

IMPORTS

ITACS FACT SHEET

ITACS (Import Trade Auxiliary Communications System) basic functionality was released in August 2011 and provides the import trade community with four functions: the ability to check the status of FDA-regulated entries and lines, the ability to submit entry documentation electronically, the ability to electronically submit the location of goods targeted for FDA exam, and the ability to check the estimated laboratory analysis completion date for sampled lines.

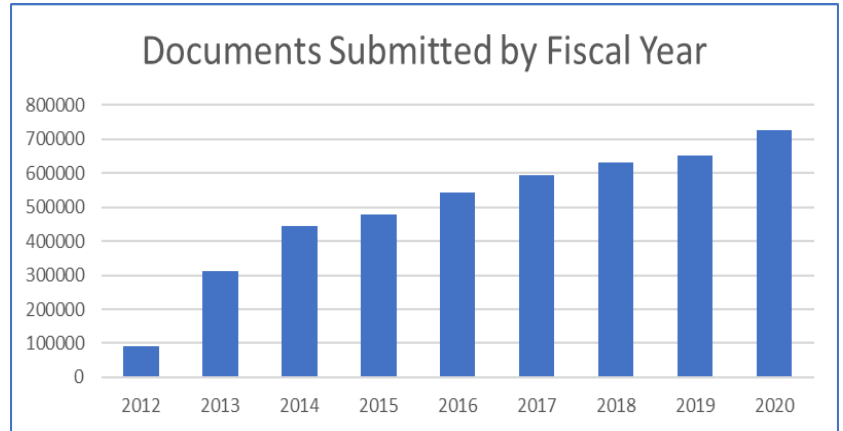
Documents may be submitted as PDF files as well as other common file and picture types including Microsoft Word documents and jpeg files.

Note that review of documents submitted to FDA via ITACS is prioritized over review of documents submitted to FDA via other means.

When submitting availability of goods for examination, the user may either indicate that the goods are located at the consignee as filed in the FDA entry, or at another location as entered by the user.

ITACS basic functionality may be accessed via the web at <https://itacs.fda.gov>. No login accounts are necessary. All that is needed is a valid Customs entry number that has been successfully transmitted to FDA.

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, which are currently delivered via hard copy Notices of FDA Action. ITACS Account Management functionality may be used by Filers, Importers of Record and Consignees with an approved ITACS account.

Note that an ITACS account is not required to import FDA regulated goods. To be granted an ITACS account a firm must have been a party to a previously transmitted, non-disclaimed FDA entry.

ITACS accounts are limited to one individual per firm at the corporate level. This person should be a high-ranking individual within the firm as they will have the responsibility to create and manage ITACS accounts for other users within their firm.

ITACS accounts can be requested via the FDA Unified Registration and Listing System (FURLS) at <https://www.access.fda.gov/oa/>

Use of ITACS offers several benefits to the Import Trade Community as well as to FDA, including more detailed FDA entry/line statuses than what is currently transmitted to filers via CBP systems reducing the need for phone calls inquiring about entry status, eliminating the need to email or fax entry documentation and goods availability to FDA, and no problems with lost documents.

Benefits of ITACS accounts include faster receipt of Notices of FDA Action via email or download in ITACS, no need to maintain paper copies of Notices of FDA Action as they will continue to be available in ITACS even after an entry is closed and faster receipt of requests for specific information by email or ITACS.

For questions about ITACS as well as to report problems and suggest improvements, please contact itacssupport@fda.hhs.gov.

