

Division of West Coast Imports (DWCI) Communication Document

For general FDA import questions <u>not</u> related to a specific entry, please use the following email address: <u>FDAImportsInquiry@fda.hhs.gov</u>.

To request the status on an entry, check <u>ITACS</u> before contacting the DWCI.

For FDA Import offices and DWCI contact information use the following link: <u>https://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm</u>

Background

Import Trade Auxiliary Communications System (ITACS) basic functionality 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 availability for those lines targeted for FDA exam and the ability to check the estimated laboratory analysis completion dates for lines which have been sampled. No login accounts are necessary to access these functions. 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 will also allow account holders to view the details of specific information requests, which are currently delivered via hard copy Notices of FDA Action. Implementation of login accounts will also allow for future enhancements requested by the Import Trade Community which require user verification.

Benefits to the trade 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. Note: If a firm chooses to receive their Notices of FDA Action electronically, paper copies will no longer be mailed to that firm.

ITACS account management functionality will be available to Importers of Record, Filers, and/or Consignees which have been associated with at least one previous FDA entry. ITACS accounts will be limited to one individual per firm at the corporate level. That person will have the responsibility to create and manage ITACS accounts for other users within the same firm, regardless of their location. ITACS accounts will be requested via the FDA Unified Registration and Listing System (FURLS).

More information can be found on FDA's ITACS for Industry web page at: <u>https://www.fda.gov/forindustry/importprogram/entryprocess/importsystems/ucm480953.htm</u>



Emailing Division of West Coast Imports (DWCI): WCID@fda.hhs.gov DWCI covers port codes in CA, HI, OR, NV, WA

While ITACS is the preferred method for uploading documents and checking status, DWCI understands that there will be instances when you will need to email the division directly. To ensure that your questions are reviewed and routed in an efficient and timely manner, it is important that you format the subject line as follows:

SUBJECT LINE FORMATTING

Properly formatted subject lines will consist of 7 elements:

- 1. Entry number (Only one entry number per email)
- 2. Comma
- 3. One space
- 4. Reason for the email (See examples below)
- 5. Comma
- 6. One space
- 7. Port code

Examples of properly formatted subject lines:

- 000-1234567-8, Compliance Documents, 2704
- ABC-1234567-8, Extension Request, 2801
- 000-1234567-8, Cancellation Request, 3001
- ABC-1234567-8, Status Inquiry, 2709

Improperly formatted emails will be returned to the sender for correction. DWCI may request that the documents be submitted via ITACS if it will result in a faster response.

RECIPIENTS

Please send all electronic correspondence through <u>WCID@fda.hhs.gov</u>. Please do not copy multiple FDA addressees on emails. WCID@fda.hhs.gov *is the main conduit for email distribution and will route your email to the appropriate FDA personnel.*

ATTACHMENTS

Due to security and IT restrictions, FDA can only process pdf attachments. Any non-pdf documents sent to <u>WCID@fda.hhs.gov</u> will be returned to the sender to be resubmitted as pdf attachments. Attachments are not to exceed 10 MB.

Please note that <u>ITACS</u> can process any type of attachment, up to 5x 50MB and these documents will be received and reviewed faster than if submitted via <u>WCID@fda.hhs.gov</u>.



PLEASE BE SURE TO READ YOUR NOTICE OF FDA ACTION IN ITS ENTIRETY

Entry Review:

Entry Review is the initial status that all entries will go through. Entries will be processed by our system and if an examination is required, the entry will be assigned to an entry reviewer. **Please** wait 5 business days before requesting status update.

Please use the following reasons for communication:

- Status: If you would like an update on status, please first check ITACS. Please email <u>WCID@fda.hhs.gov</u> if you have additional questions. Please wait 5 business days before requesting status update.
- Entry Documents: If requested, please upload entry documents via ITACS. If for some reason you are unable to upload entry documents via ITACS, please send an email to ITACSSupport@fda.hhs.gov. Once the issue is addressed, you should be able to upload your documents. Note: Please be sure to upload your documents as one file whenever possible.
- Location: If requested, please submit location/line availability via ITACS. If for some reason you are unable to submit location/line availability via ITACS, please send an email to <u>ITACSSupport@fda.hhs.gov</u>. Once the issue is addressed, you should be able to submit your location/line availability.

Investigations Branch:

Investigative work may be requested before an admissibility decision can be made.

Please use the following reasons for communication:

- Exam status: Please wait 5 business days from the date of location submission before contacting FDA. If over 5 business days without a call from investigator, please email <u>WCID@fda.hhs.gov</u> for status update.
- CBP Cancellation request (Only for Los Angeles/Long Beach and LAX ports): Prior to submitting cancellation request to CBP, you will need to obtain an authorization letter from FDA. Please gather the following documents and FDA will issue cancellation authorization letter: Letter on company letterhead stating in detail the reasons for cancellation, the old entry number and documents, the new entry number and documents. If cancellation is not processed within 5 business days, please email <u>WCID@fda.hhs.gov</u> requesting status on the cancellation request.



- For high priority cancellations (at terminal accruing storage charge): Please follow the above steps for entry cancellation. Please format your subject line as follows: "Entry number to be cancelled, CBP cancellation request- High priority terminal hold, port number."
- ** Please note that prior notice cancellations will need to go through the Division of Food Defense and Targeting (DFDT). You can contact them at 866-521-2297 or email them at prior.notice@fda.hhs.gov. **

Compliance Branch:

Entries are under compliance review after being detained. You can check the status of your entry by utilizing <u>ITACS</u>.

Please use the following reasons for communication:

- Labs: External lab analysis packets to be submitted to FDA for review.
- **Extension Request**: Extension request for detained entries/lines. Please note how many days you are asking for extension and which lines you are requesting for.
- **Reconditioning**: Request to recondition detained entries. Includes both initial reconditioning requests via email and Form FDA 766
- **Refusal request**: Request to have detained entry/lines refused so that exportation/destruction process can begin.
- **Correspondence**: All other compliance-related documents not mentioned above. Includes all responses to notice of detention including pictures, labels, testimony, etc.

For expedited processing, please upload compliance documents via <u>ITACS</u>. If you require additional assistance, please contact FDA at <u>WCID@fda.hhs.gov</u>.

DWCI Refusal Process: Refusal Redelivery Notice (RRN) (Only for ports covered by Los Angeles/Long Beach and LAX):

In January of 2013, CBP and FDA created the Federal Destruction and Redelivery Team, or Team FDR. Instead of receiving a separate CBPF 4647 and Notice of FDA Action (Refusal of Admission), importers receive a combined RRN. The RRN is the Refusal of Admission issued by FDA and stamped by CBP to indicate redelivery. A cover sheet with port specific instructions for exportation or destruction of FDA refused merchandise will be included along with the CBP Los Angeles-Long Beach Public Bulletin LA19-007, Los Angeles Field Office Procedures for CBP/FDA Refused Merchandise effective July 18, 2019.



Please use the following reasons for communication:

- RRN reprints: hard copy or electronic, may be requested via <u>WCID@fda.hhs.gov</u> for RRNs that have not been received five (5) business days after issuance. This provides for printing, processing and mailing time, and helps to avoid duplicative work. For more information, please see CBP Los Angeles-Long Beach Public Bulletin LA19-007. Copies of the public bulletin may be requested via <u>WCID@fda.hhs.gov</u> or through a local CBP office.
- Refusal Verification Exam Appointment: Please wait 5 business days from the date you submitted the refusal package to CBP before contacting FDA. If you have not received a call and it has been over 5 business days, please email <u>WCID@fda.hhs.gov</u> for status update.

CLOSING

Electronic communications programs are dynamic resources for both regulated industry and government agencies. Electronic communications will help to improve processing times, while helping to reduce the environmental impact of operations. Comments and feedback are always welcome.

Thank you,

Division of West Coast Imports

Office of Regulatory Affairs Office of Enforcement and Import Operations Division of West Coast Imports WCID@fda.hhs.gov