

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 and devices 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 merchandise released under immediate delivery.

The procedures outlined in this chapter cover imported merchandise subject to, but not limited to, the following Acts/Regulations:

1. Federal Food, Drug, and Cosmetic Act
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.)

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 EIR to be sent to the compliance branch. Follow your district procedures, IOM Chapter 5 for preparation of the EIR and IOM Subchapter 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.

SUBCHAPTER 6.2 - IMPORT PROCEDURES**6.2.1 - SCOPE**

These procedures in this section cover imported merchandise. 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 enforced by FDA. 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 merchandise is carried out under the direction of Customs. However, at some ports the actual supervision of the destruction of violative merchandise 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 merchandise, 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(k) 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 reviewed on screen (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 merchandise 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 the 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, a bond must be executed providing for payment of liquidated damages in accordance with the Bureau of Customs and Border Protection's (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

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

1. Ensure the IFE Entry is copied from the IFE shipments for the last 30 days list 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 - 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 process (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 interim final rule is data usually provided by importers or brokers to Customs and Border Protection (CBP) when foods arrive in the United States. The Bioterrorism Act requires that this information also be provided to FDA in advance of an imported **article of food's** arrival to the United States. FDA uses this information in advance of the arrival to review and assess the information, and determine whether to inspect the imported food. Prior notices 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 5 days before arrival 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. Fish and seafood
6. Dairy products and shell 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. Food in diplomatic pouches.

6.2.3.5.4 - PRIOR NOTICE SUBMISSION

The prior notice must be submitted electronically and contain the following information:

1. Identification of the submitter, including name, telephone and fax numbers, email address, and firm

name and address

2. Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
3. Entry type and CBP identifier
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 smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable)
5. The identification of the manufacturer, including registration number of the facility that manufactured/processed the food
6. The identification of the grower, if known
7. The FDA Country of Production
8. The identification of the shipper, including the registration number if applicable, except for food imported by international mail
9. The country from which the article of food is shipped or, 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) or, if the food is imported by international mail, the U.S. recipient (name and address)
11. The identification of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States
12. The identification of the carrier and mode of transportation, except for food imported by international mail
13. Planned shipment information, except for food imported by international mail

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. FDA provided guidance to its stakeholders and U.S. Customs and Border Protection 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.cfsan.fda.gov/~pn/cpgpn6.html>. 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

This 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 due to **inadequate** prior notices, the response to requests for review of refusals, 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 admissibility 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 means of receiving notification for non-ABI/OASIS entries can be arranged through local Customs/FDA District agreements.

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.

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 and FD2. 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. 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.

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.) and
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, 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," and 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, 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 can not 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 Proceeded" 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 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," (FD Form 766 - See Exhibit 6-2). This form is also available in fillable formats online at http://www.fda.gov/opacom/more_choices/fdaforms/FDA-766.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, and 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 re-labeling 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 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 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 merchandise was either destroyed or exported.

FDA is responsible for the protection of the U.S. public regarding foods, drugs, cosmetics, 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 an FDA 790 (See Exhibit 6-3, Charges for Supervision) of officers or employees of the FDA 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. Inspector'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 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 of 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 Merchandise Refused Admission

Exportation of refused merchandise 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 merchandise.

Bond actions are taken when an entry is distributed prior to FDA release and can not 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 merchandise, 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 Inspection 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 simply 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 storage or intransit damage, inadequate refrigeration, rodent or insect activity, lead in dinnerware (Quick Color Test - QCT), odor and label compliance

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 of a product's label or labeling, in addition to the specific items discussed in the following sections, be alert for any overlabeling where a product name or identify may have been changed; products without mandatory English labeling; changes in expiration date or lot numbers or similar questionable practices. If you encounter any of these items, collect an example 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 can not 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 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 can not 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, for the 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 DFS intranet site.](#)

6.4.3.3 - Food and Color Additives

The only valid field examination which can be performed for these materials is a visual examination through the container and a label review for the mandatory labeling requirements, i.e., is a color additive declared for a product without natural coloring; determining if an additive declaration includes its function, for example, "Sodium Benzoate as a preservative".

NOTE: Label examination of products to determine whether there is a declaration of certain food and/or color additives must be reported as an import investigation.

6.4.3.4 - Nutrition and Nutrition Labeling

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 Nutritional Products Labeling and Dietary Supplements, ONPLDS, website (<http://www.cfsan.fda.gov/~dms/lab-hlth.html>) 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 at <http://www.cfsan.fda.gov/~dms/opa-appa.html#col>),
4. Warning Statements (21 CFR 740.11, 740.12, 740.17, and 740.19),
5. Cautionary/Other Required Statements (FD&C Act sec. 601(a), 21 CFR 73.2396, 73.2110, and 73.2190)
6. Tamper Resistant Packaging Requirements (21 CFR 700.25)

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 include electrode lead wires, patient cables, labeling, and physical damage. Lead wires and patient cable exams should conform to applicable standards set forth in 21CFR Part 898.

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 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 Enforcement and Regulatory Policy 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 - 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 (301-827-1168).

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. The Center (301-827-1168) should have records of any exemptions or permission granted for personal imports.

6.4.7.2 - Devices

Devices intended for animal 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 (301-827-1168).

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 (301-827-1168).

6.4.7.4 – Animal Grooming Aids

'Cosmetics' for animals are referred to as "animal grooming aids". While the Center 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 the Center for appropriate guidance. The Division of Compliance (301-827-1168) can answer regulatory and enforcement questions. The Division of Surveillance (301-827-0158) tracks reporting of complaints and adverse reactions, including those for animal grooming aides.

6.4.7.5 - Biologicals

CVM does regulate animal biologic products. They are considered as drugs. However, the Center 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.

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. 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 C.R. 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 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 to 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 merchandise that has not been entered into the commerce of the US. Merchandise is 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. Merchandise in the warehouse can be held for up to 5 years. After 5 years the merchandise must be entered, exported, or destroyed. Merchandise 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 merchandise is 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 merchandise 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 merchandise.

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 merchandise from CBP custody, or the act of filing the documentation.

6.7.13 - ENTRY DOCUMENTS (ENTRY PACKAGE)

Information submitted to CBP to determine the merchandise 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.

6.7.14 - FILER

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

6.7.15 - 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 merchandise 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.

6.7.16 - FOREIGN TRADE ZONES

Foreign Trade Zones are established under the Foreign Trade Zones Act. Merchandise properly admitted into an FTZ is considered outside the territory of the US for the purposes of duty and taxes. Several classes of merchandise are present in an FTZ at any one time. Some of these classes provide duty advantages when the merchandise is eventually entered into the commerce of the US. Other classes of merchandise are prohibited by law from entering the commerce and must be exported or destroyed. There is no time limit on how long merchandise can remain in a FTZ without entry or export. If the FTZ is located in the US, the merchandise is in interstate commerce and subject to the FD&C Act.

6.7.17 - IMMEDIATE DELIVERY (ID) / CONDITIONAL RELEASE

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

6.7.18 - 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.

6.7.19 - 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

merchandise. 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)].

6.7.20 - IMPORT SECTIONS

Import Sections (536, 801 and 802) are those sections of the Federal Food, Drug, and Cosmetic Act containing the Import/Export Provisions

6.7.21 - IMPORT STATUS

The standing of an article in the import system which is not yet released.

6.7.22 - 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.

6.7.23 – IMMEDIATE TRANSPORTATION (IT)

An entry document filed with Customs by the importer. It allows the immediate transport of merchandise 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 merchandise. FDA typically examines this merchandise at inland port of entry.

6.7.24 - LINE (LINE ITEM)

Each portion of an entry which is listed as a separate item on an entry document. An importer may identify merchandise 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.

6.7.25 - LOT

An entry, group of entries, or a portion of an entry of merchandise which can clearly be defined as appropriate for FDA sampling and examination purposes.

6.7.26 - MARKS

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

6.7.27 - PORT (POINT) OF ENTRY

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.)

6.7.28 - 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.

6.7.29 - STRIPPING (OF CONTAINERS)

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

6.7.30 - SUPERVISORY CHARGES

The charges for FDA supervision of the reconditioning and examination of articles after detention. (See 21 CFR 1.99).

6.7.31 - 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	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
Entry Number: 112-9861457-6

Notice Number: 2
Page: 3

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: 12/31/08

Paper work Reduction Act Statement 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. 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:

Department of Health and Human Services
Food and Drug Administration
15800CrabbsBranchParkway
Rockville, MD 20855-2613

TO: DIRECTOR _____ District Food and Drug Administration Application is hereby made for authorization to bring the merchandise Below into compliance with the Act.	DATE	SAMPLE NO.
	PRODUCT	
	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
--------------------------------	----------	------

IMPORTER'S CERTIFICATE

PLACE	DATE
-------	------

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
-------------------------	-----------

REPORT OF INVESTIGATOR / INSPECTOR

TO PORT DIRECTOR OR DISTRICT DIRECTOR	DATE
--	------

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
---------------------	------

CHARGES FOR SUPERVISION					
<input type="checkbox"/> Federal Food, Drug and Cosmetic Act, Section 801 (b) and (c) <input type="checkbox"/> 21 CFR 1005.24					
TO: <i>(Insert Address)</i> DISTRICT DIRECTOR OF CUSTOMS			FROM: <i>(Insert Address)</i> DHHS FOOD AND DRUG ADMINISTRATION		
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		
INVESTIGATORS TIME					
ANALYSTS TIME					
PER DIEM, PAID PER GOVERNMENT TRAVEL REGULATIONS					
AUTOMOBILE USE					
OTHER TRANSPORTATION EXPENSES <i>(itemize)</i>					
MISCELLANEOUS EXPENSES <i>(itemize)</i>					
GRAND TOTAL					
REMARKS					

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 <p style="text-align: center;">Texas</p>	COUNTY OF <p style="text-align: center;">Hunt</p>	
<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><i>Felicia M. Rodriguez</i></u> , Import Manager		
FIRM'S NAME AND ADDRESS (Include ZIP Code) ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428		
Subscribed and sworn to before me at <u>ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428</u> this <u>17th</u> day of <u>August, 2004</u> .		
<u><i>Sydney H. Rogers</i></u> (Employee Signature)		
Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.		