capacity to generate and mail hard-copy Notices of FDA Action (release notices, sampling notices, etc.). FDA strongly encourages all members of the import community who deal in FDA-regulated articles to utilize the FDA Import Trade Auxiliary Communication System (ITACS) for current entry status and to receive FDA notices electronically.

The ITACS Account Management functionality enables the electronic distribution of Notices of FDA Action via email and as downloads from within ITACS. It also allows account holders to view the details of specific information requests, versus delivery of hard copy Notices of FDA Action. ITACS Account Management functionality may be used by customs brokers (entry filers), importers of record, and consignees with an approved ITACS account.

ITACS accounts can be requested via the FDA Unified Registration and Listing System (FURLS) at <https://www.access.fda.gov/oa> for those who have not already created an account. Please follow the step by step instructions provided in the ITACS Account Management Presentation at <https://www.fda.gov/industry/import-systems/itacs> to request an account. Please note that approval of an account request may take 2-3 business days, or longer if additional information is needed from the requestor.

ITACS basic functionality can always be accessed at <https://itacs.fda.gov>. This includes checking statuses, providing requested documentation electronically, and providing location of goods for examination electronically.

Additional information on ITACS, including questions and answers, can be found on FDA's ITACS for Industry webpage. For further questions regarding ITACS, please contact itacssupport@fda.hhs.gov.

FDA is continuously monitoring COVID-19 events and will provide updates as circumstances warrant. Additionally, COVID-19 information can be found on FDA's website for Coronavirus Disease 2019 (COVID-19).

Entry related questions and/or issues:

- For issues related to Prior Notice processing, contact FDA's Division of Food Defense Targeting at their main number 866-521-2297;
- For issues related to FDA entry admissibility processing, contact your usual local FDA contacts. These can be found using FDA's "FDA Import Offices and Ports of

Entry” webpage at this link:

<https://www.fda.gov/forindustry/importprogram/ucm319216.htm>

- For questions regarding product coding, intended use codes, and/or general inquiries, please contact: FDAImportsInquiry@fda.hhs.gov.
- For ACE inquiries, contact FDA ACE Support, 877-345-1101, ACE_Support@fda.hhs.gov. ACE Support Hours: Monday - Friday, 6AM-8PM EST, Saturdays, 8AM-4PM EST. ACE Support is Closed on Sundays.

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