ITACS Questions & Answers

ITACS is an online communication system for submitting entry documentation, goods availability information and checking entry status for FDA entries. Learn answers to frequently asked questions on FDA's Import Trade Auxiliary Communication System, ITACS.

Q: What does it mean if ITACS says, "FDA entry status information is not available pending receipt of Conveyance Arrival Notification"?

A: ITACS will provide status information on truck and air shipments only after U.S. Customs and Border Protection (CBP) marks the shipment as having arrived. You might get this message even if the goods have physically arrived and have received a Conditional Release. CBP can give a Conditional Release before the entry has arrived. If you get this message, you may still upload documents via ITACS to allow for FDA review of the entry.

Q: What does it mean when ITACS says "Entry number could not be found or is not valid." when I search for an entry?

A: It means the entry number provided has not been transmitted to FDA. If you have verified that the entry number is correct, you will need to contact your CBP Client representative to determine the transmission status of the entry.

Q: What does it mean when ITACS says "Line number could not be found or is not valid." when I search for an entry?

A: It means the line numbers provided are incorrect or provided in an incorrect format. Line numbers are optional and will return no results if entered incorrectly. Searching on just the entry number is recommended.

Q: Why won't ITACS allow me to submit availability information for my entry?

A: ITACS will allow you to submit availability information only for lines that have been selected for physical examination or sampling by FDA. Otherwise, ITACS will not accept information regarding the availability of goods.

Q: Why won't ITACS allow me to submit documents for my entry?

A: ITACS will not allow document upload for an entry that has been closed by FDA. This indicates that FDA has made an admissibility decision for all lines of the entry.

Q: Why does the system display the message "no public status available"?

A: This message indicates that the FDA office has not yet taken an action and the line is pending review. Receipt of this message does not prevent you from uploading documents.

Q: Can you review my documents and provide an FDA release if I email you at ITACS?

A: No, the ITACS email address (<u>itacssupport@fda.hhs.gov</u>) is for technical assistance with ITACS. To submit documents via ITACS, go to <u>https://itacs.fda.gov</u>. If you have questions about your specific entry contact the FDA office at the <u>Port of Entry</u>.

Q: How do I find out further information regarding the status of my entry or pending FDA exam?

A: The most up to date entry status can be viewed via ITACS at <u>https://itacs.fda.gov</u>. For further information regarding entry status or pending FDA exam contact the FDA office at the <u>Port of Entry</u>.

Q: How do I view the documents uploaded to ITACS?

A: ITACS is to be used for submitting documentation to FDA. Documents uploaded via ITACS cannot be viewed by ITACS users.

Q: I can't open ITACS. Is it working?

A: Be sure you are using the direct link to ITACS, <u>https://itacs.fda.gov</u>, rather than a bookmarked or saved link. If you continue to have problems accessing ITACS contact ITACS Support at <u>itacssupport@fda.hhs.gov</u>.

Q: Do I need an ITACS account?

A: An ITACS account allows the account holder to receive electronic Notices of FDA Action via email and/or as a downloadable pdf from within ITACS. ITACS accounts are approved for firms that have been named as an interested party, Filer, Importer of Record and/or Consignee, in a previously transmitted FDA entry. Note: an ITACS account is not required to submit documents or availability information for FDA review via ITACS.

Q: How do I request an ITACS account?

A: ITACS accounts can be requested via the FDA Unified Registration and Listing System (FURLS) at <u>https://www.access.fda.gov/oaa/</u>. Also see the ITACS Account Management Presentation.

If you have additional questions, please e-mail <u>itacssupport@fda.hhs.gov</u>.