

CHAPTER 6 - IMPORTS

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SUBCHAPTER 6.1 - IMPORTS

6.1.1 - AUTHORITY

[Section 801 of the FD&C Act](#) [21 U.S.C. 381] authorizes FDA examination of 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 regulations authorizes employees of 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:

1. [Federal Food, Drug, and Cosmetic Act](#) (FD&C)
2. [Fair Packaging and Labeling Act](#)
3. [Nutrition Labeling and Education Act](#) (NLEA)
4. [Import Milk Act / Filled Milk Act](#)
5. [Federal Caustic Poison Act](#)
6. [Bioterrorism Act](#)
7. [Public Health Service Act](#), Part F, Subpart 1, Biologic Products
8. [Title 21 CFR Subpart E](#) - Imports and Exports ([1.83](#)), etc.

9. [Title 19 CFR Customs Duties](#) (authority to sample delegated by Custom Regulations, etc.)

10. [Federal Cigarette Labeling and Advertising Act](#)
11. [Comprehensive Smokeless Tobacco Health Education Act](#)
12. [Family Smoking Prevention and Tobacco Control Act](#)

6.1.2 – IMPORT INVESTIGATIONS

Import operations, normally focus on entry review, field examinations, and sample collections. However, investigations are an essential tool in uncovering and developing evidence documenting violations such as entry misdeclaration, product substitutions, and “port shopping.” Invaluable sources of information include: Import Alerts, assignments from headquarters or other districts, interagency cooperation and local intelligence.

When documenting these situations, your supervisor may request a memo of investigation or an Establishment Inspection Report (EIR) to be sent to the compliance branch. Follow your district procedures, IOM Chapter 5 for preparation of the EIR and IOM Subchapter 8.1 and 8.10 for preparation of 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 4.4.8 and Exhibit 6-5 for guidance on preparation of an affidavit.

6.1.3 - INVESTIGATIONS INVOLVING THE IMPORTATION PROCESS

During the importation process, FDA personnel 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 FDA detention, refusal, and placement onto an Import Alert, FDA performs investigations and forwards the evidence collected to support a recommendation for Customs and Border Protection (CBP) sanction under Title 19 which include administrative seizures, civil money penalties, revocation of conditional release privileges, and bond actions (liquidated damages, increases to bond amount, requirement of single-transaction bond).

6.1.3.1 - Import Violation Patterns

The below investigational points should be covered to promote a thorough investigation. 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 6.1.3.2)
2. Substitution (See IOM 6.1.3.5)
3. Importer misdeclaration (See IOM 6.1.3.6)
4. Filer misdeclaration (See IOM 6.1.3.7)

6.1.3.2 - 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, and verification of a reconditioning. 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 - collect and analyze pertinent distribution records.
3. Determine who authorized the distribution.
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 as a result 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.

6.1.3.3 - Failure To Hold – Health Hazards – Direct FDA Evidence

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 elements listed above, the following additional step should be taken:

1. 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.

6.1.3.4 - Failure To Hold - Health Hazards – Detention Without Physical Examination (DWPE)

Distribution of goods where there is evidence of a significant health hazard which 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 be regarded as a concern of high

priority. In addition to the eight common elements listed above, the following additional steps should be taken:

1. Consult with supervisory staff and compliance staff as needed to determine if the FDA should collect samples for analysis.
2. 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.

6.1.3.5 - Substitution

Substitution is an attempt by the importer or importer's agent to present goods to 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 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 the presented goods were substituted. This may include labeling, lot codes, and the condition of the goods themselves. Photos are invaluable. Examination of the entire shipment would minimize the possibility the importer will be able to successfully claim 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 6.1.3.2 FAILURE TO HOLD.

6.1.3.6 - Importer Misdeclaration

Importer misdeclaration refers to the importer's provision of incorrect and/or incomplete information to 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 examples may apply:

1. The importer provides information to the filer that does NOT include a product that is actually present in the entry and as a result that product is not included in the declaration (undeclared goods).
2. 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).

6.1.3.7 - Filer Misdeclaration

Although this section is oriented to filer interventions, it must always be recognized 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 Custom and Border Protection (CBP). The following examples may apply:

1. The filer omits a product properly listed on the entry invoice from the declaration (undeclared goods).
2. The importer provides the filer information that a product is manufactured by firm X, but the filer declares it as manufactured by firm Y (misdeclared goods).
3. 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 (misdeclared goods).
4. 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).

6.1.3.7.1 - REPEATED FILER MISDECLARATION

In the event a filer continues to mis-declare a product to CBP or 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 misdeclared products through the collection of labeling and/or photos.
3. Obtain the filer's explanation for the discrepancies. Collect this in an affidavit along with (1).
4. It may be necessary to also collect an affidavit from the importer in some fact patterns. 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. A Filer Evaluation should be conducted to examine records and to determine the extent of the problem. FDA should gather enough evidence to support a possible broker penalty and the following should be considered:
 - a. If the filer has no history of filing erroneous entries to FDA, Districts 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), FDA should contact Customs and Border Protection (CBP) to request a broker penalty be assessed against the filer.

6.1.3.8 - Reporting Investigations Involving the Importation Process

An investigational memo with supervisory endorsement should be generated for all instances described under IOM 6.1.3.1 (import violation patterns), IOM 6.1.3.7 (filer misdeclaration), IOM 6.1.3.5 (substitution) and IOM 6.1.2 (import investigations). The memo should normally be provided to supervisory staff for endorsement within ten business days of the last investigational activity. The memo should normally be endorsed by supervisory staff within five business days. Memos that are endorsed for regulatory consideration should then be forwarded to Compliance for further follow-up. If no memo is generated, then the importer and/or broker should be advised and that advisement should be documented in accordance with district policy.

SUBCHAPTER 6.2 - IMPORT PROCEDURES

6.2.1 - 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 5.2.1.2.

6.2.2 - DIVISION OF AUTHORITY

FDA determines if an article is in compliance with the Acts it enforces. It also determines whether or not 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 FDA or Customs as mutually arranged. At ports in reasonably close proximity to an FDA office, supervision is

ordinarily exercised by FDA. At remote ports supervision may be exercised by Customs.

The refusal of admission, exportation, or destruction of goods is carried out under the direction of Customs. However, at some ports the actual supervision of the destruction of violative goods may be conducted by FDA pursuant to a local FDA/Customs agreement.

6.2.3 - ENTRIES

6.2.3.1 - Formal Entries

All articles offered for entry into the U.S. and subject to the Acts enforced by FDA, with a value greater than \$2000 (current), are considered formal entries. They are subject to bond requirements, which include a condition for the redelivery of the goods, or any part of it, upon demand by Customs at any time, as prescribed for in the Custom's regulations in force on the date of entry. (See [section 801\(b\) of the FD&C Act](#) [21 U.S.C. 381(b)], [19 CFR Part 113](#)) The bond is filed with Customs which, in case of default, takes appropriate action to effect the collection of liquidated damages provided for in the bond after consultation with FDA. (See [19 CFR Section 113.62\(l\)](#) and [21 CFR Section 1.97](#)).

Notification of the Customs entry is generally accomplished by electronic submission through the Customs Automated Commercial System (ACS). Non-electronic entries are submitted directly to FDA. Electronic entries received by FDA may be subject to on screen review (OSR) to determine if further action is needed, or if full documentation must be submitted. For entries requiring further review, FDA will be provided the appropriate Customs Entry documents (CF 3461/3461ALT, commercial invoice, bill of lading and any other relevant documents to aid in making an admissibility decision), and which also document interstate commerce. If an entry is not filed electronically, these documents will be submitted to FDA at the time Customs entry is made, in accordance with local port operations.

6.2.3.2 - Informal Entries

Normally, informal entries (value less than \$2000 currently) do not require posting a redelivery bond. All informal entries of articles subject to FDA jurisdiction, entered electronically, are forwarded to FDA through the Customs/FDA ACS interface. When FDA takes action on an informal entry not filed electronically by the filer, FDA personnel will input the informal entry into OASIS as a manual entry. When taking FDA action with an informal entry, Customs will be requested to convert it into a formal consumption entry.

6.2.3.3 - Mail/Personal Baggage

In the case of imports by mail or personal baggage, FDA districts should arrange for coverage with their local Customs International Mail Office or border crossing office. This should include agreements designating who is

responsible for coverage, when (how often), etc. Customs is responsible for examination of personal baggage. If an article subject to FDA review is encountered, the Customs officer will determine if it should be brought to the attention of the local FDA office. Personal importations meeting the criteria of a formal entry will be processed in accordance with normal non-electronic entries. Generally, 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".)

"Section 321 entries" for Customs are those entries with a value of \$200 or less. Generally, this form of entry applies to articles which pass free of duty and tax, as defined in [19 C.F.R. 101.1\(o\)](#), and imported by one person. Customs and FDA may conduct periodic "blitzes" to determine the volume and type of FDA-regulated goods admitted under "Section 321 entries." The use of the 321 entry process should not apply to multiple shipments covered by a single order or contract, sent separately for the express purpose of securing free entry and avoiding compliance with pertinent law or regulation.

6.2.3.4 – Import for Export (IFE) Entries

PRODUCTS IMPORTED UNDER THE PROVISIONS OF SECTION 801(d)(3) OF THE FD&C Act [21 U.S.C. 381 (d)(3)]: Import For Export (IFE) Processing and Follow-Up

PURPOSE: To establish procedures facilitating the uniform review of Import for Export (IFE) at the time of entry and domestic follow up to insure articles entered as Import for Export are either exported or destroyed but not distributed domestically.

REFERENCES: [Regulatory Procedures Manual Chapter 9-15](#), Federal Food, Drug, and Cosmetic Act

BACKGROUND: [Section 801\(d\)\(3\) of the FD&C Act](#) [21 U.S.C. 381 (d)(3)] allows the importation of certain violative FDA-regulated articles into the U.S. on a conditional basis 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.

Documentation required at the time of importation under section 801(d)(3) of the Act [21 U.S.C. 381 (d)(3)] includes:

A statement that article is intended to be further processed or incorporated into a drug, biologics product, device, food, food additive, color additive or dietary supplement that 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);

Information to identify the manufacturer of the article and each processor, packer, distributor, or other entity in chain of possession from manufacturer to importer;

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)] - blood and blood components;

In addition, an **IFE applicable** bond must be executed providing for payment of liquidated damages in accordance with CBP requirements.

6.2.3.4.1 – IFE ENTRY REVIEW

Import for Export entry procedures are as follows:

1. If electronic submission is made, it is unlikely all of the information required under [section 801\(d\)\(3\) FD&C Act](#) [21 U.S.C. 381 (d)(3)] will be provided electronically. Districts should request the supporting documents (if not already received from the broker or importer) by setting an entry option of Documents Requested (DRQ) and/or Entry Incomplete (DEF) on all entries with IFE in the Affirmation of Compliance (AOC) field in OASIS, or those suspected to be IFE, which lack complete supporting documents.
2. If the entry is indeed an IFE entry and the AOC was not included in the original entry, the entry reviewer should modify the AOC field in OASIS to indicate "IFE". If the required documentation is not provided after a DRQ, entry reviewers should take the appropriate compliance follow-up, under the basis the required IFE documentation was not provided to FDA at the time of initial importation. Districts should determine the appropriate time frame for receiving the required IFE documents in particular circumstances. It is anticipated three (3) days from the DRQ or DEF notice will usually be adequate for the required IFE documentation to be submitted. This is because the broker may need to communicate FDA's requirement for documents to an importer. If all required documentation is provided, the entry should be given a "May Proceed". NOTE: All documentation supporting the IFE entry should be processed in accordance with step 4 below. If documentation is not adequate, the district should issue a detention after review of the documentation, in accordance with normal procedures outlined in the [RPM Chapter 9](#).
3. If the entry is marked IFE, but review of the entry information or supporting documents indicates the AOC was entered inappropriately, the entry reviewer should note this in the entry remarks section.
4. Copy and attach all entry documentation and forward to the FDA home district of the initial owner or consignee, identifying the following:
 - a. FOREIGN MANUFACTURER/SHIPPER
 - b. ENTRY NO.
 - c. U.S.IMPORTER OF RECORD
 - d. INITIAL OWNER/CONSIGNEE
 - e. ARTICLE/PRODUCT

6.2.3.4.2 – DOMESTIC FOLLOW-UP OF IFE ENTRIES

The FDA home district of the initial owner or consignee should:

1. Ensure the IFE Entry is copied from the list of IFE shipments for the last 30 days which is generated by the Division of Import Operations and Policy (DIOP).
2. Ensure supporting documents are sent to the establishment file of the initial owner or consignee.
3. Ensure follow-up inspections are conducted within 6 - 9 months of the initial notification the firm is receiving an IFE entry. All existing IFE entries for the firm should be investigated during the initial IFE inspection. If the product has not been "further processed" or "incorporated" into product for export, the home district should monitor the firm's practices to ensure there is no violation of the IFE provisions of the Act.

6.2.3.4.3 – IFE DOMESTIC INSPECTION GUIDANCE

When a firm is scheduled for inspection, you should:

1. Review the IFE entry documentation and/or follow-up inspection information from the establishment file prior to conducting the inspection.
2. Verify during the inspection the IFE article:
 - a. Was used to produce an exported product,
 - b. Was destroyed, or
 - c. Still under the firm's control pending disposition. If the article is pending disposition, verify a current and valid Customs bond covering the article exists, and the article is the same article that was offered for entry.

If the article was exported or destroyed, you should request the manufacturer's import, export, and/or destruction records to verify the imported article was further processed or incorporated into another product and was exported in accordance with sections [801\(e\)](#) or [802](#) of the FD&C Act [21 U.S.C. 381 (e) or 382] or section 351(h) of the PHSA, or destroyed. Please note, for drug products, an initial owner or consignee may be allowed to retain a sample of the imported article in order to comply with good manufacturing practices (GMP) regulations concerning sample retention.

Include in the Establishment Inspection Report or a memo the status of the IFE product and if further follow-up is required.

Following review and determination of the necessity of further follow-up, forward the completed EIR or memo and supporting documents to the District which initiated the IFE follow-up.

Upon receipt of the completed IFE Follow-up, ensure the following actions are taken:

1. Verify if further follow-up is needed. If so, schedule a follow-up inspection. If further follow-up is NOT needed, document the completed follow-up.
2. Any inspections identifying a prohibited act under [section 301\(w\) of the FD&C Act](#) [21 U.S.C. 331 (w)]

should be forwarded immediately to the district compliance branch for regulatory action. See [RPM Chapter 9](#). In addition, a copy of the violative inspection findings should be forwarded to DIOP immediately.

6.2.3.5 - Prior Notice of Importation of Food and Animal Feed

The [Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#) (the Bioterrorism Act) requires that FDA receive prior notice of food imported into the United States. Most of the prior notice information required by the final rule is data usually provided by importers or brokers to CBP when foods arrive in the United States. The Bioterrorism Act requires that this information also be provided to FDA in prior to an imported article of food's arrival to the United States. FDA uses this data in advance of the arrival to review and assess the prior notice data, and determine whether to examine the imported food for potential bioterrorism or significant public health risks. Prior notice can be submitted either through ABI/ACS or FDA's Prior Notice System Interface (PNSI).

6.2.3.5.1 - PRIOR NOTICE RECEPTION

Prior notice for food articles subject to the rule must be received and confirmed electronically by FDA no more than 15 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/ACS, and as specified by the mode of transportation below, no fewer than:

1. 2 hours before arrival by land by road
2. 4 hours before arrival by air or by land by rail
3. 8 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.)

6.2.3.5.2 - 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 reference to [section 201\(f\) of the Federal Food, Drug, and Cosmetic Act](#). Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles.

Examples of "food" include:

1. Dietary supplements and dietary ingredients
2. Infant formula
3. Beverages (including alcoholic beverages and bottled water)
4. Fruits and vegetables
5. Seafood
6. Dairy products and eggs

7. Raw agricultural commodities for use as food or components of food
8. Canned and frozen foods
9. Bakery goods, snack food, and candy (including chewing gum)
10. Live food animals
11. Animal feeds and pet food

6.2.3.5.3 - PRODUCTS EXCLUDED FROM PRIOR NOTICE

Foods that are excluded from the prior notice requirement are:

1. Food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution);
2. Food that is exported without leaving the port of arrival until export;
3. Meat food 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](#), the [Poultry Products Inspection Act](#), or the [Egg Products Inspection Act](#);
4. Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; and
5. Articles of food subject to Art. 27 (3) of the [Vienna Convention on Diplomatic Relations \(1961\)](#), i.e. shipped as baggage or cargo constituting the diplomatic bag.

6.2.3.5.4 - 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 submitting 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\(b\)\(8\)](#)), 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 of grower, if known, and growing location
7. The FDA Country of Production
8. The identification of the shipper, express consignment operators, carriers, other private delivery service or sender's if the food is mailed. This is to 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 is shipped. If the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
10. The anticipated arrival information (location, date, and time). If the food is imported by international mail, the U.S. recipient (name and address). 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, actual date the article arrived is required
11. The identification and full address of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States. 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 is 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 and the flight number for prior notices submitted via PNSI
14. The name of any country to which the article of food has been refused entry.

6.2.3.5.5 - 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 secure storage facility. FDA provided guidance to its stakeholders and CBP staff on enforcing the prior notice requirements in a Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 at <http://www.fda.gov/Food/FoodDefense/Bioterrorism/PriorNotice/default.htm>. This guidance, however, does not affect 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 Federal Food, Drug, and Cosmetic Act. This policy will

also not affect the ability of Customs to assess penalties under [19 U.S.C. 1595a\(b\)](#) or to take enforcement action under any other authority.

6.2.3.5.6 - PRIOR NOTICE PROCESS

The prior notice process begins with an automated screening process. If additional evaluation of the prior notice information is necessary, all review of prior notice information is performed by the Prior Notice Center (PNC); FDA headquarters staff, operating 24 hours a day, 7 days a week. The review process is a manual review by the PNC. It is designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon arrival in the United States. The review process is not impacted by the method of electronic submission. The results of this process will be transmitted to CBP.

The PNC reviews and assesses the prior notice information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site. The PNC will advise the FDA field offices and/or Customs of the inspection requirements. The PNC is also responsible for communication with submitters regarding the compliance of prior notice, the initiation of refusal or hold due to inadequate prior notices, the response to requests for review of refusals or holds, and the completion of the prior notice process.

In addition, the OASIS system review will determine if further staff evaluation of the article of food is necessary for admissibility determinations under section 801(a) of the FD&C Act (e.g., subject to the guidance in an import alert). If the food meets the prior notice requirements; the food will be subject to further review by FDA staff for determination of admissibility under section 801(a) of the FD&C Act.

This admissibility examination may take place at the border but may also take place at an examination site, a public warehouse, or other appropriate locations. If FDA determines that refusal under [section 801\(a\) of the FD&C Act](#) is appropriate, the appropriate refusal procedures will be used.

6.2.3.6 - Entry Processing

FDA district offices generally receive notification of all formal and informal entries subject to FDA's jurisdiction at ports of entry located in its territory. However, through the use of Custom's Automated Commercial System and FDA's Operational and Administrative System for Import Support (ACS/OASIS) some electronic entries may be forwarded to off-site districts for processing during certain periods of time, i.e., late night coverage of air carrier hubs.

The most satisfactory and efficient means of getting notification is through FDA's OASIS system. Electronic

entries processed through this system are electronically screened against criteria established by FDA for coverage. Automated Broker Interface (ABI) filers using the Customs ACS for cargo release are required to provide FDA information on entries subject to its jurisdiction submitted through ACS. The means of receiving notification for non-ABI/OASIS entries can be arranged through local Customs/FDA District agreements.

6.2.3.6.1 - U. S. CUSTOMS

Customs' ACS uses guides established by each Federal agency to identify which commodities are subject to their jurisdiction. These guides are known as Other Government Agency (OGA) flags. FDA flags are identified as FD0, FD1, FD2, FD3 and FD4.

FD0 indicates the article, even though subject to FDA regulation, may be released without further presentation of entry information to FDA.

For entries flagged FD1 the commodity may or may not be subject to FDA regulation. Electronic entries for the filer may, based on information received from the importer regarding the intended use of the commodity, specify the entry is not subject to FDA regulation and "Disclaim" the entry. Otherwise, FDA required information must be submitted. FDA review of "Disclaimed" entries is performed periodically to confirm the accuracy of the declaration.

Entries covered by an FD2 flag must include FDA required information.

FD3 indicates that the article may be subject to prior notice under [section 801 \(m\) of the FD&C Act](#) and [21 CFR Part 1, subpart I](#), e.g. 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 indicates that the article is "food" for which prior notice is required under section 801(m) of the FD&C Act and 21 CFR Part 1, subpart 1. Entries covered by FD4 flag must include prior notice required information.

Electronic entries for Customs review includes all mandatory Customs entry required information, i.e., 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 ACS, Customs determines if the article is subject to FDA examination (see OGA flag identifications above).

6.2.3.6.2 - FDA

FDA's electronic screening of the Customs ABI/ACS entry requires the filer to provide the following information.

1. FDA product code. (FDA's product code is not the same as the HTS codes used for Customs screening purposes).
2. The "Manufacturer's Identification" (MID) code (a Customs designation) of the foreign manufacturer. The MID consists, at a minimum, of the 2 letter identification of the foreign country, the name of the foreign firm, generally made up of the first three letters of the first and second names of the firm, where applicable. Up to 4 numbers, if present in the address, and the first three letters of the city where the firm is located. This code is subsequently transmitted to FDA's screen as the un-coded identified firm.
3. The MID information of the foreign shipper, including city and country; which may or may not be the same as the foreign manufacturer.
4. The country of origin; which may be different from the country of origin identified for Customs purposes.

FDA has also established Affirmation of Compliance (A of C) codes which are designed to provide FDA reviewers with information concerning the imported article (example: medical device listing number). Use of the A of C is voluntary, and may or may not provide for a more expeditious screening of the entry.

In OASIS, the FDA forms identified as: "Notice of Sampling," "Release Notice," "Notice of Detention and Hearing," and "Notice of Refusal of Admission," are no longer issued as specific forms. OASIS generates a "Notice of FDA Action" providing information on the actions taken regarding a particular entry line. The notice identifies the specific line(s) of the entry, where appropriate, with the description of the sample collected or intended for sampling, specific line(s) identified as detained, and/or the specific line(s) identified as released, refused, etc. As the status changes for a particular line, a new "Notice of FDA Action" is issued to advise the appropriate individuals of the changes. The use of the designation "Product Collected by FDA," "Detained," "Released," "Refused," etc., or similar wording on the "Notice of FDA Action," meet the requirements of the wording of the law and regulation when applied to "giving notice thereof to the owner or consignee." See Exhibit 6-1.

OASIS notices are designed to be mailed to the addressees. A copy of each notice is produced with the filer, importer of record, and consignee 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 which provide FDA decisions on entries. The distribution of the notices is made by FDA, not the filer, to ensure proper notification to the parties involved (i.e., FAX, express pick-up services, postal service, etc.). The intention is for FDA to distribute to the responsible firm without an intermediary.

6.2.4 - SAMPLING

6.2.4.1 - 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. 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 designated items need be held; etc.

6.2.4.2 - Ports not Covered by FDA

For those ports where Customs does not maintain its ACS electronic entry process, and FDA does not generally cover the port under its normal operating schedule, the responsible FDA district office will coordinate coverage with the responsible Customs Port manager to assure FDA notification. If FDA decides to examine or sample articles being entered through such a port, Customs, 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 Customs 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 Customs officials and importer by the responsible district.

6.2.4.3 - Entry Sampling

If no examination or sample is requested, FDA will notify Customs and the filer (who is responsible for notifying the importer, or other designated parties). This electronic notification is called a "May Proceed Notice". It indicates the shipment may proceed without further FDA examination. In the ACS/OASIS process, this may occur as a result of the initial FDA/OASIS screening or after the district performs an "On-Screen-Review".

NOTE: Since the article is allowed entry without FDA examination, should the article, at a later time, be found in violation of the law, the Agency is not prevented from taking legal action because the article was allowed admission by FDA without examination at the time of importation. (See [section 304\(d\) of the FD&C Act](#) [21 USC 334(d)])

If an examination or sample is requested, FDA notifies Customs, broker or filer, importer, or other designated

parties. Notification is either through the electronic entry system or other form of notification (Notice of FDA Action), to hold the entry and will identify the specific product(s) to be sampled, etc.

6.2.4.4 - Notice of Sampling

When a sample is collected by FDA, a Notice of FDA Action is issued to the importer of record, consignee, and filer. If Customs collects the sample for FDA, the district will enter the entry information into OASIS and issue the Notice of FDA Action.

For those entries where specific lines (items) of an entry are not sampled or examined, the Notice of FDA Action will be amended to indicate which lines (items) "May Proceed." (See [RPM Chapter 9-19](#) "Notice of Sampling" for detailed guidance.)

6.2.4.5 - Payment for Samples

The FDA will pay for all physical samples found in compliance or collected as an audit of private laboratory reports of analysis submitted to FDA in response to detention (See [21 CFR 1.91](#)). (NOTE: This does not apply in the case of an audit sample collected to document reconditioning). See IOM 4.2.8.2 for guidance on sample costs.

Billing for reimbursement should be made to the FDA district 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. For this reason, do not pay for samples at the time of collection.

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

6.2.5 - PROCEDURE WHEN PRODUCTS CANNOT BE SAMPLED OR EXAMINED

If the entry is still under control of the district inspection operations, and the sample collection cannot be completed, the district may annotate the notice to the filer and importer 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.

In the OASIS system, when a notice is issued for the collection or examination of a product, 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 also print a detail section "Lines Which May Proceed."

In OASIS, 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.)

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

6.2.6 - PROCEDURE WHEN NO VIOLATION IS FOUND

If the shipment is found in compliance after examination, the importer of record, consignee (where applicable), filer, and Customs are notified with a Notice of Release. The shipment may be admitted. (See [RPM Chapter 9-5](#) "Release Notices" for detailed guidance).

6.2.7 - PROCEDURE WHEN VIOLATION IS FOUND

6.2.7.1 - "Notice of Detention & Hearing"

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 district, the filer, owner and consignee, where applicable, are advised of such action by "Notice of Detention and Hearing." 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 district, 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 district determines ten (10) working days are insufficient; this time period may be extended. On the OASIS generated "Notice of FDA Action", this date is identified under the caption "Respond By". A copy of this Notice is also sent to Customs. (See [RPM Chapter 9-7](#) "Notice of Detention and Hearing".)

6.2.7.2 - Response to "Notice of Detention & Hearing"

Response to the Notice of Detention and Hearing 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 a method to remove the product from the authority of the FD&C Act.

6.2.7.3 - Request for Authorization to Relabel or Perform Other Acts

FDA may authorize relabeling or other remedial action upon the timely submission of an "Application for Authorization to Relabel or To Perform Other Action," (Form FDA 766 - See Exhibit 6-2). This form is also available in fillable formats online at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072766.pdf>.

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 District Director of Customs 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 district files. (See [RPM Chapter 9-8](#) "Response (Hearing) to Notice of Detention and Hearing", and [RPM Chapter 9-10](#) "Reconditioning" for detailed guidance).

6.2.7.4 - Inspection after Completion of Authorization to Bring Article into Compliance

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (the reverse side of Form FDA 766, Exhibit 6-2) or advise the district that reconditioning is complete. At this point, FDA may conduct a follow-up inspection and/or sampling to determine compliance with the terms of the authorization, 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 Customs, depending on agreements between the district and the local Customs. The "Report of Inspector" (reverse side of Form FDA 766, Exhibit 6-2), or other appropriately completed summary of reconditioning, should be forwarded to the appropriate FDA office.

6.2.7.5 - Procedure when Conditions of Authorization Have Been Fulfilled

If the conditions of the authorization have been fulfilled, the district will notify the owner or consignee by Notice of Release. This notice is usually identified as "Originally Detained and Now Released." A copy is also sent to Customs and filer. Where there is a non-admissible portion (rejects), they must be destroyed or re-exported under FDA or Customs supervision. A Notice of Refusal of Admission should be issued for the rejected portion. 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.

6.2.7.6 - Procedure when Conditions of Reconditioning Have Not Been Fulfilled

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

If the conditions of the authorization have not been fulfilled, a "Notice of Refusal of Admission" is issued to the importer, consignee, where applicable, to the filer, and to Customs.

6.2.7.7 - Procedure after Hearing - "Notice of Release"

If, after presentation of testimony, the district determines the article should be released, the importer of record and consignee are issued a "Notice of Release". The Notice will declare the detained goods may be admitted. The Notice will also be identified "Originally Detained and Now Released" and, where appropriate, explain the reason for the change of action. A copy of the Notice is sent to Customs, and all parties receiving the Notice of Sampling/Notice of Detention. (See [RPM Chapter 9-5](#) "Release Notices" for detailed guidance.)

6.2.7.8 - Procedure after Hearing - "Refusal of Admission"

When the importer requests the district issue a "Notice of Refusal of Admission", or the district decides the shipment still appears to be in violation, the importer, owner, and consignee where applicable, are issued a "Notice of Refusal of Admission". On this Notice, the charge(s) is stated exactly as shown on the original (or amended) "Notice of Detention and Hearing". A copy of the Notice is also sent to Customs. (See [RPM Chapter 9-9](#) "Notice of Refusal of Admission" for detailed guidance.)

The "Notice of Refusal" provides for the exportation or destruction of the shipment, under Customs supervision, within 90 days of the date of the notice, or within such additional time as specified by Customs Regulation. Under

OASIS, the Notice will also contain language which includes reference to the requirement for redelivery, and contain all the above required information concerning the product and charge(s). The FDA file remains open until the district receives notification indicating the goods were either destroyed or exported.

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.

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

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

1. Investigator's time
2. Analyst's time
3. Per diem allowance
4. Travel other than by auto - actual cost of such travel
5. Travel by auto (mileage, toll fees, etc.)
6. Administrative support

Future enhancements to FDA import system may result in electronic processing of the supervisory charges submitted to Customs, in which case the Form FDA 790 will no longer be used. (See [RPM Chapter 9-11](#) "Supervisory Charges" for detailed guidance.)

Customs, 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 Customs. Payment of supervisory charges should not be accepted by FDA district offices.

6.2.7.10 - Exportation of Goods Refused Admission

Exportation of refused goods is done under Customs supervision. However, if after a reasonable time, FDA has not received notification of exportation or destruction, the district should investigate the status of disposition. Districts should also consider, under certain conditions, verifying the refused goods have been held intact pending exportation or destruction, or that re-export actually occurred. Guidance on refusals to be verified may change, based on the reason for detention.

6.2.7.11 - 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 Customs 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 Customs notice of assessment of 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 district has evidence 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\(l\)\(1\)](#)) they should immediately contact the appropriate Customs office.

The district, upon receiving evidence the refused article was not exported or destroyed should immediately investigate the matter. Send a detailed statement showing the importer's liability under the redelivery bond or other applicable customs bond to the responsible Customs 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 Customs.

Upon the receipt of an application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages), Customs may agree to mitigate the amount of damages. However, in cases involving FDA goods, Customs does not usually mitigate unless FDA is in full agreement with the action [see [21 CFR section 1.97\(b\)](#)]. (See [RPM Chapter 9-12](#) "Bond Actions" for detailed guidance.)

SUBCHAPTER 6.3 - REVIEW OF RECORDS

6.3.1 - GENERAL

"Records review" is the initial examination provided the importer's documentation (including any electronic entry filing information.) Also, see IOM 5.4.1.4 for Food and Cosmetics Defense Inspectional Activities. This operation is performed on every entry of regulated product to determine if additional action, such as sampling, is necessary. (Review of electronic filings follows the same decision-making criteria applied to hard-copy entry filings.) At this point, one of four decisions is made:

1. Release the lot, or
2. Detain the lot, or

3. Examine the lot by Field Examination or Sampling, or
4. Verify registration, listing, declarations, certifications, etc. where applicable.

The decision will be supported by:

1. Electronic screening on entry information,
2. Computerized information (FIARS, local/regional data systems),
3. Import Alerts,
4. Monthly Refusals List,
5. Past history,
6. Compliance Program Guidance Manual,
7. Assignments, and
8. Local assignments and programs (e.g., Regional Pesticide Sampling Plan)

See [Regulatory Procedure Manual \(RPM\) Chapter 9](#) for additional guidance concerning the review/processing of entries of specific types of commodities, including products under detention without physical examination.

Record reviews are reported into PODS as Entry Reviews.

SUBCHAPTER 6.4 - FIELD EXAMINATION

6.4.1 - GENERAL

A field examination is an on-the-spot examination or field test performed on a product to support a specific decision. It may be conducted on products discharged from vessels on to the wharves (piers), pier sheds, and other locations; products in trucks, trains, freezers, and containers, etc., at border entry points; or on products set aside for FDA examination. Some compliance program guidance manuals do not address field examinations. Nevertheless, field examinations are appropriate for certain problems and/or commodities and should be conducted.

A field examination involves actual physical examination of the product for such things as:

1. Confirming quantity present corresponds to quantity declared on shipping documents,
2. In transit or storage damage,
3. Inadequate storage temperature conditions,
4. Rodent or insect activity,
5. Lead in ceramic ware (Quick Color Test – QCT and Rapid Abrasion Test - RAT),
6. Odors uncharacteristic for the product or of spoilage,
7. Non-permitted food and/or color additives, and
8. General label compliance

When conducting a field examination, compare documents provided by filer/importer, to what is physically available during your inspection.

A field examination does not have the same level of confidence as a laboratory examination. Consequently, more rigorous standards of acceptance are applied 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. The decision to sample is, to some degree, left to your discretion. In most instances, it should be based on findings significantly lower than specified by the formal guideline.

A field examination begins when the physical examination is started. Do not include, as reported Field Examination time, the time to locate the lot or travel time. Time spent in locating the lot is reported as import investigation.

See IOM 5.1.4.3 for suggestions on what to do when 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.

6.4.2 - 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 Program Guidance Manuals, specific product examination schedules (e.g., LACF), or other guidance.

When you conduct any field examination, in addition to specific items discussed in the following sections, be alert for any over labeling where a product name or identity may have been changed; product without mandatory English labeling; changes in expiration date or lot numbers; product quantity differences; product integrity; country of origin or similar questionable practices. If you encounter any of these items, document your findings and discuss the appropriate action with your Supervisor.

6.4.3 - FIELD EXAMINATIONS - FOODS

See IOM 5.4.1.4.2 for guidance on performing reconciliation examinations during import field examinations.

6.4.3.1 - Food Sanitation

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, e.g., products which can be probed, products in see-through containers, etc. See 5.1.5, et al for some specific guidance on performing field examinations.

Low acid and other Canned Foods – See IOM Chapter 4 SAMPLE SCHEDULE CHART 2.

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

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

Field examinations cannot be performed for most of these materials, except for metals in dinnerware and the side seam solders of cans.

NOTE: Districts should use commercial versions of the Quick Color Test (QCT) and the Rapid Abrasion Test for lead, e.g. 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 [CPGM 7304.019B](#). Specific information regarding the techniques of testing dinnerware and can side seam solder can be found in Lab Information Bulletin (LIB) 4127 and LIB 4041, respectively on the Division of Field Science (DFS) intranet site.

6.4.3.3 - Food and Color Additives

Perform a visual examination of the container and a label review for the mandatory labeling requirements. For example, determine if a color additive is declared for a product which appears coloring has been added. Determine if a preservative declaration includes its function; for example, "Sodium Benzoate as a preservative."

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 given 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](#). 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."

NOTE: Label examinations of products to determine whether there is a declaration of certain food and/or color additives are reported as import investigations.

6.4.3.4 - Nutrition and Food Allergen Labeling and Consumer Protection Act (FALCPA)

The only valid field examination which can be performed for this type of problem is a label examination for the mandatory labeling requirements. See the "[Guide to](#)

[Nutritional Labeling and Education Act \(NLEA\) Requirements](#)" document. Also see the Office of Nutrition, Labeling and Dietary Supplements (ONLDS), website (<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm>) for the most up-to-date information regarding claims in labeling. Also, see [CPGM 7321.005](#) to determine enforcement priorities for food labeling violations.

6.4.3.5 - Food Economics (On Consumer Size Containers only)

Label Examination - Review labels for all aspects of the labeling requirements.

Net weight - See IOM 4.3.8.1

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.

NOTE: Label examinations of products to determine if the labeling meets the mandatory labeling requirements for a particular Food Standard must be reported as an Import Investigation.

6.4.3.6 - 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 [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](#)),
5. Cautionary/Other Required Statements (Coal tar hair dyes not displaying the caution statement can be considered adulterated - [FD&C Act sec. 601\(a\)](#), caution statement for the color additive lead acetate - [21 CFR 73.2396](#), required label information for the color additive bismuth citrate - [73.2110](#), and required label information for the color additive henna - [73.2190](#))
6. Tamper Resistant Packaging Requirements ([21 CFR 700.25](#))

For further questions contact the Office of Cosmetics and Colors, (240) 402-1130.

NOTE: Label examinations of products to determine whether their labeling declares certain ingredients must be reported as an Import Investigation.

6.4.4 - FIELD EXAMINATION - DRUGS

When you conduct field examinations of drugs (bulk drugs and finished dosage forms) ensure you check:

1. Labeling compliance (e.g., Reye Syndrome warning)
2. Probable contamination
3. Tamper Resistant Packaging Requirements

6.4.4.1 - Labeling

Bulk drugs and finished dosage forms should be evaluated for compliance with the Drug Listing Act, [21 CFR 207.40](#). Refer to the Drug Listing Compliance Program Guidance Manual.

6.4.4.2 - Contamination

Drugs should be examined for container integrity, e.g.: cracked vials, ampoules, bottles, etc.

6.4.4.3 - Samples

A decision to collect samples for Drug Listing Act compliance evaluation should be made in accordance with the drug listing CPGM. The nature of samples to be taken 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.

6.4.4.4 - Special Instructions

Field examinations may be made of drug lots to obtain information in determining the new drug status of a given shipment. Districts should contact the Division of New Drugs and Labeling Compliance, Import/Export International Drug Team, (HFD-319) for guidance.

6.4.5 - FIELD EXAMINATIONS – DEVICES

Medical device field exams involve mostly label or labeling review. The label should include the name and business of the manufacturer, packer or distributor and product identity. Be aware of misdeclared devices, for example, TENS (transcutaneous electrical nerve stimulation) devices are often declared as therapeutic massagers but in fact should be declared as neurological therapeutic device. 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 further guidance for labeling provisions refer to [21 CFR Part 801](#).

Medical device field exams include electrode lead wires, patient cables, labeling, and physical damage. Lead wires and patient cable exams should conform to applicable standards set forth in [21 CFR Part 898](#).

Field examination guidance documents issued by CDRH are found at [Division of Import Operations and Policy intranet site](#).

During any field exam you may conduct of "sterile" devices offered for entry, which are destined for sterilization at a sterilizer, per [21 CFR 801.150](#): each pallet, carton, or other designated unit is 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. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g., "sterilized--awaiting test results" or an equivalent designation. 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. FDA will not initiate regulatory 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. This cite also requires a written agreement between the foreign firm and the importer of record. Specifically, there is in effect a written agreement 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.

6.4.6 - FIELD EXAMINATIONS - BIOLOGICS

Review [RPM Chapter 9-3](#) "Importation of Biologics" and the Import Alert regarding biologics prior to conducting any field examinations of biological products.

In general, products controlled by Center for Biologics Evaluation and Research (CBER) do not require 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.

Products imported under Investigational New Drug (IND) Applications are also monitored, but due to the small volumes involved, no specific guidance is necessary.

Shipments of biologics which are not licensed, or are not directly related to an active IND should be examined for:

1. Labeling
2. Consignee
3. Manufacturer
4. Intended use

Contact CBER/OC/Division of Case Management (HFM-610) for guidance.

6.4.7 - FIELD EXAMINATIONS - VETERINARY PRODUCTS

Contact the CVM Division of Compliance (HFV-230), the [Post-Market Compliance](#) Team, with general questions on the importation of veterinary products. You should be aware of various Import Alerts, Compliance Policy Guides or Guidance Documents as they affect individual import situations. See the [CVM website](#) for additional information or notifications on current import situations

6.4.7.1 – Veterinary Drugs

Field examinations of veterinary drugs are visual examinations to determine potential misbranding or adulteration. This may include examination for:

1. Container Integrity
2. Labeling Compliance
3. Product adulteration

Dosage form drugs must be examined to determine if they are new animal drugs. If the products are new animal drugs, you need to determine if an approved NADA/ANADA exists or if there is a valid INAD exemption in place. You should consult with CVM's Division of Compliance (HFV-230) regarding the status of imported veterinary products (240-276-9200).

Bulk New Animal Drug substances and Active Pharmaceutical Ingredients (APIs) may be legally imported only if destined to the holder of an approved NADA or INAD exemption. You will need to consult with the Center for the status of particular drugs.

Entries of prescription animal drugs for use by the consumers (laymen) must be examined for labeling content, consignee (name and address) and to determine if a valid prescription/order exists from an appropriately licensed veterinarian. CVM (240-276-9200) should have records of any exemptions or permission granted for personal imports.

6.4.7.2 - Devices

Devices intended for animals do not require premarket approval. However, they are still subject to examinations for misbranding violations. Animal devices must bear adequate directions for use and label claims must not be false or misleading. You should consult with CVM for guidance (240-276-9200).

6.4.7.3 - Animal Feed

Animal feeds and feed components, including pet foods should be examined for conformance with all applicable and appropriate food labeling requirements, drug claims, food additive violations and use of banned or objectionable ingredients as well as filth and foreign objects. You should consult with CVM on individual issues and to determine specific requirements (240-276-9200).

6.4.7.4 – Animal Grooming Aids

'Cosmetics' for animals are referred to as "animal grooming aids". While CVM does not actively pursue enforcement actions with animal grooming aids, the products are expected to be safe, effective and properly labeled. The labels and labeling of any incoming animal grooming aids are subject to examination and review for potential instances of misbranding. Consult with CVM for appropriate guidance. The Division of Compliance (240-276-9200) can answer regulatory and enforcement questions.

6.4.7.5 - Biologicals

CVM does regulate animal biologic products. They are considered as drugs. However, CVM does not regulate animal vaccines. The vaccines are regulated by USDA/APHIS.

6.4.8 - FIELD EXAMINATIONS RADIOLOGICAL HEALTH

Field Examinations for imported electronic products consist of reviewing the Entry Documents and [FDA-2877](#), Declaration for 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](#), [optical](#), [microwave](#) and [acoustic](#) radiation-emitting products, are specified in 21 CFR 1020 through 1050.

For electronic products, physical samples may only be collected on specific assignment. DTR/DER recommendations are to be submitted when the Field Examination indicates the product may not be in compliance and detention is recommended.

Import coverage for radiation emitting products is provided for in a CDRH Compliance Program Guidance Manual. Do not collect physical samples except on specific assignment, or with concurrence of CDRH.

6.4.9 - FIELD EXAMINATIONS – TOBACCO PRODUCTS

Contact the CTP Office of Compliance and Enforcement, Enforcement and Manufacturing Group, with general questions on the importation of tobacco products. See the

CTP website for additional guidance, compliance, and regulatory information for tobacco products.

SUBCHAPTER 6.5 - IMPORT SAMPLE COLLECTION**6.5.1 - 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. However, these are district options. See Chapter 4 for sampling instructions and guidelines. There will be instances when the collection of a reserve portion and an official seal is warranted, i.e., when enforcement action (e.g., seizure, injunction, prosecution) is contemplated. Many sample sizes are provided in the Sample Schedule Section (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 district. In addition, when preparing to collect import samples, you should be aware of your personal safety. Refer to IOM 5.2.1.2.

FDA does not pay for import samples at the time of collection. The Importer should be told to bill the responsible district. FDA will not pay for violative import samples, per [21 CFR Part 1.91](#), see IOM 6.2.4.5.

When collecting IMPORT "ADDITIONAL Samples", the original Import Collection Report (CR) number should be used. Under OASIS, this will be the entry number with appropriate line information, etc.

Import Samples are compliance samples, except for those collected for pesticide analysis. These samples MUST BE FLAGGED either "Pesticide Surveillance" or "Pesticide Compliance" depending on the basis for sampling. See IOM Sample Schedule Chart 3 (Chapter 4) for guidance.

6.5.2 - PROCEDURES

Review the submitted entry (electronic or hard copy documentation) to assure 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 FDA should match the description of the product(s) in the invoice from the broker.

6.5.3 - TECHNIQUES

Follow guidance furnished in IOM Subchapter 4.3 - Collection Technique.

6.5.4 - IMPORT FORMS PROCEDURES

Because forms are now generated electronically by OASIS, individuals performing field examination or sample

collections should follow guidance provided in the OASIS Training Manual, or consult their lead OASIS personnel.

6.5.5 - SAMPLE COLLECTION REPORTS

See IOM 1.1 English language requirement. For every sample collected, a corresponding electronic collection report must be completed in OASIS. (See IOM Exhibit 6-4.) You are responsible for making sure the date collected, quantity collected, unit of weight, and description of text fields are completed accurately. The following are instructions for completing an OASIS Collection Report:

1. Highlight the line sampled in your available work personal in box in OASIS or self assign the sample request.
2. Prior to entering any data, double check all entered data for accuracy.
3. Double click the work type, i.e. "SAM" and click the "line Details" button. The line details screen is the only place you can make corrections to the entered data.
4. Verify all data is correct, i.e., product code matches actual product, manufacturer, country of origin, quantity and value are correct. If there is a build button on the line you need to correct, you must use the build function to make corrections. Once data has been changed, click on save button; enter brief description in pop up box of corrections made.
5. Click on "Rescreen" in the Application Tool bar to see if changing any data caused the line to hit on any other criteria or alerts.
6. Highlight the line sampled and click on "Wk Detail" in the Application Toolbar.
7. Click to highlight the appropriate PAFs in the bottom area of the screen. If you are sending the sample to more than one laboratory, highlight the PAF for each laboratory individually and complete a separate collection report for each lab.
8. Click "Work Result" button near the top right of the screen.

OASIS completes the following fields for you. **Entry number, Investigator initials, Date Collected, Product Code, Product Code Description, Importers Corrected Description, Location of Goods**, default laboratory in **Submitted To** and the FACTS **Lab Number**. The **Date Collected, Location of Goods** and **Submitted To** fields can be corrected on this screen.

Enter data in the following fields:

6.5.5.1 - Collection Date

Collection Date: Make sure the date reflects the date the sample was actually collected, not the date you are entering the sample in OASIS.

6.5.5.2 - Episode

An "episode" is defined as a violative pesticide (or other chemical contaminant) finding and 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 (e.g. growing season). For example, samples of cantaloupes from Mexico reveal violative residues. Any destination point samples or subsequent compliance samples from the same shipper or grower would along with the original sample be considered an episode. Enter the episode number.

6.5.5.3 - Submitted To

Select the appropriate lab from the pull-down menu. The default will be your district servicing laboratory for the type of analysis. It can be changed if necessary.

6.5.5.4 - Quantity Collected

Enter the number of sampled units you collected.

6.5.5.5 - Units

Select the appropriate units from the pull-down menu. If the appropriate unit does not appear on the menu, go back to the line detail screen and correct the units before you complete the collection report. Note: at this point a new lab number will be assigned when you return to your collection report screen.

6.5.5.6 - DescText

Enter a description of the sample. Be guided by your District policy on how you enter the description. Any text you enter in this field will be printed on the "Notice of FDA Action". Describe how you collected the sample. Relate the number and size of the sampled units to show how each was taken and note any special sampling techniques used.

6.5.5.7 - Hand Ship

This field does not transfer to FACTS for the laboratory view. If special handling instructions are needed, enter them in Remarks. Enter the method of shipping, collecting district, country of origin, collector's name and phone number.

6.5.5.8 - Remarks

Enter any information your District, Laboratory, or the compliance program requires. Make sure you review the entire screen before you click "OK". The sample will be transferred immediately in FACTS to the respective lab once the OK button is clicked. (Unless your supervisor has set up a supervisory review of your work)

6.5.5.9 - Record Time Screen

The Record Time Screen will appear. Enter your time. If more than one person worked on the sample, click on "add" button to the right. A box will come up; enter the person's initials and the tab key. Highlight the person's

name, click on OK. Enter other person's time. Repeat for each person that worked on the sample. Click on OK
Note: time is entered in decimal format for OASIS.

SUBCHAPTER 6.6 - FILER EVALUATIONS

6.6.1 - GENERAL

Since we now handle the majority of entries utilizing the OASIS system, evaluation of the data submitted by the electronic filers is done on a periodic basis. These audits of submitted data are done on a periodic basis depending on the number of entries, quality of the data and other factors. You should follow DIOP policy in the conduct of these evaluations.

SUBCHAPTER 6.7 - GLOSSARY OF IMPORT TERMS

Refer to the [Regulatory Procedures Manual Chapter 11 "Glossary"](#) for a more complete listing of import terms. Below is some common import language:

6.7.1 - AMERICAN GOODS RETURNED

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

6.7.2 - BONDED WAREHOUSE

One of several classes of Customs Warehouses authorized to receive goods that has not been entered into the commerce of the US. 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 5 years. After 5 years the goods must be entered, exported, or destroyed. Goods in a CWB can be manipulated, but except in certain smelting operations, cannot be manufactured into something else. If the CBW is located in the US, the goods are in interstate commerce and subject to the FD&C Act.

6.7.3 - BREAK-BULK CARGO

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

6.7.4 - CONSUMPTION ENTRY (CE)

"Entered for Consumption" means 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.

6.7.5 – CONTAINER FREIGHT STATION (CFS)

Another location authorized to receive goods under Customs Bond for the purpose of breaking bulk and redelivery of cargo. Containerized cargo can be moved from the place of unloading 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.

6.7.6 - DATE COLLECTED

The date an import sample is collected.

6.7.7 - DATE OF ARRIVAL

The date a carrier transporting imported cargo arrives in the U.S.

6.7.8 - DATE OF AVAILABILITY

The date imported cargo is available/accessible for sampling by FDA. Goods may not be available for sampling as soon as they arrive in the U.S., due to the way the items were shipped/stored.

6.7.9 - DETENTION

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

6.7.10 - DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE)

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

6.7.11 - DOMESTIC IMPORT (DI) SAMPLE

A sample of an imported article collected after it has been released from import status. See IOM 4.1.4.8.

6.7.12 - ENTRY

"Entry" means documentation required by CBP to be filed with the appropriate Customs Officer to secure the release of imported goods from CBP custody, or the act of filing the documentation.

6.7.13 – ENTRY ADMISSIBILITY FILE

Entry admissibility file refers to the file, hard copy and/or electronic, as appropriate, maintained by the District,

which contains relevant documentation to support the District's admissibility decision.

6.7.14 - 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 a CBP Form CF-3461, and an invoice. Entry documents can be submitted by paper, or through an electronic transmission in CBP's Automated Commercial System (ACS), or a combination of both.

6.7.15 – 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 6.7.31 – REDELIVERY BOND.

6.7.16 - FILER

A CBP term used to identify the individual or firm responsible for filing an entry.

6.7.17 - FORMAL ENTRY

The entry type required for shipments valued over \$2000 or for shipments containing specific commodities designated by CBP. Formal entry is usually a three-step process, "Entry" – which gains the release of the goods from CBP control, "Entry Summary" – which includes determination of the classification and collection of the duty/taxes owed, and "Liquidation" – which is the finalization of the entry process and the completion of an CBP changes to classification and monies owed.

6.7.18 - FOREIGN TRADE ZONES

Foreign Trade Zones (FTZ) are established under the Foreign Trade Zones Act. Goods properly admitted into an FTZ is considered outside the territory of the US for the purposed 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 is eventually entered into the commerce of the US. 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 a FTZ without entry or export. If the FTZ is located in the US, the goods is in interstate commerce and subject to the FD&C Act.

6.7.19 - IMMEDIATE DELIVERY (ID)/ CONDITIONAL RELEASE

Entry/Immediate Delivery (CF 3461) must be filed within 15 calendar days of arrival of goods in the U.S. Goods

may be released for immediate delivery if it is 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, FDA regulated products are conditionally released until FDA makes an admissibility decision. The conditional release period ends when FDA May Proceeds the entry or issues a refusal.

6.7.20 - IMPORT ALERTS

Import Alerts are guidance documents concerning significant re-occurring new or unusual problems affecting import coverage. They are available on the internet at www.fda.gov/ora/fiars/ora_import_alerts.html.

6.7.21 - IMPORTER OF RECORD

The party in whose name the entry is made. For example, a Customs House Broker might make an entry and become the "importer of record" by using his importer ID and bond on behalf of his 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)].

6.7.22 - IMPORT SECTIONS

Import Sections ([536](#), [801](#) and [802](#)) are those sections of the FD&C Act containing the Import/Export Provisions

6.7.23 - IMPORT STATUS

Import Status is the standing of an article in the import database system which has not yet been released.

6.7.24 – IMPORTER MISDECLARATION

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

6.7.25 - 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.

6.7.26 – IMMEDIATE TRANSPORTATION (IT)

An entry document filed with Customs by the importer. It allows the immediate transport of goods without a

determination of admissibility, from the port of unloading under Customs bond. In general, the importer must file a consumption entry within 6 months of the date of importation or export the goods. FDA typically examines this goods at inland port of entry.

6.7.27 - 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 he chooses, except each item in the entry having a different tariff description and rate must be listed separately.

6.7.28 - LOT

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

6.7.29 - MARKS

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

6.7.30 - PORT (POINT) OF ENTRY

A port is the Customs 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 U.S.)

6.7.31 - REDELIVERY BOND (AKA ENTRY BOND)

A bond posted by the importer of record with Customs. 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.

6.7.32 - STRIPPING (OF CONTAINERS)

Stripping is the removal of articles from transportation "Container" for examination or sampling.

6.7.33 – SUBSTITUTION

Substitution is 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 6.7.15, FAILURE TO HOLD.

6.7.34 - SUPERVISORY CHARGES

Supervisory charges are the charges for FDA supervision of the reconditioning and examination of articles after detention. (See [21 CFR 1.99](#)).

6.7.35 - WAREHOUSE ENTRY (WE)

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

EXAMPLE

United States Food and Drug Administration
Los Angeles District Office

Notice of FDA Action¹

Entry Number: 112-9861457-6

Notice Number: 2
November 6, 1996

Filer:
FBN Freight Services Attention: George
500 Canal St.
New Orleans LA 70130

>

Port of Entry: 2704, Los Angeles,
Carrier: NOL RUBY
Entry Date: November 2, 1996
Arrival Date: November 4, 1996

Importer of Record: Shipley's Donut Shop Inc., Lafayette, LA
Consignee: a: Shipley's Donut Shop Inc., Lafayette, LA
 b: Specialty Commodities Inc., Fargo, ND

HOLD DESIGNATED

Notify FDA of Availability

Summary of Current Status of Individual Lines

Document: 1

Invoice: PRAC004

@ LINE

ACS/FDA	Product Description	Quantity	Current Status
* a 001/001	PINEAPPLE, DEHYDRATED	500 CT	RELEASED 11-6-96
* a 002/001	DEHYDRATED GINGER SLICES	10 KG	Product Collected by FDA 11-06-96
* b 003/001	PAPAYA, DEHYDRATED	10 KG	Detained 11-06-96

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

@ = Consignee id

¹This 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 districts from the Operational and Administrative System for Import Support (OASIS) may appear different.

Notice of FDA Action
 Entry Number: 112-9861457-6

Notice Number: 2
 Page: 2

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

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 office below. Include the USCS document (e.g., CF-3461 or CF-7501) and commercial invoice for these products, annotated to show the ACS/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include date, location, and warehouse control number, where applicable, for all lines in this entry.

Jennifer A Thomas, Inspector
 U.S. Food & Drug Administration (213) 555-1212
 2nd and Chestnut Streets (HFR-MA100)
 Philadelphia, PA 19106

DETENTION WITHOUT EXAMINATION

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/FDA	Product Description	Respond	By
003/001 DEHYDRATED	Product:	PAPAYA,	
	November 26, 1996		

FD&CA Section 402(a)(1), 801(a)(3); ADULTERATION

The article appears to be held in a container containing a poisonous or deleterious substance which may render it injurious to health.

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION

The article appears to be a raw agricultural commodity that bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a). The article appears to contain quinalphos.

Jennifer A Thomas, Inspector
 U.S. Food & Drug Administration (213) 555-1212
 2nd and Chestnut Streets (HFR-MA100)
 Philadelphia, PA 19106

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.

Notice of FDA Action
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SAMPLES COLLECTED

LINE ACS/FDA	Product Description	Est. Cost
001/001 \$ 15.00	PINEAPPLE,	DEHYDRATED

Sample: 10 KG Collected 1 KG from each of 10 cartons

LINE ACS/FDA	Product Description	Est. Cost
002/001 \$.23	DEHYDRATED GINGER SLICES	

Sample: .1 KG Collected approximately 4 ounces from one carton.

LINES RELEASED

LINE ACS/FDA	Product Description
001/001	PINEAPPLE, DEHYDRATED

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 by: Thomas J. DiNunzio (QA5)
U. S. Food and Drug Administration

SUBMIT IN TRIPLICATE (Submit in **QUADRUPPLICATE** if you desire copy returned to you.)

APPLICATION FOR AUTHORIZATION TO RELABEL OR TO PERFORM OTHER ACTION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND OTHER RELATED ACTS

FORM APPROVED: OMB No. 0910-0025
EXPIRATION DATE: 5/31/10

Public reporting burden for this collection of information is estimated to average 25 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing of review of the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

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.

TO: DIRECTOR _____ District, Food and Drug Administration	DATE	SAMPLE NO.
	PRODUCT	
Application is hereby made for authorization to bring the merchandise below into compliance with the Act.	ENTRY NO.	ENTRY DATE
	CARRIER	AMOUNT AND MARKS

Redelivery bond has been posted by the applicant. The merchandise will be kept apart from all other merchandise 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 merchandise will be brought into compliance is given in the space below:

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

FIRM NAME	ADDRESS OF FIRM
APPLICANT'S SIGNATURE	

ACTION ON APPLICATION

TO: (Name and Address)	DATE
------------------------	------

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.

SIGNATURE OF DISTRICT DIRECTOR	DISTRICT	DATE
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IMPORTER'S CERTIFICATE

PLACE	DATE
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I certify that the work to be performed under the authorization has been completed and the goods are now ready for inspection at: _____

The rejected portion is ready for destruction under Customs' supervision and is held at: _____

TYPED NAME OF APPLICANT	SIGNATURE
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REPORT OF INVESTIGATOR / INSPECTOR

TO PORT DIRECTOR OR DISTRICT DIRECTOR	DATE
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I have examined the within-described goods and find them to be the identical goods described herein, and that they have been: _____ on: _____, 20 ____, as authorized, except:

DATA ON CLEANED GOODS

Good Portion: _____

Rejections: _____

Loss (if any): _____

Did importer clean entire shipment? _____

Time and cost of supervision: _____

INSPECTING OFFICER	DATE
--------------------	------

DIRECTOR OF DISTRICT

Disposed of as noted above.

DIRECTOR OF CUSTOMS	DATE
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Saving, Retrieving, or Emailing your data can only be done with the Adobe Acrobat/Designer, Adobe Approval, or the Adobe Reader Extensions Server, and not with the free Adobe Reader.

Save As... Save Data Print Retrieve Data E-mail Form Reset Form

CHARGES FOR SUPERVISION

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

TO: <i>(Insert Address)</i> DISTRICT DIRECTOR OF CUSTOMS	FROM: <i>(Insert Address)</i> DHHS FOOD AND DRUG ADMINISTRATION
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PRODUCT	FDA SAMPLE NO.
CARRIER	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		
					\$0.00
INVESTIGATORS TIME					\$0.00
ANALYSTS TIME					\$0.00
PER FIEM, PAID PER GOVERNMENT TRAVEL REGULATIONS					\$0.00
AUTOMOBILE USE					
OTHER TRANSPORTATION EXPENSES <i>(itemize)</i>					
MISCELLANEOUS EXPENSES <i>(itemize)</i>					
GRAND TOTAL					\$0.00

REMARKS

Save Data Print Email Form

OASIS_PROD - MetaFrame Presentation Server Client

OASIS Version 4.13.00 (OPERATIONS) - [Product Collection]

File Edit View Add Action District National Reference Products Admin User Opts Window Help

Collections

Entry/Doc/Line No: XYZ-1234567-1 1 1 Lead Init: PMP Date Collected: 08-30-2005

Product Code: 16 A G T 82 Product Code Desc: Freshwater Non-Ictalurus Fish

Imprtr/Crctd Desc: Frozen Basa Steak

Location of Goods: ABC Imports, 325 Western Ave, Louisville, KY 321-343-5555

Episode: Submitted To: RRL Lab No: 349456

Quantity Collected: 16 Units: LB Calculated Cost: 14.40

Desc Text: Collected 1 pkg from each of 12 different cartons for mala

Hand/ Ship: Subs 1-6 ID "XYZ-1234567-1 ; 8-30-05; CLD"; subs 7-12 ID

Remarks: Vietnam; 04018; freezer; LOS; master carton labeling in cc

?

OK

Cancel

Wk Details

Entry Smry

Collection Problem Area

PAF	Reference
ANT	Malachite Green In Seafood

Record: 1/1 <OSC> <DBG>

AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Hunt	
<p>Before me, <u>Sydney H. Rogers</u>, 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. 96-98, 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 <u>Felicia M. Rodriguez</u> in the county and State aforesaid, who, being duly sworn, deposes and says:</p> <p>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.</p> <p>On 8/12/04, 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.</p> <p>On 8/13/04, my firm repacked this shipment of peppers into 25 kg burlap bags for distribution to restaurants and other customers.</p> <p>On 8/17/04, 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 8/10/04 and invoice 45678, dated 8/8/04. I am familiar with these documents and they cover the shipment of peppers my firm received.</p> <p>Part of the repackaged peppers from Entry BAD-123456-7 were sold and distributed by my firm on 8/16/04. 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 8/14/04 and UPS B/L 787878000009, dated 8/16/04 which covers the shipment to John's Pepper House and invoice 757575, 8/14/04 and UPS B/L 2323232323, 8/16/04 which covers the shipment to Casa De Juanita. The rest of the repackaged peppers remain at my firm.</p> <p>I received the Customs and Border Protection release for this entry on 8/12/04 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.</p> <p style="text-align: center;"><i>I read this statement and agree it is true.</i></p>		
AFFIANT'S SIGNATURE AND TITLE <u>Felicia M. Rodriguez, Import Manager</u>		
FIRM'S NAME AND ADDRESS (Include ZIP Code) ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428		
Subscribed and sworn to before me at <u>ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428</u> this <u>17th</u> day of <u>August, 2004</u> .		
<p><u>Sydney H. Rogers</u> (Employee Signature)</p>		
<p><small>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.</small></p>		

