CHAPTER 6 - IMPORTS

CONTENTS

CHAPTER 6 - IMPORTS....6-1
SUBCHAPTER 6.1 - IMPORTS....6-2
6.1.1 - AUTHORITY....6-2
6.1.2 – IMPORT INVESTIGATIONS....6-3
6.1.3 - INVESTIGATIONS INVOLVING THE IMPORTATION PROCESS....6-3
6.1.3.1 - Import Violation Patterns....6-3
6.1.3.2 - Failure To Hold....6-3
6.1.3.3 - Failure To Hold – Health Hazards – Direct FDA Evidence....6-3
6.1.3.4 - Failure To Hold - Health Hazards – Detention Without Physical Examination (DWPE)....6-3
6.1.3.5 - Substitution....6-3
6.1.3.6 - Importer Misdeclaration....6-4
6.1.3.7 - Filer Misdeclaration....6-4
6.1.3.7.1 - REPEATED FILER MISDECLARATION....6-4
6.1.3.8 - Reporting Investigations Involving the Importation Process....6-4
SUBCHAPTER 6.2 - IMPORT PROCEDURES....6-5
6.2.1 - SCOPE....6-5
6.2.2 - DIVISION OF AUTHORITY....6-5
6.2.3 - ENTRIES....6-5
6.2.3.1 - Formal Entries....6-5
6.2.3.2 - Informal Entries....6-5
6.2.3.3 - Mail/Personal Baggage....6-5
6.2.3.4 – Import for Export (IFE) Entries....6-5
6.2.3.4.1 – IFE ENTRY REVIEW....6-6
6.2.3.4.2 – DOMESTIC Follow-up of IFE entries....6-6
6.2.3.4.3 – IFE DOMESTIC INSPECTION GUIDANCE....6-6
6.2.3.5 - Prior Notice of Importation of Food and Animal Feed6-7
6.2.3.5.1 - PRIOR NOTICE RECEPTION....6-7
6.2.3.5.2 - PRODUCTS REQUIRING PRIOR NOTICE....6-7
6.2.3.5.3 - PRODUCTS EXCLUDED FROM PRIOR NOTICE 6-7
6.2.3.5.4 - PRIOR NOTICE SUBMISSION....6-8
6.2.3.5.5 - INADEQUATE PRIOR NOTICE SUBMISSION ...6-8
6.2.3.5.6 - PRIOR NOTICE PROCESS....6-8
6.2.3.6 - Entry Processing....6-9
6.2.3.6.1 - U.S. CUSTOMS AND BORDER PROTECTION..6-9
6.2.3.6.2 - FDA....6-9
6.2.3.7 – VQIP Entry Processing....6-10
6.2.4 - SAMPLING....6-10
6.2.4.1 - Ports Covered by FDA....6-10
6.2.4.2 - Ports not Covered by FDA....6-10
6.2.4.3 - Entry Sampling....6-10
6.2.4.4 - Notice of Sampling....6-11
6.2.4.5 - Payment for Samples....6-11
6.2.5 - PROCEDURE WHEN PRODUCTS CANNOT BE SAMPLED OR EXAMINED....6-11
6.2.6 - PROCEDURE WHEN NO VIOLATION IS FOUND..6-11
6.2.7 - PROCEDURE WHEN VIOLATION IS FOUND....6-11
6.2.7.1 - "Notice of Detention & Hearing"....6-11
6.2.7.2 - Response to "Notice of Detention & Hearing"....6-12
6.2.7.3 - Request for Authorization to Relabel or Recondition Non-compliant Articles....6-12
6.2.7.4 - Inspection after Approved Reconditioning has been Completed....6-12
6.2.7.5 - Procedure when Conditions of the Approved Reconditioning Application Have Been Fulfilled....6-12
6.2.7.6 - Procedure when Conditions of the Approved Reconditioning Application Have Not Been Fulfilled....6-12
6.2.7.7 - Procedure after Hearing - "Notice of Release"....6-12
6.2.7.8 - Procedure after Hearing - "Refusal of Admission" 6-12
6.2.7.9 - Payment of Costs of Supervision of Relabeling and/or Other Action....6-13
6.2.7.10 - Exportation of Goods Refused Admission....6-13
6.2.7.11 - Bond Action....6-13
6.2.8 – PHOTOGRAPHS: IDENTIFICATION AND STORAGE....6-13
SUBCHAPTER 6.3 – ENTRY REVIEW....6-14
6.3.1 - GENERAL....6-14
6.3.2 – INITIAL ENTRY REVIEW....6-15
6.3.2.1 –Emergency and Perishable Shipments....6-15
6.3.2.2 – Reviewing Entry Data and Information....6-15
6.3.2.2.1 – Manual “May Proceed”....6-16
6.3.2.2.2 – Rescinding a “May Proceed” or IB Release....6-16
6.3.2.2.3 – Recommend Detention (DER/DTR)....6-17
6.3.2.2.4 – Request Examination and/or Sampling (LEX/FEX/SAM)....6-17
6.3.2.2.5 – Notices....6-17
6.3.2.2.6 – Cancelled Entries....6-17
6.3.2.2.7 - Partner/Other Government Agency (OGA) Referral....6-17
6.3.3 – ENTRY DOCUMENTATION....6-18
6.3.3.1 – Request of Entry Documents (DRQ)....6-18
6.3.3.2 – Receipt of Entry Documents....6-18
6.3.3.2.1 – Uploading documents received outside of ITACS. 6-18
6.3.3.3 – Review of Entry Documents....6-18
6.3.3.4 – Failure to Submit Entry Documents and Follow-up Requests....6-19
6.3.4 – ENTRY DECISION....6-19
6.3.5 - DETENTION RECOMMENDATIONS BY ENTRY REVIEWERS....6-19
6.3.5.1 - Submission of Detention Recommendations to the Compliance Branch at the Entry Review Step....6-20
6.3.5.2 - General Procedures Pertaining to all Detention Recommendations (DER and DTR)....6-20
6.3.5.2.1 - Entry Documents....6-20
6.3.5.3 - DER - Import Alert (IA)....6-20
6.3.5.4 - DTR....6-21
6.3.5.4.1 - Similar to Import Alert....6-21
6.3.5.4.2 - Previous Violative Results (pending IA addition)6-21
6.3.5.4.2.1 Direct Reference Authority for DWPE....6-21
6.3.5.4.2.2 - No Direct Reference Authority for DWPE....6-22
6.3.5.5 - Registration/Listing/Approval....6-22
6.3.5.6 - IFE....6-22
SUBCHAPTER 6.4 - FIELD EXAMINATION....6-22
6.4.1 - GENERAL....6-22
6.4.2 - FIELD EXAMINATION SCHEDULE....6-23
6.4.3 - FIELD AND LABEL EXAMINATIONS – FOODS AND COSMETICS....6-23
6.4.3.1 - Food Sanitation....6-23
6.4.3.2 - Pesticides, Industrial Chemicals, Aflatoxins, & Toxic Elements....6-23
6.4.3.3 - Food and Color Additives....6-24
6.4.3.4 – Nutrition Labeling and Food Allergen Labeling....6-24
6.4.3.5 - Food Economics (On Consumer Size Containers only)....6-24
6.4.3.6 - Cosmetics....6-24
6.4.4 - FIELD AND LABEL EXAMINATION – DRUGS....6-24
6.4.4.1 - Labeling....6-25
6.4.4.2 - Contamination....6-25
6.4.4.3 - Samples....6-25
6.4.4.4 - Special Instructions....6-25
6.4.5 - FIELD AND LABEL EXAMINATIONS – DEVICES..6-25
6.4.6 – FIELD AND LABEL EXAMINATIONS - BIOLOGICS..6-25
6.4.7 - LABEL EXAMINATIONS - ANIMAL PRODUCTS...6-26

6.4.7.1 – Animal Drugs 6-26
6.4.7.2 – Animal Devices 6-26
6.4.7.3 - Animal Food 6-26
6.4.7.4 – Animal Grooming Aids....6-26
6.4.7.5 – Animal Biological Products 6-27
6.4.8 - FIELD AND LABEL EXAMINATIONS -RADIOLOGICAL HEALTH 6-27
6.4.9 - FIELD EXAMINATIONS – TOBACCO PRODUCTS 6-27
6.4.10 – FIELD/LABEL EXAMINATION RESULTS 6-27
6.4.10.1 – Date Completed 6-28
6.4.10.2 – Location of goods....6-28
6.4.10.3 – Remarks 6-28
6.4.10.4 – Summary 6-28
6.4.10.5 – Exam Class....6-28
6.4.10.6 – Record Time 6-29
6.4.10.7 – Next Steps 6-29
SUBCHAPTER 6.5 - IMPORT SAMPLE COLLECTION 6-29
6.5.1 - GENERAL 6-29
6.5.2 - PROCEDURES 6-30
6.5.3 - TECHNIQUES....6-30
6.5.4 - IMPORT FORMS PROCEDURES....6-30
6.5.5 - SAMPLE COLLECTION REPORTS 6-30
6.5.5.1 - Collection Date 6-30
6.5.5.2 - Episode 6-31
6.5.5.3 - Submitted To 6-31
6.5.5.4 - Quantity Collected....6-31
6.5.5.5 - Units....6-31
6.5.5.6 - DescText 6-31
6.5.5.7 - Hand Ship 6-31
6.5.5.8 - Remarks....6-31
6.5.5.9 - Record Time Screen 6-32
6.5.6 – Updating a Sample Collection Report 6-32
6.5.7- Special Domestic Import Samples (SDI) 6-32
SUBCHAPTER 6.6 - FILER EVALUATIONS 6-32
6.6.1 - GENERAL....6-32
SUBCHAPTER 6.7 - GLOSSARY OF IMPORT TERMS 6-32
6.7.1 - American Goods Returned....6-33
6.7.2 - Bonded Warehouse 6-33
6.7.3 - Break-Bulk Cargo 6-33
6.7.4 - Consumption Entry (CE) 6-33
6.7.5 – Container Freight Station (CFS)....6-33
6.7.6 - Date Collected....6-33
6.7.7 - Date of Arrival....6-33
6.7.8 - Date of Availability 6-33
6.7.9 - Detention....6-33
6.7.10 - Detention Without Physical Examination (DWPE) .6-33
6.7.11 - Domestic Import (DI) Sample 6-33
6.7.12 - ENTRY....6-33
6.7.13 – ENTRY ADMISSIBILITY FILE 6-33
6.7.14 - Entry Documents (Entry Package)....6-33
6.7.15 – FAILURE TO HOLD 6-33
6.7.16 - FILER....6-34
6.7.17 - Formal Entry....6-34
6.7.18 - Foreign Trade Zones 6-34
6.7.19 - Immediate Delivery (ID)/ Conditional Release 6-34
6.7.20 - Import Alerts....6-34
6.7.21 - Importer of Record....6-34
6.7.22 - Import Sections....6-34
6.7.23 - Import Status....6-34
6.7.24 – IMPORTER MISDECLARATION 6-34
6.7.25 - Informal Entry....6-34
6.7.26 – Immediate Transportation (IT) 6-34
6.7.27 - Line (Line Item)....6-34
6.7.28 - LOT....6-34
6.7.29 - MARKS 6-35
6.7.30 - Port (Point) of Entry 6-35
6.7.31 - Redelivery Bond (AKA Entry Bond) 6-35
6.7.32 - Stripping (Of Containers)....6-35
6.7.33 – SUBSTITUTION....6-35
6.7.34 - Supervisory Charges 6-35
6.7.35 - Warehouse Entry (WE)....6-35
6.7.36 – VQIP QUALITY ASSURANCE PROGRAM....6-35
6.7.37 – FSVP AND/OR HACCP IMPORTER....6-35
6.7.38 – DATA UNIVERSAL NUMBER SYSTEM (DUNS). 6-35
6.7.39 – FOOD SAFETY MODERNIZATION ACT (FSMA) 6-35
6.7.40 – FOREGIN SUPPLIER VERFICATION PROGRAM (FSVP)....6-35
SUBCHAPTER 6.8 FOREIGN SUPPLIER VERIFICATION PROGRAM....6-35
6.8.1 - FSVP INSPECTIONS....6-35
6.8.1.1 - Pre-Inspection Activities 6-36
6.8.1.2 - Preparation and References 6-36
6.8.1.3 - Inspectional Authority 6-36
6.8.1.4 - FSVP Inspectional Activities 6-36
6.8.1.4.1 - CONDUCTING THE FSVP RECORDS REVIEW.. 6-36
6.8.2 - FSVP OBSERVATIONS....6-37
6.8.2.1 - Preparation of Form FDA 483a 6-37
6.8.2.1.1 - INDIVIDUAL HEADINGS....6-37
6.8.2.1.2 - SIGNATURE POLICY....6-38
SUBCHAPTER 6.9– FSVP REPORTING 6-38
6.9.1– ESTABLISHMENT INSPECTION REPORT (EIR)...6-38
6.9.1.1- FSVP RECORDS REVIEW 6-38
6-1 Notice of FDA Action....6-40
6-2 FORM FDA 766 – Application for Authorization to Relabel or Recondition Non-Compliant Articles 6-44
6-3 Form FDA 790 Charges for Supervision 6-46
6-4 Sample Collection in OASIS Screen Shot 6-47
6-5 FORM FDA 463a AFFIDAVIT....6-48

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 and Border Protection (CBP) 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 (FPLA)
3. Nutrition Labeling and Education Act (NLEA)
4. Import Milk Act/ Filled Milk Act
5. Federal Caustic Poison Act Bioterrorism Act
6. Public Health Service Act, Part, Part F, Subpart 1, Biologic Products
7. Title 21 CFR Subpart E - Imports and Exports (1.83), etc.
8. Title 19 CFR Customs Duties (authority to sample delegated by CBP Regulations, etc.)
9. *Federal Cigarette Labeling and Advertising Act* Comprehensive Smokeless Tobacco Health Education Act
10. 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 8.1.9. 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 4.4.5 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 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, verification of a reconditioning, and refusal verification. The following steps should be taken on all failure to hold cases:

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

- 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 (mis declared 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 (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 (mis declared 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 (mis declared 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 (mis declared 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 mis declared 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 (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 CBP 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 CBP.

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 $2,500 (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 CBP at any time, as prescribed for in the CBP regulations in force on the date of entry. (section 801(b) of the FD&C Act [21 U.S.C. 381(b)], 19 CFR Part 113) The bond is filed with CBP which, in case of default, takes appropriate action to effect the collection of liquidated damages provided for in the bond after consultation with FDA. (19 CFR Section 113.62and 21 CFR Section 1.97).

Notification of the CBP entry is generally accomplished by electronic submission through the CBP Automated Commercial Environment (ACE). 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 CBP Entry documents (CF 3461/3461ALT, commercial invoice, bill of lading and any other relevant documents to aid in making an admissibility decision), which also document interstate commerce. If an entry is not filed electronically, these documents will be submitted to FDA at the time CBP entry is made, in accordance with local port operations.

6.2.3.2 - Informal Entries

Normally, informal entries (value less than $2,500 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 CBP/FDA ACE interface. When FDA takes action on an informal entry not filed electronically by the filer, FDA personnel will input the informal entry into FDA import systems (ER,SERIO, OASIS) as a manual entry. When taking FDA action with an informal entry, CBP 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 CBP International Mail Office or border crossing office. This should include agreements designating who is responsible for coverage, when (how often), etc. CBP is responsible for examination of personal baggage. If an article subject to FDA review is encountered, the CBP 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 CBP are those entries with a value of $800 or less. Generally, this form of entry applies to articles which pass free of duty and tax, and are imported by one person, on one day (19 C.F.R. 101.1 (o)). CBP 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:

1. 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);

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

3. Such certificates of analysis as necessary to identify the article, unless it is a device or falls under section 801 (d)(4) of the FD&C Act [21 U.S.C. 381 (d)(4)] - 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. Divisions 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 , 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 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.

   Divisions 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 (DIO).
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 if 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 that 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 DIO 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 prior to an imported article of food's arrival to the United States. FDA uses this data in advance of the arrival of the article of food to review and assess the prior notice data and determine whether to examine the imported food for potential contamination by bioterrorism act or significant public health risks. Prior notice can be submitted either through ABI/ACE 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 calendar days before the anticipated date of arrival for submission made through the PNSI and no more than 30 calendar days before the anticipated date of arrival for submission made through ABI/ACE, and 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 (21 USC 601), (21 USC 601), 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), (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 transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address
3. Entry type and CBP entry identifier, if available
4. The identification of the article of food, including complete FDA product code, the common or usual name or market name, the estimated quantity described from the largest container size to the smallest package, and the lot or code numbers or other identifier (if applicable)
5. If the food is no longer in its natural state (21 CFR 1.276(b)(10)), 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 https://www.fda.gov/food/importing-food-products-united-states/prior-notice-imported-foods. 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 CBP 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 Division of Food Defense Targeting (DFDT); FDA headquarters staff, operating 24 hours a day, 7 days a week. The review process is a manual review by the DFDT. It is designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon arrival of article of food in the United States. The review process is not impacted by the method of electronic submission. The results of this process are transmitted to CBP.

The DFDT 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 DFDT will advise the FDA field offices and/or CBP of the inspection requirements. The DFDT 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 to the prior notice process, 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 division offices generally receive notification of all formal and informal entries subject to FDA's jurisdiction. Management for each port of entry determines coverage, hours of operation and resource allocation for any office closures impacting normal working hours. In addition, FDA's import systems allow for entries to be reviewed remotely by off-site personnel.

Entries submitted electronically to FDA are screened against criteria established by FDA. Filers submitting entries via the Automated Broker Interface (ABI) to Customs for cargo release are required to provide FDA information on entries subject to its jurisdiction submitted through ACE. The means of receiving notification for non-ABI entries can be arranged through local Customs/FDA division agreements.

6.2.3.6.1 - U.S. CUSTOMS AND BORDER PROTECTION

CBP's ACE 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 FD1, FD2, FD3 and FD4.

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, 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 CBP review include all mandatory CBP 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 ACE, CBP determines if the article is subject to FDA examination (see OGA flag identifications above).

6.2.3.6.2 - FDA

In collaboration with the U.S. Customs and Border Protection (CBP) and 46 partner government agencies, the Food and Drug Administration has been working to modernize business processes through the implementation of the Automated Commercial Environment/International Trade Data System (ACE/ITDS). ACE/ITDS is a single access point whereby industry can electronically submit all data required by various government agencies involved in international trade. ACE replaced the Automated Commercial System (ACE) in 2016.

FDA has established Intended Use Codes (IUC) to assist FDA reviewers in determining the end use of the imported product. Some commodities require the use of IUC, some commodities have optional IUC, and IUC are not applicable for some commodities.

Affirmation of Compliance (A of C) codes provide FDA reviewers with information concerning the imported article. They are also used by filers to affirm that the firm and/or product identified in an FDA line meets the requirements specific to the product being imported. A of C code requirements are dependent on the commodity being imported and can be impacted by the IUC.

To review the specifications and requirements for filing in ACE as per the final rule, refer to 81 FR 85854 Submission of Food and Drug Administration Import Data in the Automated Commercial Environment, and the FDA's Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) Version 2.5.

OASIS generates a "Notice of FDA Action" providing information on the actions taken regarding a particular entry line e.g. "Notice of Sampling", "Release Notice", "Notice of Detention and Hearing", and "Notice of Refusal of Admission" 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 any 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.

Notices are designed to be electronically or physically distributed to the addressees. Those who hold an approved ITACS account may opt to receive Notices via email or as a download within ITACS. A copy of each Notice is produced with the filer, importer of record, and consignee and delivered to the party on the addressee line. (If the same firm acts in one or more of those functions, only one copy is produced for the firm.) Notices are official documents which provide notification of a change in the status for an FDA regulated entry/line. 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.

6.2.3.7 – VQIP Entry Processing

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

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. The filer can also submit the entry documents electronically to FDA via the Import Trade Auxiliary Communications System (ITACS).For those entries submitted by paper, all appropriate entry documents should be included with the package sent to the local FDA office.

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

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

6.2.4.2 - Ports not Covered by FDA

For those ports where CBP does not maintain its ACE 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 CBP Port manager to assure FDA notification. If FDA decides to examine or sample articles being entered through such a port, CBP, the importer, and broker will be notified.

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

6.2.4.3 - Entry Sampling

If no examination or sample is requested, FDA will notify CBP 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. This may occur as a result of the initial FDA import systems screening or after the division 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 CBP, 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 CBP collects the sample for FDA, the division will enter the entry information into FDA Import systems and issue the Notice of FDA Action.

For those entries where specific lines (items) of an entry are not sampled or examined, the Notice of FDA Action will be amended to indicate which lines (items) have been issued a "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 collected by FDA and found to be in compliance (See 21 CFR 1.91). In addition, FDA will pay for physical samples collected by FDA as an audit of private laboratory analytical results submitted to FDA when the FDA audit sample is found to be in compliance. (NOTE: FDA does not pay for samples found to be non-compliant (violative) or for samples taken in connection with the supervision of a reconditioning.) See IOM 4.2.8.2 for guidance on sample costs.

Billing for reimbursement should be made to the FDA 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 CBP 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 CBP. (See RPM Chapter 9-10 “Response (Hearing) to Notice of FDA Action – Detained.)

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 Recondition Non-compliant Articles

FDA may authorize relabeling or other remedial action upon the timely submission of an "Application for Authorization to Relabel or To Recondition Non-Compliant Articles," (Form FDA 766 - See Exhibit 6-2). This form is also available in fillable formats online at http://www.fda.gov/media/71537/download.

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

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

6.2.7.4 - Inspection after Approved Reconditioning has been Completed

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (page 2 of Form FDA 766, Exhibit 6-2) or advise the 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 approved reconditioning application, or it may accept the statement from the importer with no further follow-up. The follow-up inspection and/or sampling may be made by FDA or CBP, depending on agreements between the division and local CBP. The "Report of Investigator/Inspector" (section 4, page 2 of Form FDA 766, Exhibit 6-2), or other appropriately completed summary of reconditioning, should be forwarded to the appropriate FDA office.

6.2.7.5 - Procedure when Conditions of the Approved Reconditioning Application Have Been Fulfilled

If the conditions of the approved reconditioning application have been fulfilled, the district will notify the owner or consignee by Notice of Release. This notice is usually identified as "Released after reconditioning." A copy is also sent to CBP and the filer. Where there is a non-admissible portion (rejects), they must be destroyed or re-exported under FDA or CBP 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 the Approved Reconditioning Application Have Not Been Fulfilled

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

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

6.2.7.7 - Procedure after Hearing - "Notice of Release"

If, after presentation of testimony, the division determines the article should be released, the importer of record and consignee are issued a "Notice of Release". The Notice will declare 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 CBP, and all parties receiving the Notice of Sampling/Notice of Detention. (See RPM Chapter 9-7 "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 CBP. (See RPM Chapter 9-11"Notice of Refusal of Admission" for detailed guidance.)

The "Notice of Refusal" provides for the exportation or destruction of the shipment, under CBP supervision, within 90 days of the date of the notice, or within such additional time as specified by CBP Regulation. 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 IOM Exhibit 6-3, Charges for Supervision). This is completed by FDA employees regarding the supervision of the authorized relabeling or other action to U.S. Customs and Border Protection – Revenue Division. The expenses shall be computed on the following basis:

1. Supervising Officer'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 CBP, in which case the Form FDA 790 will no longer be used. (See RPM Chapter 9-13"Supervisory Charges" for detailed guidance.)

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

6.2.7.10 - Exportation of Goods Refused Admission

Exportation of refused goods is done under CBP 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. Each District involved in performing Import Operations has been assigned a set number of import exams of refused entries as part of ORA's Performance Goals.

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 CBP regulations (19 CFR 113.62) a bond is required for all conditionally released articles offered for importation. This bond provides relief to the government on the default of the conditions of the bond and the payment of liquidated damages in the amount specified in CBP 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. See Section 6.1.3 of the IOM, Investigations Involving the Import Process. Send a detailed statement showing the importer's liability under the redelivery bond or other applicable customs bond to the responsible CBP office. If the facts warrant, and the article was under detention, and the Notice of Refusal of Admission has not been issued, immediately issue a Notice of Refusal to the owner or consignee, with a copy to CBP.

Upon the receipt of an application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages), CBP may agree to mitigate the amount of damages. However, in cases involving FDA goods, CBP 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.)

6.2.8 – PHOTOGRAPHS: IDENTIFICATION AND STORAGE

Photographs are evidence documented during import field work and are a crucial element in case development. They should be clear and capture evidence needed to support the appearance of a violation and the proposed charges. The photographs should capture, at a minimum, all sides of the product packaging, labeling, (i.e. top, bottom, and sides; including blank sides), all labeling (e.g. package inserts and any labeling that provides the intended use of the product, product value, directions for use, daily intake, and firm information) any available production (lot) codes and/or dates, an overall view of the lot(s) examined, and any adverse conditions observed.

Photographs must be collected and uploaded electronically to the entry/line via FDA import systems (ER, OASIS, SERIO) for all sample collections, Class 2 and Class 3 field/label exams, detention requests (when warranted), destructions, reconditioning, refusal verification discrepancies, and other situations as warranted.

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

Photographs may be uploaded directly from a government issued mobile device or computer file to an entry/line via FDA import systems. The system records the date/time and investigators initials at the time of upload. The required information described above must be included within the file name and/or using the Document Remarks section (See SERIO manual instructions) specific to each photograph during the document upload process. However, there is no need to include the entry/line number when uploading from a mobile device or computer file as the photograph(s) will be directly associated to the entry/line. For example, the file name or Document Remarks would include "information panel/right side, 1 of 4".

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

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

Note: If additional enforcement or legal actions including but not limited to seizure, injunction, debarment or prosecution are contemplated with respect to an import case, the procedures for preparing and maintaining digital photographs and video as evidence, as described in IOM 5.3.4.2.5 and IOM 5.3.8.3, must be followed.

SUBCHAPTER 6.3 – ENTRY REVIEW

6.3.1 - GENERAL

Entry review consists of the examination of any electronic data and/or hard-copy entry documentation received by FDA for an FDA regulated entry line. The information received is reviewed to determine if entry admissibility criteria for the commodity are met, and if additional actions, such as examination sampling, or detention request, are applicable and/or necessary.

An investigator may be assigned the role of an import entry reviewer. Entry reviewers use sound judgment based on their experience and training when performing entry review. All import entry reviewers receive both formal training and on-the-job training to ensure they are familiar with admissibility requirements and can effectively use FDA databases. Along with attending national import courses, on-the-job training should result in the ability to conduct entry review independently with minimal supervision.

An entry reviewer is expected to possess the knowledge to:

- Utilize the electronic Imports Entry Review (ER) system.
- Access and reference appropriate FDA databases.
- Reference initial admissibility job aids and other FDA work instructions to ensure accurate and consistent entry processing.
- Use the internet to access and review regulatory requirements not included in an FDA database (e.g. the Interstate Certified Shellfish Shippers List).
- Make the appropriate initial admissibility entry decision (e.g. "May Proceed", request field work, recommend detention) and provide remarks/justification as appropriate.
- Understand ORA Field Work Plan and Sample Collection Operation Planning Effort (SCOPE) obligations to assure that center-prioritized work is completed.
- Refer entries to OCI and Partner Government Agencies (PGA) when warranted.
- Refer entries to a supervisor and/or Compliance Branch (CB) when information is uncovered during ER that may require a national screening criteria recommendation by CB.

The entry reviewer takes one of three final entry review actions:

1. "May Proceed",
2. Detention Request (DER/DTR), or
3. Request Field Examination (FEX), Label Examination (LEX), and/or Sample Collection (SAM).

Entry review actions can be supported by:

1. Electronic and/or hard-copy entry documentation including declarations of intended use
2. Electronic systems screening of entry information
3. Affirmations of Compliance (AofC) such as Registration and Listing.
4. Database Query
5. Import Alerts (IA)/Import Bulletins (IB)
6. Past compliance history
7. Compliance Program Guidance Manuals (CPGM)
8. Import Assignments, DIO Field Advisories and Notices, and SCOPE
9. Intelligence from PGAs
10. Management directives

NOTE:
The Automated Commercial Environment (ACE) requires filers to submit certain data elements for FDA regulated products. For specific ACE requirements, refer to the most current FDA Supplemental Guide. If inaccuracies are found with the transmitted manufacturer, shipper, product code, or country data elements that could affect entry screening, correct the information, assign fault, save, and rescreen the entry/line

- If information exists to support the appearance of a violation or if compliance with the regulations cannot be confirmed (e.g., Registration, Listing, Approval), forward a Detention Request to the Compliance Branch.
- The reviewer may, at any time, assign or set up a work request for examination or sample collection (e.g. LEX, FEX, or SAM).

See Regulatory Procedure Manual (RPM) Chapter 9 and Initial Admissibility Job Aids for additional information concerning the review/processing of entries of specific types of commodities, including products under detention without physical examination.

Entry review activity is reported as Import Investigation Time in OASIS.

6.3.2 – INITIAL ENTRY REVIEW

Lines submitted electronically to FDA are received with the initial work types of Quantity and Value (QAV) or No Quantity and Value (NQV). In addition to receiving electronic entries, FDA receives non-ABI (paper) entries. For non-ABI entries, follow the same decision-making criteria as electronic entry filing, but electronically transmitted entries will be given review priority. NOTE: If setting up work on a non-ABI entry, refer to the Entry Review Job Aid for specific instructions on creating a manual entry in ER.

Use the actual arrival date/time (for truck ports of entry) and submission date/time (for air, rail and sea ports of entry) when prioritizing entry review lines. In general:

- Lines with a QAV work type take priority over lines with an NQV work type.
- Lines with documents sent via Import Trade Auxiliary Communications System (ITACS) take priority over lines with documents sent via alternative means of transmission.

The quantity and value for each line are typically provided electronically for FDA review to aid in the admissibility process. Quantity and value are required to setup a work request.

6.3.2.1 –Emergency and Perishable Shipments

Emergency or perishable shipments take priority over non-perishable shipments.

An emergency shipment consists of one or more lines that require immediate review based on a demonstrated and urgent need or situation. Emergency entries are to be handled per import division discretion to control and prevent abuse by regulated industry and individuals.

Perishable products are articles not otherwise preserved in a manner so as to prevent the quality, safety and/or effectiveness of the article from being adversely affected if held for an extended period of time under normal shipping and storage conditions. Perishable products are raw and fresh products stored in ambient or refrigerated conditions. These products typically consist of raw/fresh seafood, raw/fresh produce (fruits and vegetables), and temperature and/or time sensitive drugs, vaccinations, lab reagents, or biologics.

Device shipments may be released if the entry documents include documentation verifying approval by CDRH. If unable to verify the authenticity of the approved document, please contact the center at cdrhimport@fda.hha.gov.

6.3.2.2 – Reviewing Entry Data and Information

Electronically submitted entry lines that are not issued a “May Proceed” by the system are manually reviewed by entry reviewers.

Review of entry lines submitted electronically is conducted using the ER system. ER incorporates PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting), a screening tool that uses automated data mining, pattern discovery, and automated queries of FDA databases to determine the potential risk of a shipment. It takes into consideration the inherent risk of certain commodities and information about the previous history of importers, manufacturers, and shippers. Those lines with the highest risk are flagged for additional review. ER system recommendations should be reviewed and considered before taking any action. For specific instructions on navigating through and using ER, refer to the Entry Review Job Aid.

When an entry reviewer issues a “May Proceed” for a line flagged for an IA that is indicated as Priority Review, record a remark in the Priority Review “Remarks” field that provides a clear justification as to why the line is not subject to detention without physical examination (DWPE). NOTE: The firm taking a corrective action is not a sufficient reason to issue a “May Proceed” for the line. If the firm has taken corrective action, they should request to be removed from the IA, and the request will be reviewed by the appropriate center and DIO. The following are some examples of acceptable remarks:

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

The Admissibility requirements that need to be verified when performing entry review for electronic and non-ABI (paper) entries are depended upon the commodity being offered for import (e.g. food, medical, devices, drugs, radiological health products, cosmetics, biologics, and tobacco products). Commodity specific requirements are outlined in the Initial Admissibility Job Aids.

The following are some activities performed by entry reviewers prior to making an initial entry admissibility decision:

- Review the commodity-based PREDICT cumulative percentile rank and mashup in ER which shows the risk score. Request the most recent copy of the PREDICT Guide for Rules and Scoring
- Review all entry line flags in ER. For example:
  - If you observe an IA flag in ER, determine if the firm and/or product combination is subject to DWPE
  - If you suspect that the firm/product should have an IA flag in ER but is not flagged, conduct follow-up investigative work to determine if the firm and/or product combination is subject to DWPE.
  - Report problems and provide feedback using the ER feedback functionality when a PREDICT rule does not fire or fires in error. For additional instructions on this functionality, refer to the Entry Review Job Aid.
- Perform firm/product searches on applicable center databases. Review entry documents when necessary.
- Request field work that aligns with the ORA Field Work Plan, SCOPE, obligations, and center assignments.
- Use applicable guidance and instructional documents to determine compliance with regulatory requirements.

The following is a list of resources that an entry reviewer should be familiar with when performing entry review functions:

- Commodity-Specific Resources, which provide center-specific Import resources that include links to additional information (e.g. center contact information and case routing, initial admissibility resources, field and label examination work instructions and additional resources).
- FDA Affirmations of Compliance (AofC) for the Automated Commercial Environment, which provides definitions of required AofCs for articles offered for entry.
- Compliance Program Guidance Manuals which provide instructions to assist FDA personnel in evaluating compliance with the FD&C Act and other laws administered by FDA.
- Internal documents such as the ORA Field Work Plan, SCOPE, active import assignments, internal notices, advisories, bulletins, and Standard Operating Procedures (SOP).
- RPM Chapter 9 “Import Operations and Actions”.
- PREDICT Guide for Rules and Scoring

6.3.2.2.1 – Manual “May Proceed”

If compliance with regulatory requirements can be confirmed using information transmitted electronically and/or information provided in entry documents, and there is no indication that a detention recommendation or request for field work is appropriate, the entry reviewer should issue a “May Proceed” for the entry line.

NOTE: No further manual verification of AofC data is needed if the line passes the automated database look-up.

6.3.2.2.2 – Rescinding a “May Proceed” or IB Release

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

When an entry receives a “May Proceed” or IB Release, the conditional release period of the entry ends (Section 6.3.4) and does not re-open when the “May Proceed” or IB Release is rescinded.

If an entry line inadvertently receives a “May Proceed” or IB Release or additional information is received that warrants further review for admissibility:

- Obtain supervisory approval prior to rescinding the “May Proceed” or IB Release.
- Notify import filer immediately the FDA MAY Proceed or IB release has been rescinded pending an FDA Admissibility decision.
- Generate an updated Notice of FDA Action and forward it to the filer, importer, and consignee within 24 hours of rescinding the “May Proceed” or IB Release. Manually generating the notice is necessary because rescinding a “May Proceed” or IB Release does not generate electronic messaging back to the filer via ABI.
- Request CBP within 24 hours of rescinding the May Proceed or IB Release to Unset/Hold the CBP Bond from liquidating in case Compliance Branch needs to pursue a liquidated damages case against the bond for cargo FDA refuse and not redelievered for export or destruction.
- If the shipment has been distributed, notify CBP and request that they issue a demand for redelivery. (See IOM 6.2.3.2 for information regarding informal entries.) CBP has 30 days to demand redelivery from the date the conditional release period ended (i.e. the “May Proceed” was

issued.) Any delays compromise FDA's ability to request CBP issue a Notice to Redeliver.
- This process and communication with CBP shall be recorded in OASIS to document FDA follow-up when FDA issues a May Process or IB Release inadvertently.

6.3.2.2.3 – Recommend Detention (DER/DTR)

The detention recommendation process is described in IOM section 6.3.5 – Detention Recommendations by Entry Reviewers.

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

When requesting field work, the entry reviewer should:

- Update transmitted data in line details if inaccuracies are found that would affect an admissibility decision or would result in inaccurate information being populated on a Notice of FDA Action. Record reason for update, save, and rescreen the data.
- Set the entry up for examination and/or sample collection by choosing the correct work type/Problem Area Flag (PAF) combination. Work should be set up in accordance with agency priorities, work plans, SCOPE, and assignments.
- Enter instructions in the "Instruction Text" field for the investigator to reference when work is set up for any reason other than routine surveillance. Instructions might be necessary, for example, when:
    - ORA Assignments may require specific remarks;
    - Specifying if exam instructions should be used during the examination (e.g. "further instructions, follow DOPG-Device-05 for Glucose Meters and Glucose Strips, Field Examinations.");
    - A specific discrepancy is found during the entry review process that should be evaluated during the examination and/or sampling;
    - Referencing the results of previous violative examinations/samples (include the previous entry/sample numbers for reference);
    - Indicated in an Import Bulletin;
    - Special notes are applicable (e.g. any known safety precautions, or specifics about the product itself).

NOTES:

- Do not routinely set up work on a line that is confirmed to be subject to an IA. However, there could be special situations when a line subject to IA may need to be examined for a reason unrelated to the IA. In these situations, work may be set up under a PAF that is not related to the IA.
- The Entry Review Job Aid includes specific instructions on updating and re-screening electronic data, setting up work, and entering work instructions in the "Instruction Text" field.

6.3.2.2.5 – Notices

When the entry reviewer recommends detention or requests field work, the filer is notified through ABI (Automated Broker Interface) and a Notice of FDA Action generated in OASIS. Notices of FDA Action are to be distributed as described in IOM 6.2.3.6.2. – FDA.

6.3.2.2.6 – Cancelled Entries

Entry reviewers should be able to identify CBP cancelled entries in ER. Entries that have been cancelled by CBP will display static text at the top of multiple creens indicating "This Entry is Cancelled". The Entry Review Grab Bag (ERGB) will display a "Y" in the "Cncld" column and the Current Entry Status field will display "ACS/ACE Entry Cancelled".

6.3.2.2.7 - Partner/Other Government Agency (OGA) Referral

The purpose of OGI (Other Government Agency - Investigations Branch) and OGC (Other Government Agency – Compliance Branch) work types are to close a line without an admissibility decision being recorded by FDA. Selecting OGI/OGA from Possible Actions allows Investigations Branch (IB) to close a line with no further action after OGA referral from the OGA Entry Review Grab Bag. Selecting OGC/OGA from Possible Actions will route the line to Compliance Branch (CB) and allow CB to close the line with no further action after OGA referral from the OGA Compliance Grab Bag.

Note: In some areas, OGAs are referred to as PGAs (Partnering Government Agencies).

One situation IB may use OGA referral to close a line without an FDA admissibility decision is when an entry has been refused or seized by another government agency (i.e., APHIS or CBP) and FDA did not have the opportunity to examine the entry. Therefore, FDA does not have adequate information to make an initial entry admissibility decision. The line(s) within the entry may be closed with no further FDA action after referral to an OGA has been recorded. When this occurs, documentation showing evidence of the final disposition of the product should be obtained and uploaded to the entry/line prior to closure with OGA referral.

An Ad-Hoc OGA referral, found under the Action menu, allows the field to record an OGA referral but does not allow closure of the line with no further action after OGA referral. Ad-Hoc OGA Referrals differ from the use of OGI/OGC work types in that they are used strictly to provide information to the OGA without deferring FDA's responsibility to make an admissibility decision. If an Ad-Hoc OGA referral is recorded the line will still need to be processed with an entry admissibility decision.

Regardless of whether FDA did or did not have the opportunity to examine the goods but has adequate information to make an initial entry admissibility decision, the entry should be processed according to established procedure. This includes May Proceed or detention recommendation (DTR or DER). The OGA referral can still be recorded using an Ad-Hoc OGA Referral if needed.

If an entry has been acted on by an OGA and the entry has been cancelled by CBP, the entry will be automatically closed by the system if no work has been assigned. If work has been assigned, the field can send a request to close the cancelled entry to the ORA OISM DSS ISB Import Systems Problem Reports group at ORAOISMDSSISBImportSysProblemRpts@fda.hhs.gov .

If there is a need to refer a line to an OGA that is not found in the system, please contact the Division DIALs who will then work with DSS to have the OGA added.

6.3.3 – ENTRY DOCUMENTATION

The admissibility of an article may depend on the submission of entry documentation, which may include the following: Bill of Lading (BOL) or Airway Bill (AWB), invoice, purchase order, certificates of analysis, copies of labeling, intended use statement, or other related documentation.

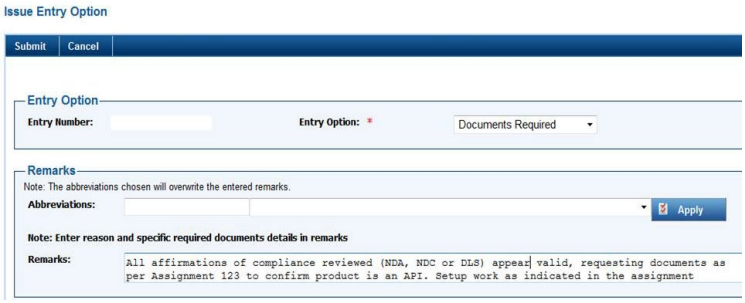
The 3461 and 7501 have been eliminated for electronic transmission of entries in ACE. Reviewers should not be holding up admissibility of lines to review these documents. They are still used for Non-ABI or paper entries.

6.3.3.1 – Request of Entry Documents (DRQ)

If during the initial review of an entry, the reviewer determines that additional information is necessary to make an admissibility decision, request documents via the "Documents Required" Entry Option (DRQ). In the "Remarks" field of the "Issue Entry Option" page enter:

- The reason the documents were requested to assist in the future review of the entry or line.
  - NOTE: Do not routinely request documents solely for the purpose of verifying the accuracy of submitted data.
- A summary of the data elements reviewed and admissibility requirements needed for review.

This information will expedite review of the documents once they are received and will avoid a duplication of efforts. For example:



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

6.3.3.2 – Receipt of Entry Documents

Entry documents may be submitted to FDA in several ways. Documents received via ITACS, are given priority over documents received via other means. Documents can be submitted prior to or at the time of a DRQ.

If documents are not received, refer to Section 6.3.3.4 Failure to Submit Entry Documents and Follow-up Requests.

6.3.3.2.1 – Uploading documents received outside of ITACS

When work has been set up on an entry and documents have subsequently been received from the filer or importer outside of ITACS (e.g. email, mail, fax), upload the documents using ER. Instructions for uploading documents can be found in the Entry Review Job Aid. Examples of documents that should be uploaded by the entry reviewer include:

- Product labeling
- Email correspondence that contains information that might affect admissibility
- Entry documentation such as invoices, packing slips, FDA forms, or CBP forms

NOTES: Electronically viewed material such as web pages can also be uploaded via ER. Ensure that for all records, the record retention policy is adhered to.

6.3.3.3 – Review of Entry Documents

When documents are received, review entries in chronological order (e.g. by earliest submission date in Imports Entry Review, by email receipt date). Documents received via ITACS are given priority over documents received via other means.

If, after review of the entry documents, sufficient information exists to support the appearance of a violation or if compliance with the regulations cannot be confirmed (e.g., Registration, Listing, Approval), forward a Detention Request to the Compliance Branch (See IOM 6.3.5).

If examination or sample collection is indicated, assign or set up a work request (e.g., LEX, FEX, or SAM).

If the documents submitted do not provide sufficient information to make an entry admissibility decision, the reviewer may follow-up by using:

- Direct communication (i.e. email, phone call) with the filer or importer
- Entry Incomplete – Return, Deficient Entry (DEF) Entry Option
- Request Information (INF) Activity

In the follow-up communication, indicate to the importer/filer the specific additional information needed, and that if the information is not provided, FDA may take other action to continue the admissibility review.

Record direct communications with the filer or importer in the "Remarks" field of the Entry Details page or via the "Log Miscellaneous information received" (MIB) function. Include the date, method of communication (i.e. email, phone), content requested, point of contact and reviewer name or initials in the remarks.

Please note that neither the DEF Entry Option nor the INF Activity sends an electronic message to the filer via the FDA-CBP interface, however, they do generate a Notice of FDA Action. Specify the information requested in the "Narrative" field of the DEF Entry Option and the "Information Requested" field of the INF Activity. In addition, if the INF Activity is used, it will display as a status in ITACS, advising the user to view the narrative for details via the Notice of FDA Action.

NOTE: Information entered in the "Remarks" field is for internal use only. Information entered in the "Narrative" field appears in the Notice of FDA action.

6.3.3.4 – Failure to Submit Entry Documents and Follow-up Requests

If entry documents are not received within three business days after requesting documents via the DRQ entry option (under 6.3.3.1), the system will automatically send an electronic message to the filer stating, 'Second and Final Request for Information' (DR2). This automated message does not generate a Notice of FDA Action. Documents received outside of ITACS must be uploaded into ER/OASIS to prevent the DR2 message.

In addition, the reviewer can also send a follow-up request to the filer. The reviewer may follow-up by using any of the following options available:

- Direct communication (i.e. email, phone call) with the filer or importer
- Deficient Entry (DEF) Option or
- Request Information (INF) Activity

In the follow-up request to the filer/importer, indicate the specific additional information needed, and that if additional information is not received, FDA will continue its admissibility review without the benefit of the additional information.

Record direct communications with the filer or importer in the "Remarks" field of the Entry Details page or via the "MIB function". Include the date, method of communication (i.e. email, phone), content requested, and reviewer name or initials.

If additional information is received after follow-up communication, proceed to making an entry decision unless additional follow-up is warranted.

If the requested information is not received, take appropriate action (e.g. setup field work or request detention). If detention is requested, refer to IOM 6.3.5.

6.3.4 – ENTRY DECISION

Under the conditions of the entry bond, articles may receive a conditional release by CBP pending a final admissibility decision by FDA. An FDA entry decision must be made prior to the end of the conditional release period (within 30 calendar days after CBP has conditionally released the product), unless otherwise extended. If FDA does not take an action to extend the conditional release period, it will terminate upon the earliest occurring of the following events:

- The date that FDA issues a notice of refusal of admission;
- The date that FDA issues a notice that the merchandise may proceed;
- Upon the end of the 30-day period following the date of release.

As indicated in 19 CFR 141.113(c), to extend the conditional release period, FDA must issue a written or electronic notice (within 30 days of the conditional release of the merchandise), informing the bond principal (i.e., importer of record) that the product will be examined, sampled or has been detained. The DRQ, DTR, DER, DEF and INF functions do not extend the conditional release period.

6.3.5 - DETENTION RECOMMENDATIONS BY ENTRY REVIEWERS

Importers introduce goods through multiple ports of entry and work with a variety of districts. FDA personnel review these import entries utilizing data submitted by filers/brokers to make an initial admissibility decision. FDA regulated products which appear to be non-compliant and/or subject to an Import Alert or Import Bulletin should be considered for field work or submission to the Compliance Branch (CB) with a detention recommendation. Since filers have interactions with multiple FDA districts, it is vital that entries be handled by a uniform procedure regardless of the port of entry.

6.3.5.1 - Submission of Detention Recommendations to the Compliance Branch at the Entry Review Step

Entry reviewers recommend detention using one of two work types: DER or DTR.

1. DER refers to a detention recommendation based on Detention without Physical Examination (DWPE), and is utilized when a product is subject to DWPE and is either listed on an Import Alert (IA) or meets the criteria found in Direct Reference Authority for DWPE (6.3.5.4.2.1, below).
2. DTR refers to all other detention recommendations for products with the appearance of a violation, either because administrative requirements cannot be verified or other evidence supports the appearance of a violation.

NOTE: If additional entry documentation is needed to support the detention recommendation, collect prior to submitting a recommendation. Include comments for all detention recommendations articulating the reason why the entry is being sent to the CB for review.

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

Entry Reviewers ensure detention recommendations are aligned with center specific requirements. To promote consistency across districts, refer to the Center Specific *Initial Admissibility Job Aids* for instructions on commodity-specific requirements and center database use. The entry reviewer is responsible for searching all applicable center databases prior to a detention recommendation. Ensure research conducted in the FDA database systems is documented in the remarks section of the detention recommendation.

Prior to submitting a detention recommendation, verify accuracy for all Line Details in the entry.

1. If at any time data is found to be incorrect, correct the inaccuracies. **NOTE:** Quantity and Value are required to take a "Next Step" and for CB to take action.
2. Split lines if necessary.
3. Rescreen updated lines.
    a. If data has been changed, click on "Save", then enter a brief description in the pop-up box, and assign fault to any errors as appropriate.

NOTE: Some firms or products may be subject to multiple import alerts or compliance with multiple regulations cannot be verified at the time of entry. In these situations, the entry reviewer should recommend detention for all applicable import alerts and/or problem area flags (PAFs).

6.3.5.2.1 - Entry Documents

Entry documents are not required for all detention recommendations made by an entry reviewer, as indicated below in sections 6.3.5.3, 6.3.5.4, and 6.3.5.5. However, the CO does require entry documents for case review. For detention recommendations made by the entry reviewer without having the entry documents, the entry documents should be requested for CO use per the instructions below.

1. If entry documents were not obtained prior to making the detention recommendation (DER or DTR), ensure the "Entry Option" selected in the drop-down menu includes a document request, e.g. "Hold Designated, Others Go, Docs Required". This designation alerts the filer to submit entry documents to FDA.
2. Entry documents received by the investigations branch outside of ITACS are to be uploaded via FDA import systems (ER, SERIO).

    a. JA-000038 - Job Aid for the Entry Review Application contains instructions for uploading entry documents via ER.
    b. OASIS Mail/Baggage Procedures contains instructions for attaching entry documents via OASIS.
    c. MAN-000091 - System for Entry Review and Import Operations (SERIO) User Manual contains instructions for uploading documents via SERIO.

6.3.5.3 - DER - Import Alert (IA)

A Detention without Exam Recommendation or DER is utilized in Entry Review for entries/lines that are subject to an Import Alert (IA).

Entry documents and additional evidence are not required prior to submission to the CB if all the following requirements are met:

- The elements in the electronic submission match the criteria found in the IA (e.g. Country of Origin ("CofO"), declared manufacturer, product description).
- The IA does not specify that entry documents be submitted
- No additional information is necessary to make an initial admissibility decision
- No additional line information is required

NOTE: Request entry documents and/or additional evidence prior to a DER submission when the IA specifies that the shipment may be detained if it is not accompanied by certain additional entry documents and/or evidence. Example: IA 28-02 for Indian Black Pepper states that Districts may detain all shipments of black pepper from India not accompanied by a certificate, containing certain information, from the Indian EIC.

When submitting a DER:

1. Ensure that you follow the instructions for each applicable IA (more than one IA may apply to a line).
    a. Verify electronic entry information matches the IA prior to submitting the DER to CB. This includes:

- CofO
- Firm Name and Address (for the manufacturer, shipper, consignee, or importer, as applicable to the import alert)
- Importer Description/Product Description (Some IAs are very general - ensure the specific product is subject to the IA)

2. Update and rescreen as appropriate.
3. Enter the following comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen:
   a. Example: "Manufacturer/Product is subject to IA XX-XX" or "CofO/Product combination is subject to IA XX-XX"
   b. If required by the IA, ensure that any research conducted in the FDA database systems are documented in the remarks section. Example: "Per IA XX-XX (Database Name) was reviewed and (Manf/Supplier) was issued a W/L".
4. If it is suspected that an entry/line may be subject to an IA but cannot be confirmed from the electronic entry data, request and/or review entry documents. This may occur when a manufacturer name is listed on an IA, but the address differs from what was electronically transmitted.
   a. If the entry documents show that the electronic information submitted was incorrect, update and rescreen the entry/line. If the updated entry/line is subject to an IA follow the DER procedures above.
   b. If review of the entry documents show that the entry/lines are not subject to the IA, the reviewer can determine the appropriate next step (MPro, FEX/LEX, SAM, DTR).

6.3.5.4 - DTR

A Detention Recommendation (DTR) is utilized at the entry review step when the reviewer cannot confirm that products being offered for import meet FDA's admissibility criteria. Prior to recommending a DTR, the reviewer may utilize the electronic submission, internal FDA databases, and any entry documentation submitted by the filer to make a determination. A field/label exam or sample collection may be assigned to aid in determining admissibility.

6.3.5.4.1 - Similar to Import Alert

If the product appears to be similar to a product/manufacturer/CofO combination on IA and additional information is needed to determine if the product is subject to IA:

1. Request and review the entry documents.
2. Update and rescreen inaccurate data.
3. If the entry is subject to IA, follow procedures for DER (See IOM Section 6.3.5.3).
4. If the product does not match the IA, determine the next step, which could include any of the following:
   a. May Proceed
      If the entry flagged for the IA, and is subsequently released:
      - Provide feedback to the Import Compliance Systems Branch (ICSB) using ER if the line flagged incorrectly for an IA. (PREDICT Guide: Rules and Scoring)
      - Include a comment as to why the product was not subject to the IA. Example: "Firm flagged for IA XX-XX but product is not subject to IA (include reason why product is not subject to IA)".
   b. Request Field Work (SAM/FEX/LEX):
      - Include pertinent instructions in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Example: "Firm/product may be subject to IA XX-XX, collect pertinent evidence (labeling, photographs, entry documents, sample)".
   c. If a violation (different from the IA) has been determined, submit a DTR to CB.
      - Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Example: "No (Listing) found in (database searched) for (manf/product)".

6.3.5.4.2 - Previous Violative Results (pending IA addition)

At times the Entry Reviewer may come across entries/lines that contain the same product and manufacturer as a previous entry/line that was found violative and is pending addition to Import Alert. Depending on the screening criteria and whether or not ORA has direct reference will impact the reviewer's next step.

NOTE: In these situations, a screening criteria may have been implemented by the CO to ensure reviewers are aware of the violative findings.

6.3.5.4.2.1 Direct Reference Authority for DWPE

When ORA has direct reference authority (DIO Advisory #1) and the electronic entry is an exact match to the previously found violative shipment, additional entry documents and/or evidence may not be necessary.
NOTE: Ensure any additional requirements included within an assignment are met.

When you encounter one of these shipments and ORA has direct reference authority:

a. Recommend Detention (DER).
b. Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen:
   a. Previous violative findings, CMS/work activity number and/or entry number, Reference to the IA, any evidence collected. Example: "Previous violative findings (issue found, CMS/work activity number and/or entry number) firm/product awaiting addition to IA XX-XX. Direct reference authority for (product) for addition to DWPE. No physical exam conducted."

6.3.5.4.2.2 - No Direct Reference Authority for DWPE

When ORA does not have direct reference authority, the entry must stand on its own. There are many factors to consider in these types of situations such as risk and pending cases. Discuss the next steps with your supervisor and CB. Possible next steps could include the following:

1. Request and/or review entry documents.
2. Request Field Work (SAM/FEX/LEX)
   a. Include pertinent instructions in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. This includes: Previous findings, CMS/work activity number and/or entry number, instruction for field work. Example: "Previous violative findings (issue found and entry number) firm/product awaiting addition to IA XX-XX. Review labeling for ephedrine alkaloids."
3. If a violation is determined for the current shipment, submit to CB under the applicable Problem Area Flag (PAF).
4. May Proceed the entry if no violation is found with the current shipment.

6.3.5.5 - Registration/Listing/Approval

Some products may require registration, listing, and/or approval. The steps below describe how to recommend detention when compliance with these requirements cannot be verified.

Registration and Listing

1. When registration and/or listing is required, review the electronic submission. For those entries where compliance cannot be confirmed using the electronic data transmitted and internal FDA databases, request and review entry documentation.
2. Recommend detention (DTR) if the necessary registration or listing cannot be verified after reviewing the entry documents and the appropriate center database.
   NOTE: Failure to submit Affirmation of Compliance data or a look-up failure is not sufficient to recommend detention. Prior to recommending detention, make a reasonable effort to verify compliance with registration and listing requirements in the center databases using the manufacturer and product information provided.
   a. Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Such as, the database reviewed, findings, any evidence collected.
      Example: "No registration or listing found in (database) for manufacturing company (Provide specifics as to what does not match (i.e. name, street address, city))".
3. If additional information is not submitted in the electronic or paper entry and is required to make an initial admissibility decision (e.g. drop ball test or can size), request that specific information from the filer.

Approval

1. When the required approval cannot be verified after reviewing the entry documents and searching the appropriate database, collecting additional product labeling is not required to recommend detention, unless specifically noted by additional guidance. If the entry reviewer is unable to determine if the product requires approval, collect the product labeling. Legible copies or photos of the labeling from the current shipment should accompany the detention recommendation.
   a. Reference the pertinent *Initial Admissibility Job Aids* for center requirements, e.g., intended use, end use, and annual reports (IOM Section 6.3.5.2).
   b. Include pertinent comments in the "Instruction Text" field located in the "Work Details" section of the "Work Request and Work Request Details" screen. Such as the database reviewed, findings, and any evidence collected.
      Example: "No (approval e.g. NDA, ANDA, 510(k), PMA, etc.) found in (database) for manufacturing/product combination. Labeling, end use letter, and intended use included in submission."

6.3.5.6 - IFE

Follow current procedures for reviewing IFE (Import for Export) entries (IOM 6.2.3.4 and RPM 9-15).

SUBCHAPTER 6.4 - FIELD EXAMINATION

6.4.1 - GENERAL

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

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

1. Confirming that product and quantity present corresponds to product and quantity declared on shipping documents,
2. In transit or storage damage,
3. Inadequate storage temperature conditions,
4. Rodent, bird 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 (label examinations)

A label examination (LEX) is used when the investigations branch conducts a label review (LBL) of the physical product in the field to determine labeling compliance. The

remarks entered and exam class selected can be used by compliance to make an admissibility decision for the product. A Label exam should be recorded as LEX. All other field examinations should be recorded as a FEX along with the appropriate problem area flag (PAF)
When conducting a field examination, compare documents provided by the filer/importer, to what is physically available during your inspection and to the information that was electronically submitted. Record your observations in your regulatory notebook at the time of the field exam. Information to record includes:

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

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

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.

See IOM 5.1.4.3 for suggestions on what to do when conducting a field examination when the firm responsible for the products invites individuals who are not directly employed by the firm to observe the examination. See IOM 6.4.10 for instructions on recording field/label examination results in OASIS.

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 Programs, specific product examination schedules (e.g., LACF), or other guidance. All containers opened for exam should be identified with FDA, division abbreviation, the date of the examination, and the lead investigator's initials.

When you conduct any field examination, in addition to specific items discussed in the following sections, be alert for any over labeling where a product name or identity may have been changed; different manufacturer than that transmitted or provided in the entry documents; product without mandatory English labeling; changes in expiration date or lot numbers; product quantity differences; product integrity; country of origin (under CBP authority 19 CFR 134) 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 AND LABEL EXAMINATIONS – FOODS AND COSMETICS

See IOM 5.4.1.4.2 for information 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, for additional instructions on performing field examinations.

Canned and Acidified 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 pesticides, chemical contaminants, natural toxins and metals, except for metals in dinnerware and the side seam solders of cans.

NOTE: Divisions should use commercial versions of the Quick Color Test (QCT) and the Rapid Abrasion Test for lead, 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 CP 7304.019. Specific information regarding the techniques of testing dinnerware and can side seam solder can be found in Lab Information Bulletins (LIB) 4127and LIB 4041, respectively on the Office of Regulatory Science (ORS) 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. Determine if a color additive is declared for a product to which it appears coloring has been added. Determineif a declared color additive is acceptable for use in the product.

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

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

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

6.4.3.4 – Nutrition Labeling and Food Allergen Labeling

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

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

Also see the "Food Labeling & Nutrition" website for the most up-to-date information regarding claims in labeling. Also, see CP 7321.005 to determine areas as emphasis 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 4.3.7.1

Food Standards - The only valid field examination which can be performed for Food Standards is a label examination for the mandatory labeling requirements of a particular Food Standard.

6.4.3.6 - 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 21 CFR 250.250)
3. Non-permitted color additives (see Color Additives Status Lists)
4. Warning Statements (21 CFR 740.11, 740.12, 740.17, and 740.19)
5. Cautionary/Other Required Statements (for example, required caution statement and directions for patch test for coal-tar hair dyes - FD&C Act sec. 601(a); required caution statement for the color additive lead acetate - 21 CFR 73.2396; required label information for the color additive bismuth citrate – 21 CFR 73.2110; and required label information for the color additive henna – 21 CFR 73.2190)
6. Tamper Resistant Packaging Requirements (21 CFR 700.25)
7. Other Labeling Requirements (21 CFR 701.10 through 701.13)

For further questions contact the Office of Cosmetics and Colors.

6.4.4 - FIELD AND LABEL EXAMINATION – DRUGS

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

- Confirm that product and quantity present corresponds to product and quantity declared on shipping documents.
- Examine security and integrity of the container including tamper resistant packaging requirements.
- Examine for in-transit or storage damage or inadequate storage temperature conditions.
- Examine for any over labeling where a product name or identity may have been changed.
- Examine if the manufacturer is the same as the one transmitted or provided in the entry documents.

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

6.4.4.1 - Labeling

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

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 should be made in accordance with relevant CPs and any applicable assignments. Samples collected from lots where the drug substance or finished product has been subjected to actual or suspected contamination should be decided on a case-by-case basis.

6.4.4.4 - Special Instructions

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

6.4.5 - FIELD AND LABEL EXAMINATIONS – DEVICES

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

At a minimum, the label should include the name and place of business of the manufacturer, packer or distributor and product identity. Be aware of mis declared devices, for example, TENS (transcutaneous electrical nerve stimulation) devices are often declared as therapeutic massagers but in fact should be declared as neurological therapeutic 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 information refer to **21 CFR Part 801**.

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

FDA will not support import action against the device as misbranded or adulterated when the non-sterile device as labeled sterile if the lot is marked appropriately as noted previously. 21 CFR 801.150i 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. This should be verified upon import.

6.4.6 – FIELD AND LABEL EXAMINATIONS - BIOLOGICS

Review applicable import alerts regarding biologics prior to conducting any field examinations of biological products subject to import alert.

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

If it is determined that a field examination is warranted for licensed or unlicensed CBER-regulated products, labeling for the product and its intended use should be examined. Any questions should be sent to CBER Import Inquiry at CBERImportInquiry@fda.hhs.gov

6.4.7 - LABEL EXAMINATIONS - ANIMAL PRODUCTS

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

6.4.7.1 – Animal Drugs

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

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

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

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

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

6.4.7.2 – Animal Devices

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

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

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

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

6.4.7.3 - Animal Food

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

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

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

6.4.7.4 – Animal Grooming Aids

FDA does not regulate products intended solely to cleanse or beautify animals, commonly referred to as grooming aids. Cosmetic regulations outlined in the FD&C Act do not apply to products intended for animal use. Products

purporting to be animal grooming aids that are labeled as or otherwise intended for therapeutic purposes may be considered animal drugs. This may occur when a grooming aid is labeled to contain an active drug ingredient or to suggest or imply a therapeutic benefit. Refer to CPG Sec. 653.100 Animal Grooming Aids.

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

6.4.7.5 – Animal Biological Products

Although animal biological products are "drugs" within the meaning of the FD&C Act, animal drugs produced and distributed in full conformance with the Virus, Serum, Toxin Act (VSTA) and its implementing regulations administered by the United States Department of Agriculture Animal Health Inspection Service (USDA-APHIS) are not subject to the animal drug approval requirements in section 512 of the FD&C Act.

Under the regulations implementing the VSTA, 9 CFR part 101, animal biological products are defined, in part, as "all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response." (9CFR 101.2)

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

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

6.4.8 - FIELD AND LABEL EXAMINATIONS -RADIOLOGICAL HEALTH

Import coverage for radiation emitting products is provided for in CPGM 7386.007, Imported Electronic Product.

When conducting fieldwork on radiation emitting products refer to the field and label examination work instructions issued by CDRH and located on the Import Program intranet site under commodity specific resources. Additionally, field and label examinations for imported electronic products should include of entry documents and FDA-2877, Declaration for Imported Electronic Products Subject to Radiation Control Standards, to determine if they are properly completed and accurate. This applies to each shipment of electronic products for which performance standards exist. Performance standards, covering ionizing, optical, microwave and acoustic radiation-emitting products, are specified in 21 CFR 1020 through 1050.

6.4.9 - FIELD EXAMINATIONS – TOBACCO PRODUCTS

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

6.4.10 – FIELD/LABEL EXAMINATION RESULTS

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

Review the Line Details screen prior to completing the OASIS Field Exam Results Screen.

1. Access the Line details by double clicking the work type field, i.e. "FEX". This will open the "Entry/Line Summary" screen. Click the "Line Details" button.
2. Review all the data and verify that it is complete and correct. For example, make sure the product code matches the product, and that the manufacturer, country of origin, quantity and value are correct. Add any lot codes if applicable and update the Line Availability information if needed. If there is a build button on the line you need to correct, you must use the build function to make corrections. All fields that are white or highlighted in purple can be updated.
3. If data has been changed, click the "Save" button. Then enter a brief description in the pop-up box of corrections made. Assign fault to any errors as appropriate.
4. After any changes are made, save the changes and "Rescreen" the line to see if changing the data caused the line to hit on any other criteria or alerts.

Complete the examination results by navigating to Work Results:

The system auto fills the following fields: entry number, Lead Initials, Date Completed, Product Code, Product Description, Importer/Corrected Description, PAF, PAC, and Reference.

Enter data in the following fields:

6.4.10.1 – Date Completed

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

6.4.10.2 – Location of goods

Enter the location where the examination was conducted if availability and location of goods have not been entered or if the exam location has changed. Include location name and address or resident post location.

6.4.10.3 – Remarks

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

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

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

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

6.4.10.4 – Summary

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

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

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

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

6.4.10.5 – Exam Class

Select the appropriate Exam Class.

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

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

1. Potential adverse findings were observed. Observations lead to the collection of a sample or referral to compliance branch in the specified problem area for final admissibility determination.

2. The product appears to be in violation within the limitations of a field examination for the specified problem area; however, investigations branch is using discretionary authority to release the product. If this option is used, describe in detail in the Summary field the reason(s) why this violative product is being released, such as, "This product meets the criteria for release under the Personal Importation Policy (PIP) as stated in the Regulatory Procedures Manual (RPM)." Note: The exemption for releasing a personal importation with a class 2 field exam findings, only applies to the mail environment.

3. No adverse findings were observed within the limitations of an examination for the specified problem area; however, the line is sampled within the same problem area due to the firm/product having a violative history in that problem area or as directed by an assignment, import bulletin or other guidance.

4. No adverse findings were noted within the limitations of an examination for the specified problem area; however, the line is being held and referred to compliance branch pending sample analysis of another line. (Note: it is inappropriate to record a field examination if no physical examination occurred. The "Same

Action As" function allows for the holding of lines where no examination occurred pending the analytical results of another sampled line)

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

NOTE: If a LEX is conducted and the examination identifies labeling claims that may warrant marketing clearance and/or approval, record the findings as a Class 3 LEX and submit to compliance as a DTR/AAP.

Click "OK" to save the examination results.

6.4.10.6 – Record Time

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

6.4.10.7 – Next Steps

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

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

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

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

If the exam was classified as Class 2 with No Adverse Findings, but the line is to be held pending sample analysis of another line, follow Division procedures for notifying Compliance Branch.

If the exam was classified as Class 3 you will have the option to Refer to CB or Add Work IB Release Remarks should include a detailed description of why the product was released if Adverse Findings were found.

If "Yes" is chosen, the system will prompt you to return to the Possible Actions page to add work as appropriate.

If "No" is chosen, the system will display the message: "Performing Hold Designated/Others Go!" Click "OK". The line will move to the Compliance Branch Grab Bag. Follow Division procedures for notifying the compliance branch.

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 division options. See Chapter 4 for sampling instructions and guidelines. There are 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. Some 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 division. In addition, when preparing to collect import samples, you should be aware of your personal safety. Refer to IOM 5.2.1.2.

Import sub samples should be identified in accordance with IOM 4.7.2.1. However, if the sample number is not available at the time of shipment or sample delivery (e.g. a situation arises where the investigator collects the sample and must deliver it to a servicing lab prior to completing the collection report.) the entry/line number may be used in lieu of the sample number for identification. In these cases, complete the collection report as soon as possible and notify the sample custodian of the sample number. The collection report should clearly indicate how the sub samples are identified and provide reasoning as to why the sample number was not used.

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

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

- Sample number, if available at time of shipment
- Entry/Line number if sample number not available at the time of shipment or sample delivery
- PAC/PAF (include all if multiple PAC/PAFs going to the same lab) see IOM 6.5.5
- Date of collection

- Storage Condition (ambient/frozen/refrigerated)
- Lead CSO's initials
- The number of bags/cartons in sample if more than 1 and the sub numbers in each container, i.e. bag/box 1 of 3, subs 1-10, etc.

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

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

FDA does not pay for import samples at the time of collection. The Importer should be advised they may bill the responsible division. 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. 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.)

Prior to completing the collection report, review the Line Details for the product sampled. You are responsible for making sure all fields in the Line Details screen are complete and correct. The Line Details screen is the only place you can make corrections to the entered data.

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

To review the Line Details:

1. Access the Line Details screen by double clicking the work type field, i.e. "SAM". This will open the Entry/Line Summary screen. Click the "Line Details" button.
2. Review all data and verify that it is complete and correct. For example, make sure the product code matches actual product, and that the manufacturer, country of origin, quantity and value are correct. Add any lot codes if applicable and update the Line Availability information if needed. If there is a build button on the line you need to correct, you must use the build function to make corrections. All fields that are white or highlighted in purple can be updated.
3. If data has been changed, click the "Save" button, then enter a brief description in the pop-up box of corrections made. Assign fault to any errors as appropriate.
4. After any changes are saved, click on "Rescreen" in the Application Tool bar to see if changing the data caused the line to hit on any other criteria or alerts.

Complete the OASIS Collection Report:

1. Highlight the line sampled in your Personal In Box and click on "Wk Detail" in the Application Toolbar.
2. If the line was sampled for more than one PAF, and analysis will be performed at the same laboratory, only one collection report should be generated; unless otherwise directed. Use Ctrl+Click to highlight all PAFs going to the same laboratory.

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

3. If the sample will be split and sent to more than one laboratory, highlight the PAF(s) for each laboratory individually and complete a separate collection report for each laboratory.
4. Click the "Work Result" button near the top right of the screen to access the Product Collection 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**, and the **Lab Number**. The **Date Collected, and Location of Goods** can be corrected on this screen if needed.

Enter data in the following fields:

6.5.5.1 - Collection Date

The Date Collected should reflect the date the sample was collected, not the date the sample was entered into OASIS. Only one date can be entered. If the sample collection was

accomplished over several days use the last date of collection. Be consistent. This date should also be used to identify the physical sample.

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. See IOM 4.6.2.27.8.

6.5.5.3 - Submitted To

To select the appropriate servicing laboratory, click the "Get Lab" button. The National Sample Distributor (NSD) is currently inactive. All lab capabilities have been set to "0". Districts are instructed to submit samples utilizing the Servicing Laboratory Table (SLT) located in the ORA Workplan. If the servicing laboratory presented by the NSD does not match the specific assignment instructions or the SLT, override the NSD (See IOM 4.6.3). The NSD-assigned laboratory can be overridden by choosing another laboratory from the drop-down menu. Override Reason must also be selected from the dropdown menu. Click "Proceed" to return to the collection report. The chosen laboratory should be displayed in the Submitted To field.

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. The Calculated Cost will automatically populate based on the Value submitted in the Line Details, Quantity Collected and Units selected.

6.5.5.6 - DescText

Enter a description of the sample. The description should include:

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

Describe how you collected the sample:

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

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

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

6.5.5.7 - Hand Ship

Enter the method of shipping and describe how sample integrity is maintained including sample chain of custody.

1. Describe how the sample was held and stored until shipment.
2. Include how the sample was prepared for shipping and
3. Method of shipment

For example: "Transported from firm in a closed cooler with gel packs, sample was then transferred to freezer #1 in the locked sample room until shipped via UPS to PRL-NW in a cooler with Gel packs."

NOTE: This field does not transfer to FACTS for the laboratory to view**. Please enter any special handling instructions in the Remarks field.**

6.5.5.8 - Remarks

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

1. Special handling instructions or storage condition requirements as necessary;
2. When applicable, note the use of guidance documents used for the collection such as Compliance Program Guidance Manuals, Assignment, or field examination guidance document.
3. Additional information your District, Laboratory, Compliance Program, Assignment, or Import Alert/Bulletin requires;
4. Any specific analysis instructions needed (i.e. any specific pathogen or mycotoxin screen needed.)
5. Any controls or photos collected

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

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

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

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

6.5.5.9 - 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 pop-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.

6.5.6 – Updating a Sample Collection Report

OASIS will allow users to make corrections to collection reports until the laboratory has set the sample to "In Progress" in FACTS. Note that a collection report may only be corrected once. To update a collection report, query the entry by clicking on "Query" and then "Entry". From the Entry Query screen enter the entry number and click on "Execute Query". Once you are at the Entry Details screen, select the line you want to update and click "All Activities". Finally, double click on the "Product Collect Comp" field under the Pending text column to open the collection report and click the "Update" button. The updatable fields will become enabled for modification. They are Quantity Collected, Units, Desc Text, Hand/Ship and Remarks. Once all necessary changes have been made, click "Save". At that point, the "View Update" button will become enabled. If a change was made to the Quantity Collected, Units, or Desc Text the "Print Notices" button will also be enabled. It is very important to generate and send the Notice that notifies the parties that changes were made to the collection data.

NOTE: If a change was made to Hand/Ship or Remarks fields ONLY, then no new Notice is needed and the "Print Notices" button will not be enabled.

6.5.7- Special Domestic Import Samples (SDI)

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

If a product is identified for collection as an SDI under a special sampling assignment, or other directive, follow the instructions outlined in the assignment or directive.
SDI samples should be recorded per IOM 6.5.5 – Sample Collection Reports. Additionally, SDI samples require the following:

- A description of the product label as per IOM 4.5.9 - Product Label in the "Remarks" section.
  - Include brand names and size of lot if not already recorded in the "Line Details" screen.
- An official seal (Form FDA 415a) on the sample container(s).
  - Follow instructions in IOM 4.7.4.3-4.7.4.5.
- Collectors ID on the seal as per IOM 4.6.2.12 Collector's ID on Seal.
  - Include collectors ID on the seal in the "Remarks" section.

Note: This information is required for FDA to utilize its domestic authority if the sample analysis results are violative.

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

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

SUBCHAPTER 6.6 - FILER EVALUATIONS

6.6.1 - GENERAL

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

The FDA conducts periodic filer evaluations to monitor the accuracy of entry data transmitted electronically to the FDA. Filer evaluations are conducted based on the physical location within an import division and may include entry lines transmitted by filers that are physically located within a different import division. Follow SOP-000217 "Import Filer Evaluation" when conducting import filer evaluations.

SUBCHAPTER 6.7 - GLOSSARY OF IMPORT TERMS

Refer to the "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 CBP Warehouses authorized to receive goods that have 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 CBW 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. See CPG Sec. 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers

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 unlading to a designated container station or may be received directly at the container station from a bonded carrier after transportation in-bond, before the filing of an entry of goods.

6.7.6 - 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, or are 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 4.1.4.2.5.

6.7.12 - ENTRY

Delivery or offer for delivery of merchandise into the Customs Territory of the U.S. from an outside point.

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 an invoice, purchase order, AWB and/or BOL. Entry documents can be submitted electronically to FDA, preferably through the Import Trade Auxiliary Communications System (ITACS) or via paper submission.

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. Also known as a Customs House Broker.

6.7.17 - Formal Entry

The entry type required for shipments valued over $2500 or for shipments containing specific commodities designated by CBP. Formal entry is usually a three-step process, "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 are 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 an FTZ without entry or export. If the FTZ is located in the US, the goods are in interstate commerce and subject to the FD&C Act **See CPG Sec. 110.200 Export of FDA Regulated Products from U.S. Foreign Trade Zones**

6.7.19 - 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 https://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm

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&CAct [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 CBP by the importer. It allows the immediate transport of goods without a determination of admissibility, from the port of unloading under CBP bond. In general, the importer must file a consumption entry within 6 months of the date of importation or export the goods. FDA typically examines these goods at an 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 CBP requirement.

6.7.30 - Port (Point) of Entry

A port is the CBP location where the Consumption Entry is made. This may or may not be at the Port of Unloading (the point of physical entry into the U.S.)

6.7.31 - Redelivery Bond (AKA Entry Bond)

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

6.7.32 - 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 CBP by the importer which allows the goods to go immediately into a bonded warehouse.

6.7.36 – VQIP QUALITY ASSURANCE PROGRAM

VQIP Quality Assurance Program (QAP) is a compilation of the written policies and procedures used to ensure adequate control over the safety and security of the foods being imported by the VQIP importer. Any format can be used to organize the QAP to include all foods and all of the written policies and procedures under VQIP.

6.7.37 – FSVP AND/OR HACCP IMPORTER

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

6.7.38 – DATA UNIVERSAL NUMBER SYSTEM (DUNS)

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

6.7.39 – FOOD SAFETY MODERNIZATION ACT (FSMA)

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

6.7.40 – FOREGIN SUPPLIER VERFICATION PROGRAM (FSVP)

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

SUBCHAPTER 6.8 FOREIGN SUPPLIER VERIFICATION PROGRAM

6.8.1 - FSVP INSPECTIONS

FSVP inspections are conducted to verify human and animal food imported into the United States is as safe as food produced and sold within the United States.
The FSVP website contains resources for legal, regulatory, guidance, and policy issues for the FSVP regulation.

6.8.1.1 - Pre-Inspection Activities

Prior to conducting an FSVP inspection, contact the person identified at entry as the FSVP importer by phone. During the pre-inspection phone call, you should:

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

6.8.1.2 - Preparation and References

Before undertaking an inspection:

1. Review the firm's FSVP inspection history, the compliance history of the products, and the foreign supplier associated with the products targeted for FSVP review. Ensure the highest risk products are covered.
2. Prepare a list of the foods imported by the importer and the foreign supplier for each food.
3. Review the entry date of the assigned products and the associated foreign suppliers to ensure the compliance date has passed.
4. Conduct the pre-inspectional hazard analysis to determine the known or reasonably foreseeable hazards that should be addressed in the importer's hazard analysis, if applicable.
5. Review and become familiar with the appropriate parts of the FSVP regulation 21 CFR Part 1, subpart L.
6. Ensure that you have received all necessary training that may be required. Consult your supervisor with questions.

6.8.1.3 - Inspectional Authority

Authority to review records required of FSVP importers falls under the statutory provisions of section 805 of the FD&C Act, 21 CFR 1.510(b)(1), 21 CFR 1.510(b)(3), 21 CFR 1.512(b)(5)(ii)(A), and/or 21 CFR 1.512(b)(5)(ii)(C). See IOM subchapter 2.2 for broader information on inspectional authority.

6.8.1.4 - FSVP Inspectional Activities

Upon arrival at the firm locate the person identified at entry as the FSVP importer. Introduce yourself by name, title and organization. Show your credentials, explain the purpose of the inspection, and issue a properly signed, completed original of the Form FDA 482d, Request for FSVP Records (the division office address should be the pre-alignment district office associated with the importer's geographical location).
If this is an initial inspection, provide FSVP education materials. Briefly explain the fact sheets and refer the importer to additional documents that can be found on the FDA.gov FSVP website.
See IOM subchapter 5.2.2 for general information on issuing the Notice of Inspection.

6.8.1.4.1 - CONDUCTING THE FSVP RECORDS REVIEW

Review the importer's required FSVP records for the products and foreign suppliers as assigned or as needed to ensure appropriate coverage of the firm's FSVP programs. When following up on an inspection during which an FDA 483a was issued, review the FSVP records for the observations documented on the FDA 483a during the previous inspection. Determine whether the importer corrected the observations that were identified during the previous inspection and what corrective actions were taken. Verify that those actions corrected the observations.

For each FSVP product reviewed during the inspection, review documentation that the importer meets the definition of "importer" as defined in 21 CFR 1.500. Review the prepared list of the imported foods with the importer and document which foods do not have an FSVP plan.

If the importer is required to comply with the requirements in section 1.504, request to review the importer's hazard analysis. It is important to determine if the importer identified any known or reasonably foreseeable hazards for each food. Compare your pre-inspection hazard analysis to the importer's hazard analysis. If there are discrepancies, discuss with the importer to determine their reasoning behind the discrepancy. After reviewing the importer's hazard analysis, request to review the necessary records.

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

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

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

6.8.2 - FSVP OBSERVATIONS

The FDA 483a, FSVP Observations is intended to assist firms inspected in complying with the laws and regulations enforced by the Food and Drug Administration. The FDA 483a notifies the inspected establishment's top management in writing of significant objectionable conditions relating to violations of the FD&C Act which were observed during the inspection. The issuance of written inspectional observations is mandated by law and ORA policy.

6.8.2.1 - Preparation of Form FDA 483a

The FDA 483a should be issued at the conclusion of the inspection and prior to leaving the premises. During the inspection, do not show the firm's management a draft, unsigned copy of the FDA 483a or an electronic copy of the FDA 483a on your computer screen. You should issue only a signed FDA 483a at the closeout discussion with management.

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

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

The FDA 483a should have the following characteristics:

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

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

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

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

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

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

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

6.8.2.1.1 - INDIVIDUAL HEADINGS

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

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

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

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

Street Address - Enter street address (Not P.O. Box unless P.O. Box is part of the address such as on a Rural Route).

City, State and ZIP Code - Enter city, state and ZIP Code.

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

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

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

Employee(s) signature and Employee(s) name and title - The names of everyone who participated in the inspection with the issuance of an FDA 482d should be listed on the FDA 483a even if they are not available to sign the FDA 483a. Each member of an inspection team should sign the FDA 483a. However, absence of a team member at the conclusion of an inspection need not prevent issuance of the FDA 483a. See IOM 5.1.2.5.1. If you use an eNSpect-generated FDA 483a, assure you have a copy for the program division files -- an unsigned photocopy or printed duplicate is unacceptable. See IOM 5.2.3.6.2.

6.8.2.1.2 - SIGNATURE POLICY

Everyone present at issuance signs the first and last pages of the FDA 483a and initials each intervening page in the signature block. The lead CSO's signature will appear on all pages of the FDA 483a and the remaining team members' signature will appear on the last page. See IOM 5.2.3 for more information on Reports of Observations.

SUBCHAPTER 6.9– FSVP REPORTING

Following an inspection, you are required to prepare a report of your findings. Reporting includes the data and summary entered using eNSpect, a narrative report, attachments and exhibits. Your narrative report should be prepared to accurately and concisely communicate the findings of your inspection and be adequate for its intended use.

6.9.1– ESTABLISHMENT INSPECTION REPORT (EIR)

Based on the observations documented on the FDA 483a and other information captured on the IP in eNSpect, you will use the FSVP Establishment Inspection Report (EIR) application in the eNSpect system to generate the EIR. The requirement to answer IP Question 1.5.1. replaces the requirement to complete the PRA "Memorandum to File"; document the reason for selecting the importer for inspection in the EIR. Write the EIR according to this subsection and IOM subchapter 5.11.

6.9.1.1- FSVP RECORDS REVIEW

Document the review of the importer's required FSVP records in the EIR. Identify the product and foreign supplier covered by each FSVP. Report the results of the comparison of your pre-inspection hazard analysis and the importer's hazard analysis, if conducted, and any resulting discussion with the importer. This information must be documented with sufficient detail to demonstrate the firm's compliance with FSVP or lack thereof.

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

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

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

during the inspection in the corrective action reporting system (CARS) within eNSpect

6-1 Notice of FDA Action

EXAMPLE

United States Food and Drug Administration

DIVISION OF SOUTHWEST IMPORTS

Notice of FDA Action

Entry Number: ABC-0345241-2

Notice Number: 1
July 11, 2017

Importer:
WARREN'S Produce
PO Box 12345
McAllen, TX 78502

Port of Entry: 2305, Freer, TX
Carrier: EXPRESS Services

Date Received: July 11, 2017
Arrival Date: July 11, 2017

Filer of Record Salinas Brothers Brokerage, Pharr, TX 78577-9499
Consignee: WARREN'S PRODUCE CO., McAllen, TX 78502-4185

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
	11/1	FRESH JALAPENO PEPPERS	700 CT	May proceed 07-11-2017
*	11/2	FRESH SERRANO PEPPERS	200 CT	Pending Review By FDA Compliance Staff 07-11-2017
*	11/3	CALIFORNIA PEPPERS	196 CT	Product Collected by FDA 07-11-2017
*	11/4	FRESH AVOCADOS	1056 PCS	Released 07-11-2017

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

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following 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.

Notice of FDA Action
Entry Number: ABC-0345241-2

Notice Number 1
Page: 2

SAMPLES COLLECTED

Line ACS/FDA	Product Description	Est. Cost
11/3	CALIFORNIA PEPPERS	$3.00

Sample : 12 KG - Sample consists of 12 subs /16 oz (1lb) each of fresh Anaheim peppers collected at random from lot B129A1. Sample was collected aseptically from 12 master cases and packed in 12 whirlpak bags.

LINES RELEASED

Line ACS/FDA	Product Description
11/4	FRESH AVOCADOS

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.

Charles Dominguez, Investigator
U.S. Food and Drug Administration
222 West Avenue
Freer, TX 78041

(956)225-1234
(956) 225-2255 (FAX)
CHARLES.DOMINGUEZ@FDA.HHS.GOV

Notice Prepared For: The District Director, U.S. Food and Drug Administration

Notice Prepared By: CD

[1]This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by districts from the Operational and Administrative System for Import Support (OASIS) may appear different.

EXAMPLE

United States Food and Drug Administration

DIVISION OF SOUTHWEST IMPORTS

Notice of FDA Action

Entry Number: ABC-0345241-2

Notice Number: 2
July 15, 2017

Importer:
WARREN'S Produce
PO Box 12345
McAllen, TX 78502

Port of Entry: 2305, Freer, TX
Carrier: EXPRESS Services

Date Received: July 11, 2017
Arrival Date: July 11, 2017

Filer of Record Salinas Brothers Brokerage, Pharr, TX 78577-9499
Consignee: WARREN'S PRODUCE CO., McAllen, TX 78502-4185

HOLD DESIGNATED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	11/2	FRESH SERRANO PEPPERS	200 CT	Detained 07-15-2017

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

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following 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.

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:

Notice of FDA Action
Entry Number: ABC-0345241-2

Notice Number 2
Page: 2

Line ACS/FDA	Product Description	Respond by
11/2	FRESH SERRANO PEPPERS	August 10, 2017

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

Manuel Salinas, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 West Avenue
Freer, TX 78041

(956)225-2255
(956) 225-2256
MANUEL.SALINAS@FDA.HHS.GOV

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

Notice Prepared For: The District Director, U.S. Food and Drug Administration

Notice Prepared By: ES

[1]This example of a Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by districts from the Operational and Administrative System for Import Support (OASIS) may appear different.

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

APPLICATION FOR AUTHORIZATION TO RELABEL OR RECONDITION NON-COMPLIANT ARTICLES

FORM APPROVED: OMB No. 0910-0046
EXPIRATION DATE: 6/30/2023

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

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

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

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

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

1. TO: Director of _____ Division, Food and Drug Administration

Application is hereby made for authorization to bring the article(s) below into compliance with the Federal Food, Drug, and Cosmetic Act and other related Act(s).

2. APPLICATION DATE

3. ENTRY NO. AND LINE NO.

4. PRODUCT

5. QUANTITY

6. QUANTITY TO BE RECONDITIONED

7. PRODUCTION CODES

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

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

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

9. APPLICANT AND FIRM NAME

10. ADDRESS OF FIRM

11. APPLICANT'S SIGNATURE

SECTION 2 - FDA ACTION ON APPLICATION

12. TO: *(Name and Address)*

13. DATE

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

Time limit within which to complete authorized operations: _____

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

15. SIGNATURE OF DIVISION DIRECTOR

16. DIVISION

17. DATE

FORM FDA 766 (11/20) **Page 1**

PSC Publishing Services (301) 443-6740 EF

SECTION 3 - IMPORTER'S CERTIFICATE

18. Location where reconditioning operation occurred	19. DATE

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

20b. Contact Information: _____

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

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

SECTION 4 - REPORT OF INVESTIGATOR / INSPECTOR

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

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

_____ on: _____, 20 ____,

as authorized, except:

SECTION 5 - DATA ON RECONDITIONED ARTICLE(S)

26. Acceptable Portion:

27. Rejections:

28. Loss (if any):

29. Did importer recondition entire shipment?

30. Time and cost of supervision:

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

33. INSPECTING OFFICER SIGNATURE

6-3 Form FDA 790 Charges for Supervision

CHARGES FOR SUPERVISION

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

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

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

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

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

REMARKS

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

6-4 Sample Collection in OASIS Screen Shot

OASIS Version 5.13.00 (PRDPP) - [Product Collection]

Collections

Entry/Doc/Line No: ABC-1234567-1 | 6 | 1 | Lead Init: IOM | Date Collected: 07-23-2014

Product Code: 28 | B | G | H | 08 | Product Code Desc: Capsicums (Cayenne Chili, Hot Peppers), Grou

Imprtr/Crctd Desc: CHILI POWDER

Location of Goods: ABC Importers, 12345 Main Street NW, Kent, WA

Episode: | Submitted To: PRL-NW | Lab No: 711992

Quantity Collected: 3.5 | Units: KG | Calculated Cost: 11.80

Desc Text: Sample consists of 30 subs/100g each of chili powder collected at ran

Hand/ Ship: Transported from firm in a paper bag, stored in the locked sample prep

Remarks: Storage: ambient. Open and closed controls included. Analyze for Sa

OK | Cancel | Wk Details | Entry Smry | Update | Save Update | View Update | Print Notices

Collection Problem Area

PAF	FACTS PAF	PAC	Reference
MIC	MIC	03819C	Import Foods - General Program (Microbiology)

Get Lab

Desc Text:

OASIS Editor

Sample consists of 30 subs/100g each of chili powder collected at random from lot A124C1. Sample was collected aseptically from 30 bulk master cases and packed in sterile whirl-pak bags.

Hand/Ship:

OASIS Editor

Transported from firm in a paper bag, stored in the locked sample prep room until shipped via UPS to PRL-NW in a cardboard box.

Remarks:

OASIS Editor

Storage: ambient. Open and closed controls included. Analyze for Salmonella.

6-5 FORM FDA 463a AFFIDAVIT

AFFIDAVIT

SAMPLE NO.

STATE OF Texas

COUNTY OF Hunt

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

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

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

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

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

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

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

I read this statement and agree it is true.

AFFIANT'S SIGNATURE AND TITLE

Felicia M. Rodriguez, Import Manager

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

ABC Foods Warehouse, 234 Industry Avenue, Commerce, TX 75428

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

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

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

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

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