Chapter 6 - Imports

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6.1 – Imports General

6.1.1 – Authority

Section 801 of the Food Drug and Cosmetics Act (FD&C) Act [21 U.S.C. 381] authorizes the FDA to examine foods, drugs, cosmetics, devices, and tobacco products offered for entry into the United States. Section 536 of the FD&C Act [21 U.S.C. 360mm] authorizes refusal of radiation-emitting products which fail to comply with the requirements of Section 534 (h) of the FD&C Act [21 U.S.C. 360kk (h)]. 19 CFR 151.4 of the U.S. Customs and Border Protection (CBP) regulations authorizes employees of the FDA to examine or take samples of entry goods released under immediate delivery.

The procedures outlined in this chapter cover imported goods subject to, but not limited to, the following acts/regulations:

- Federal Food, Drug, and Cosmetic Act (FD&C)
- Fair Packaging and Labeling Act (FPLA)
- Nutrition Labeling and Education Act (NLEA)
- Import Milk Act/ Filled Milk Act
- Federal Caustic Poison Act
- Bioterrorism Preparedness Act of 2002
- Public Health Service Act, Part, Part F, Subpart 1, Biologic Products
- Title 21 CFR Subpart E - Imports and Exports (1.83), etc.
- Title 19 CFR Customs Duties (authority to sample delegated by CBP Regulations, etc.)
- Federal Cigarette Labeling and Advertising Act and Comprehensive Smokeless Tobacco Health Education Act
- Family Smoking Prevention and Tobacco Control Act

6.1.2 – Scope

The procedures in this section cover imported goods. Your personal safety during any import procedures outlined in this subchapter is important. For more information concerning personal safety, see IOM 5.3 and IOM Chapter 10.

6.1.3 – Division of Authority

The FDA determines if an article complies with the Acts it enforces. It also determines whether the article can be brought into compliance with the appropriate statute and authorizes reconditioning for that purpose.

Supervision over the reconditioning is exercised by either the FDA, or CBP, as mutually arranged. At ports in reasonable proximity to an FDA office, supervision is ordinarily exercised by the FDA. At remote ports, supervision may be exercised by CBP.

In the case of a refusal of admission action is by compliance, exportation and / or destruction of goods is carried out under the direction of CBP. However, the actual supervision of the destruction and / or exportation of violative goods may be conducted by FDA pursuant to a local FDA/CBP agreement.

6.1.4 – Entry Types

6.1.4.1 - Formal Entries

All articles offered for entry into the United States that are subject to the acts enforced by the FDA and possess a value greater than $2,500 are considered formal entries. These entries are subject to bond requirements, which include a condition for the redelivery of the goods, or any part of them, upon demand by CBP, at any time, and as prescribed for in the CBP regulations in effect on the date of entry. (Section 801(b) of the FD&C Act [21 U.S.C. 381(b)], 19 CFR Part 113). The bond is filed with CBP which, in case of default, will take appropriate action for the collection of liquidated damages provided for in the bond after consultation with the FDA. (19 CFR Section 113.62 and 21 CFR Section 1.97). Notification of the entry is generally accomplished by electronic submission through the CBP Automated Commercial Environment (ACE). Non-electronic entries are submitted directly to the FDA. Electronic entries received by the FDA may be subject to manual review to determine if further action is needed,

or if additional documentation is required. For entries requiring further review, the FDA will be provided the appropriate CBP entry documents (such as the CF 3461 / 3461ALT, commercial invoice, bill of lading and any other relevant documents to aid in making an admissibility decision), which will also document the extent of the interstate commerce. If an entry is not filed electronically, these documents will be submitted to the FDA at the time the CBP entry is made, in accordance with local port of entry operations.

6.1.4.2 - Informal Entries

Normally, informal entries with a value of less than $2,500) do not require a redelivery bond. All informal entries of articles subject to FDA jurisdiction and entered electronically, are forwarded to the FDA through the CBP/FDA ACE interface. In instances when the FDA takes action on an informal entry not filed electronically, agency personnel will record the informal entry in the FDA Import Systems as a manual entry (IOM 6.1.4.5). If agency action is indicated, the FDA will then request that a formal consumption entry be filed.

6.1.4.3 – Mail Entries

Mail entries consist of articles offered for entry by USPS international mail through International Mail Facilities (IMFs). They are often valued at less than $2,500 and are considered informal entries that do not require a bond or formal entry to be filed with CBP. When USPS receives international mail, CBP will screen the parcels and refer any FDA-regulated products of interest to the FDA. FDA divisions should arrange for coverage at their local IMF to receive these referrals. FDA personnel will review the referrals based on priority and determine whether the parcel should be sampled, released, or referred to compliance, or a Partner Government Agency / Other Government Agency (PGA/OGA), or if the Office of Criminal Investigations (OCI) should be notified. Note that drugs or devices encountered through international mail may be subject to destruction. For further details, refer to the Procedures for FDA-Regulated Articles Shipped Through International Mail Facilities.

6.1.4.4 – Personal Baggage

CBP is responsible for examination of personal baggage at border-crossing offices, airports, and seaports. If CBP encounters an article subject to FDA regulations, they may refer it to the local FDA office for review.

During this review, if FDA personnel determine that the products referred are in violation of FDA regulations, they should refer the entry to compliance for applicable charges. FDA personnel may also need to determine if the products qualify as an exemption under personal importation. If it's found that a personal importation meets the criteria of a formal entry, FDA personnel should request thru CBP that a formal entry be filed. If no formal entry is filed, the referral should be processed in accordance with manual entry procedures (IOM 6.1.4.5). Since most personal importations are small in size and value, guidance has been developed for evaluating these importations. (See RPM Chapter 9-2"Coverage of Personal Importations".)

Entries with a value of $800 or less may fall under "Section 321."Generally, this form of entry applies to articles which pass free of duty and tax, and are imported by one person on a single business day (19 C.F.R. 101.1 . CBP and the FDA may conduct periodic "blitzes" on such entries to determine the volume and type of FDA-regulated goods being admitted under "Section 321." Note, however, that the use of the "Section 321" entry process should not apply to multiple shipments covered by a single order or contract that have been sent separately for the express purpose of securing free entry and avoiding compliance with pertinent laws or regulations.

6.1.4.5 – Manual Entries

Manual Entry is a term often used interchangeably with non-ABI entry and/or paper entry in the context of entries submitted to CBP and the FDA in a non-electronic manner outside of ACE.

Detailed instructions for creating a manual entry can be found in the Job Aid for the Entry Review Application.

When a manual entry is received, it may be necessary to enter the entry information into an FDA Import System. You should do this when the agency plans to conduct additional work on an entry (for instance, examination, sampling, detention, etc.). Note that information entered by the FDA is not transmitted to CBP as the FDA does not collect all the information CBP requires for a given entry. Once you have input relevant information into an FDA

Imports Systems, (ER, SERIO, OASIS), the entry will be processed following usual procedures. Remember that for entries manually entered by FDA, there is no bond or monetary value attached.

In instances of manual entries not requiring further action, you should not need to create an electronic record. This includes entries directly released by the FDA after review of entry documentation.

Note: If the product being offered for manual entry is a human food or animal food/feed, prior notice filing is still required in advance of its arrival in the United States (IOM 6.1.5). For non-electronic entry filings, prior notice can be submitted through FDA's Prior Notice System Interface (PNSI).

As indicated in RPM 9-1, the FDA historically has and will continue to accept and process paper entries to determine admissibility for imported FDA-regulated products (regardless of value), if the paper entry submission process continues to be an acceptable entry submission process for CBP. And though the FDA accepts entry data submitted via non-ABI (paper/manual) means, electronically filed entries do take priority. CBP regulation, found at 19 CFR 141.61, cover the completion of entry and entry summary documentation.

***Note:** For detailed instructions on how to create a manual entry, please see the Job Aid for the Entry Review Application.

6.1.4.6 – Import for Export (IFE) Entries

These are products imported under the provisions of FD&C Act Section 801(d)(3) [21 U.S.C. 381(d)(3)].

REFERENCES: Regulatory Procedures Manual Chapter 9-17, FD&C Act Section 801(d)(3) [21 U.S.C. 381(d)(3)] allows the importation of certain violative FDA-regulated articles into the U.S. on a conditional basis ensuring that they are not for domestic distribution. Those articles include human and veterinary drugs (or their components); device components or accessories, or other devices requiring further processing for health-related purposes; and food additives, color additives, and dietary supplements including in bulk form. They must be explicitly intended for further processing or incorporation into other products and subsequent export. This section outlines procedures to help you facilitate the uniform review and admissibility process for IFE entries, and those that enable sufficient notification for domestic follow-up of IFE shipments.

The following documentation is required at the time of importation according to section 801(d)(3) of the Act [21 U.S.C. 381 (d)(3)] includes:

1. A statement that the article is intended to be further processed or incorporated into a drug, biologics product, device, food, food additive, color additive, or dietary supplement and will be exported under sections 801(e)or 802 of the FD&C Act [21 U.S.C. 381 (e) or 382] or Section 351(h) of the Public Health Service Act (PHSA) [42 U.S.C . 262(h)].
2. Information/documentation that identifies the manufacturer of the article, as well as each processor, packer, distributor, and/or other entity in the chain of possession from manufacturer to importer. (Attempt to gather the name and address of each entity in the chain of possession if such details not evident.)
3. Such certificates of analysis as necessary to identify the article, unless it is a device or falls under section 801 (d)(4) of the FD&C Act [21 U.S.C. 381 (d)(4)] - to include blood and blood components.

In addition, a good and sufficient bond must be executed providing for payment of liquidated damages in accordance with CBP requirements. Refer to RPM 9-17. However, note that some entry types may not be accompanied by a bond.

6.1.4.6.1 – IFE Entry Review

Import for Export entry procedures are as follows:

1. Divisions should ensure that all information required under section 801(d)(3) FD&C Act [21 U.S.C. 381 (d)(3)] is provided and that supporting documents are uploaded (if not already received from the broker or importer).

a. Confirm that IFE or suspected IFE entry/lines are submitted with an intended use code (IUC) of "Import for Export" and with the IFE in the Affirmation of Compliance (A of C). If the entry/line lacks the IUC IFE and/or the IFE A of C, update the entry/line, record the reason for the update, save, and rescreen the entry/line. For entry/lines lacking complete supporting documents, request documents per IOM 6.2.3.1.
b. If the required documents are not provided after they are requested, entry reviewers should request detention, indicating the products do not meet the regulatory requirements, are being offered for import using the IFE provisions, and are missing the required IFE documentation at the time of initial importation. Refer to RPM 9-17-3 for additional information.
c. If all required documents are provided, including the IUC, and per conditions required by section 801(d)(3) FD&C Act 21 U.S.C. 381 (d)(3), a "May Proceed" may be issued. NOTE: Ensure that all entry documentation has been uploaded to the entry/line prior to making an admissibility decision.

2. If the entry/line was transmitted as an IFE, but review of the entry/line information or supporting documentation indicates that the articles are not intended to be further processed and exported per section 801(d)(3) of the Act 21 U.S.C. 381 (d)(3):
   a. Update the entry/line with appropriate IUC and A of Cs, as appropriate.
   b. Record the reason for update, save, and rescreen the entry/line.
   c. Review the entry/line according to applicable requirements.

NOTE: If receiving a non-ABI entry declared as IFE, refer to the Entry Review Job Aid for specific instructions on creating a manual entry in ER.

6.1.5 - Prior Notice of Importation of Food and Animal Feed

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as the Bioterrorism Act) requires that FDA receive prior notice of food, including animal feed, that is imported into the United States. Most of the information required by the final rule is provided to CBP by importers and brokers when foods arrive in the United States. The Bioterrorism Act requires that this information also be provided to FDA, prior to the arrival of an imported article of food into the country. Advance notice of import shipments allows the FDA, with the support of CBP, to target import inspections more effectively and better protect the nation's food supply against potential contamination from acts of bioterrorism and other public health emergencies. Prior notice can be submitted either through the Automated Broker Interface (ABI)/Automated Commercial Environment (ACE) or FDA's Prior Notice System Interface (PNSI).

6.1.5.1 – Prior Notice Inspection

Prior notice for food articles subject to the rule must be received and confirmed electronically by the FDA *no more than 15 calendar days* before the anticipated date of arrival for submission made through the PNSI, and *no more than 30 calendar days* before the anticipated date of arrival for submission made through ABI/ACE, and, dependent on the mode of transportation below, no fewer than:

- Two hours before arrival by land by road
- Four hours before arrival by air or by land by rail
- Eight hours before arrival by water

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. (The parcel must be accompanied by confirmation of FDA receipt of prior notice.)

6.1.5.2 – Products Requiring Prior Notice

Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of prior notice requirements, "food" is defined by Section 201(f) of the FD&C Act [21 U.S.C 321(f)] as articles used for food or drink for man or other animals (including chewing gum) and articles used for components of any such articles.

Examples of "food" include:

- Dietary supplements and dietary ingredients.
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Seafood
- Dairy products and eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack foods, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

6.1.5.3 – Products Excluded from Prior Notice

Foods that are excluded from the prior notice requirement include:

- Food carried by, or otherwise accompanying, an individual arriving in the United States for that individual's personal use (that is, for consumption by themselves, family, or friends, and not for sale or other distribution).
- Food that is exported without leaving the port of arrival until export.
- Meat products, poultry products, and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 USC 601), (21 USC 601), the Poultry Products Inspection Act, or the Egg Products Inspection Act.;
- Food made by an individual in their personal residence and sent by that individual as a personal gift (that is., for non-business reasons) to an individual in the United States.
- Articles of food subject to Article 27.3 of the Vienna Convention on Diplomatic Relations (1961). For example, shipped as baggage or cargo constituting the diplomatic bag.

6.1.5.4 – Prior Notice Submission

The prior notice must be submitted electronically and contain the following information, in accordance with 21 CFR 1.281:

1. Identification of the submitter, including name, telephone number, email address, and firm name and address.
2. Identification of the transmitter (if different from the submitter), including name, telephone number, email address, and firm name and address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.
3. Entry type and CBP entry identifier, if available.
4. The identification of the article of food, including complete FDA product code, the common or usual name or market name, the estimated quantity described from the largest container size to the smallest package, and the lot or code numbers or other identifier (if applicable).
5. If the food is no longer in its natural state (21 CFR 1.276(b)(10)), the name of the manufacturer and either (1) the registration number, city and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided.
6. If the food is in its natural state, the name and growing location address of the grower, if known. If the identity of the grower is unknown, or the article has been consolidated from multiple unknown growers, the name and address of the firm that consolidated the articles of food from different growers or different growing locations can be provided.
7. The FDA country of production.

8. The identification of the shipper, express consignment operators, carriers, other private delivery service or senders if the food is mailed. This should include the name and full address of the shipper if the shipper is different from the manufacturer. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper's registered facility city and country instead of the facility's full address.
9. The country from which the article of food was shipped. If the food was imported by international mail, the country from which the food was mailed.
10. The anticipated arrival information (port of arrival, date, and time). If the food is imported by international mail, the anticipated date of mailing. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the anticipated arrival information. For post-refusal submissions, the actual date the article arrived is required.
11. The name and full address of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States. The name and address of the U.S. recipient should be provided for food arriving by international mail. If the business address of the importer, owner, or ultimate consignee is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address.
12. The identification of the carrier and mode of transportation, except for food imported by international mail.
13. Planned shipment information as applicable by mode of transportation and when it exists. For food arriving by express consignment operator or carrier, when neither the submitter nor transmitter is the express consignment operator or carrier, the tracking number can be submitted in lieu of the Bill of Lading or Airway Bill number for prior notices submitted via PNSI.
14. The name of any country to which the article of food has been refused entry.
15. The anticipated date of mailing, and beginning October 1, 2026, the name of the mail service and the mail tracking number 21 CFR 1.281 (b) (10).

6.1.5.5 – Inadequate Prior Notice Submission

Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in a secure storage facility. The FDA provided guidance to its stakeholders and CBP staff on enforcing such prior notice requirements in its Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This guidance, however, does not limit the FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns, or taking any other action under the FD&C Act. This policy will also not affect the ability of CBP to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

6.1.5.6 – Prior Notice Process

The prior notice review process begins with automated electronic screening. If additional evaluation of the prior notice information is necessary, a manual review is performed by FDA headquarters staff at the Division of Targeting and Analysis (DTA), which operates 24 hours a day, 7 days a week. The review process is designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon their arrival in the United States. Note that the review process is not impacted by the method of electronic submission and that results of the process are transmitted to CBP.

The DTA may initiate an examination or other action by the FDA or CBP at the port of arrival or elsewhere, or in the case of rail shipments, at the closest appropriate examination site. The DTA will advise the FDA field offices and/or CBP of the inspection requirements. The DTA is also responsible for communication with submitters regarding the following: prior notice compliance, the initiation of a refusal or hold due to inadequate prior notice

information or unregistered foreign manufacturers, responses to requests for review of refusals or holds, and completion of the prior notice process.

Food that meets prior notice requirements will be subject to further review by FDA staff for admissibility determination under section 801(a) of the FD&C Act. The FDA Import Systems screening will determine if further evaluation of the article of food is necessary (for instance, subject to the guidance in an import alert). If the FDA determines that refusal under section 801(a) of the FD&C Act is applicable, the appropriate procedures will be followed.

6.1.6 - Entry Processing

FDA division offices generally receive notification of all formal and informal entries subject to FDA's jurisdiction. Management for each port of entry determines coverage, hours of operation, and resource allocation for any office closures impacting normal working hours. In addition, FDA Import Systems allow for entries to be reviewed remotely by off-site personnel.

Entries submitted electronically to the FDA are screened against criteria established by FDA laws and regulations. Filers who submit entries via the ABI to Customs for cargo release are required to provide FDA-pertinent information on entries subject to its jurisdiction submitted through ACE. The means of receiving notification for non-ABI entries can be arranged through local Customs/FDA division agreements.

6.1.6.1 - U.S. Customs and Border Protection (CBP)

CBP's ACE uses guides established by each federal agency to identify which commodities are subject to their jurisdiction. These guides are known as Partner Government Agencies (PGA) flags. FDA flags include FD1, FD2, FD3, and FD4, which are defined accordingly:

- FD1: Entries covered by an FD1 flag may or may not be subject to FDA regulations. Electronic entries made by the filer may, based on information received from the importer regarding the intended use of the commodity, specify that the entry is not subject to FDA regulations, hence the resulting decision to "Disclaim" the entry. Otherwise, FDA required information must be submitted. The agency periodically performs reviews of "Disclaimed" entries is to help ensure the accuracy of declarations.
- FD2: Entries covered by an FD2 flag must include or reflect FDA-required information.
- FD3: Entries covered by an FD3 flag may be subject to prior notice under section 801 (m) of the FD&C Act and 21 CFR Part 1, subpart I (for instance, when the article has both food and non-food uses). The filer may, based on information received from the importer regarding the intended use of the commodity, specify the entry is not subject to prior notice and “Disclaim” the entry. If the product is an FDA-regulated product, but not a food, the entry can be disclaimed from prior notice by using the affirmation of compliance code “PND” in the entry.
- FD4: Entries covered by an FD4 flag may be “food” for which prior notice is required under section 801(m) of the FD&C Act and 21 CFR Part 1, subpart I. Entries covered by FD4 flag must include prior notice required information.

Electronic entries for CBP review include all mandatory CBP entry-required information, (that is, entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff System (HTS) code for product description, information on foreign shipper, country of origin, etc.) Through the screening process in ACE, CBP determines if the article is subject to FDA examination (see OGA flag identifications above). Note that CBP, the FDA, and 46 other PGAs have been working to modernize business processes through the implementation of the Automated Commercial Environment/International Trade Data System (ACE/ITDS). ACE/ITDS is a single-access point whereby industry can electronically submit all data required by various government agencies involved in international trade. (ACE replaced the Automated Commercial System (ACS) in 2016.)

6.1.6.2 – FDA

FDA's system enhancements include establishing Intended Use Codes (IUC) to assist entry reviewers in determining the end-use of the imported product. Commodities will fall in one of the three categories:

- IUC is required.
- IUC is optional.
- IUC is not applicable.

Affirmation of Compliance (or A of C) codes provide FDA reviewers with information concerning the imported article. They are also used by filers to affirm that the firm and/or product identified in an FDA line meet the requirements specific to the product being imported. A of C code requirements are dependent on the commodity being imported and can be impacted by the IUC. If you need to review the specifications and requirements for filing in ACE as per the final rule, refer to 81 FR 85854 Submission of Food and Drug Administration Import Data in the Automated Commercial Environment, and the FDA's Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS). (Direct link to the Supplemental Guide.)

FDA Import Systems will generate a "Notice of FDA Action," which will provide more specific information on the actions taken, broken down by each entry line (for example, "Samples Collected", "Detention," "Lines Released," or "Refusal of Admission"). As the status changes for a particular line, a new "Notice of FDA Action" will be issued to advise appropriate parties of the changes. For parcels not received through a USPS IMF, the use of one of the following designations: "Product Collected by FDA," "Detained," "Released," "Refused," or similar language on the "Notice of FDA Action," should be considered as satisfying the requirements of the law for "giving notice thereof to the owner or consignee." (See 21 USC 381(a).) See Exhibit 6-1 for an example of the "Notice of FDA Action".

Notices are designed to be electronically or physically distributed to the addressees. Those who hold an approved Import Trade Auxiliary Communication System (ITACS) account may opt to receive notices via email or as a download within ITACS. A copy of each notice is generated for the filer, importer of record, and consignee, and delivered to the party on the addressee line. (If the same firm acts in one or more of those functions, only one copy is produced for the firm.) Notices are official documents that provide notification of a change in the status of an FDA-regulated entry/line. The distribution of the notices is made by the FDA, not the filer, to ensure proper notification to the parties involved. The intention is for the FDA to distribute notices to the responsible parties without an intermediary.

6.1.7 – Voluntary Qualified Importer Program (VQIP) Entry Processing

The Voluntary Qualified Importer Program (VQIP) is a voluntary, fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers who must meet eligibility criteria and pay a user fee that covers costs associated with the FDA's administration of the program.

The FDA works with CBP to expedite entry of VQIP foods into the United States. The agency sets screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening system to recognize shipments of food that are the subject of an approved VQIP application. The system is designed to recognize the information and release the shipment immediately after the receipt of entry information, unless examination and/or sampling are necessary for public health reasons. The FDA limits its examination and/or sampling of VQIP food entries to "for cause" situations for instance, when a food is or may be associated with a risk to the public health), to obtain statistically necessary risk-based microbiological samples, and to audit the effectiveness of VQIP.

6.1.8 – Photographs: Identification and Storage

Photographs are evidence documented during import field work and are a crucial element in case development. They should be clear (not fuzzy or pixelated, with labels legible) and capture evidence needed to support the appearance of a violation and the associated proposed charges. The photographs should capture, at a minimum, all sides of the product packaging (top, bottom, and sides); labeling (particularly any package inserts with labeling that provides or reveals the intended use of the product, product value, directions for use, daily intake, and firm information); any

available production (lot) codes and/or dates; an overall view of the lot(s) examined; and any adverse conditions observed.

Photographic evidence must be captured with a government-issued digital device and copied to your work computer's hard drive to prepare it for labeling and uploading to an FDA Import System. Blurry or otherwise unusable photographs may be deleted once you confirm that you have captured all the necessary clear usable photographs. Briefly document in your regulatory notes that photographs were taken and uploaded to the FDA Import Systems.

Photographic evidence must be uploaded electronically to the entry/line via FDA Import Systems for all sample collections, Class 2 and Class 3 field/label exams, detention requests (when warranted), destructions, reconditioning, refusal verification discrepancies, and other situations as warranted. Digital photographs may be deleted from your work computer's hard drive *after* you have uploaded them to an FDA Import Systems.

All photographic evidence (including photographs of labeling) must be identified with the following required information: entry/line number, collection/examination date, investigator's initials, a brief description of the photo, and numbering that allows future reviewers to determine if any pages or photos are missing. (An example of an adequately identified photographic notation: 123-456789-1/11/1; 8/10/20; RS, information panel, right side, 1 of 4).

Photographs may be uploaded directly from a government-issued mobile device or computer file to an entry/line via FDA Import Systems. The system records the date, time, and investigator's initials at the time of upload. The required information described above must be included within the file name and/or using the Document Remarks section specific to each photograph during the document upload process. However, there is no need to include the entry/line number when uploading from a mobile device or computer file as the photograph(s) will be directly associated to the entry/line. As such and using the example given above, the file name or Document Remarks section would be fulfilled by simply including the remarks: "information panel/right side, 1 of 4."

Photographs may also be downloaded and combined into a single document (Word or PDF) for each entry/line, with the required information included within the document.

If photographic evidence is printed, it should be documented in your regulatory notes and the required information must be permanently affixed to the printed photos so that there is never any loss of association between the photographic evidence and the associated entry/line. This information must be recorded immediately above or below the photograph(s) (not directly on the photos) so that the integrity of the evidence is not compromised.

Note: If additional enforcement or legal actions, including, but not limited to, seizure, injunction, debarment, or prosecution are contemplated with respect to an import case, the procedures for preparing and maintaining digital photographs and video as evidence, as described in IOM 5.6.7 and IOM 5.7.3, must be followed.

6.2 – Entry Review

The FDA uses the Entry Review (ER) process to decide if a regulated product can legally enter the United States. In this process, reviewers examine the product's electronic and hard-copy documentation. All reviewers must complete both formal and on-the-job training before they can conduct these reviews independently.

6.2.1 – Responsibilities

Use Import Systems Correctly

- Conduct ER using the appropriate FDA Import Systems
- Report your entry review activities as import investigation time in FDA Import Systems and OASIS

Ensure Data Integrity

- Correct any inaccurate data (manufacturer, shipper, product code, quantity, etc.) that could affect PREDICT screening.
- Assign fault to the responsible party.
- Save and rescreen the entry/line after making corrections.

Verify Admissibility Requirements

- Use PREDICT screening information and FDA databases/applications (Center Views, Interstate Certified Shipper List, etc.) to verify commodity-specific requirements
- Manually verify information if database lookups fail

Document Your Decisions

- Provide clear remarks in the FDA Import System when you:
    - Request a detention
    - Request field work
    - Issue a may proceed that contradicts PREDICT screening results
- Avoid vague remarks like "May Proceed" or "N/A"
- Note: remarks field is for internal FDA use only.

Use Available Resources

Base your decisions on:

- Electronic and hard-copy entry documentation, including declarations of intended use
- PREDICT screening (scores, mashup grid, rule flags)
- Import Alerts (IA) and Import Bulletins (IB)
- Compliance Program Guidance Manuals (CPGM)
- Past compliance history and database queries
- Import Assignments, DIO Field Advisories and Notices, and SCOPE
- Intelligence from Other Government Agencies (OGAs)
    - Note: Other Government Agencies (OGAs) are also known as Partnering Government Agencies (PGAs).
- Management directives

Coordinate and Escalate When Needed

- Understand OII Field Work Plan and SCOPE obligations to ensure center-prioritized work is completed
- Notify OCI when appropriate
- Refer entries to PGA/OGAs when warranted
- Engage division management for situations that may require a national screening criteria recommendation

6.2.2 – Initial Entry Review

The FDA receives electronically submitted lines with one of two initial work types:

- Quantity and Value (QAV)
- No Quantity and Value (NQV)

To aid in the admissibility process, filers typically provide the quantity and value for each line electronically. Both are required to set up a work request. For paper (non-ABI) entries, apply the same decision-making criteria as you would for electronic entries.

NOTE: For instructions on creating a manual entry in the Entry Review (ER) application for a non-ABI entry, please consult the ER Job Aid.

To prioritize lines for review, use the following date and time information:

- Trucks: Actual arrival date and time.
- Air, Rail, and Sea: Submission date and time.

In general, prioritize lines as follows:

1. Lines with a QAV work type have priority over those with an NQV work type.
2. Lines with documents submitted through the Import Trade Auxiliary Communications System (ITACS) take priority over lines with documents sent by other methods.

6.2.2.1 –Emergency and Perishable Shipments

Emergency and perishable products are time sensitive and take precedence over all others.

Emergency products are when one or more items need immediate review due to an urgent situation. Import divisions decide how to handle these entries to prevent abuse.

Perishable products are items that can spoil or lose quality if stored too long under normal conditions. Examples include:

- Raw/fresh seafood
- Fresh fruits and vegetables

The Centers identify time-sensitive products to help divisions prioritize their reviews.

Release device shipments only if the entry documents show CDRH approval. If you can't verify the approval document, contact CDRH at cdrhimport@fda.hhs.gov.

6.2.2.2 – Reviewing Entry Data and Information

When the FDA's initial automated screening does not issue a "May Proceed," an entry reviewer must manually review it.

You will use the FDA Import Systems to conduct your review. This system includes PREDICT, a screening tool that helps identify high-risk shipments. PREDICT does this by analyzing:

- The product's known risks.
- The history of the importer, manufacturer, and shipper.

The system then flags the highest-risk lines for your review.

Before you take any action, you must review and consider the recommendations from the FDA Import System, including the PREDICT risk score and any rule flags.

Priority Review Flags

A "Priority Review" flag points to a major public safety risk. This includes products that are subject to Detention Without Physical Examination (DWPE).

If you decide to issue a "May Proceed" for a line with a priority review flag, you must write a clear reason in the "Remarks" field. Vague remarks do not provide enough information.

Examples of Clear Remarks:

- “The product brand submitted for entry is not a brand name subject to DWPE.”
- “Product is in powdered rather than liquid form.”
- “Specific manufacturer and/or product is exempt from IA XX-XX.”
- “Documentation shows imported item does not contain heparin.”

Examples of Vague Remarks:

- “Line is not subject to IA”
- “NA”
- “May Proceeded”

Before deciding, you must perform the following activities:

- Analyze Risk: Review the PREDICT risk score and all flags in the FDA Import Systems.

- Investigate Alerts: If you see an Import Alert (IA) flag, confirm if the firm or product is subject to DWPE. If you believe a flag is missing, investigate it.
- Report Errors: If a PREDICT rule works incorrectly, report it using the system's feedback function.
- Research: Search for the firm and product in the relevant databases and review entry documents as needed.
- Request Field Work: Set-up field work based on current plans, assignments, and obligations.
- Follow Guidance: Use the correct guidance documents to check for compliance.

As an entry reviewer, you must be familiar with the following resources:

- Commodity-Specific Information: Find product-specific details and contacts on the Import Program page.
- Compliance Manuals and Guides: Use these to help you evaluate if a product follows FDA laws. This includes Compliance Program Guidance Manuals, the PREDICT Guide for Rules and Scoring, and Chapter 9 of the RPM.
- Internal Documents: Refer to the OII Field Work Plan, SCOPE, active assignments, and other internal notices and procedures.
- Affirmations of Compliance (A of C): Understand the definitions for the codes used with entries.
- The most current FDA Supplemental Guide for specific ACE submission requirements and mandatory data elements
- Regulatory Procedure Manual (RPM) Chapter 9 and the OIO SharePoint site for additional information.
-

6.2.2.2.1 – Manual "May Proceed"

Issuing a "May Proceed"

You should issue a "May Proceed" for an entry line if you can confirm it meets all regulatory requirements using the electronic information and documents, and you see no need to detain it or request field work.

NOTE: If the system's automated check clears the line, do not manually verify the Affirmation of Compliance (A of C) data.

The "May Proceed" Notice

The FDA automatically sends a "May Proceed Notice" to both Customs and Border Protection (CBP) and the filer. The filer is then responsible for telling the importer. This notice means the shipment can continue without further FDA examination.

A shipment can receive a "May Proceed" notice in two ways:

1. It passes the FDA's initial automated screening.
2. An entry reviewer manually issues a "May Proceed" it after review.

Important: A product that is allowed to enter the country can still face legal action later if the FDA finds it violates the law (as stated in section 304(d) of the FD&C Act).

6.2.2.2.2 – Rescinding a "May Proceed"

You should only rescind a "May Proceed" in rare cases, such as when a product requires a compliance action. You must act immediately, as this action is not for routine examinations.

Once you issue a "May Proceed," the conditional release period for that entry ends permanently. Even if you rescind the notice, the period does not reopen.

Steps to Rescind a "May Proceed"

If a "May Proceed" was issued in error or new information requires another review, follow these steps:

1. Get your supervisor's approval before taking any other action.

2. Notify the filer immediately that you rescinded the "May Proceed" and are holding the line for a new admissibility decision.
3. Send an updated "Notice of FDA Action" to the filer, importer, and consignee within 24 hours.
4. Request a bond hold from CBP within 24 hours to protect against financial loss if the product is refused.
5. Confirm the system sends the ABI codes to the filer, which tells them not to distribute the product.
6. Instruct CBP to demand redelivery if the shipment has already been distributed. Act quickly, as CBP has a 30-day window to issue this demand.
7. Document all your actions and communications in the FDA's Import system to maintain a clear record.

6.2.2.2.3 – Request Examination and/or Sampling (LEX/FEX/SAM)

As an entry reviewer, follow these steps when you need to request a field examination or sample collection.

1. Correct Inaccurate Data

If you find errors in the transmitted data that could affect the admissibility decision, correct them first. Record the reason for the update, save your changes, and then rescreen the data.

2. Set Up the Work Request

Next, set up the examination or sample collection using the correct work type and Problem Area Flag (PAF). Align the work request with the agency's current priorities, work plans, and assignments.

3. Provide Clear Instructions

For any non-routine work, you must give the investigator clear directions in the "Instruction Text" field.

Provide instructions when:

- An OII assignment requires specific remarks.
- The exam requires special instructions (e.g., following a specific procedure guide).
- You found a specific issue during your review that needs to be checked.
- You need to reference a previous violation (include the entry/sample number).
- An Import Bulletin directs you to do so.
- You need to note safety precautions or other important product details.

Important Notes

- Import Alerts (IA): Do not routinely request work for a line that is already subject to an Import Alert.
- Job Aid: For more detailed instructions on these steps, refer to the Job Aid for the Entry Review Application.

6.2.2.2.4 – Notices

When you recommend detention or request field work, the FDA's Import systems automatically notify the filer in two ways:

- Through the Automated Broker Interface (ABI).
- With a "Notice of FDA Action."

Distribute Notices of FDA Action per IOM 6.1.6.2. You can also find additional information regarding the issuance of notices in RPM Chapter 9.

6.2.2.2.5 – Cancelled Entries

Entry reviewers can identify CBP cancelled entries in FDA Import Systems. Cancelled CBP entries display static text at the top of multiple screens that reads, "This Entry is Cancelled." The Entry Review Grab Bag (ERGB) displays a "Y" in the "Cncld" column, and the Current Entry Status field displays "ACS/ACE Entry Cancelled."

6.2.2.2.6 – Partner/Other Government Agency (OGA) Referral

Use the OGI (Other Government Agency - Investigations) and OGC (Other Government Agency - Compliance) work types to close an entry line without the FDA making an admissibility decision. This is done when another government agency is handling the entry.

- To send a line to the Investigations Branch (IB): Select "OGI/OGA" from the "Possible Actions." This allows the IB to close the line with no further FDA action.
- To send a line to the Compliance Branch (CB): Select "OGC/OGA" from the "Possible Actions." This routes the line to the CB and allows them to close it with no further FDA action.

When to Use an OGA Referral to Close a Line

You can close a line with an OGA referral when another agency (like CBP) has decided to refuse or seize a shipment. Before you close the line, you must obtain and upload documents that show what the other agency did with the product.

Sharing Information vs. Closing a Line

If you only need to *share information* with another agency but the FDA will make an initial admissibility decision, use an Ad-Hoc OGA Referral (an Ad-Hoc referral does not close the line).

Handling Cancelled Entries

If CBP cancels an entry, the entry is handled in one of two ways:

- No Work Assigned: The system will automatically close the entry.
- Work Assigned: You must email OII-OBISM-DIBIS-IMPORT-APPS-PROBLEM-REPORTS@fda.hhs.gov to request that they close the cancelled entry.

Requesting a New OGA

If you need to refer an entry to an agency that is not listed in the system, submit your request using the Import Support Form.

6.2.3 - Entry Documentation

To decide if an article is admissible, you may need to review its entry documents. These can include:

- Bills of Lading (BOL) or Airway Bills (AWB)
- Invoices or purchase orders
- Certificates of analysis
- Copies of labeling
- Intended use statements

Do not delay electronic entries waiting for CBP Forms 3461 and 7501. The ACE system has eliminated these forms for electronic entries. However, you will still use these forms when processing paper (Non-ABI) entries.

6.2.3.1 – Request of Entry Documents (DRQ)

Request documents using the "Documents Required" Entry Option (DRQ) when you need additional information to make an admissibility decision.

In the "Remarks" field of the "Issue Entry Option" page, enter:

- Why you requested documents. Explain how they will assist future review of the entry or line.
- Summarize the data elements you reviewed, and the admissibility requirements needed for review.

Example: "All affirmations of compliance reviewed (NDA, NDC or DLS) appear valid; requesting documents per Assignment 123 to confirm product is an API. Set up work as indicated in the assignment."

The DRQ entry option sends an electronic message to the filer via the FDA/CBP ACE Interface but does NOT generate a Notice of FDA Action.

6.2.3.2 – Receipt of Entry Documents

Filers can submit entry documents to the FDA in various ways. Documents sent through ITACS receive priority over those sent by other methods. Filers can send documents before or when you request them (DRQ).

If you do not receive the documents, refer to IOM 6.2.3.4, "Failure to Submit Entry Documents and Follow-up Requests."

6.2.3.2.1 – Uploading documents received outside of ITACS

If you receive documents for an entry outside of ITACS (for example, by email), you must upload them into the FDA Import Systems.

For instructions on how to do this, refer to the Job Aid for the Entry Review Application.

You should upload documents such as:

- Product labeling
- Email conversations that could affect admissibility
- Entry paperwork like invoices, packing slips, or official forms

Note: You can also upload screenshots of web pages. Always follow the official record retention policy for all documents you upload.

6.2.3.3 – Review of Entry Documents

Review documents in the order they arrive.

After reviewing the documents, decide which action to take next.

- If you find evidence of a violation (or cannot confirm compliance), send a Detention Request (DTR) to the Compliance Branch.
- If an examination or sample collection is indicated, set up a work request (e.g., LEX, FEX, or SAM).

If the documents are not sufficient, you have three ways to follow up with the filer:

1. Direct Communication: Email or call the filer.
2. DEF Option: Use the "Entry Incomplete - Return, Deficient Entry" option.
3. INF Activity: Use the "Request Information" activity.

In your message, clearly state the specific information you need and let the filer know that the admissibility review will proceed without it if not provided.

If you do not receive the requested documents within three business days, the system will automatically send a "Second and Final Request" (DR2) to the filer. Note: This is an electronic message, not a formal "Notice of FDA Action."

Documenting Your Communication

- Direct Calls/Emails: Log all direct communications in the "Remarks" field or use the "Log Miscellaneous Information" (MIB) function. Include the date, contact person, information requested, and your initials.
- DEF and INF: These options generate a formal "Notice of FDA Action." You must write the details of your request in the "Narrative" or "Information Requested" field.
- Note: narrative field appears on the public "Notice of FDA Action".

6.2.4 – Conditional Release Period

Customs and Border Protection (CBP) may conditionally release a product while it awaits an FDA admissibility decision. You must make this decision before the conditional release period ends.

This period typically lasts for 30 days. It ends as soon as one of these things happens first:

- The FDA issues a "May Proceed" notice.
- The FDA issues a notice of refusal.
- The 30-day period expires.

How to Extend the Period

To extend the conditional release period, you must notify the importer in writing within the first 30 days. Your notice must state that the FDA will examine, sample, or detain the product.

Important: The following actions do not extend the conditional release period:

- Requesting Documents (DRQ)
- Detention Requests (DTR or DER)
- Deficient Entry (DEF)
- Requesting Information (INF)

6.2.5 - Detention Recommendations by Entry Reviewers

If a product appears non-compliant, you have two options:

1. Request field work.
2. Recommend detention to the Compliance Branch (CB).

6.2.5.1 - Submission of Detention Recommendations to the Compliance Branch

As an entry reviewer, you will use one of two work types to recommend detention: DER or DTR.

DER (Detention without Physical Examination): Use DER when a product is subject to Detention without Physical Examination (DWPE).

DTR (All Other Detentions): Use DTR for all other situations where a product appears to be violative.

Before sending the detention request to the Compliance Branch (CB), you must:

- Gather all necessary documents to support your case.
- Add clear comments explaining the reason for detention for each line.
- Include photos when needed to support the violation.

6.2.5.2 - General Procedures Pertaining to all Detention Recommendations (DER and DTR)

Before you submit a detention recommendation, you must complete the following steps to ensure it is accurate and aligns with FDA requirements.

Check the Import Program page for any product-specific instructions. Then, search all relevant center databases.

Important: You must document all the research you conduct in the detention recommendation's "Remarks" section.

Note: All information in "Line Details" must be accurate. Inaccurate data will affect PREDICT screening.

If a product has multiple violations (for example, it is subject to more than one Import Alert), you must include all applicable alerts and problem area flags (PAFs) in your detention recommendation.

6.2.5.2.1 – Obtaining Entry Documents for Compliance Review

Entry documents are needed for the Compliance Officer (CO) to review the case. If you do not have the documents, follow these steps.

When you select the detention option (DER or DTR), choose an "Entry Option" from the drop-down menu that also requests documents.

For example, select "Hold Designated, Others Go, Docs Required." This automatically tells the filer to submit the needed paperwork.

If you receive documents outside of ITACS, you must upload them into the FDA Import system.

Refer to these guides for specific instructions on how to upload documents:

- Job Aid for the Entry Review Application
- SERIO User Manual

6.2.5.3 - DER - Import Alert (IA)

Use a DER when an entry is subject to DWPE.

You can submit a DER to the Compliance Branch (CB) without requesting entry documents if all the following are true:

- The electronic data matches the Import Alert criteria (e.g., country, manufacturer, product).
- The Import Alert does not require specific documents.
- You do not need any additional information.

When You MUST Request Documents First

You must request and review documents before submitting a DER if the Import Alert requires specific paperwork for a product to be released.

For example, IA 28-02 requires a certificate for all shipments of black pepper from India. If the certificate is missing, you must request it before recommending detention.

How to Submit a DER

1. Confirm that all the electronic information (country, firm name, product description) matches the criteria in the Import Alert. Update and rescreen the entry if you make corrections.
2. In the "Instruction Text" field, explain why you are recommending detention. For example: "Manufacturer is subject to IA XX-XX." Also, document any database research you performed if the IA requires it.
3. Submit to the Compliance Branch (CB).

6.2.5.4 - DTR

Use a DTR when you cannot confirm that a product meets the FDA's admissibility requirements.

To make this decision, first review all available information, including:

- The electronic submission
- Internal FDA databases
- Any documents submitted by the filer

If you still need more information, you can also request a field exam or sample collection.

6.2.5.4.1 - Similar to Import Alert Listing

If an entry line appears to match an Import Alert (IA) listing, but you need more information to be sure, follow these steps.

First, request and review the entry documents. If you find any errors in the electronic data, correct them and rescreen the line.

Determine the Next Step

- If the entry line is matches an IA listing (red/green/yellow list) follow the guidance section in the IA.
- If the entry line does not match the IA listing:
    - Continue your initial admissibility review.
    - Using the feedback functionality in SERIO Entry Review, explain why it was not subject to the IA. For example: "Flagged for IA XX-XX, but manufacturer not listed on IA".

6.2.5.4.2 – Pending Addition to DWPE

As an entry reviewer, you may find entries with the same product and manufacturer as a previous violative entry. That previous entry may be pending addition to DWPE.

What you do next depends on if OII has direct reference authority.

NOTE: The CO may set up screening criteria in these cases. This helps reviewers know about violative findings.

6.2.5.4.2.1 Direct Reference Authority for DWPE

When OII has direct reference authority (DIO Advisory #1) AND the electronic entry exactly matches a previous violative entry.

When you encounter this:

1. Recommend Detention without physical examination (DER).
2. Add comments in the "Instruction Text" field (found in Work Details > Work Request and Work Request Details screen). Include:
    - Previous violative findings
    - CMS/work activity number and/or entry number
    - Reference to the IA
    - Any evidence you collected

6.2.5.4.2.2 - No Direct Reference Authority for DWPE

When OII does not have direct reference authority, the entry must stand on its own.

Discuss next steps with your supervisor and CB. Possible next steps could include the following:

- Request and/or review entry documents.
- Request Field Work (via SAM/FEX/LEX).

When requesting field work, note any pertinent instructions in the “Instruction Text” field located in the “Work Details” section of the “Work Request and Work Request Details” screen. This may include previous findings, CMS/work activity number and/or entry number, instruction for field work.

6.2.5.5 - Registration/Listing/Approval

Some products require registration, listing, and/or approval. Follow these steps to recommend detention when you cannot verify compliance.

Registration and Listing

1. If you cannot confirm compliance using the electronic data and internal FDA databases, request and review entry documentation.
2. Recommend detention if you cannot verify the required registration or listing after reviewing entry documents and the appropriate center database.

You must make a reasonable effort to verify compliance using the information provided. Do not recommend detention based solely on a failed data lookup or missing Affirmation of Compliance data.

Documenting Your Findings

Add comments in the "Instruction Text" field detailing the databases you reviewed and the information that did not match.

- Example: "Searched DEVICE database. No listing found for manufacturing company XYZ Corp at 123 Main St, Anytown."

Verifying Approval

1. Check for approval: Review the entry documents and search the appropriate FDA database to verify the product's approval (e.g., NDA, 510(k), PMA).
2. Recommend detention: If you cannot verify the approval, you may recommend detention. You do not need to collect product labeling unless other guidance requires it.
3. Collect labeling if unsure: If you are unable to determine whether the product requires approval, collect the product's label.

Documenting Your Findings

Add comments in the "Instruction Text" field noting the databases you checked and your findings.

- Example: "Searched AURA database. No PMA found for this product/manufacturer. Labeling and intended use letter are included in the submission."

6.3 - Field Examination

6.3.1 – General

A field examination is a physical inspection of products subject to FDA jurisdiction. Examinations may take place at the port of entry, warehouse, cold storage facility, or other designated examination site. Additional information about performing field examinations, specific to product and program area, may be addressed in the Compliance Program Guidance Manuals (CPGMs) and the Compliance Policy Guides (CPGs).

A field examination involves actual physical examination of the product to determine, for instance:

1. If the product and quantity present correspond to the product and quantity declared on shipping documents.
2. If there is any transit or storage damage.
3. If the product has been subjected to inadequate storage temperature conditions.
4. If there is any evident rodent, bird, or insect activity.
5. If there is lead present in any ceramic ware (via a Quick Color Test or QCT and/or Rapid Abrasion Test or RAT).
6. If any odors, uncharacteristic for the product or of spoilage, exist.
7. If any non-permitted food ingredients and/or color additives, are present in the product.

8. If there is general label compliance (via label examinations).

A label examination (LEX) is used when the investigations branch conducts a label review (LBL) of the physical product in the field to determine labeling compliance. This is significant as the remarks you enter and exam class you select may be used by compliance to make an admissibility decision for the product. A label exam should be consistently recorded as LEX. All other field examinations should be recorded as a FEX, along with the appropriate problem area flag (PAF)

When conducting a field examination, you should compare the documents provided by the filer/importer to those physically available during your inspection as well as to those electronically submitted. Record your observations in your regulatory notebook at the time of the field exam, including such information as:

- Date
- Entry number
- Name and address of the location where the exam is taking place
- Name and title of the persons providing information about the entry/lot being examined
- Information from the product labeling including the name of the product and any lot numbers or codes identified
- Number of units examined
- Documentation of any photos or labels collected
- Any abnormalities or discrepancies observed
- A record of the quantity of any product that was destroyed in the field as part of the field examination process, if any

Note: Additional instructions on taking regulatory notes can be found in IOM Subchapter 2.1 REGULATORY NOTES.

A field examination, of course, does not have the same level of confidence as a laboratory sample analysis. Consequently, you should be prepared to apply more rigorous standards of acceptance in the field than those used for formal regulatory levels. For example, if the formal action guideline for whole insects is 10 per 100 gm in product X, you may sample product X when your field examination shows only one or two insects per 100 gm. A decision to collect samples should be made in accordance with relevant CPs and any applicable assignments but is ultimately your discretion; sample collection based on field exam results should be based on findings significantly lower than specified by the formal guideline.

When the examination is classified as Class 2 or Class 3, you should take clear photographs of all products examined. (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE for more details and instructions.)

Additionally, see IOM 5.5.9.3 for suggestions on what to do if you're conducting a field examination and the firm responsible for the products invites individuals who are not directly employed by the firm to observe the examination. IOM 6.3.10 provides instructions on recording field/label examination results in FDA Import Systems.

6.3.2 - Field Examination Schedule

A field examination should include a physical examination of a minimum of five containers (cases, cans, bags, etc.) of a product--or as directed by Compliance Programs, specific product examination schedules (for example, LACF), or other guidance. All containers opened for exam should be identified with FDA, division abbreviation, the date of the examination, and the lead investigator's initials.

When you conduct any field examination, in addition to specific items discussed in the following sections, be alert to these possible discrepancies and situations too: "over-labeling," where a product name or identity may have been changed; a different manufacturer than the one transmitted or provided in the entry documents; a product without mandatory English labeling; changes in the expiration date or lot numbers; product quantity differences; product integrity issues; country of origin marking (under CBP authority 19 CFR 134), or similar questionable practices. If you

encounter any of these situations, document your findings and discuss the appropriate action with your supervisor if needed.

6.3.3 - Field and Label Examinations – Foods and Cosmetics

6.3.3.1 - Food Safety

Microbiological - field examinations cannot be used for suspected microbiological contamination.

Filth and Foreign Objects - field examine only those product/container combinations in which you can physically view and examine the product, for instance, products which can be probed, products in see-through containers, etc.

Canned and Acidified Foods – See IOM Chapter 4 SAMPLE SCHEDULE CHART 1 ITEM 2.

Decomposition in Non-sealed Foods - This can include organoleptic examination for fish, seafood, frozen eggs, etc.

6.3.3.2 - Pesticides, Industrial Chemicals, Aflatoxins, & Toxic Elements

Field examinations cannot be performed for most pesticides, chemical contaminants, natural toxins, and metals, except for metals in dinnerware and the side-seam solders of cans.

NOTE: Divisions should use commercial versions of the Quick Color Test (QCT) and the Rapid Abrasion Test for lead, for instance, Lead Check Swabs, while conducting field examination of dinnerware and food cans to determine if follow-up sampling is required. The testing scheme for dinnerware can be found in CP 7304.019. Specific information regarding the techniques of testing dinnerware can be found in Lab Information Bulletin (LIB) 4127 on the Office of Regulatory Testing and Surveillance (ORTS) intranet site.

6.3.3.3 - Food and Color Additives

With regards to food and color additives, you should perform a visual examination of the container and a label review for the mandatory labeling requirements. Determine if a color additive is declared for a product to which coloring appears to have been added. Determine if a declared color additive is acceptable for use in the product.

The use of a color additive must conform with the requirements stated in the color additive's listing regulation. These requirements are outlined in the "Color Additive Status List" and the "Summary of Color Additives Listed for Use in the United States in Food, Drugs, Cosmetics, and Medical Devices." These lists provide the current status and use limitations of color additives permitted in food, drug, cosmetic, and medical device products.

Requirements for declaring color additives on food labels are provided in 21 CFR 101.22 (k). Color additives subject to certification may be declared by the names listed in 21 CFR parts 74 and 82 or by abbreviated names that omit "FD&C" and "No." The term "Lake" must be included in the names of color additive lakes. FD&C Yellow No. 5 is specifically required to be declared on food labels under 21 CFR 101.22 (k) and 21 CFR 74.705. Cochineal extract and carmine are specifically required to be declared on food labels under 21 CFR 101.22(k) and 21 CFR 73.100. Other color additives not subject to certification may be declared by the names listed in 21 CFR part 73 or in general terms such as "Artificial Color," "Artificial Color Added," or "Color Added."

Determine if a preservative declaration includes its purpose; for example, "Sodium Benzoate as a preservative."

6.3.3.4 – Nutrition Labeling and Food Allergen Labeling

The only valid field examination which can be performed for a nutritional or food allergen labeling related issues is a label examination for the mandatory labeling requirements. Refer to the "Industry Resources on the Changes to the Nutrition Facts Label" and Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requirements for guidance.

Note that there are requirements for voluntary gluten-free label claims. Such claims must meet the requirements in the gluten-free labeling of foods regulation (found at 21 CFR 101.91). This is an important public health issue for persons suffering from Celiac disease. For products that bear gluten-free claims, refer to "Gluten and Food Labeling" page for guidance.

Also see the "Nutrition, Food Labeling, and Critical Foods" website for the most up-to-date information regarding claims in labeling. Also, see CP 7321.005 to determine areas of emphasis for food labeling violations.

6.3.3.5 - Food Economics (On Consumer Size Containers only)

Field exam guidance as it relates to the following aspects:

- Label Examination - Review labels for all aspects of the labeling requirements.
- Net weight - See IOM 4.3.7.1
- Food Standards - The only valid field examination which can be performed for Food Standards is a label examination for the mandatory labeling requirements of a particular Food Standard.

6.3.3.6 – Cosmetics

Valid cosmetic field examinations include a reconciliation examination for security purposes and/or a label examination for the mandatory labeling requirements. The most important labeling considerations are:

1. Ingredient Labeling (21 CFR 701.3).
2. Prohibited ingredients (21 CFR 700.11 through 700.27 and 21 CFR 250.250).
3. Non-permitted color additives (see Color Additives Status Lists).
4. Warning Statements (21 CFR 740.11, 740.12, 740.17, and 740.19).
2. Cautionary/Other Required Statements (for example, required caution statement and directions for patch test for coal-tar hair dyes - FD&C Act sec. 601(a); required caution statement for the color additive lead acetate - 21 CFR 73.2396; required label information for the color additive bismuth citrate – 21 CFR 73.2110; and required label information for the color additive henna – 21 CFR 73.2190).
3. Tamper-Resistant Packaging Requirements (21 CFR 700.25).
4. Other Labeling Requirements (21 CFR 701.10 through 701.13).

For further cosmetic-related questions, contact the Office of Cosmetics and Colors.

6.3.4 - Field and Label Examination – Drugs

A field examination involves actual physical examination of the product (minimum of five containers, or as directed by Compliance Programs). Please verify the following:

- Confirm that the product and quantity present correspond to the product and quantity declared on shipping documents. If using a pill counter to determine quantity, ensure to follow manufacturer's instructions regarding safety and cleaning procedures and utilize engineering controls, as appropriate (e.g., fume hoods, etc.) to limit potential particulate generation.
- Examine the security and integrity of the container, including tamper-resistant packaging requirements.
- Examine product for any in-transit or storage damage, or inadequate storage temperature conditions.
- Examine for any over-labeling, where a product name or identity may have been changed.
- Examine if the manufacturer is the same as the one transmitted or provided in the entry documents.

A label exam involves an examination of the product label and all accompanying labeling. The drug products examined must comply with the general labeling requirements found in 21 CFR 201.1 – 201.328. Product labeling should bear all required information in English. If product labeling includes a language other than English, it should contain all required information in both languages. Exception: Labels in Spanish for distribution in the Commonwealth of Puerto Rico is authorized under 21 CFR 201.15 (c). For bulk drugs verify that product labeling complies with the requirement(s) found in 21 CFR 201.122. (Section 201.125 does not apply to bulk drugs but only to finished dosage prescription drug products.)

6.3.4.1 – Drug Listing and Establishment Registration

Bulk drugs and finished dosage forms should be evaluated for compliance with the drug listing and drug establishment registration requirements.

6.3.4.2 – Contamination

Drugs should be examined for container integrity, for example, cracked vials, ampoules, bottles, etc. Do not examine loose powders, broken capsules or tablets without proper controls.

6.3.4.3 – Samples

Samples collected from lots where the drug substance or finished product has been subjected to actual or suspected contamination should be decided on a case-by-case basis.

6.3.4.4 - Special Instructions

Field examinations may be performed on drug lots to obtain information to determine the new drug status of a given shipment. Divisions should contact the CDER Office of Compliance, Office of Drug Security, Integrity and Response, Division of Imports Exports and Recalls, Import Export Compliance Branch for guidance.

6.3.5 - Field and Label Examinations – Devices

Field and label examination instructions issued by CDRH for specific devices are located on the Import Program intranet site under product resources.

At a minimum, the label should include the name and place of business of the manufacturer, UDI, packer or distributor, and product identity. Be aware of mis-declared devices, (for example, TENS (transcutaneous electrical nerve stimulation) devices are often declared as therapeutic massagers but, in fact, should be declared as neurological therapeutic devices.) Products declared as destined for veterinary use only must include such a statement on the packaging and product.

CAUTION: If the sealed packaging, such as an outer crate, of a medical device indicates that the manufacturer's warranty will be violated should it be opened by someone other than a factory representative, DO NOT open the packaging. Consult with your supervisor regarding any further action. For additional information please contact cdrhimport@fda.hhs.gov.

It is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment, and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization. During a field exam of non-sterile devices offered for entry that are labeled as sterile, which are destined for sterilization, per 21 CFR 801.150, each pallet, carton, or other designated unit must be conspicuously marked to show its non-sterile nature when it is introduced into and moving in interstate commerce, and while it is being held prior to sterilization.

The FDA will not support import action against the device as misbranded or adulterated when the non-sterile device is labeled sterile if the lot is marked appropriately as noted previously. 21 CFR 801.150 also requires a written agreement between the foreign firm and the importer of record. Specifically, there should be a written agreement in effect which: (i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and (iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act. This should be verified upon import.

6.3.6 – Field and Label Examinations – Biologics

With regards to biologics, you should review any applicable import alerts prior to conducting any field examinations of biological products subject to import alert.

In general, products regulated by Center for Biologics Evaluation and Research (CBER) do not warrant a field examination, because they are licensed under Section 351 of the PHS Act. In addition, lot release procedures pursuant to 21 CFR 610.2 apply to many products, such as vaccines.

If it is determined that a field examination is warranted for licensed or unlicensed CBER-regulated products, labeling for the product and its intended use should be examined.

Any questions should be sent to CBER Import Inquiry at CBERImportInquiry@fda.hhs.gov

6.3.7 - Label Examinations - Animal Products

Contact the CVM mailbox CVMImportRequests@fda.hhs.gov with questions on the importation of animal foods, drugs, devices, and other animal products. You should also be aware of any relevant import alerts, Compliance Policy Guides, or other guidance documents as they affect individual import situations. See the Product Resources section in the Import Program intranet site for additional information or notifications on current import situations.

6.3.7.1 – Animal Drugs

Label examinations of animal drugs are visual examinations that are sometimes needed to determine product admissibility. A label examination may be necessary if:

- the product is an unapproved new animal drug, especially one for use in food animals,
- the product is sterile,
- the manufacturer is not registered with FDA or differs from the firm in the foreign drug manufacturer registration,
- the drug is not listed with CVM, or
- discrepancies between the information on the product label and the import documentation exist.

Bulk New Animal Drug substances and Active Pharmaceutical Ingredients (APIs) may be legally imported if the firm is registered with the FDA and it is destined to the holder of an approved New Animal Drug Application (NADA), Abbreviated New Animal Drug Application (ANADA), Index Listing or a Generic Investigational New Animal Drug Number (JINAD) or Investigational New Animal Drug Number (INAD) exemption. For bulk drugs for use in compounding for animals, confirm the registration and listing status of the firm and product, and consult with the Center for the current status of the bulk drug substance presented for import.

Type A Medicated Articles are animal drugs and must meet the appropriate drug requirements listed above.

FDA personnel may allow veterinarians and animal owners to import unapproved drugs under the Personal Importation Policy (PIP). For more information, refer to the Regulatory Procedures Manual, section 9-2 Coverage of Personal Importations.

6.3.7.2 – Animal Devices

Devices intended for animals do not require 510(k), PMA, or any premarket approval. However, they are still subject to examination for adulteration and misbranding violations. When conducting your label exam, verify that labeling is not false, or misleading, and bears adequate instruction for use in each target animal group. When conducting your label exam, you should ensure that:

- Devices for animal use are clearly marked for animal use only.
- Prescription animal medical devices are labeled in the following manner: “Caution Federal law restricts this device to sale by or on the order of a licensed veterinarian.”
- Non-prescription animal medical device labeling bears adequate directions for use by the lay user.

In addition to being regulated by CVM, animal devices that are radiation-emitting products are also regulated by CDRH. Import coverage for radiation-emitting products is provided for in CP 7386.007 Imported Electronic Product.

Note: Animal devices that include a drug component should be referred to CVMImportRequests@fda.hhs.gov.

6.3.7.3 - Animal Food and Feeds

Animal food and food components, including pet food, should be examined for conformance with all applicable and appropriate food labeling requirements listed in 21 CFR 501; be acceptable for animal food (for instance, not contain drug claims; be an approved food additive, generally recognized as safe (GRAS) for an intended use, or otherwise found acceptable as an animal food ingredient; and not contain hazardous levels of contaminants). For example, determine if a preservative declaration includes its function, such as "Sodium Propionate (preservative)."

A list of approved food additives for use in animal food is found in 21 CFR 573 and a partial list of GRAS substances for use in animal food is found in 21 CFR 582. Substances affirmed as GRAS for use in animal foods are listed under 21 CFR 584. Irradiation is considered a food additive and approvals for the use of irradiation for animal food are found in 21 CFR 579. Additionally, animal food GRAS substances that have been notified to the FDA can be found in the Animal Food GRAS Notices Inventory.

Ensure the use of a color additive conforms with the requirements stated in the color additive's listing regulation. For further questions, contact CVMImportRequests@fda.hhs.gov.

6.3.7.4 – Animal Grooming Aids

FDA does not regulate products intended solely to cleanse or beautify animals, commonly referred to as grooming aids. Cosmetic regulations outlined in the FD&C Act do not apply to products intended for animal use. Note, however, that products purporting to be animal grooming aids that are labeled as or otherwise intended for therapeutic purposes, may be considered animal drugs. This may occur when a grooming aid is labeled to contain an active drug ingredient, or to suggest or imply a therapeutic benefit. Refer to CPG Sec. 653.100 Animal Grooming Aids.

NOTE: Medicated shampoos are not animal grooming aids and are regulated by the FDA as animal drugs. Consult CVM before detaining these products.

6.3.7.5 – Animal Biological Products

Although animal biological products are "drugs" within the meaning of the FD&C Act, animal drugs produced and distributed in full conformance with the Virus, Serum, Toxin Act (VSTA) and its implementing regulations administered by the United States Department of Agriculture Animal Health Inspection Service (USDA-APHIS) are not subject to the animal drug approval requirements in section 512 of the FD&C Act. Under the regulations implementing the VSTA, 9 CFR part 101, animal biological products are defined, in part, as "all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response." (9CFR 101.2)

An MOU between APHIS and FDA (APHIS Agreement #04-9100-0859-MU, FDA Serial #225-05-7000) addresses jurisdictional issues concerning the regulation of certain animal products as biological products. Examples of products listed in the MOU as products generally regulated as animal biological products by USDA-APHIS include vaccines, viruses, bacterins, bacterial extracts, allergens, antiserums, antitoxins, toxoids, immunomodulators, immunoglobulins, and serum and plasma for passive transfer. Examples of products listed in the MOU as products generally regulated as animal drugs by FDA include antibiotics, antimicrobial peptides, anti-inflammatories, anthelmintic, antiprotozoal, competitive exclusion products, genetic constructs (non-vaccine), stem cell therapies, gene and somatic cell therapies, hormones, growth factors, growth promotants, whole blood, transfusions, and clotting products (except serum and plasma for passive immunity).

For questions regarding whether a product is regulated as a drug by the FDA, or an animal biological product by USDA-APHIS, contact CVMimportrequests@fda.hhs.gov.

6.3.8 - Field and Label Examinations -Radiological Health

Import coverage for radiation-emitting products is provided for in CP 7386.007, Imported Electronic Products.

When conducting fieldwork on radiation-emitting products, refer to the field and label examination work instructions issued by CDRH and located on the Import Program intranet site under product resources. Additionally, field and label examinations for imported electronic products should include a review of the entry documents and FDA-2877, Declaration for Imported Electronic Products Subject to Radiation Control Standards, to determine if they are properly completed and accurate. This applies to each shipment of electronic products for which performance standards exist. Performance standards covering ionizing, microwave, and light-emitting radiation-emitting products are specified in 21 CFR 1020 through 1040.

6.3.9 - Field Examinations – Tobacco Products

Contact the Center for Tobacco Products (CTP) Office of Compliance and Enforcement, Division of Enforcement and Manufacturing, at CTP-ComplianceImports@fda.hhs.gov with general questions on the importation of tobacco products. Label examination instructions issued by CTP are located on the Import Program intranet site under product resources.

6.3.10 – Field/Label Examination Results

Examination results should be reported via FDA Import Systems for those lines that have been physically examined. Results should reflect the findings within the limitations of an examination for the specified problem area. An examination should not be reported on lines that have not been physically examined. If adverse findings are encountered, examination work type(s) should be added to the line, if needed, to record the adverse findings under the appropriate problem area.

Review the Line Details screen prior to completing the examination results. For example, make sure the product code matches the product, and that the manufacturer, country of origin, quantity, and value are correct. Add any lot codes, if applicable, and update the Location of Goods if needed. If data has been changed, enter pertinent remarks for the change, assign fault as appropriate, and rescreen the line to see if changes in the data result in changes to the flags and/or other screening hits.

Complete the examination results by navigating to Work Results:

The system will auto-fill the following fields: Entry/Doc/Line (Suffix), Lead Initials, Date Completed, Product Code, Product Description, Importer/Corrected Description, Requested By, Requested Of, PAF, PAC, and Reference.

However, you will need to enter data in the following fields, as described below.

6.3.10.1 – Date Completed

The Date Completed field will default to the current date. If necessary, update the Date Completed field to the date the examination was completed.

6.3.10.2 – Location of goods

Enter the location where the examination was or will be conducted, if availability and location of goods have not been entered, or if the exam location has changed. Include location name and address or resident post location. Note: if location and availability has been provided by the Broker through ITACS, changes to this field cannot be made.

6.3.10.3 – Remarks

Enter the type of examination performed, describe how the examination was performed, and note any samples collected or photos taken, or product and quantity destroyed in the field, as part of the examination process. If the examination was performed due to an assignment, import bulletin, or import alert, then enter pertinent information as instructed.

Example entries:

"Conducted food filth exam under CP03819A. Viewed outer cases under a black light. Opened 5 of 10 cases and viewed contents through transparent packaging. Collected a sample for micro analysis under CP03819C."

"Exam was conducted according to DOPG-XXXX-XX. Examined 200 units and found 6 devices with integrity issues. A sample was collected for integrity analysis and 7 photos documenting the exam were uploaded."

Note: Text entered in the Remarks Field does not appear on the Notice of FDA Action

6.3.10.4 – Summary

Enter the findings of the examination. Be as specific as possible in the allowed space. If the examination will be reported as Class 2, provide specific remarks detailing why Class 2 was chosen.

Example entries:

"All cartons are accounted for. No macro filth observed during examination. Exam Class 2 as this line to be held for analysis of line 1 of 4."

"Observations include no ingredients statement, no serving size, and incomplete nutrition info. Label submitted to CB for review."

Note: Text entered in the Summary Field does not appear on the Notice of FDA Action.

6.3.10.5 – Exam Class

Select the appropriate Exam Class:

Class 1 – No Adverse Findings within Problem Area: No adverse findings were noted within the limitations of the examination for the specified problem area. The entry line may be IB Released, sampled for a different problem area, referred to Compliance Branch for a different problem area or have additional work types added to it as appropriate. Additional action should not be taken within the specified problem area that was deemed Class 1

Class 2 – Other Findings: Class 2 is intended to be used only for those situations that do not meet the definitions of Class 1 or Class 3. Some examples of when to use Class 2 include the following (this list is not intended to be all-inclusive):

1. Potential adverse findings were observed. Observations lead to the collection of a sample or referral to compliance branch in the specified problem area for final admissibility determination.
2. The product appears to be in violation, within the limitations of a field examination for the specified problem area; however, investigations branch is using discretionary authority to release the product. If this option is used, describe in detail in the Summary field the reason(s) why this violative product is being released, such as, "This product meets the criteria for release under the Personal Importation Policy (PIP) as stated in the Regulatory Procedures Manual (RPM)." Note: The exemption for releasing a personal importation with a class 2 field exam findings only applies to the mail environment.
3. No adverse findings were observed, within the limitations of an examination for the specified problem area; however, the line is sampled within the same problem area due to the firm/product having a violative history in that problem area, or as directed by an assignment, import bulletin or other guidance.
4. No adverse findings were noted, within the limitations of an examination for the specified problem area; however, the line is being held and referred to compliance branch pending sample analysis of another line. (Note: it is inappropriate to record a field examination if no physical examination occurred. The "Same Action As" function allows for the holding of lines where no examination occurred pending the analytical results of another sampled line.)

Class 3 – Adverse Findings within Problem Area: The product appears to be in violation within the limitations of an examination for the specified problem area. Further action must be taken under the specified problem area, i.e., sampled or referred to the compliance branch for final admissibility determination.

NOTE: If a FEX/LEX is conducted and the examination identifies a violation, you should record the findings as a Class 3 FEX/LEX and submit to compliance as a DTR with the appropriate PAF. For example, if there are labeling claims that may warrant marketing clearance and/or approval, record the findings as a Class 3 LEX and submit to Compliance as a DTR/AAP.

Be sure to click "OK" to save the examination results.

6.3.10.6 – Record Time

Select the correct PAC from the drop-down menu. Enter your time. If more than one person worked on the examination, click on the "Add" button. A box will come up, and you can then select the person's name from the drop-down menu and select the correct PAC from the drop-down menu. Enter that person's time. Repeat for each person who worked on the examination. Click "OK." Note: Time is entered in decimal format in tenths of an hour (6-minute increments).

6.3.10.7 – Next Steps

Once the work has been submitted, and if no other work was set up on the line, you will be prompted to Next Steps.

If the exam was classified as Class 1, you will have the option to IB Release or Add Work.

If no other work needs to be added to the line, the line will be released by selecting IB Release and entering Remarks, including an appropriate summary of remarks entered in the Exam Results. If product was destroyed in the field as part of the field examination process, record what was destroyed in the Remarks field. Note: Text entered in the Remarks field does not appear on the Notice of FDA Action.

If work needs to be added to the line, select Add Work. The system will take you to the Work Request and Work Request Details page to add work as appropriate.

If the exam was classified as Class 2, you will have the option to IB Release, Refer to CB, or Add Work.

If the exam was classified as Class 2 with no adverse findings, but the line is to be held pending sample analysis of another line, follow Division procedures for notifying Compliance Branch. If the exam was class 2 with adverse findings, but IB is using discretionary authority to IB Release the line, remarks should include a detailed description of why the product was released when adverse findings were found.

If the exam was classified as Class 3, you will have the option to Refer to CB or Add Work.

If no other work needs to be added to the line, the line will be referred to CB by selecting Refer to CB and entering Remarks, including an appropriate summary of remarks entered in the Exam Results.

6.3.11 – Rescinding an IB Release

Rescinding an IB Release should only occur for articles that are subject to a compliance action, or in other exceptional cases, and must be accomplished immediately. This action should not be used for routine or work plan examination or sampling purposes (See IOM 6.2.2.2.2 for Rescinding a May Proceed).

Note that when an entry receives an IB Release, the conditional release period of the entry ends (See IOM 6.2.4) and does not re-open when IB Release is rescinded.

If an entry line inadvertently receives an IB Release or additional information is received that warrants further review for admissibility, you should:

- Obtain supervisory approval prior to rescinding the IB Release.
- Notify the import filer immediately that the FDA IB release has been rescinded and the line is pending an FDA Admissibility decision.
- Generate an updated Notice of FDA Action and forward it to the filer, importer of record, and consignee within 24 hours of rescinding the IB Release.
- Send a request to CBP, within 24 hours of rescinding the IB Release, to Unset/Hold the CBP Bond from liquidating in case Compliance Branch needs to pursue a liquidated damages case against the bond for cargo that the FDA has refused and not redelivered for export or destruction.
- Send to the filer ABI codes to indicate "PGA Decision Rescinded-Do Not Distribute Product" and "Release Rescinded-Hold for Further Information From PGA".

- If the shipment has been distributed, notify CBP and request that they issue a demand for redelivery. (See IOM 6.1.4.2 for information regarding informal entries.) CBP has 30 days to demand redelivery from the date the conditional release period ended (i.e., the "IB Release" was issued.) Any delays compromise FDA's ability to request CBP issue a Notice to Redeliver.
- Record this process and communication with CBPI in the Entry Remarks and/or Miscellaneous Info Received field to document FDA follow-up when FDA issues an IB Release inadvertently.

6.4 - Import Sample Collection

6.4.1 – General

In general, the difference between official domestic and import samples is that import samples do not require official seals or collection of a 702(b), reserve portion (See Chapter 4 for sampling instructions and guidelines.) There are instances when the collection of a reserve portion and an official seal is warranted, for instance, when enforcement action (a seizure, injunction, prosecution) is contemplated. Some sample sizes are provided in the Sample Schedule Section (See IOM Chapter 4). When using the sample sizes furnished elsewhere in this manual, do not collect the duplicate portion of the sample unless directed by your division. In addition, when preparing to collect import samples, you should always be aware of your personal safety. (Refer to IOM 5.3.)

Import sub samples should be identified in accordance with IOM 4.7.2.1. If an Entry number is used for subsample identification, ensure the collection report is completed as soon as possible and notify the sample custodian of the sample number. The collection report should clearly indicate how the sub samples are identified.

Collect, prepare, handle, and ship import samples in a manner which ensures the samples' integrity. It is important that samples are packaged properly and labeled completely and legibly on the outside of the immediate sample container before delivery to the laboratory. This allows the sample custodian to properly store the samples and expedite delivery to the appropriate laboratory branch.

Attaching a Form FDA 525, Sample Package Identification, is not required; however, if a Form FDA 525 is not used, the outside of the immediate sample package should be identified with the following information:

- Sample number, if available at time of shipment.
- Entry/Line number if sample number not available at the time of shipment or sample delivery.
- PAC/PAF (include all if multiple PAC/PAFs going to the same lab) See IOM 6.4.6, Sample Collection Reports.
- Date of collection.
- Storage Condition (for instance, ambient, frozen, or refrigerated).
- Lead CSO's initials.
- The number of bags/cartons in the sample if more than one, and the sub numbers in each container, (for instance, bag/box 1 of 3, subs 1-10, etc.)

Note: If an FDA 525 is used, affix it to the outside of the sample container. Do not affix it on the outside of the shipping container.

Including a copy of the collection report (CR) is not required unless specifically requested by a lab.

You should also take clear photographs of all samples collected. (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE for more details and instructions.)

The FDA does not pay for import samples at the time of collection. The importer should be advised they may bill the responsible division. Also, the FDA will not pay for violative import samples, per 21 CFR Part 1.91, (see IOM 6.4.2.5).

When collecting an import additional sample (ADS), the original import collection report (CR) or sample number should be referenced in the remarks section of the CR. An ADS should always be recorded on the same entry/line as the original sample.

Import Samples are compliance samples, except for those collected for pesticide analysis. (See IOM Sample Schedule Chart 3 (Chapter 4) for guidance.)

6.4.2 – General Import Sampling Policies

6.4.2.1 - Ports Covered by FDA

For electronic entry submissions, if the filer receives a message indicating FDA review, the filer will provide appropriate entry information to the FDA office having jurisdiction over the port of entry. The filer can also submit the entry documents electronically to the FDA via the Import Trade Auxiliary Communications System (ITACS). For those entries submitted by paper, all appropriate entry documents should be included with the package sent to the local FDA office.

After evaluating the entry, if FDA decides to collect a sample, the appropriate individuals/firms will be provided with a Notice for Sampling and advised:

1. If the entry is to be held intact for FDA examination or sampling.
2. Only those items designated for examination or sampling items need be held.

6.4.2.2 – Sampling for Ports with no FDA personnel present

For those ports where the FDA does not generally have staff located under its normal operating schedule, the responsible FDA division office will coordinate coverage with the responsible CBP Port manager to assure FDA notification. If the FDA decides to examine or sample articles being entered through such a port, then CBP, the importer, and broker will be notified.

Generally, for these entries, examination and/or sampling can take place at the point of destination. Under certain conditions, however, FDA may ask CBP to collect a sample at the point of entry for forwarding to the FDA servicing laboratory. Appropriate information on the entry, sample requirement, and requirements for holding the entry will be provided to the CBP officials and importer by the responsible division.

6.4.2.3 – Notification of Exam/Sampling Requested

If an examination or sample is requested, the FDA must notify CBP, the broker or filer, importer, or other designated parties. Notification, either through the electronic entry system or other form of notification (Notice of FDA Action), will indicate there is a hold on the entry identifies the specific product(s) to be sampled, etc.

6.4.2.4 - "Notice of FDA Action - Samples Collected"

After a sample has been collected by FDA, a "Notice of FDA Action - Samples Collected" is issued to the importer of record, consignee, and filer. If CBP collects the sample for FDA, depending on local FDA/CBP agreement, the division will enter the entry information into FDA Import systems and issue the Notice of FDA Action.

For those entries where specific lines (items) of an entry are not sampled, examined, or are pending further review, the Notice of FDA Action will indicate which lines (items) have been issued a "May Proceed." (See RPM Chapter 9, subchapter 9-21 "Notice of Sampling" for detailed guidance.)

6.4.2.5 - Payment for Samples

The FDA will pay for all physical samples collected by FDA and found to be in compliance (See 21 CFR 1.91). In addition, the agency will pay for physical samples collected by FDA as an audit of private laboratory analytical results submitted to FDA when the FDA audit sample is found in compliance. (NOTE: The agency does not pay for samples found to be non-compliant (violative) or for samples taken in connection with the supervision of a reconditioning.) (See IOM 4.2.8.2 for guidance on sample costs.)

Billing for reimbursement should be made to the FDA division office in whose territory the shipment was offered for import. FDA will not pay for a sample if the article is initially found to be in violation, even though it is subsequently released. Refer to IOM 4.2.8 for payment for samples.

Samples taken in connection with the supervision of a reconditioning are not paid for by FDA.

6.4.3 - Procedure When Products Cannot Be Sampled or Examined

If the entry is still under the control of the import division, yet the sample collection cannot be completed, the division may annotate the notice to the filer and importer that no product was collected and return the entry to the filer designating the entry "May Proceed." If the designated product was part of a multi-line entry where other products were collected, the notice issued for the other items sampled will be appropriately updated with the release of the product not sampled.

When a notice is issued for the collection or examination of a product in the FDA Import Systems, and neither operation is accomplished, the filer will be advised through a revised Notice indicating the article is given a "May Proceed" status. The system will print a status of "May Proceed" in the Line Summary, and print a detail section "Lines Which May Proceed."

In FDA Import Systems, the following are definitions used to describe "May Proceed" or "Release" actions:

May Proceed: "Product may proceed without FDA examination. FDA has made no determination the product complies with all provisions of the Food, Drug, and Cosmetic Act, or other related acts. This message does not preclude action should the products later be found violative." (No compliance decision has been made.)

Release: "The product is released after FDA examination. This message does not constitute assurance the product complies with all provisions of the Food, Drug and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative." (A compliance decision has been made.)

Divisions will follow the appropriate guidance under each of the above procedures, according to their import operations.

6.4.4 – Pre-Sampling Procedures

Review the submitted entry (electronic or hard copy documentation) to ensure that the location of the product(s) is known and the lots are available for FDA examination/ sampling before initiating action. The general description of the shipment in the entry documentation submitted to the FDA should match the description of the product(s) in the invoice from the broker.

6.4.5 – Sampling Techniques

Follow guidance furnished in IOM Subchapter 4.3 - Collection Technique.

6.4.6 - Sample Collection Reports

For every sample collected, a corresponding electronic collection report must be completed in FDA Import Systems (See IOM 2.4 English language requirement.)

Review the Line Details prior to completing the collection report. (See below for detailed steps.) You are responsible for making sure all fields in the Line Details screen are complete and correct. For example, make sure the product code matches the product, and that the manufacturer, country of origin, quantity, and value are correct. Add any lot codes if applicable and update the Location of Goods if needed. If the data has been changed, enter pertinent remarks for the change, assign fault as appropriate, and rescreen the line to see if changes in the data result in changes to the flags and/or other screening hits.

NOTE**:** If you start a collection report and need to exit at any time to make a correction in the Line Details, you will lose the original collection report and a new sample number will be assigned when you return to the Collection Report screen.

To review the Line Details:

1. Access the Line Details screen by double clicking the work type field, (for example, “SAM”). This will open the Entry/Line Summary screen. Click the “Line Details” button.
2. Review all data and verify that it is complete and correct. For example, make sure the product code matches actual product, and that the manufacturer, country of origin, quantity, and value are correct. Add any lot codes, if applicable, and update the Line Availability information if needed. If there is a “build button” on the line you

need to correct, you must use the build function to make corrections. All fields that are white or highlighted in purple can be updated.

3. If data has been changed, click the “Save” button, then enter a brief description in the pop-up box of corrections made. Assign fault to any errors as appropriate.
4. After any changes are saved, click on “Rescreen” in the Application Tool bar to see if changing the data caused the line to hit on any other criteria or alerts.

Complete the collection report by navigating to Work Results.

If the line was sampled for more than one PAF, and analysis will be performed at the same laboratory, only one collection report should be generated, unless otherwise directed. Select all PAFs going to the same laboratory before navigating to work results.

NOTE: Collect a separate set of subs for each PAF, unless otherwise directed by the laboratory or assignment. MIC/MET samples cannot be split or shared between labs.

If the sample will be split and sent to more than one laboratory, complete a separate collection report for each laboratory. The system autofills the following fields for you: Entry/Doc/Line (Suffix), Lead initials, Date Collected, Product Code, Product Code Description, Importer Corrected Description, Requested By, Requested Of, Location of Goods, and the Sample Number, Total Quantity, PAF, PAC, and Reference. The Date Collected, and Location of Goods can be corrected on this screen if needed.

However, you will need to enter data in the fields below.

6.4.6.1 - Date Collected

The Date Collected should reflect the date the sample was collected, not the date the sample was recorded. Only one date can be entered. If the sample collection was accomplished over several days, use the last date of collection. This date should also be used to identify the physical sample.

6.4.6.2 – Episode

An "episode" is defined as a violative pesticide (or other chemical contaminant) finding along with all samples collected in follow-up to that finding. All samples must be associated with one responsible firm (grower, pesticide applicator, etc.) and one specific time period (for instance, growing season). For example, if samples of cantaloupes from Mexico revealed violative residues, then any destination point samples or subsequent compliance samples from the same shipper or grower would, along with the original sample, be considered an episode. For this, you would enter the episode number. (See IOM 4.6.2.27.8.)

6.4.6.3 - Submitted To

Divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORTS Sample Distribution site. The LST Dashboard is an interactive tool showing respective sample capacities by PAF and servicing lab. The LST Dashboard can be used to identify all servicing labs with current available capacity for a selected PAF. Special notes or instructions are also included on the LST Dashboard, which may include directions pertaining to diversions and/or suspensions.

The Lab Servicing Table (LST) will continue to be updated as a reference. The LST Dashboard is a supplement to the LST.

When completing a sample collection, the Lab Selection screen will include a "Lab Reference" button that links to the LST Dashboard. After referring to the LST Dashboard to identify a lab with available capacity, select the appropriate servicing lab via the listed laboratory values.

6.4.6.4 - Quantity Collected

Enter the number of sampled units you collected.

6.4.6.5 – Units

Select the appropriate units from the pull-down menu. The Calculated Cost will automatically populate based on the Value submitted in the Line Details, along with Quantity Collected, and Units selected.

6.4.6.6 – DescText

Enter a description of the sample, which includes the following details:

1. Number of subs collected.
2. Weight/volume of each sub.
3. Brief product description.
4. Type of container the subs were collected in.
5. Lot sampled.

Describe how you collected the sample:

Specify any special sampling techniques; if the sample was collected randomly, aseptically, selectively, etc.; and the number of master cases that were collected from.

For example: *"Sample consists of 12 subs /16 oz. (1lb) each of IQF Cod Fillets collected at random from lot B129A1. Sample was collected aseptically from 12 master cases and packed in 12 whirl-pak bags."*

Note that any text you enter in this field will be printed on the "Notice of FDA Action." This field also transfers to the "Sample Description" field in FACTS.

6.4.6.7 - Hand Ship

Enter the method of shipping and describe how sample integrity is maintained, including the sample chain of custody. This should reflect all of the following:

1. How the sample was held and stored until shipment.
2. How the sample was prepared for shipping.
3. The method of shipment
4. The sub sample identification

For example: "Transported from firm in a closed cooler with gel packs, sample was then transferred to freezer #1 in the locked sample room until shipped via UPS to PRL- NW in a cooler with Gel packs." Subs id'd 123-1234567-1,JD, 1/1/2024

NOTE: This field only transfers to the "Lab Receipt of Samples" screen in FACTS and may not be easily seen by laboratory personnel. **As such, please enter any special handling instructions in the Remarks field.**

6.4.6.8 – Remarks

Enter any additional information that is pertinent to the sample collection, such as:

1. Special handling instructions or storage condition requirements as necessary.
2. When applicable, any guidance documents that were consulted to complete the collection, such as Compliance Program Guidance Manuals, and assignment or field examination guidance documents.
3. Additional information that your Division, Laboratory, Compliance Program, Assignment, or Import Alert/Bulletin requires.
4. Any specific analysis instructions needed (for instance, any specific pathogen or mycotoxin screen needed).
5. Any controls or photos collected.

Examples: "Store frozen. Master case code: PRODUCTION DATE 1319. Open and closed controls submitted with the sample. Analyze for milk protein per IB XX-BXX"

"Store Ambient. Sample collected per DOPG-XXXX-XXXX. Examined 200 units from lot 1234 for defects and identified 6 with pitting. Analyze for device integrity"

Notes: This field transfers to the "Collection Remarks" field in FACTS.

Be sure to review the entire screen before clicking "OK." The sample will be transferred immediately in FACTS to the respective laboratory once the OK button is clicked (unless your supervisor has set up a supervisory review of your work).

6.4.6.9 - Record Time Screen

Enter your time in the Record Time screen. If more than one person has worked on the sample, click "Add". A box will pop-up. You may then select the other person(s) from the drop-down list, select the PAC, and enter their time.

Note: Time is entered in decimal format in tenths of an hour (6-minute increments).

Examples:

- 6 min = 0.1
- 12 min = 0.2
- 18 min = 0.3
- 24 min = 0.4
- 30 min = 0.5

6.4.7 – Updating a Sample Collection Report

FDA Import Systems will allow users to make corrections to a collection report up until the laboratory has set the sample to "In Progress" in FACTS. Note that a collection report may only be corrected once. To update a collection report, select Sample Query from the Query drop down menu and search by sample number or entry number. Select the applicable sample number and click Update Collection Report. The updatable fields will become enabled for modification. These include: Quantity Collected, Units, Desc Text, Handling/Shipping, and Remarks. Once all necessary changes have been made, enter a reason for the update and click submit. At this point, the View Update will become enabled. If a change was made to the Quantity Collected, Units, or Desc Text, a new Notice of FDA Action must be generated.

Note: It is important to generate and send the Notice as it notifies the parties that changes were made to the collection data. However, if a change was made to Hand/Ship or Remarks fields ONLY, then no new Notice is needed.

6.4.8 – Additional Samples (ADS)

An additional sample (referred to as "ADS" in FDA Import Systems) is a physical sample collected from a previously sampled lot of either a domestic or imported product. Additional import samples will have a different sample number from the original sample number. Generally, an additional sample is used to complete an initially designated analysis, or to allow the lab to perform additional analyses. Situations where an additional sample may be appropriate:

- When you need to convert a sample from surveillance to compliance for the same PAF.
- When sample is damaged in route, in cases where a new sample and sample number is needed (for instance, Lab Class 5).
- When a new sample collection under the same PAF/PAC is needed as FDA Import Systems do not allow for a new sample collection on those situations.

The additional sample must be collected from the same entry line as originally sampled. In the collection report, reference the original sample number in Remarks section of Collection Report to explain the link to the original sample (for instance, why the additional sample was collected). The additional sample may be pulled from the same product boxes/containers, or from previously unopened ones, depending on the situation.

6.4.9- Special Domestic Import Samples (SDI)

The SDI sample work type should only be used when directed by a special sampling assignment, for certain perishable products collected for metal (MET) analysis or for products collected for nutritional analysis (NIS). It should not be used when collecting samples for multiple PAFs, or if the product appears to be violative or has a history of being violative.

If a product is identified for collection as an SDI under a special sampling assignment, or other directive, follow the instructions outlined in the assignment or directive.

SDI samples should be recorded per IOM 6.4.6 – Sample Collection Reports. Additionally, SDI samples require the following:

- A description of the product label as per IOM 4.5.9 - Product Label in the “Remarks” section.
    - Include brand names and size of lot if not already recorded in the “Line Details” screen.
- An official seal (Form FDA 415a) on the sample container(s).
    - Follow instructions in IOM 4.7.4.
- Collector’s ID on the seal per IOM 4.6.2.12 Collector’s ID on Seal.
    - Include collectors ID on the seal in the “Remarks” section.

Note: This information is required so that the FDA can utilize its domestic authority if the sample analysis results are violative.

After sample collection time is recorded, the user will be prompted to “Add Work” or “IB Release.” The collector should select “IB Release” after any necessary work is completed. After the “SDI” sample work type has been recorded, additional work that would hold the line cannot be added. Once the line is released, the user should generate the Notice of FDA Action (NOA). The NOA will contain a section labeled “SAMPLES COLLECTED AND RELEASED” with additional language pertaining to the release of those lines. When the SDI line is released, the line will be closed. If all lines in the entry have been closed, the entry will be closed.

The import compliance branch will be notified of and responsible for any necessary follow up (such as submitting a screening criteria request and/or coordinating with the appropriate domestic division and program for follow-up actions) on SDI samples found to be violative.

6.5 - Import Procedures After Examination / Sampling

6.5.1 - Procedure When No Violation Is Found

If the shipment is found in compliance after examination, the importer of record, consignee (where applicable), filer, and CBP are notified with a Notice of Release. The shipment may be admitted. (See RPM Chapter 9-7 “Release Notices" for detailed guidance).

6.5.2 - Procedure When Violation Is Found

6.5.2.1 - "Notice of FDA Action - Detained"

If examination of the sample or other evidence indicates the article appears to be in violation and detention is the course of action chosen by the Division, the filer, owner, and consignee (where applicable) are advised of such action by "Notice of FDA Action - Detained." The Notice will specify the nature of the violation charged and designate a site for the owner or consignee (or authorized representative) to appear at a hearing. These hearings are informal meetings with the Division, designed to provide the respondents an opportunity to present evidence supporting admissibility of the article. Ordinarily, the respondents are allowed 10 working days to appear. However, if for some compelling reason the Division determines ten (10) working days are insufficient, this time period may be extended. On the FDA Import System generated "Notice of FDA Action," this date is identified under the caption "Respond By." (See RPM Chapter 9, subchapter 9-10 “Response (Hearing) to Notice of FDA Action – Detained.)

6.5.2.2 - Response to "Notice of FDA Action - Detained"

Response to the "Notice of FDA Action - Detained" may be made personally by representative, or by mail. The importer may present evidence supporting the admissibility of the article, request refusal of admission, propose an effective manner of reconditioning or other method to remove the product from the authority of the FD&C Act.

6.5.2.3 - Request for Authorization to Relabel or Recondition Non-Compliant Articles

The FDA may authorize relabeling or other remedial action upon the timely submission of an "Application for Authorization to Relabel or To Recondition Non-Compliant Articles," (Form FDA 766 - See Exhibit 6-2). This form is also available in fillable formats online here.

Application may also be made by letter and the execution of a good and sufficient bond by the owner or consignee (See Section 801(b) of the FD&C Act [21 U.S.C. 381(b)]). The redelivery bond on file with the Port Director of CBP for the particular importation applies to any relabeling or other action authorized; a new bond will not have to be filed.

After review of the application, FDA will notify the importer of its approval or disapproval. If approved the original application will be returned outlining the conditions to be fulfilled and the time limit within which to fulfill them will be noted. Notification to other parties will be made where appropriate. A copy will be retained in the division files. (RPM Chapter 9, subchapter 9-10 "Response (Hearing) to Notice of FDA Action - Detained", and subchapter 9-12, "Reconditioning" for detailed guidance).

6.5.2.4 - Inspection after Approved Reconditioning Has Been Completed

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (page 2 of Form FDA 766, Exhibit 6-2) or advise the division that reconditioning is complete. At this point, the FDA may conduct a follow-up inspection and/or sampling to determine compliance with the terms of the approved reconditioning application, or it may accept the statement from the importer with no further follow-up. The follow-up inspection and/or sampling may be made by FDA or CBP, depending on agreements between the division and local CBP. Photographs should also be taken as warranted (See 6.1.8 PHOTOGRAPHS: IDENTIFICATION AND STORAGE for more information and instructions). The "Report of Investigator/Inspector" (section 4, page 2 of Form FDA 766, Exhibit 6-2), or other appropriately completed summary of reconditioning, should be forwarded to the appropriate FDA office.

6.5.2.5 - Procedure When Conditions of the Approved Reconditioning Application Have Been Fulfilled

If the conditions of the approved reconditioning application have been fulfilled, the division will notify the owner or consignee by Notice of Release. This notice is usually identified as "Released after Reconditioning." A copy is also sent to the filer. Where there is a non-admissible portion (or rejects), they must be destroyed or re-exported under FDA or CBP supervision. A Notice of Refusal of Admission should also be issued for the rejected portion. Additionally, the FDA may include in its approval of the reconditioning a provision for the non-admissible portions (rejects) of the reconditioning to be destroyed and not exported.

6.5.2.6 - Procedure when Conditions of the Approved Reconditioning Application Have Not Been Fulfilled

If the initial attempt at reconditioning is unsuccessful, a second attempt should not be considered unless a revised method of reconditioning shows a reasonable assurance of success.

If the conditions of the approved reconditioning application have not been fulfilled, a "Notice of Refusal of Admission" is issued to the importer, consignee (where applicable) to the filer, with a copy also sent to CBP.

6.5.2.7 - Procedure after Hearing – Release Notice

If, after presentation of testimony, the division determines the article should be released, the importer of record and consignee are issued a notice of release. The Notice will declare that the detained goods may be admitted. The Notice will also be identified "LINES RELEASED AFTER DETENTION" and, where appropriate, explain the reason for the change of action. A copy of the Notice is sent to all parties receiving the Notice of Sampling/Notice of Detention. (See RPM Chapter 9, subchapter 9-7 "Release Notices" for detailed guidance.)

6.5.2.8 - Procedure after Hearing - Refusal of Admission

When the importer requests the Division issue a “Notice of FDA Action - Refusal of Admission,” or the Division decides the shipment still appears to be in violation, the importer, owner, and consignee where applicable, are issued a "Notice of FDA Action - Refusal of Admission." On this Notice, the charge(s) is stated exactly as shown on the original (or amended) “Notice of FDA Action - Detained”. A copy of the Notice is also sent to CBP. (See RPM Chapter 9, subchapter 9-11 "Notice of FDA Action - Refusal of Admission" for detailed guidance.)

The “Notice of FDA Action - Refusal of Admission” provides for the exportation or destruction of the shipment, under CBP supervision, within 90 days of the date of the notice, or within such additional time as specified by CBP Regulation. The Notice will also contain language regarding the requirement for redelivery and contain all the above required information concerning the product and associated charge(s). The FDA file remains open until the division receives notification indicating that the goods were either destroyed or exported.

Following issuance of the “Notice of FDA Action - Refusal of Admission,” the entry refusal is communicated with CBP for the issuance of the CBP form 4647 Notice to Mark and/or Redeliver (CBP form 4647), per Work Instruction WI-000618. In certain situations, CBP may follow up to ask for the hard copy notice of refusal. CBP then issues the CBP form 4647 (Demand for Redelivery) for the entry and notifies the appropriate FDA Division Mailbox. Divisions should follow local port post-refusal processes after receipt of the CBP form 4647 email, including uploading a copy of the CBP form 4647 to the entry/line. If it is discovered that the CBP form 4647 has not been issued for a refused entry, please check with the compliance officer and notify CBP CTAC (CTAC@cbp.dhs.gov).

Keep in mind that, throughout this process, the FDA is responsible for the protection of the U.S. public regarding foods, drugs, cosmetics, tobacco products, etc., until the violative article is either destroyed or exported.

6.5.2.9 - Payment of Costs of Supervision of Relabeling and/or Other Action

After completion of the authorized relabeling or other action, the FDA will submit a detailed statement of expenses incurred, including travel, per diem or subsistence, and supervisory charges on a Form FDA 790 (See IOM Exhibit 6-3, Charges for Supervision). This is completed by FDA employees regarding the supervision of the authorized relabeling or other action to CBP–Revenue Division. The expenses shall be computed based upon the following:

- Supervising officer’s time
- Analyst's time
- Per diem allowance
- Travel other than by auto (actual cost of such travel)
- Travel by auto (mileage, toll fees, etc.)
- Administrative support

Future enhancements to FDA’s import system may result in electronic processing of the supervisory charges submitted to CBP, in which case the Form FDA 790 will no longer be used. (See RPM Chapter 9, subchapter 9-13 "Supervisory Charges" for detailed guidance.)

CBP, upon receipt of the charges for supervision, will send a notice for payment to the identified importer of record. The expenses shall include charges for supervision of destruction of the article or rejects. The remittance by the owner or consignee shall be to CBP. Payment of supervisory charges should not be accepted by any FDA division offices.

6.5.2.10 – Exportation and Destruction of Goods Refused Admission -

Exportation and destruction of refused goods are done under CBP supervision. However, if after a reasonable time, the FDA has not received notification of exportation or destruction, the Division should investigate the status of disposition. Divisions should also consider, under certain conditions, verifying that the refused goods have, in fact, been held intact pending exportation or destruction, or that a re-export actually occurred. During these activities, plan to take photographs of destructions witnessed and any discrepancies noted as warranted (See 6.1.8

PHOTOGRAPHS: IDENTIFICATION AND STORAGE). Note, too, that guidance on refusals to be verified may change, based on the reason for detention and other factors, and that each Division involved in performing Import Operations has been assigned a set number of import exams of refused entries as part of OII's workplan.

6.5.2.11 – Bond Action

Under the provisions of the FD&C Act (Section 801(b) of the FD&C Act [21 U.S.C. 381(b)]) and CBP regulations (19 CFR 113.62), a bond is required for all conditionally released articles offered for importation. This bond provides relief to the government on the default of the conditions of the bond and the payment of liquidated damages in the amount specified in the CBP *Notice of Assessment or Liquidated Damages* for failure to redeliver such goods.

Bond actions are taken when an entry is distributed prior to FDA release and cannot be redelivered, or when an article has been detained and refused, and the article is not destroyed or exported in accordance with the requirements of the law.

If the division has evidence that the entry, or any portion of an entry subject to FDA jurisdiction, was disposed of in violation of the terms of the appropriate Act, or its regulations, or of the terms of the bond, (see 19 CFR Section 113.62 (l)(1)) it should immediately contact the appropriate Customs office.

The division, upon receiving evidence that the refused article was not exported or destroyed, should immediately investigate the matter. (See IOM 6.5- Import Investigations.) The division should also send a detailed statement showing the importer's liability under the redelivery bond or other applicable customs bond to the responsible CBP office. If the facts warrant, *and* the article was under detention, *and* the Notice of Refusal of Admission has not been issued, immediately issue a Notice of Refusal to the owner or consignee, with a copy to CBP.

Upon the receipt of an application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages), CBP may agree to mitigate the damages assessed. However, in cases involving FDA goods, CBP does not usually mitigate unless the FDA is in full agreement with the action [see 21 CFR section 1.97 (b)]. (See RPM Chapter 9, subchapter 9-14 "Bond Actions" for detailed guidance.)

6.6 - Import Investigations

6.6.1 – Import Investigations General

Import operations normally focus on entry review, field examinations, and sample collections. However, investigations are also an essential tool in uncovering and developing evidence documenting violations such as entry misdeclaration, product substitutions, and "port shopping." Invaluable sources of information that may prove relevant to such violations include Import Alerts, assignments from headquarters or other Programs / Divisions, interagency cooperation, and local intelligence.

When documenting these situations, your supervisor will request a memo of investigation be sent to the compliance branch. Refer to IOM Subchapter 8.1.9.2 and Exhibit 8-3-1 for preparing import investigation memorandums.

When examining, sampling, or following up on refused imported products, you may use an affidavit to document the facts surrounding the situation. (Refer to IOM 4.4.5 and Exhibit 6-5 for guidance on preparation of an affidavit.)

6.6.2 - Investigations Involving the Importation Process

During the importation process, FDA personnel often encounter attempts to bypass proper FDA record review, inspection and/or sampling, as well as the willful attempt to import goods known to violate the Act. In addition to such actions as detention, refusal, and placement onto an Import Alert, the FDA also performs investigations and forwards the evidence collected to support a recommendation for CBP sanction under Title 19, which includes authorities for administrative seizures, civil money penalties, revocation of conditional release privileges, and bond actions (including liquidated damages, increases to bond amount, requirement of single-transaction bond).

As outlined in IOM 8.1.4, OII's Office of Criminal Investigations (OCI) has primary responsibility for all criminal investigations conducted by FDA, including the importation of unlawful FDA-regulated products. Unlawful FDA-

regulated products encountered during the importation process may serve as criminal evidence. OCI may generally take possession of such products for evidentiary purposes *only after* they have gone through the FDA regulatory process for refusal of admission and are subject to destruction; or after they have undergone CBP's administrative seizure and forfeiture process. FDA personnel involved in the import process will handle the FDA-regulated products according to existing authorities and processes. The possibility that these products could serve as criminal evidence will not result in the application of different standards or processes for their handling.

6.6.3 - Reporting Investigations Involving the Importation Process

An investigational memo with supervisory endorsement should be generated for all instances described under IOM 6.6.4, Import Violation Patterns. The memo should normally be provided to supervisory staff for endorsement within ten business days of the last investigational activity and endorsed by supervisory staff within five business days. The Compliance Branch should be notified for further follow-up when the investigation memo is endorsed for regulatory consideration. If no memo is generated, then the importer and/or broker should be advised, and that advisement should be documented in accordance with division policy. Refer to IOM Subchapter 8.1.9.2 for preparing and recording import investigation memorandums.

6.6.4 - Import Violation Patterns

The below investigational points should be covered to promote a thorough investigation. Note than any given situation may overlap into more than one pattern. While not an exhaustive list, the following four patterns may be encountered:

1. Failure to hold (See IOM 6.6.4.1 – 6.6.4.3)
2. Substitution (See IOM 6.6.4.4)
3. Importer misdeclaration (See IOM 6.6.4.5)
4. Filer misdeclaration (See IOM 6.6.4.6)

6.6.4.1 - Failure to Hold

Failure to hold means that the goods have been distributed by the importer/consignee without an FDA release from import status. *Please note that this is defined as distribution without a release, not merely moving the goods outside of the port area. FDA personnel may encounter this situation at various points in the importation process, including initial exam/inspection, sample collection, audit sample collection, reconciliation examination after a health hazard finding, verification of a reconditioning, and refusal verification. The following steps should be taken on all Failure to Hold cases:

1. Collect entry documentation (CBP form 3461 or 7501, invoice, packing list, bill of lading).
2. Determine distribution, by collecting and analyzing pertinent distribution records.
3. Determine who authorized the distribution. (Note: There may be more than one responsible party.)
4. Determine if the importer was aware of the health hazard associated with the product.
5. Obtain the authorizing person's explanation as to why the goods were distributed. (Items (1), (2), (3), (4), and (5) should be covered in one or more affidavits.)
6. Perform a data search via ORADSS or other means to determine the importer's history and discuss relevant findings with supervisory and compliance staff.
7. Coordinate with CBP the issuance of a Demand for Redelivery (form 4647) if one has not already issued per a refusal. Form 4647 can be issued for the purposes of examination/sampling, not merely because of an FDA refusal. In such circumstances, the deadline for redelivery is 30 days, instead of the 90 days post-refusal.
8. Determine the importer's bond type and amount.

6.6.4.2 - Failure to Hold – Health Hazards

Distribution of goods where there is direct evidence of a significant health hazard, such as an FDA finding of *Salmonella* contamination in a ready-to-eat food entry, should be regarded as a concern of the highest priority. In addition to the eight common steps listed above, the following additional step should be taken:

- Consult with supervisory staff, compliance staff, and the division's Recall and Emergency Coordinator as needed to address retrieval from and/or notification to the consignees, as well as consideration for any public warning.

6.6.4.3 - Failure to Hold - Health Hazards – Detention Without Physical Examination (DWPE)

Distribution of goods where there is evidence of a significant health hazard that only meets the appearance of a violation evidentiary standard (the standard under the 801(a), admissibility process) --such as an entry of a ready-to-eat food detained without physical examination (DWPE) due to a history of *Salmonella* contamination--should still be regarded as a concern of high priority. In addition to the eight common elements listed above under IOM 6.6.4.1, the following additional steps should be taken:

- Consult with supervisory staff and compliance staff as needed to determine if the FDA should collect samples for analysis.
- Consult with supervisory staff, compliance staff, and the district's Recall and Emergency Coordinator, as needed, to address retrieval from and/or notification to the consignees, as well as consideration for any public warning.

6.6.4.4 – Substitution

Substitution is an attempt by the importer or importer's agent to present goods to the FDA as corresponding to a particular entry when they are, in fact, not the goods from that entry. FDA personnel may encounter this situation at various points in the importation process, including initial exam/inspection, sample collection, audit sample collection, reconciliation examination after a health hazard finding, verification of a reconditioning, and redelivery examination. Substitution may occur as an attempt to hide distribution without FDA release (Failure to Hold). The investigation may reveal negligence, gross negligence, or fraud. The following steps should be taken when evidence of substitution is encountered:

1. Confirm that the goods are being presented to the FDA as corresponding to a particular entry. In some situations, you may only be able to show associated entry documents to the importer or importer's agent and request confirmation that the goods presented correspond to that entry. Confirmation can be accomplished by performing the following steps:
    a. Collect all available evidence supporting that the presented goods were substituted. This may include labeling, lot codes, and the condition of the goods themselves. Photos are invaluable in these instances. Examine the entire shipment as this would minimize the possibility of the importer successfully claiming at a later time that the portion not examined was in fact not substituted.
    b. Collect all available evidence to show any attempt to conceal the substitution. For example, in a partially substituted entry, the substituted goods are in the center, bottom position on a pallet; or placement of the substituted goods is in the front position of the trailer.
2. Determine the importer's, or importer's agent's, explanation for the discrepancies. Collect this in an affidavit, along with a description of the declared/actual goods and the substituted goods.
3. Until it is determined otherwise, consider all substitution cases to involve distribution of the actual goods without FDA release. (See IOM 6.6.4.1, FAILURE TO HOLD.)

6.6.4.5 - Importer Misdeclaration

Importer misdeclaration refers to the importer's provision of incorrect and/or incomplete information to the FDA and CBP, usually via the filer. When FDA personnel encounter this situation, it is usually during the initial examination or sampling of the entry. It may be the case that the investigation reveals negligence, gross negligence, or fraud. The following are examples of this kind of activity:

- The importer provides information to the filer that does NOT include a product that is present in the entry, and as a result, that product is not included in the declaration (undeclared goods).

- The importer provides the filer information that a product is manufactured by firm X, when it is, in fact, manufactured by firm Y. As a result, the filer declares the product as manufactured by firm X (misdeclared goods).

6.6.4.6 - Filer Misdeclaration

Although this section is oriented to filer interventions, it must always be recognized that the filer is the agent of the importer, and the importer is ultimately responsible. Filer misdeclaration refers to the importer's provision of correct information to the filer who then files an erroneous entry to CBP. The following are examples of this activity:

- The filer omits a product properly listed on the entry invoice from the declaration (undeclared goods).
- The importer provides the filer information that a product is manufactured by firm X, but the filer declares it as manufactured by firm Y (mis-declared goods).
- The importer provides an invoice to the filer that lists product X, but the filer declares product Y. When FDA personnel encounter this situation, it is usually during the initial examination or sampling of the entry (mis-declared goods).
- The filer selects a food Process Identification Code (PIC) for packaged food (which should only be selected when no other PIC applies, per the instructions of the FDA's Product Code Builder on the Web) when the broker does not have sufficient information to determine if any other PIC applies (misdeclared goods).

6.6.4.6.1 - Repeated Filer Misdeclaration

In the event a filer continues to mis-declare a product to CBP or the FDA, and/or continues to introduce or present to CBP or FDA any erroneous types of documentation which may violate the FD&C Act, the following steps should be taken:

1. Document what information was available to the filer to file the entry. Collect any relevant records not already obtained.
2. Document the undeclared or mis-declared products through the collection of labeling and/or photos.
3. Obtain the filer's explanation for the discrepancies in an affidavit along with (1).
4. It may be necessary, in some fact patterns, to also collect an affidavit from the importer. For example, if a filer declares a cosmetic product code for fluoridated toothpaste because the importer failed to provide the filer information about whether the toothpaste did or did not contain fluoride, it may be necessary to collect that information via an affidavit from the importer.
5. Conduct a Filer Evaluation to examine records and determine the extent of the problem. The FDA should gather enough evidence to support a possible broker penalty, with the following to be considered:
    a. If the filer has no history of filing erroneous entries to FDA, divisions should consider further training and or placing the filer back to phase 1 filing status and withhold a request to assess a broker penalty against the filer.
    b. If the filer has a history of filing erroneous entries to FDA, and the filer continues to disregard FDA's attempts to provide guidance, train, and document guidance provided of filing entries through the Automated Broker Interface (ABI), the FDA should contact (CBP) to request that a broker penalty be assessed against the filer.

6.7 - Filer Evaluations

6.7.1 – General

The FDA makes admissibility decisions based on the electronic entry data transmitted by the filers. The admissibility process is reliant upon data provided by parties outside of the FDA, most notably, the entry filers transmitting import entry information to the FDA on behalf of importers. As such, the FDA is dependent on entry filers to submit the most accurate data to make sound, risk-based admissibility decisions.

Towards this end, the FDA also conducts periodic filer evaluations to monitor the accuracy of this transmitted entry data. Filer evaluations are conducted based on the physical location within an import division and may include entry lines transmitted by filers that are physically located within a different import division. (Follow SOP-000217 "Import Filer Evaluation". when conducting import filer evaluations. and the Filer Evaluation Program Resources.) The FDA's Filer Evaluation website also contains helpful regarding the Filer Evaluation Program.

6.8 – Foreign Supplier Verification Programs (FSVP)

6.8.1 - FSVP Inspections

FSVP inspections are conducted to ensure that imported food is produced using processes and procedures that provide at least the same level of public health protection as food produced in the United States. The FSVP website contains resources for legal, regulatory, guidance, and policy issues for the FSVP regulation.

The FSVP Resources website also contains an all-in-one resource for investigators who are conducting FSVP Inspections.

Refer to the FSVP Implementation Work Instructions in conjunction with this subchapter when conducting an FSVP Inspection.

Additionally, refer to Compliance Program 7303.878 Foreign Supplier Verification Programs Inspections for more information on FSVP.

6.8.1.1 - Pre-Inspection Activities

Prior to conducting an FSVP inspection, you'll want to contact the FSVP importer by email, using the FSVP Pre-Inspectional Contact Email Template. If the FSVP Importer does not provide their telephone number in response to the email, or does not respond to the email, you should call the importer. During this pre-inspection communication you should:

1. Identify yourself and inform the importer that the FDA will be conducting an FSVP inspection.
2. Verify the firm or person identified at entry is the "importer," as defined in 21 CFR 1.500, and that the imported food is subject to the FSVP regulation.
3. Verify the importer's contact information (their name, email address, phone number, and physical address).
4. Determine if the importer of the food is a manufacturer/processor or re-packer, and if they should be inspected under any other specific human or animal programs, such as the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods Regulation (Preventive Controls for Human Foods Rule) or Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Foods Regulation (Preventive Controls for Animal Food Rule).
5. If the importer is a produce importer, determine whether the importer is also a grower, and as such should be inspected under the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule).
6. Verify the FSVP records are available on-site. If the records are off-site, advise the importer that they will need to retrieve the records.
7. Determine if any FSVP records need to be translated. If translation is required, the importer may be given a reasonable time-period to acquire the translated versions of the document.

6.8.1.2 - Preparation and References

Steps to take before undertaking an inspection:

1. Using FDA Import Systems, review the firm's FSVP inspectional history (including active consumer complaints), the compliance history of the products, and the foreign supplier associated with the products targeted for FSVP review. Ensure the highest risk products are covered.

2. Using FDA Import Systems, prepare a list of the foods imported by the importer and the foreign supplier for each food.
3. Conduct the preliminary assessment of potential hazards to determine the known, or reasonably foreseeable hazards, that should be addressed in the importer's hazard analysis, if applicable.
4. Still using FDA Import Systems, determine if the FSVP Importer may be a Very Small Importer (VSI) as defined by 21 CFR 1.512(b)(1)(i)(B). If you determine that the importer may be a VSI, confirm with the importer during the inspection that this is the case and if, as a VSI, they choose to follow the VSI Modified Requirements. Document this VSI status discussion, including the importer's response, in the Tabular EIR (T-EIR).
5. Review and become familiar with the appropriate parts of the FSVP regulation found at 21 CFR Part 1, subpart L.
6. Ensure that you have received all necessary training that may be required. Consult your supervisor with any questions.

6.8.1.3 - Inspectional Authority

Authority to review records required of FSVP importers falls under the statutory provisions of section 805 of the FD&C Act, 21 CFR 1.510(b)(1), 21 CFR 1.510(b)(3), 21 CFR 1.512(b)(5)(ii)(A), and/or 21 CFR 1.512(b)(5)(ii)(C).

You can also consult IOM subchapter 3.2 for broader information on inspectional authority.

6.8.1.4 - FSVP Inspectional Activities

At the start of the inspection, locate the person who is most responsible on site. Introduce yourself by name, title, and organization. Show your credentials (for on-site inspections only), explain the purpose of the inspection, and issue a properly signed and completed original of the Form FDA 482d, Request for FSVP Records (the division office address should be the pre-alignment district office associated with the importer's geographical location).

If this is an initial inspection, provide FSVP education materials. Briefly explain the fact sheets and refer the importer to additional documents that can be found on the FSVP website.

(See also IOM subchapter 5.1.4.2.1 for general information on issuing the Notice of Inspection.)

If this is a remote inspection, refer to the FSVP Implementation Work Instructions for conducting Remote Inspectional Activities.

6.8.1.4.1 – Conducting the FSVP Records Review

Review the importer's required FSVP records for the products and foreign suppliers as assigned, or as needed, to ensure appropriate coverage of the firm's FSVP programs. When following up on an inspection during which an FDA 483a was issued, review the FSVP records for the observations documented on the FDA 483a during the previous inspection. You'll also want to determine, of course, if the importer corrected the observations that were identified during the previous inspection and what those corrective actions were. Also, verify that it was those specific actions that corrected the observations.

For each FSVP product reviewed during the inspection, review documentation that the importer meets the definition of "importer," per 21 CFR 1.500.

Review the list of the imported foods you prepared in IOM Subchapter 6.8.1.2 with the importer, and then document which foods do not have an FSVP plan. If the importer is required to comply with the requirements in 21 CFR 1.504, request to review the importer's hazard analysis. It is important to determine if the importer has identified any known or reasonably foreseeable hazards for each food. Compare your preliminary assessment of potential hazards to the importer's hazard analysis. If there are discrepancies, discuss with the importer to determine their reasoning behind the discrepancy. After reviewing the importer's hazard analysis, request to review the necessary records. Document the results of your preliminary assessment of potential hazards comparison to the importer's hazard analysis in the T-EIR.

If the importer states that they do not have an FSVP, determine whether the importer maintains records that satisfy the FSVP requirements. Importers may not be aware of the specific requirements of the FSVP regulation, but upon further questioning, may be able to provide documents that fulfill FSVP requirements. Encourage the importer to take corrective actions for any observations identified during the inspection.

If the records review indicates there may be a public health concern relating to a food or foreign supplier (for instance, evidence that the food is adulterated or misbranded, or that there are significant deficiencies at the foreign supplier), determine if the importer took the appropriate corrective actions and also documented the corrective actions taken. For example, if an importer's sampling and testing records indicate that a sample was positive for *Salmonella,* determine if the importer took appropriate corrective actions (for example, importer did not import the food, imported food was recalled, importer worked with the foreign supplier to address the problem, importer discontinued use of the foreign supplier). In addition, document and collect available information relating to the food and foreign supplier; document FSVP observations on the Form FDA 483a, when applicable; and report the findings to your supervisor.

Document all discussions with the importer as it relates to FSVP and the records review in the T-EIR.

6.8.2 - FSVP Observations

The FDA 483a, FSVP Observations is intended to assist firms inspected in complying with the laws and regulations enforced by the FDA. The FDA 483a is the agency's primary means of notifying, in writing, an inspected establishment's top management of significant objectionable conditions relating to violations of the FD&C Act observed during an inspection. The issuance of written inspectional observations is mandated by law and by OII policy.

6.8.2.1 - Preparation of Form FDA 483a

The FDA 483a should only be issued at the conclusion of the inspection. Use care, during the inspection, to not show or reveal to the firm's management any draft, unsigned copy of the FDA 483a, or electronic copy of the FDA 483a on your computer screen. You should issue only a signed FDA 483a at the closeout discussion with management.

The FDA 483a should adhere to the following general principles:

- Observations that are listed should be significant and correlate to regulated products being inspected.
- Observations of questionable significance should not be listed on the FDA 483a. Discuss these observations with the firm's management immediately so that they understand how uncorrected problems could become a violation. Detail this discussion in the T-EIR.

The FDA 483a should have the following characteristics:

- Each observation should be clear and specific.
- Each observation should be significant and ranked in order of significance.
- All copies of the FDA-483a should be legible.

If an observation made during a prior inspection has not been corrected, or is a recurring observation, it is appropriate to note this on the FDA 483a and document it in the T-EIR. Corrective actions are not listed on the FDA 483a but are reported in the T-EIR.

The products and foreign supplier inspected must be identified on the FDA 483a, when documenting an observation for the importer's lack of an FSVP.

Collect documentation to support observations. Do not copy records that do not support observations, unless otherwise directed. Contact your supervisor if you are unsure of the evidence required to support an observation.

Generate the FDA 483a in eNSpect. To generate the FDA 483a, complete the FSMA and FSVP Inspection Protocol (IP) for each FSVP product that is reviewed.

At the close of the inspection, provide the importer with a copy of the FDA 483a and discuss each observation with them. Also discuss any non-significant observations not documented on the FDA 483a. Encourage the importer to make voluntarily corrective actions.

During the closeout discussion with the FSVP importer, inform the importer that they should respond to the FDA 483a *within 15 business days* after the end-date of the inspection and that their response may impact FDA's determination of the need for follow-up action. Provide information to the importer on where to send their response according to their division's procedures (That should be the address of the Division office associated with the importer's geographical location, which is listed on the FDA 483a or FDA 483a response e-mail address associated with the applicable division). Hard copies of inspections records should be stored at the pre-alignment district office associated with the importer's geographical location.

6.8.2.1.1 - Individual Headings

Enter data in the individual FDA483 headings as advised here:

District Office Address and Phone Number – Legibly print the district office address where the firm is physically located, regardless of investigator's division or duty station. Include the district office commercial telephone number and area code.

For example, if a firm is located in Salt Lake City, UT, then the district office would be Denver District Office. See Appendix E for boundary maps.

Name and Title of Individual to Whom Report Is Issued – Enter the legal first name, middle initial, and last name, along with full title, of the person to whom the form is being issued.

Firm Name - Enter the full, legal name of the firm, including any abbreviations, quotation marks, dashes, commas, etc.

Street Address-Enter Street address of the firm (However, not a P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

City, State and ZIP Code - Enter the firm's city, state, and ZIP code.

E-Mail Address – Enter the email address for the FSVP contact at the firm.

Date(s) of Review of your FSVP Records - Enter actual or inclusive date(s) of inspection.

FEI Number - If the FDA Establishment Identifier is on the assignment, enter it here. If not readily available, leave blank.

Employee(s) signature and Employee(s) name and title – List here the names of everyone who participated in the inspection with the issuance of an FDA 482d even *if* they are not available to sign the FDA 483a. Each member of an inspection team should sign the FDA 483a; however, absence of a team member at the conclusion of an inspection need not prevent issuance of the FDA 483a. (See IOM 5.2.8.) If you use an eNSpect-generated FDA 483a, ensure you have a copy for the program division files; an unsigned photocopy or printed duplicate is unacceptable. See IOM 5.5.10.3.

6.8.2.1.2 - Signature Policy

Everyone present at issuance signs the first and last pages of the FDA 483a and initials each intervening page in the signature block. The lead CSO's signature will appear on all pages of the FDA 483a, and the remaining team members' signature will appear on the last page.

(See IOM 5.5.10.5 for more information on Signature Policy.)

6.8.3 - FSVP Reporting

Following an inspection, you are required to prepare a report of your findings. Reporting includes the data and summary entered using eNSpect, a Tabular Establishment Inspection Report (T-EIR), attachments, and exhibits. Your (T-EIR) should be prepared to accurately and concisely communicate the findings of your inspection and be adequate for its intended use.

6.8.3.1– Establishment Inspection Report (EIR)

Based on the observations documented on the FDA 483a and other information captured on the IP in eNSpect, you will use the FSVP Tabular Establishment Inspection Report (T-EIR) application in the eNSpect system to generate the T-EIR. The requirement to answer IP Question 1.5.1. replaces the requirement to complete the PRA "Memorandum to File." Document the reason for selecting the importer for inspection in the EIR. Write the EIR according to this subsection and IOM subchapter 5.7.1.

6.8.3.1.1 - FSVP Records Review

Document the review of the importer's required FSVP records in the T-EIR. Identify the product and foreign supplier covered by each FSVP. Report the results of the comparison of your preliminary assessment of potential hazards to the importer's hazard analysis, if conducted, and any resulting discussion you had with the importer. This information must be documented with sufficient detail to demonstrate the firm's compliance with FSVP, or lack thereof.

For each product covered during the inspection, verify that the importer meets the definition of "importer" and document in the EIR as follows:

- If the importer was the owner or consignee when the food was offered for entry into the United States, attach a copy of a purchase order or some other documentary proof.
- If the importer was the U. S. agent or representative when the food was offered for entry into the United States, attach a copy of the written agreement to serve as the FSVP importer.
- If the importer does not meet the definition of importer, explain this determination in the TEIR and obtain information on the actual importer.

Document all corrective actions taken by the importer to correct the observations that were identified during the previous inspection. Describe what corrective actions were taken and whether those specific actions corrected the observations. Document any immediate corrective actions that the importer took during the inspection and any corrective actions promised for completion in the future, including when (date) they expect to complete the corrective action. In addition, document any corrective actions taken during the inspection in the corrective action reporting system (CARS) within eNSpect.

6.9 – Glossary of Import Terms

Note common import language and their meanings below. (Refer to the "Regulatory Procedures Manual Glossary" for a more complete listing of import terms.)

6.9.1 – American/ US Goods Returned (AGR or USGR)

Goods produced in the U.S. which are exported, and then returned to the United States. They are considered imports. (See Sec. 801(d)(1)of the FD&C Act [21 U.S.C. 381]).

6.9.2 – Additional Sample

A physical sample collected from a previously sampled lot of either a domestic or imported product. Generally, an additional sample is used to complete an initially designated analysis, or to allow the lab to perform additional analyses. Additional import samples will have a different sample number from the original sample. Additional domestic (or domestic import) samples may also have another sample number, but they must be flagged as an "ADD" Sample, with the original sample number referenced in the "Related Sample" block on the Collection Record.

6.9.3 – Affidavit

An affidavit is a written document for which the signer swears before an authorized official (FDA) that the statements in the document are true. The signer is referred to as the affiant and has knowledge of material facts relating to the movement or condition of the goods. FDA affidavits are used when collecting samples, establishing interstate commerce, for consumer complaints, and to document information from informants.

6.9.4 – Affirmation of Compliance (A of C)

Data elements transmitted to FDA electronically that affirm a product meets a specific FDA regulation. This value is provided to help expedite the FDA's review of product compliance in making an admissibility decision at time of entry. Some affirmations require a qualifier, which are numeric or alpha-numeric values representing a specific firm, product, certification, registration, application, or other value often on file with the FDA.

6.9.5 – Air Waybill

A type of bill of lading that serves as a receipt of goods by an airline and as a contract of carriage between the shipper and the carrier. It will include terms and conditions, description of goods, and charges. Unlike a bill of lading, an AWB is non-negotiable, and does not specify which flight the shipment will be sent on or when it will arrive.

6.9.6 – Audit Sample

A sample collected to verify analytical results provided by a certificate of analysis, or private laboratory analysis that purports to show a product complies with the FD&C Act and/or regulations. This sample type will usually be used with an import sample. At least one FDA audit sample should be included as evidence when processing removal of a product, shipper, or country from DWPE. (See IOM 4.1.4.2.8

6.9.7 – Automated Broker Interface (ABI)

A component of CBP's Automated Commercial System (ACS) that tracks, controls, and processes all goods imported into the United States. It is a voluntary program available to brokers, importers, carriers, port authorities, and independent service centers and allows qualified participants to electronically file required9import data with Customs. ACS is being replaced by CBP's Automated Commercial Environment (ACE), which will track, control, and process all imported and exported goods.

6.9.8 – Automated Commercial Environment (ACE) (ACE Supplemental Guide)

The Automated Commercial Environment, or ACE, is a centralized system for all transactions related to imports and exports. Filers electronically submit all information related to an inbound shipment using this system, and the government processes the transaction systematically and sends status updates.

6.9.9 – Bill of Lading (BOL)

The written order from a shipper to a carrier to move goods from one place to another. When available, this is the best source of shipping dates, origin, and name of shipper.

6.9.10 – Break-Bulk Cargo

Cargo transported in individual units, such as bags or cartons, which are not containerized.

6.9.11 – Bond Action

Action taken by Customs resulting in forfeiture of all, or a portion of, an entry bond when an importer fails to redeliver merchandise covered by such a bond.

6.9.12 – Consumption Entry (CE)

" Entered for Consumption" means that an entry summary for consumption has been filed with CBP in proper form, with estimated duties attached. The duty can be submitted electronically at the same time as the entry is transmitted, or on a 15-day schedule when approved by CBP. A consumption entry is a type of entry used when goods are imported for use in the United States and going directly into U.S. commerce without any time or use restrictions placed on them. "For use in the United States" means for commercial, business, or personal purposes.

6.9.13 – Conditional Release

Entry/Immediate Delivery must be filed within 15 calendar days of arrival of goods in the United States. Goods may be released for immediate delivery if they are arriving by land from Canada or Mexico. Products may be released for immediate delivery pending entry process completion. Even though CBP has allowed the immediate delivery, any FDA-

regulated products are conditionally released until the FDA makes an admissibility decision. The conditional release period ends when the FDA "May Proceeds" the entry or issues a refusal. The goods may be moved but CBP can request redelivery within 30 days.

6.9.14 – Container Freight Station (CFS)

Another location authorized to receive goods under U.S. Customs Bond for the purpose of breaking bulk and redelivery of cargo. Containerized cargo can be moved from the place of unlading to a designated container station or may be received directly at the container station from a bonded carrier after transportation in-bond before the filing of an entry of goods.

6.9.15 – Customs Bonded Warehouse (CBW)

One of several classes of CBP Warehouses authorized to receive goods that have not been entered into U.S. commerce. Goods are entered into a Customs Bonded Warehouse (CBW) by a "formal entry" or "warehouse entry" requiring complete documentation for the entry, and payment of a fee, but not payment of duty and taxes. Goods in the warehouse can be held for up to five years. After five years, the goods must be entered, exported, or destroyed. Goods in a CBW can be manipulated, but except in certain smelting operations, cannot be manufactured into something else. If the CBW is located in the United States, the goods are in interstate commerce and subject to the FD&C Act. (See CPG Sec. 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers.)

6.9.16 – Data Universal Number System (DUNS)

A unique nine-digit business identification number provided by the company Dun & Bradstreet (D&B). Upon request, D&B will assign a DUNS number for each physical location of a business.

6.9.17 – Date Collected

The date an import sample is collected.

6.9.18 – Date of Arrival

The date a carrier transporting imported cargo arrives in the United States.

6.9.19 – Date of Availability

The date imported cargo is available/accessible for examination by the FDA. Note that goods may not be available for examination as soon as they arrive in the United States, due to the way the items have been shipped/stored.

6.9.20 – Detention Recommendation (DTR)

Used when review of the entry information cannot confirm that products being offered for import meet FDA's admissibility criteria. Examples include products in which the required registration, scheduled process filing, 510(k), or pre-market approval (PMA) cannot be verified at the entry review step.

6.9.21 – Detention

A temporary administrative action taken by the FDA against articles offered for entry which are not or appear not to be in-compliance with the laws the FDA administers. Detained articles can be released if brought into compliance, or are refused entry or seized, if not brought into compliance.

6.9.22 - Detention Without Physical Examination (DWPE)

An action directed against specific products manufactured or shipped by specific foreign firms. "Import Alerts" list products that may be detained without physical examination due to their violative history or potential.

6.9.23 - Detention and Hearing Process

The opportunity for an importer or designee to present evidence, or testimony, to overcome the appearance of a violation and to give the FDA confidence that the product is in compliance. This information is provided to the FDA compliance officer listed on the Notice of Detention and Hearing. The evidence must be provided during the hearing

period. The format for providing this evidence may vary from a series of email or telephone conversations to a more formal meeting.

6.9.24 - Domestic Import (DI) Sample

A sample of an imported article collected after it has been released from import status. (See IOM 4.1.4.2.5.)

6.9.25 – Entry

Delivery, or offer for delivery, of merchandise into the Customs Territory of the United States from an outside point.

6.9.26 – Entry Admissibility File

The file, in hard copy and/or electronic (whichever is appropriate) maintained by the Division that contains relevant documentation to support the Division's admissibility decision.

6.9.27 - Entry Documents (Entry Package)

Information submitted to CBP to determine the goods quantity, its contents, and the parties of interest. Actual documentation for an individual entry can vary greatly, but it generally consists of an invoice, purchase order, AWB and/or BOL. Entry documents can be submitted electronically to the FDA, preferably through the Import Trade Auxiliary Communications System (ITACS) or via paper submission.

6.9.28 – Entry Line Item

Each portion of an entry that is listed as a separate item in an entry. An importer may identify merchandise in an entry in multiple portions; however, an item in the entry having a different tariff description must be listed separately.

6.9.29 – Establishment

A place of business or residence, including all equipment essential to such business or residence, identified, and defined accordingly as the following:

- Grower: Raises livestock, raw agricultural products, or aquaculture products for sale, via farms, feedlots, dairy farms, and botanical farms/operations).
- Manufacturer: The site-specific location where the product is manufactured, produced, or grown.
- Packer/repacker: Packs a product, or products, into different containers without making any change in the form of the product. Includes packers of raw agricultural products and medical gas repackers.
- Producer: A person who grows, mines, harvests, fishes, traps, hunts, manufactures, processes, or assembles a product.
- Salvage Operation: An establishment dealing primarily in the reconditioning and resale of damaged goods.
- Shipper: Firm or individual responsible for introducing merchandise into interstate commerce by way of transport who does not act as a manufacturer, repacker, or distributor.
- Warehouse: A private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.

6.9.30 – Failure to Hold

Failure to hold means that the goods have been distributed by the importer/consignee without an FDA release from import status. Such goods are usually subject to CBP's redelivery provisions. (See IOM 6.9.66 – REDELIVERY BOND.)

6.9.31 – FDA Import Systems

System for Entry Review and Imports Operations (SERIO) – SERIO is a 24/7/365 mission-critical system that supports the FDA's surveillance and regulatory enforcement of import products into the nation. It provides a web browser interface, as well as back-end services to process business logic. SERIO is also available as a mobile application that can be installed on an FDA iOS device. This mobile application will securely communicate with the same back-end services that are available for the web browser interface.

Operational & Administrative System for Import Support (OASIS) – OASIS is a 24/7/365 mission-critical system that supports the FDA's surveillance and regulatory enforcement of import products into the nation.

6.9.32 – Field Examination, or FEX

A comprehensive physical examination to perform surveillance activities to determine admissibility, including activities performed as part of required reconciliation exam. FEX examples: can-by-can exams, bag-by-bag exams for filth, and/or organoleptic examinations for decomposition to determine if a sample collection is indicated.

6.9.33 – Filer

A CBP term used to identify the individual or firm responsible for filing an entry. Also known as a Customs House Broker.

6.9.34 – Filer Evaluation

To determine the quality and accuracy of data that filers are submitting, the agency conducts periodic filer audits. This evaluation informs both the filer and the FDA about the overall performance of the filer.

6.9.35 – Filer Misdeclaration

Refers to the importer's provision of correct information to the filer, who then files an erroneous entry to the FDA and CBP. (IOM 6.6.4.6)

6.9.36 – Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (Pub. L. 111-353) enables the agency to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention and risk-based food safety standards, and to better respond to and contain problems when they do occur. The law also provides the FDA with important new tools to hold imported foods to the same standards as domestic foods and directs the FDA to build an integrated national food safety system in partnership with federal, state, local, tribal, and territorial authorities.

6.9.37 – Foreign Supplier Verification Program (FSVP)

A program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as U.S. safety standards--including the use of preventive controls or produce safety regulations as appropriate--and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

6.9.38 – Formal Entry

The entry type required for shipments valued over $2500, or for shipments containing specific commodities designated by CBP. Formal entry is usually a three-step process in which:

1. "Entry" gains the release of the goods from CBP control,
2. "Entry Summary" includes determination of the classification and collection of the duty/taxes owed.
3. "Liquidation" finalizes the entry process and CBP changes to classification and monies owed.

6.9.39 – Foreign Trade Zones, or FTZ

Zones established under the Foreign Trade Zones Act. Goods properly admitted into an FTZ are considered outside the territory of the United States for the purposes of duty and taxes. Several classes of goods are present in an FTZ at any one time. Some of these classes provide duty advantages when the goods are eventually entered into U.S. commerce. Other classes of goods are prohibited by law from entering the commerce and must be exported or destroyed. There is no time limit on how long goods can remain in an FTZ without entry or export. Note that if the FTZ is located in the United States, the goods are in interstate commerce and subject to the FD&C Act. (See CPG Sec. 110.200 Export of FDA Regulated Products from U.S. Foreign Trade Zones)

6.9.40 – FSVP and/or HACCP Importer

The importer who, for a specific food, is subject to the importer requirements in FDA's FSVP regulation (21 CFR part 1, subpart L), or the requirements applicable to importers in the juice or seafood HACCP regulations (21 CFR 120.14 and 123.12, respectively). Under both the FSVP and the HACCP importer regulations, the importer is the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States (21 CFR 1.500 (FSVP)); (21 CFR 120.3(h) (juice HACCP)); and (21 CFR 123.3(g) (seafood HACCP)). An FSVP or HACCP importer must be physically located in the United States. When the FSVP or HACCP importer for a food is a U.S. agent or representative for the foreign owner or consignee, the U.S. agent or representative is responsible for meeting the FSVP or HACCP requirements with respect to that food.

6.9.41 – Immediate Delivery (ID)/ Conditional Release

Entry/Immediate Delivery (CF 3461) must be filed within 15 calendar days of arrival of goods in the United States. Goods may be released for immediate delivery if they are arriving by land from Canada and Mexico. Products may be released for immediate delivery pending entry process completion. Even though CBP has allowed the immediate delivery, any FDA-regulated products will be conditionally released until the agency makes an admissibility decision. The conditional release period ends when FDA "May Proceeds" the entry or issues a refusal.

6.9.42 – Import Alerts

Guidance documents concerning significant re-occurring, new, or unusual problems affecting import coverage. They can be found online here.

6.9.43 – Importer of Record

The party in whose name the entry is made. Note that, for example, a Customs House Broker might make an entry and become the "importer of record" by using their importer ID and bond on behalf of their client, the true "importer" of the goods. For FDA purposes, the "importer of record" is the person or company filing the redelivery bond under Sections 802(b)and 536(b) of the FD&C Act [21 U.S.C. 382(b) and 360mm(b)].

6.9.44 – Import Refusal

FDA's final decision that a detained shipment is in violation of FDA laws and regulations. A refused shipment must either be destroyed or exported under the supervision of CBP and the FDA within 90 days of the date of the Notice of FDA Action (Refusal Notice).

6.9.45 – Import Sections

Import Sections 536, 801 and 802 are those sections of the FD&C Act containing the Import/Export Provisions.

6.9.46 – Import Status

The standing, or status, of an article in the import database system that has not yet been released.

6.9.47 – Importer Misdeclaration

Refers to the importer's providing incorrect and/or incomplete information to the FDA and CBP, usually via the filer. This misdeclaration may include incorrect product codes and/or product descriptions; incorrect/incomplete manufacturer/shipper name/address; and/or incorrect quantity and value. It may occur as an attempt to avoid FDA and/or CBP actions/regulations, such as DWPE, sampling, duties, etc.

6.9.48 – Informal Entry

A simplified import entry procedure accepted at the option of CBP for any shipment not exceeding a specified value. Informal entries are filed with complete paperwork and any duties and taxes are paid at the time of filing. The entry liquidates at time of filing.

6.9.49 – Immediate Transportation (IT)

An entry document filed with CBP by the importer that allows the immediate transport of goods without a determination of admissibility, from the port of unloading under CBP bond. In general, the importer must file a consumption entry within six months of the date of importation or export the goods. The FDA typically examines these goods at an inland port of entry.

6.9.50 – Import Trade Auxiliary Communication System (ITACS)

A system that 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. ITACS account management functionality enables the electronic distribution of Notices of FDA Action via email and as downloads from within ITACS.

6.9.51 – Label Examination

Surveillance activities in the field to determine admissibility of a product based on a label/labeling examination performed on the physical product.

6.9.52 - Line (Line Item)

A line is each portion of an entry which is listed as a separate item on an entry document. An importer may identify goods in an entry in as many portions as they choose, except for items in the entry having a different tariff description and rate, which must be listed separately.

6.9.53 – Lot

A lot is an entry, group of entries, or a portion of an entry of goods that can clearly be defined as appropriate for FDA sampling and examination purposes.

6.9.54 – Mail Entry

Merchandise offered for entry through the U.S. mail. In instances where the value of the merchandise is less than $2,500, an entry document is generally not required to be filed with CBP. Mail entries are often informal entries and do not generally require a bond to be filed with CBP. Industry guidance can be found here.

6.9.55 – Marks

Words or symbols, usually including the country of origin, that marked on cartons, bags, and other containers of imported goods for identification purposes. Marks are a CBP requirement.

6.9.56 – May Proceed

The release performed after identifying and determining the line/entry meets certain admissibility requirements. This means the product can be distributed into U.S. commerce. However, a release does not preclude future FDA action if a problem is found later.

6.9.57 – Notice of FDA Action

Gives notice to the owner, operator, or agent- n-charge of an imported product, providing more specific information on the actions taken by the agency, broken down by each entry line (including, "sample collected," "intended for sampling," "detained," "released," or "refused"). The notice provides notification of the right to a hearing on the detention of a product which appears violative to the FDA, or for the administrative destruction of a drug or device. The notice identifies the charges for which the product appears violative.

6.9.58 – Personal Baggage Entry

Entry of merchandise by personal baggage.

6.9.59 – Personal Import Policy (PIP)

Instructions to FDA staff for handling personal-use quantities of FDA-regulated imported products encountered in

personal baggage and mail shipments, to best protect consumers with a reasonable expenditure of resources.

6.9.60 – Port (Point) of Entry

The CBP location where the Consumption Entry is made. This may or may not be at the Port of Unloading (the point of physical entry into the United States).

6.9.61 – Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

A risk-based analytics tool that the FDA uses to electronically screen all regulated shipments imported or offered for import into the United States.

6.9.62 – Prior Notice of Imported Foods (Prior Notice)

In the case of an article of food that is being imported or offered for import into the United States, a notice provided to the FDA prior to entry in the United States, with information about the article, manufacturer, shipper, grower, the country of origin, and anticipated port of entry. Prior notice must be submitted to the FDA electronically, via either the CBP Automated Commercial Environment (ACE) or the FDA Prior Notice System Interface (FDA PNSI). (Guidance for Industry: Prior Notice of Imported Food Questions and Answers)

6.9.63 – Private Laboratory

Independent laboratories providing analytical services to importers, customshouse brokers, and others.

6.9.64 – Product Code

An FDA product code describing a specific product and containing a combination of five to seven numbers and letters. The product code submitted with each FDA line item should match the actual product name and/or invoice description of the product.

6.9.65 – Reconditioning

When a product is detained because it violates FDA laws and regulations, the importer of record may submit an application to the agency requesting permission to re-label or recondition the product in an attempt to bring it into compliance.

6.9.66 – Redelivery Bond (AKA Entry Bond) -

A bond posted by the importer of record with CBP. For FDA-regulated products, this is currently in the amount of three times the value of the imported product, to insure redelivery of the product for examination, reconditioning, export, or destruction.

6.9.67 – Re-export

A term used to identify goods shipped out of the United States after being offered for entry. This is not the same as an export of U.S. manufactured goods and is not covered by the restrictions in Section 801(e) of the FD&C Act.

6.9.68 – Relabeling -

The process of modifying labeling in order to come into compliance with FDA regulations. Relabeling is considered a form of reconditioning.

6.9.69 – Release with Comment -

An FDA compliance action releasing goods into interstate commerce advising the importer of violations with the FD&C Act that are not a health risk to the public. It also advises that future entries which continue to violate the Act may be refused.

6.9.70 – Sample/Product Collection (SAM)

SAM is a physical collection of product in the field with a subsequent analysis submitted to an FDA servicing laboratory, or a documentary sample where the sample evaluation is based upon the documents accompanying the product.

6.9.71 – Section 321 (De Minimis)

The process by which cargo can be imported by one person on one day, as cited in 19 CFR 10.151. The value of the imported cargo may be free of duties and taxes when valued at 800 U.S. dollars or less.

6.9.72 - Stripping (Of Containers)

The removal of articles from a transportation container for examination or sampling.

6.9.73 – Substitution

An attempt by the importer/consignee to present goods to the FDA as corresponding to a particular entry when they are in fact not the goods from that entry. May occur as an attempt to hide distribution without an FDA release and avoid CBP bond actions. (See IOM 6.6.4.1 Failure to hold or 6.6.4.4 Substitution.)

6.9.74 – Supervisory Charges

Supervisory charges are the charges associated with FDA supervision of the reconditioning and examination of articles after detention. (See 21 CFR 1.99.)

6.9.75 – Testimony

An individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogation. Testimony is covered by 21 CFR 20.1. Testimony may also be information a firm submits to overcome the appearance of the violation, or to otherwise support the release of their product. Testimony should be provided to the contact listed on the FDA Notice of Action, which is usually a compliance officer. It can be provided in person, or via email, telephone, fax, hard copy.

6.9.76 – VQIP Quality Assurance Program (QAP)

A compilation of the written policies and procedures used to ensure adequate control over the safety and security of the foods being imported by the VQIP importer. Any format can be used to organize the QAP to include all foods and all of the written policies and procedures under VQIP.

6.9.77 – Warehouse Entry (WE)

An entry document filed with CBP by the importer which allows the goods to go immediately into a bonded warehouse.

6-9.78 – Relabler

Relabeler - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name.

6-1 Notice of FDA Action

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 1
April 14, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907
Consignee:	Transfer Recive, Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line ACS/ACE/FDA	Product Description	Quantity	Current Status
11/1	FRESH SNOWPEAS	1600 CT	Pending FDA Review 04-14-2023
11/2	FRESH SUGAR PEAS	1640 CT	Pending FDA Review 04-14-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 2
April 18, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907 Transfer Recive,
Consignee:	Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	FRESH SNOWPEAS	1600 CT	Product Collected by FDA 04-18-2023
*	11/2	FRESH SUGAR PEAS	1640 CT	Product Collected by FDA 04-18-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Notice of FDA Action
Entry Number: F21-6048076-0

Notice Number 2
Page: 2

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

Jose Galan, Investigator
U.S. Food and Drug Administration
1800 Eller Drive, Suite 200
Fort Lauderdale, FL 33316

(954) 782-7816
(954) 782-3384 (FAX)
JOSE.GALAN@FDA.HHS.GOV

SAMPLES COLLECTED

Line ACS/ACE/FDA	Product Description	Est. Cost
11/1	FRESH SNOWPEAS	$1.22
Sample :	1 KG - Collected 1 approx 2.2 lb sub of Fresh Snowpeas from 1 carton s/a/r from a total lot of 1600 Cartons.	
11/2	FRESH SUGAR PEAS	$1.44
Sample :	1 KG - Collected 1 approx 2.2 lb sub of Fresh Sugar Peas from 1 carton s/a/r from a total lot of 1640 Cartons.	

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: FOX

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 3
April 27, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907 Transfer Recive,
Consignee:	Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	FRESH SNOWPEAS	1600 CT	Detained 04-26-2023
*	11/2	FRESH SUGAR PEAS	1640 CT	Released 04-26-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

Notice of FDA Action Notice Number 3
Entry Number: F21-6048076-0 Page: 2

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/ACE/FDA	Product Description	Respond By
11/1	FRESH SNOWPEAS	May 16, 2023

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION
The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act. Bears or contains: Sample was found positive to tebuconazole.

Please direct your response to:

Chago Martinez, Compliance Officer U.S.
Food and Drug Administration
15100 NW 67 Ave, Suite 400
Miami, FL 33014

(305) 444-1248

CHAGO.MARTINEZ@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

LINES RELEASED

Line ACS/ACE/FDA	Product Description
11/2	FRESH SUGAR PEAS

Chago Martinez, Compliance Officer U.S.
Food and Drug Administration
15100 NW 67 Ave, Suite 400
Miami, FL 33014

(305) 444-1248

CHAGO.MARTINEZ@FDA.HHS.GOV

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: SFF

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

EXAMPLE

United States Food and Drug Administration

Division of Southeast Imports

Notice of FDA Action

Entry Number: F21-6048076-0

Notice Number: 4
May 18, 2023

Importer:
Fan Marino Inc 14807 Nw
46nd Ave
Baltimore, FL 55054-0000

>

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Port of Entry:	5201, Miami, FL
Carrier:	LAMINA GRANDE LTD;
Date Received:	April 14, 2023
Arrival Date:	April 16, 2023
Filer of Record	Big Filer Company., Miramar, FL 44122-1907 Transfer Recive,
Consignee:	Davie, FL 66172-0000

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	FRESH SNOWPEAS	1600 CT	Refuse 05-17-2023
	11/2	FRESH SUGAR PEAS	1640 CT	Released 04-26-2023

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA. Include the Customs Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the Customs/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

Notice of FDA Action Notice Number: 4
Entry Number: F21-6048076-0 Page: 2

FDA's Import Trade Auxiliary Communication System (ITACS) is the preferred method for submission of entry documents and availability information. This submission will automatically link the documents and availability information to the entry in FDA's admissibility system and will facilitate FDA's processing of entries. ITACS may be accessed at https://itacs.fda.gov.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/ACE/FDA	Product Description
11/1	FRESH SNOWPEAS

Refused : 7,199 KG

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION
The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act. Bears or contains: Analytical results support the original analysis finding of 0.044 ppm tebuconazole in subject sample (LOQ: 0.010 ppm). There is no tolerance for tebuconazole in snowpeas as per 40 CFR 180.474

Additional residue detected ? violative:
0.103 Carbendazim: no tolerance for carbendazim in snowpeas as per 40CFR180.371

For the District Director of Customs:

Chago Martinez, Compliance Officer U.S.
Food and Drug Administration
15100 NW 67 Ave, Suite 400
Miami, FL 33014

(305) 816-1458

CHAGO.MARTINEZ@FDA.HHS.GOV

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the Division Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

U.S. Customs and Border Protection
8731 NW 47th Street
Room 777, Team 300

Notice of FDA Action
Entry Number: F21-6048076-0

Notice Number: 4
Page: 3

Miami, FL 33122

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: BBB

This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from their Import Systems may appear different.

6-2 FORM FDA 766 – Application for Authorization to Relabel or Recondition Non-Compliant Articles

APPLICATION FOR AUTHORIZATION TO RELABEL OR RECONDITION NON-COMPLIANT ARTICLES

FORM APPROVED: OMB No. 0910-0046
EXPIRATION DATE: 8/31/2026

Public reporting burden time for this collection of information is estimated to average .25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please do NOT send your completed form to the above PRA Staff email address.

SECTION 1 Instructions for completing the FORM FDA-766 are found on pages 3 and 4.

1. TO: Director of _____ Division, Food and Drug Administration Application is hereby made for authorization to bring the article(s) below into compliance with the Federal Food, Drug, and Cosmetic Act and other related Act(s).	2. APPLICATION DATE	3. ENTRY NO. AND LINE NO.
	4. PRODUCT	
	5. QUANTITY	
6. QUANTITY TO BE RECONDITIONED	7. PRODUCTION CODES	

8. Redelivery bond has been posted by the applicant. The article(s) will be kept apart from all other article(s) and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at:

and will require about _____ days to complete. A detailed description of the method by which the article(s) will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

9. APPLICANT AND FIRM NAME	10. ADDRESS OF FIRM
11. APPLICANT'S SIGNATURE	

SECTION 2 - FDA ACTION ON APPLICATION

12. TO: *(Name and Address)*	13. DATE

14. Your application has been: ☐ Denied because: ☐ Approved with the following conditions:

Time limit within which to complete authorized operations: _____

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

15. SIGNATURE OF DIVISION DIRECTOR	16. DIVISION	17. DATE

FORM FDA 766 (05/24) Page 1

PSC Publishing Services (301) 443-6740 EF

SECTION 3 - IMPORTER'S CERTIFICATE

18. Location where reconditioning operation occurred	19. DATE

20a. I certify that the work to be performed under the authorization has been completed and the article(s) are now ready for inspection at: _____

20b. Contact Information: _____

21. The rejected portion is ready for the approved disposition under FDA or CBP supervision and is held at:

22. APPLICANT AND FIRM NAME	23. APPLICANT'S SIGNATURE

SECTION 4 - REPORT OF INVESTIGATOR / INSPECTOR

TO PORT DIRECTOR OR DIVISION DIRECTOR	24. DATE *(MM/DD/YYYY)*

25. I have examined the within-described article(s) and find them to be the identical article(s) described herein, and that they have been:

_____ on: _____, 20___,

as authorized, except:

SECTION 5 - DATA ON RECONDITIONED ARTICLE(S)

26. Acceptable Portion:

27. Rejections:

28. Loss (if any):

29. Did importer recondition entire shipment?

30. Time and cost of supervision:

31. INSPECTING OFFICER NAME	32. DATE *(MM/DD/YYYY)*

33. INSPECTING OFFICER SIGNATURE

6-3 Form FDA 790 Charges for Supervision

CHARGES FOR SUPERVISION

☐ Federal Food, Drug, and Cosmetic Act, Section 801 (b) and (c)
☐ 21 CFR 1005.24

TO: *(Insert Address)*	FROM: *(Insert Address)* DHHS
PORT DIRECTOR OF CUSTOMS	FOOD AND DRUG ADMINISTRATION

PRODUCT	FDA SAMPLE NO.
CARRIER	CBP ENTRY NO.
IMPORTER OF RECORD	ENTRY DATE
CONSIGNEE	

The following is a list of charges incurred by this Agency for supervision of operations performed in accordance with the above-designated Act or Regulation. You are requested to collect payment, including any expenses incurred by your Department, for deposit into Treasury Miscellaneous Receipts.
Under Section 801(c), default of payment shall constitute a lien against any future importation made by the owner or consignee.

TYPE OF CHARGES	UNIT			CHARGE PER UNIT	TOTAL CHARGE
	HOURS	DAYS	MILES		
INVESTIGATORS TIME					
ANALYSTS TIME					
PER DIEM, PAID PER GOVERNMENT TRAVEL REGULATIONS					
AUTOMOBILE USE					
OTHER TRANSPORTATION EXPENSES *(Itemize)*					
MISCELLANEOUS EXPENSES *(Itemize)*					
GRAND TOTAL					

REMARKS

FORM FDA 790 (8/13) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. PSC Publishing Services (301) 443-6740 EF

6-4 FORM FDA 463a AFFIDAVIT

AFFIDAVIT | SAMPLE NO.

STATE OF: Texas | COUNTY OF: Hunt

Before me, Sydney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Felicia M. Rodriguez in the county and state aforesaid, who, being duly sworn, deposes and says:

I am the Import Manager for ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX, where I have worked for about 3 years, and as such have knowledge of products imported, held, processed and/or shipped by my firm.

On 1/06/14, we received a shipment consisting of five 200 kg burlap bags of dried Ancho Peppers, manufactured by Del Campo, Extension Del Mina #4, Guadalajara, Mexico, covered by entry BAD-1234565-7.

On 1/08/14, my firm repacked this shipment of peppers into 25 kg burlap bags for distribution to restaurants and other customers.

On 1/13/14, Investigator Rogers visited my firm and showed me copies of documents including Customs form 3461 marked with the entry number of Entry BAD-1234565-7, Bill of Lading #2345RRR678, dated 1/03/14 and invoice 45678, dated 1/02/14. I am familiar with these documents and they cover the shipment of peppers my firm received.

Part of the repackaged peppers from Entry BAD-123456-7 were sold and distributed by my firm on 1/08/14. Three 25 kg burlap bags were shipped to John's Pepper House, 3456 First Avenue, Dallas, Texas; and two 25 kg bags were shipped to Casa De Juanita, 5678 Mulberry Drive, Fort Worth, Texas. I have identified and provided copies of the shipping documents that cover this distribution to Investigator Rogers. These documents are invoice 999888, dated 1/08/14 and UPS B/L 787878000009, dated 1/10/04 which covers the shipment to John's Pepper House and invoice 757575, 1/08/14 and UPS B/L 2323232323, 1/10/14 which covers the shipment to Casa De Juanita. The rest of the repackaged peppers remain at my firm.

I received the Customs and Border Protection release for this entry on 1/06/14 and I believed I could ship the product. I was informed by Investigator Rogers I was not supposed to ship the product until I received the FDA release. I will keep the remainder of the shipment intact.

I read this statement and agree it is true.

AFFIANT'S SIGNATURE AND TITLE: Felicia M. Rodriguez, Import Manager

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*: ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428

Subscribed and sworn to before me at ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428 *(City and State)*,

this 13th **day of** January, 20 14.

Sydney H. Rogers *(Employee's Signature)*

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

FORM FDA 463a (5/07) PSC Graphics (301) 443-1090 EF Page 1 of 1