Division of West Coast Imports (DWCI) Communication Document

- For general FDA import questions not related to a specific entry, please use the following email address: FDAImportsInquiry@fda.hhs.gov.
- For issues with **Prior Notice**, please email prior.notice@fda.hhs.gov or call 866-521-2297.
- Any updates made on **PGA**, please email **ITACS Support** at ITACCSupport@fda.hhs.gov
- To request the status on an entry, check ITACS before contacting the DWCI.
- For contact information, you can access the FDA Import offices and Ports of Entry web page.
- Refer to CSMS #45364915 – FDA Recommends Use of ITACS.

Background

Import Trade Auxiliary Communications System (ITACS) provides the import trade community with four functions: (1) the ability to check the status of FDA-regulated entries and lines, (2) the ability to submit entry documentation electronically, (3) the ability to electronically submit the location of goods availability for those lines targeted for FDA exam and (4) 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.

For those that sign up, ITACS 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 currently delivered via hard copy Notices of FDA Action. Implementation of login accounts will 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: Paper copies will no longer be mailed if you choose to receive the FDA Notice of Action electronically except for Refusal Redelivery Notices (RRNs) which will continue to be mailed out via USPS.

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: https://www.fda.gov/forindustry/importprogram/entryprocess/importsystems/ucm480953.htm

Emailing Division of West Coast Imports (DWCI): WCID@fda.hhs.gov

DWCI covers air and sea port codes in CA, HI, OR, NV, WA only.

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 5 elements:

1. Entry number (Only one entry number per email)
2. One space
3. Reason for the email (See examples below)
4. One space
5. 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 may be returned to the sender for correction.

RECIPIENTS

Please send all electronic correspondence through WCID@fda.hhs.gov. 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. **The FDA strongly recommends document submission via ITACS, as this automatically notifies assigned personnel of the update**. Any non-pdf documents sent to WCID@fda.hhs.gov will be returned to the sender to be resubmitted as pdf attachments. Attachments are not to exceed 10 MB.

FDA highly recommends use of ITACS to submit any documents thorough out the import process as documents submitted to ITACS are generally received and reviewed faster than those sent via email. ITACS accepts most file types including PDF files, Microsoft Word documents, and other common file and picture types, up to 5 documents of up to 50MB each, per submission.

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 4 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. If you have additional questions about a status, please email WCID@fda.hhs.gov. Please wait 4 business days after submission 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 ITACSSupport@fda.hhs.gov. Once the issue is addressed, you should be able to submit your location/line availability.

Investigations Branch:

Entries may need to be examined and/or sampled by Investigation Branch.

Please use the following reasons for communication:

- **Updating Filer Information –** Please inform FDA of any necessary changes to filer Information as soon as possible as this ensures effective and timely communication with FDA. Please include firm name, FEI number, physical and mailing address and point of contact information including phone number and email address.

- **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 WCID@fda.hhs.gov 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 WCID@fda.hhs.gov requesting status on the cancellation request. The following instances not eligible for cancellations: entries to be sampled, entries for field exam, detained entries, and refused entries.

- **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. ****

- **Refusal Verification Notification/ Appointment:**
  - **(For all DWCI ports excluding port 2704/2720/2722):** Follow your local CBP procedures for initiating the exportation or destruction of the refused article(s). Submit via ITACS a copy of the appropriate documents and notify us via email at WCID@fda.hhs.gov. Please format your subject line as follows: "[PORT NUMBER] FDA NOTIFICATION OF EXPORTATION OR DESTRUCTION [ENTRY NUMBER]."
  - **For port 2704/2720: follow instructions in Public Bulletin LA 19-007.**
  - **For port 2722: follow instructions in Public Bulletin LA21-010.**

DWCI Refusal Process:

The Refusal Redelivery Notice (RRN) is only for ports covered by Los Angeles/Long Beach, Los Angeles International Airport (LAX) and McCarran International Airport (LAS) Ports 2704, 2720, 2722.

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.

In April of 2021, The LAS port started using the RRN process with the issuance of Public Bulletin LA21-010 the "*Los Angeles Field Office Procedures at McCarran International Airport for CBP/FDA Refused Merchandise*".

A cover sheet with port specific instructions for exportation or destruction of FDA refused merchandise will be included along with the most recent copies of the CBP Public Bulletin LA19-007 and LA21-010.

Compliance Branch:

For entries that are under compliance review, you can check the status of your entry by utilizing ITACS.

If additional documents are requested during compliance review, using the line level upload in ITACS is necessary to notify the Compliance Officer assigned to the entry. We recommend uploading compliance documents via ITACS at the line level.

Please use the following reasons for communication:

- **Labs**: External lab analysis packets to be submitted to FDA for review. Please upload lab packets using line level upload in ITACS prior to reaching out WCID**.**
- **Extension Request**: Extension requests for detained entries/lines. For each line item you are requesting, please note how many days you are asking for extension and provide your reason for extension along with any supporting documentation. Please upload any extension requests using line level upload in ITACS prior to reaching out to WCID**.**
- **Reconditioning**: Requests to recondition detained entries. Include reconditioning request and Form FDA 766, Application for Reconditioning. Please upload any reconditioning documents using line level upload in ITACS prior to reaching out to WCID**.**
- **Refusal request**: Requests to have detained entry/lines refused so that exportation/destruction process can begin.
- **Correspondence**: All other compliance-related requests or documents not mentioned above. Includes all responses to notice of detention including pictures, labels, testimony, etc. Please use ITACS first to upload documents in the line level.

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