CHAPTER 4 - SAMPLING

CONTENTS

SUBCHAPTER 4.1 - GENERAL

4.1.1 - AUTHORITY

4.1.1.1 - Examinations and Investigations

Collecting samples is a critical part of FDA's regulatory activities. The FD&C Act, Section 702 [21 U.S.C. 372(a)] gives FDA authority to conduct investigations and collect samples. A Notice of Inspection is not always required for sample collections. If during a sample collection, you begin to conduct an inspection (examining storage conditions, reviewing records for compliance with laws and regulations, etc.), issue an FDA 482 and continue your activities. See IOM 5.1.1 and 5.2.2.

While inspections and investigations may precede sample collection, a sample must ultimately be obtained for a case to proceed, under the law. Proper sample collection is the keystone of effective enforcement action.

FD&C Act - See IOM section 2.2.1 for this information.
PHS Act - See IOM 2.2.3.7 for this information.

4.1.1.2 - Notice of Inspection

Samples are often collected during the course of an establishment inspection or inspection of a vehicle. See IOM 5.1.1 and IOM 5.2.2.

1. Carriers - Issue an FDA 482 - Notice of Inspection to the driver or agent when it is necessary to inspect vehicles. See IOM 5.2.2.2.
2. Manufacturers, etc. – Issue an FDA 482 - Notice of Inspection when samples are collected from lots in possession of a manufacturer, processor, packer or repacker, whether or not regulatory action is intended toward the articles, the dealer, the manufacturer or the shipper.

4.1.1.3 - Receipt for Sample

Section 704(c) of the FD&C Act [21 U.S.C. 374 (c)] requires issuing a receipt describing any samples obtained during the course of an inspection. The receipt is to be issued to the owner, operator, or agent in charge, upon completion of the inspection and prior to leaving the premises. See IOM 5.2.4 for special situations. See IOM 4.2.5.5 for instructions on completing the form.

4.1.1.4 - Report of Analysis

Section 704(d) of the FD&C Act [21 U.S.C. 374 (d)] requires FDA furnish a report of analysis on any sample of food (including animal food and feed, medicated and non-medicated), collected during an inspection of an establishment where such food is "*** manufactured, processed, or packed ***," if the sample is examined for compliance with Section 402(a)(3) of the FD&C Act [21 U.S.C. 342 (a)(3)]. The servicing laboratory is responsible for furnishing the report of analysis. See FMD 147.

4.1.2 - VALID SAMPLE

A valid sample is the starting point and keystone for most administrative and legal actions. As evidence, the sample must support the government's charge there is a violation of the law. Also, it must conform to the rules on admissibility of evidence. A properly collected and prepared sample provides:

1. A portion of the lot of goods for laboratory analysis and reserve, a 702(b) of the FD&C Act [21 U.S.C. 374 (b)] reserve portion if appropriate, and/or an exhibit demonstrating the violation represented by the lot.
2. A report of your observations of the lot.
3. Labels and labeling, or copies of such, which "accompany" the goods.
4. Documentary evidence of federal jurisdiction over the lot, information about individuals responsible for the violation, where the violation was committed, and similar data.
5. Signed statements from persons who may be called upon as witnesses, if there is a subsequent court action.

4.1.3 - RESPONSIBILITY

Collect every sample as if you will be required to testify in court about everything you did concerning each and every event surrounding the sample collection. Mistakes or deficiencies, however trivial they may seem, can fatally damage the government's case. Be objective, accurate, and thorough.

4.1.4 - OFFICIAL SAMPLES (21 CFR 2.10)

A sample of a food, drug, or cosmetic is an "Official Sample" if records [see IOM 4.4.7] or other evidence obtained shows the lot from which the sample was collected was:

1. Introduced or delivered for introduction in interstate commerce, or
2. Was in or was received in interstate commerce, or
3. Was manufactured in a territory or the District of Columbia.

A sample of a device, a counterfeit drug, or any object associated with drug counterfeiting, no matter where it is collected, is also an "Official Sample". The statute permits proceeding against these articles, when violative, at any time. See Section 304(a)(2) of the FD&C Act [21 U.S.C. 334(a)(2)].

Import Samples are Official Samples and require the same integrity as domestic Official Samples. They must be identified with sample number, collection date and collector's handwritten initials. When sample numbers are not available, an entry/line number may be used. Notify the laboratory that a sample is being sent without a sample number and provide identifying information. Update the laboratory as soon as the sample number is available. Interstate documentation is not required; see CPG manual section 110.200 and 110.600. Import Samples need not be sealed, unless Division policy dictates, as long as the integrity of the sample is maintained.

Normally, 702(b) of the FD&C Act [21 CFR 2.10(b)] portions (hereby referred to as either 702(b) portion or 702(b) reserve portion) are not collected for routine Import Samples. However, in situations where a dispute arises or a potential for regulatory action exists, the 702(b) portions should be collected, and the sample sealed as described in IOM 4.5.4.

4.1.4.1 - Definition - Official Sample

An Official Sample is one taken from a lot for which Federal jurisdiction can be established. If violative, the Official Sample provides a basis for administrative or legal action. Official Samples generally, but not always, consist of a physical portion of the lot sampled. To be useful, an Official Sample must be:

1. Accompanied by records establishing Federal jurisdiction, and identifying the persons having knowledge of the lot's movement and custody of the records. (Evidence of Interstate movement is not required for medical device samples, but, according to policy, is to be obtained when a seizure, injunction, prosecution or civil penalty is contemplated). See IOM 4.4.7.
2. Representative of the lot from which collected.
3. If a physical sample, large enough to permit proper laboratory examination and provide a 702(b) reserve portion when necessary.
4. Handled, identified, and sealed in such a manner as to maintain its integrity as evidence, with a clear record of its chain of custody.

Every physical Official Sample will be fully documented at the time of collection and Collection Reports prepared unless instructed otherwise by the program or assignment.

4.1.4.2 - Documentary Samples

In a "Documentary" (or "DOC") sample, no actual physical sample of the product is taken. A documentary sample is not a sample of records; it is a sample representing a lot of a regulated article (e.g., food, drug, biologic or device). Other elements of an official sample described in 4.1.4 and 4.1.4.1 are required -- see special official sealing instructions below. This official sample consists of the article's labels (or label tracings, photocopies, or photos), accompanying labeling (leaflets, brochures, promotional materials, including Internet websites, etc.) and documentation of interstate movement (freight bills, bills of lading, affidavits, etc. See IOM 4.4.7) Photos of the product, drawings, sketches or schematics, production records, diagrams, invoices or similar items may also be part of the sample. See IOM Exhibits 4-1 and 4-2. As a rule, no FDA 484, receipt for samples is issued during collection of a DOC Sample. See subparagraph 5.2.4.1 for physical evidence exception.

A DOC sample is collected when an actual physical sample is not practical (e.g., very large, expensive, complex, permanently installed devices), in instances where the article is no longer available, or when there is little need for laboratory examination. A single piece of life support equipment for example, which must remain in emergency service until a replacement is available, may be sampled in this manner.

Another instance where a DOC sample might be collected involves a shipment of product recommended for seizure based on misbranding charges. During availability check, the lot sampled is found to have been distributed; however, a new shipment, identically labeled, is on hand. In this instance, the new shipment may be sampled on a DOC basis since another physical sample and examination is not required. Regulatory action may proceed on the basis of the earlier examination. Thus, only labeling, transportation records, the appropriate dealer affidavits, and an inventory of product on hand need be obtained.

A variation of this procedure involves collecting one or more units and removing (stripping) the original labels/labeling from the product container. It is frequently easier and quicker to collect relatively inexpensive units to field strip than it is to photocopy or photograph all accompanying labels. The sample is handled in exactly the same manner as any other DOC sample, once original labeling has been removed and the remainder of the sample destroyed. A prominent explanation on the C/R alerts reviewers that the original units collected were destroyed after the original labeling was removed. This procedure is not appropriate where complete, intact, labeled units are desired for exhibit purposes, even though there is no intention of analyzing the units obtained.

A documentary sample collected to document GMP deviations, should contain records obtained that document the deviations encountered. You should explain what is being documented in the remarks section of the documents obtained screen in FACTS. Fully describe any record collected as part of the DOC sample and where possible indicate the page of the document that demonstrates the deviation.

When non-digital photos are taken as part of DOC samples, the rolls of exposed film should be sent to established commercial film dealers or color processors for developing. Report the identity of the film processor on the FDA 525. Also see IOM 5.3.4.

See IOM 4.5.2.5 and ORA-wide standard operating procedures for guidance on identifying records associated with a DOC sample. Do not officially seal these records, but list them on the C/R. If any photos are taken as part of the DOC sample, the negatives or electronic media, if any, must be officially sealed per IOM 5.3.4.2 or IOM 5.3.4.3. See IOM Exhibits 4-1 and 4-2 for examples of DOC samples. Attach the documents, photos and negatives along with any other records associated with the sample to the printed FACTS Collection Record. See IOM 4.4.10.5.

Advisory Actions and Administrative Actions are types of actions that do not involve the judicial system. These actions include untitled letters, warning letters, regulatory meetings, suspension of registration, etc. Documentary samples are not required to support advisory or administrative actions.

Records of interstate commerce should be collected and incorporated into the establishment inspection report (EIR) in order to document FDA jurisdiction over products suspected to be in violation. Investigators in training may still be required to prepare documentary samples as directed by their supervisor.

4.1.4.3 - In-Transit Samples

In-Transit samples are those collected from lots held on loading/receiving docks of steamships, truck lines, or other common carriers, or being transported in vehicles. The lot is considered to be in-transit if it meets any of the following characteristics:

1. A Bill of Lading (B/L) or other order to ship a lot interstate has been issued.
2. The owner/shipper or agent acknowledges, preferably by signed affidavit, he has ordered the lot to be shipped interstate.

   The owner or operator of the common carrier acknowledges, preferably by signed affidavit, he has an order from the shipper to move the lot interstate.

4.1.4.4 - 301(k) Samples

Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] describes prohibited acts, which can result in one or more separate legal procedures. A sample collected from a lot of food, drug, device or cosmetic which became adulterated or misbranded while held for sale, whether or not the first sale, after shipment in interstate commerce is often referred to as a "301(k) Sample". The term "301(k) Sample" is misleading, but widely used within FDA to describe certain samples collected from lots which become violative after shipment in interstate commerce.

Since some act took place which resulted in the adulteration or misbranding of a previously nonviolative product after shipment in interstate commerce, the "301(k)" documentation is incomplete without identifying the act, establishing when and how it occurred, and the person(s) responsible for causing the violation. This feature, more than any other, distinguishes a "301(k) Sample" from the other Official Samples. When you report the sample collection, the responsible party will always be the dealer. See IOM Exhibits 4-1 and 4-7, “301(k) affidavit.”

For example, to document insect adulteration of a finished product, caused by a live insect population in the processing areas of a food manufacturer such as a bakery, you must document receipt of clean raw material and subsequent adulteration caused by the firm's handling or processing of the raw material. Therefore, you would need to show there was an insect infestation at the firm that either did, or may have contaminated the finished product. You would need to collect a sample of the clean incoming flour, and subsamples at points in the system to demonstrate where insect infestations exist in the system. In situations where sampling may disturb static points in the system, which may result in a higher level of adulteration of the finished product than normal, you should sample in reverse.

301(k) samples can also be used to document adulteration (including noncompliance with GMPs) or misbranding of other regulated commodities, including drugs and biologics. If possible, when collecting a 301(k) sample covering a drug product, you should attempt to document 'adulteration' or 'misbranding' of the active ingredient by the firm's actions. In the case of a biologic (for example, whole blood), which has not moved in interstate commerce, document the interstate receipt of the bag, and the firm's subsequent 'adulteration' or 'misbranding' of the anti-coagulant (considered a drug) in the blood bag.

4.1.4.5 - Induced Sample

An induced sample is an Official Sample ordered or obtained by agency response to some type of advertisement or promotional activity. The sample is procured by mail, telephone, or other means without disclosing any association of the requester or the transaction with FDA. See IOM 4.3.5.4 for additional information.

4.1.4.6 - Undercover Buy

An "undercover buy" is an Official Sample, similar to and obtained in much the same manner as an "induced sample". Undercover buys may be made in person or via a purchase completed either online, or by email, text or phone. Pre-arranged explanations or cover stories are necessary to dispel any suspicions about the requester that may surface in face-to-face, phone or email discussions. "Undercover buys" are frequently used in investigating complaints of illegal activity where the information cannot be substantiated or refuted through more conventional means “Undercover buys” may also augment existing investigation or inspection efforts and be performed to document violations in firms with a history or pattern of noncompliance.

4.1.4.7 - Post Seizure (P.S.) Sample

A lot under seizure is in the custody of the U. S. Marshal. If either the claimant or the government desires a sample from the seized lot, for any reason, it may be collected only by court order. In most cases, the order will specify how the sample is to be collected, and may provide for each party to collect samples. If the order was obtained by the claimant, permit the claimant's representative to determine how his/her sample collection is made. If the method of collection is improper, make constructive suggestions, but do not argue. Report exactly how the sample was drawn. Unless the claimant objects, mark subsamples collected with "P.S.", your initials and date. "P.S." Samples are Official Samples.

Do not pay for Post Seizure Samples or any samples collected of a lot reconditioned under a Consent Decree. See IOM 4.2.8.1.

4.1.4.8 - Domestic Import Sample

To record information on FDA's total coverage of imported products, an additional classification of samples, "Domestic Import" or "DI" was devised. These are Official Samples of foreign products, which have passed through customs and are in domestic commerce. The FDA may have previously taken a sample of the product while in import status, or the product may have been permitted entry without being sampled. If sampled while still in import status, the samples collected are import samples, and not "DI" Samples. However, once the product leaves import status and enters domestic commerce, any sample collected is considered an Official "Domestic Import" (DI) Sample. Note: When collecting DI Samples, especially if a violation is suspected, attempt to determine the port of entry and importer of record. Report this information on the CR. Include the name of the Country of Origin of the product and the Country Code if known.

A sample is classed as Domestic Import (DI), if any of the following situations apply:

1. The label declares the product to be from a foreign country.
2. The label bears the word, "Imported".
3. Records obtained or reviewed reveal the product originated in a foreign country.
4. It is known that the product is not grown or produced in the US; it is packed as a single item with few or no other ingredients added, and it is not manipulated in any major manner, which changes the product or its composition. For example, "Olive Oil" imported in bulk and merely repacked with no added ingredients and no manipulation would be a "DI" sample, while pepper which is processed, ground and packed after entry would not. However, retail packages of ground pepper processed and packaged in a foreign country would be "DI" Samples.
5. Samples of imported raw materials, which are collected before further processing or mixed with other ingredients.

DI samples are significantly different from other official samples in another important respect. Unlike domestic products, where considerable information is readily available on manufacturing and distribution channels, it is frequently difficult to identify the responsible parties for products of foreign origin once they enter domestic commerce. The most practical way is to establish a paper trail of records going back as far as possible in the distribution chain to the actual entry.

Identifying "DI" Samples - When identifying the physical samples, related documents and filling out the seals of Domestic Import samples, preface the sample number with the prefix "DI" in the same manner that other sample type prefixes are used (such as, "DOC", "FS" (See IOM 4.1.5), "PS", etc.)

4.1.4.9 - Import Sample

Import samples are physical sample collections of products, which originate from another country, collected while the goods are in import status. Import status ends when Customs has cleared an entry for the shipment. See IOM 4.1.6.1 and chapter 6.

4.1.4.9.1 Special Domestic Import Sample (SDI)

Special Domestic Import samples (SDI) are import samples collected from lines that are released from import status immediately after collection and before sample analysis is complete. This sample type is used primarily for the collection of perishable products and special sampling assignments. This sample type may also be used for other designated sampling situations as directed. See IOM chapter 6.5.7.

4.1.4.10 - Additional Sample

This is a physical sample collected from a previously sampled lot of either a domestic or imported product.

1. Additional Import Samples - The sample collected must have the same sample number as the original sample collected.
2. Additional Domestic Sample - The sample collected may have another sample number, but it must be flagged as an "ADD" Sample and the original sample number referenced in the "Related Sample" block on the Collection Record.

4.1.4.11 – Reconditioning Sample

Reconditioning Samples - These are taken from lots reconditioned under a Decree or other agreement to bring the lots into compliance with the law. The sample is taken to determine if reconditioning was satisfactorily performed. These samples should be submitted as Official Samples.

4.1.4.12 - Audit/Certification Sample

A sample collected to verify analytical results provided by a certificate of analysis or private laboratory analysis that purports to show a product complies with the FD&C Act and/or regulations. This sample type will usually be used with an import sample. See IOM 4.1.4.9.

The ORA Lab Manual, Volume 3, Section 7 provides specific guidance on FDA audit samples. FDA audit samples provide an opportunity for investigators to examine privately sampled regulated commodities for conformance with the associated submitted private lab package. Prior to collecting a FDA audit sample, careful examination of the lot should be conducted for comparison to private lab package evidence (i.e. photographs and documentation). Examples of items to note during examination and comparison of the private lab's packet include:

- Evidence of marked containers distributed throughout the lot indicative of a representative sample.
- Marked cases that are consistent with the submitted lab package.
- Quantity removed for sampling consistent with the lab package.
- Careful attention should also be paid to any indication that the containers selected for sampling by the private sample collector have been staged for sampling. Staging can occur through markings, deliberate damage to labeling, placement within the pallets, etc.

It is important, if evidence is found that a non-conforming private sample was collected, to immediately terminate audit activities/sampling and to report adverse findings to appropriate Compliance staff for evaluation. The Agency will then make decisions on a lot-by-lot, case-by case basis regarding the entries/sampled products submitted for importation.

Audit samples should be recorded under the same PAC codes as surveillance samples and can apply towards the completion of applicable Work Plan and/or Performance goals.

4.1.4.13 - Mail Entry Sample

A mail entry sample is a sample of an imported product that enters the U.S. through the U.S. Mail. See IOM 4.1.4.9.

4.1.5 - FOOD STANDARDS SAMPLE

Food Standards (FS) samples are collected to provide information on which to base Food Standards. Sample integrity is maintained in the same manner as Official Samples.

Note: Samples of standardized foods are not FS Samples.

4.1.6 - INVESTIGATIONAL SAMPLES

These samples, referred to as "INV Samples", need not be collected from lots in interstate commerce or under federal jurisdiction. They are generally collected to document observations, support regulatory actions or provide other information. They may be used as evidence in court, and they must be sealed, and their integrity and chain of custody protected. Examples of INV Samples are:

1. Samples flagged as" Factory Food Samples" or In-Line samples -Raw materials, in-process and unpackaged finished products to demonstrate manufacturing conditions. See IOM 4.3.7.7.3.

2. Exhibits -Filth exhibits and other articles taken for exhibit purposes during inspections to demonstrate e.g., manufacturing conditions, storage conditions and employee practices. Typically, filth exhibits submitted as part of an INV sample are not tied to any specific lot of product but are meant to illustrate the conditions at a firm. For example, samples flagged as "Inv. Samples of Filth Exhibits" frequently consist of apparent rodent excreta pellets, apparent nesting material, apparent rodent gnawed material, and other evidence of rodent activity. Multiple sub-samples collected along the entire perimeter of a room in a manufacturing facility, food storage area, or warehouse, may be used to demonstrate a rodent infestation. See IOM 4.4.10.1.7.

3. Environmental Samples – See IOM 4.3.7.7.1.

4. Certain Complaint Samples -Injury and illness investigation samples from certain complaints where there is no Federal jurisdiction, or where the alleged violation offers no basis for subsequent regulatory action. Complaint samples from lots for which Federal jurisdiction is clear should be submitted as Official Samples.

When identifying the sample/sub samples and documents related to the sample, and filling out seals, preface the sample number with "INV" in the same manner as other sample prefix types are used (e.g. "DOC", "DI").

Note: Photographs taken to document conditions observed, or sub-samples collected, are included as exhibits to establishment inspection reports. Photographs taken of labeling and records (e.g., B/L, invoice and manufacturing records) that are associated with sample collections are included as attachments to collection reports. See IOM 4.5.2.4, 5.3.3, and 5.3.4.

4.1.6.1 - Non-Regulatory Sample

Samples collected and analyzed by FDA for other federal, state, or local agencies of products over which the FDA has no jurisdiction.

SUBCHAPTER 4.2 - DEALER RELATIONS

4.2.1 - DEALER DEFINITION AND GOOD WILL

For sample collection purposes, the dealer is the person, firm (which could include the manufacturer), institution or other party, who has possession of a particular lot of goods. The dealer does not have to be a firm or company, which is in the business of buying or selling goods. The dealer might be a housewife in her home, a physician, or a public agency; these dealers obtain products to use but not to sell. The dealer may be a party who does not own the goods, but has possession of them, such as a public storage warehouse or transportation agency.

Rapport with the dealer is important to the success of your objective. All dealers, including hostile ones, should be approached in a friendly manner and treated with fairness, honesty, courtesy and consideration. A dealer may be called as a Government witness in a court case, and a favorable attitude on his/her part is to be sought. Never use strong-arm tactics or deception, but rather be professional and demonstrate diplomacy, tact, and persuasion. Do not make unreasonable demands.

Introduce yourself to the dealer by name, title and organization; present your credentials for examination, and, if appropriate, issue an FDA 482, Notice of Inspection. See IOM 4.1.1.2, 4.2.4, 5.1.1.3 and 5.2.2. Explain the purpose of your visit. Be prepared to answer the dealer's questions and attempt to relieve any apprehensions while at the same time being careful not to reveal any confidential information. Do not disparage the product, its manufacturer, or shipper. Do not reveal the particular violation suspected unless the dealer is responsible, or unless you ask him/her to voluntarily hold the goods. The very fact we are collecting a sample is often reason enough to arouse the dealer's suspicions about the legality of the product.

4.2.2 - DEALER OBJECTION TO SAMPLING PROCEDURE

If the dealer objects to your proposed sampling technique, attempt to reach a reasonable compromise on a method that will provide a satisfactory, though perhaps not ideal, sample. Assure the dealer that you will make every effort to restore the lot to its original state, that you are prepared to purchase a whole unit to avoid leaving broken cases, and that the Agency will reimburse him/her for additional labor costs incurred as a result of sampling. See IOM 4.2.8. If a reasonable compromise cannot be reached, proceed as a refusal to permit sampling.

4.2.3 - REFUSAL TO PERMIT SAMPLING

Challenges to FDA authority while collecting samples may be encountered by a dealer who, for various reasons including, personal and professional, opposes the activities of the Agency, or of governmental units in general.

Refusals to permit sample collection commonly emerge unless you can identify a section of the law which specifically authorizes it. The suggested approach for dealing with these individuals is to use patient, tactful persuasion, pointing out that the sample is a part of the investigations authorized in Section 702 [21 U.S.C. 372(a)]. If you have not already done so, issue an FDA 482 - Notice of Inspection (except in the case of foreign inspections- see IOM 5.1.3) as soon as it becomes apparent the dealer will continue to object.

Point out and discuss the authorities provided by FD&C Act sections 702(a), 702(b), 704(a), 704(c), 704(d) [21 U.S.C. 372(a),(b) and 374(a), (c), (d)]and the precedent case mentioned in IOM 2.2.1. If refusal persists, point out the criminal prohibitions of Section 301(f) of the FD&C Act [21 U.S.C. 331(f)].

If samples are still refused, leave the premises and contact your supervisor immediately. Refer to IOM section 5.2.5 and Compliance Policy Guide manual section 130.100 for further discussions on resolving the impasse.

4.2.3.1 - Limiting or Preventing Collection of Samples of a Drug

Preventing an authorized representative of the FDA from collecting drug samples may be considered as limiting the inspection. If you have appropriately issued a FDA 482 – Notice of Inspection and the dealer impedes your ability to collect samples, point out and discuss the authority provided by Section 501(j) of the FD&C Act [21 U.S.C. 351(j)] under Section 707 of the Food and Drug Administration Safety and Innovation Act (FDASIA), that potentially deems all drugs manufactured at the facility adulterated in the case of limiting an inspection. In situations where you have begun an inspection, but no FDA 482 is issued (e.g., foreign inspections), document this fact and the limiting activities in your notes based on the authority described above.

If refusal persists, point out that adulteration under section 501(j) of the FD&C Act [21 U.S.C. 351(j)] could lead to further prohibited acts under 301(a), (b), and (c) [21 U.S.C. 331(a), (b), (c)].

Also see IOM 2.2.1.4.

4.2.4 - NOTICE OF INSPECTION

See IOM 4.1.1.2, 5.1.1.3, 5.1.1.5 and 5.2.2.

Each time you issue an FDA 482, Notice of Inspection, and subsequently collect a sample, issue the appropriate sample receipt (FDA 472 - Carriers Receipt for Samples or FDA 484 -Receipt for Samples).

4.2.4.1 - Dealer Responsible for Condition of Lot

An FDA 482 should be issued before collecting samples from firms, carriers, or individuals whom FDA can take regulatory action against for the violative condition of the lot. See IOM 4.1.1.1. When in doubt, issue a Notice of Inspection. If there is no EIR, attach a copy of the FDA 482 to the FACTS Collection Record. See IOM 4.4.10.5.

4.2.4.2 - Refusals

See IOM 4.2.3. If a FDA 482 has been issued prior to a sample refusal situation, the copy of the FDA 482 is to accompany the EIR or a memorandum outlining the facts of the refusal if no EIR is prepared.

If you are on a foreign inspection in which a FDA 482 is not issued, reference relevant Compliance Programs and Chapter 3 of the Guide to International Inspections and Travel Manual for reporting guidance.

4.2.4.3 - Carrier In-Transit Sampling

Caution: See IOM 4.3.4 for conditions, which must be met before collecting in-transit samples from common carriers.

When collecting samples from in-transit lots in possession of a commercial carrier, issue the carrier or his agent an

FDA 482. Attach a copy to the copy of the FACTS Collection Record. See IOM 4.4.10.5.

4.2.4.4 - Dealer Requests Notice of Inspection

When inspecting a dealer, and an FDA 482 does not need to be issued, but the dealer requests a Notice of Inspection, issue an FDA 482. Attach a copy to the FACTS Collection Record. See IOM 4.4.10.5.

4.2.5 - RECEIPT FOR SAMPLES

Any time you collect a sample after issuing an FDA 482, Notice of Inspection, always issue the appropriate sample receipt FDA 472 - Carriers Receipt for Samples or FDA 484 Receipt for Samples.

Always issue an FDA 484 as a receipt for samples of prescription drugs, including narcotics and controlled substances. See IOM 4.2.5.3, 4.2.5.4, and 5.2.4.

4.2.5.1 - Carriers/In-Transit Lots

Caution: See IOM Exhibit 4-4. Give the original to the carrier or his agent and route a copy to the appropriate fiscal unit for your division. The fiscal clerk will notify the consignee and consignor that a sample has been collected so the owner can, if desired, bill FDA for the sample.

4.2.5.2 - Dealer Requests Receipt

When collecting physical samples of regulated products, not in connection with an EI or where no FDA 482 has been issued, do not routinely issue an FDA 484, Receipt for Samples, except for prescription drugs, narcotics, or controlled substances. See IOM 4.2.5.3 and 4.2.5.4. If any dealer specifically asks for a receipt, prepare and issue an FDA 484 and route a copy with any other records associated with the collection record. See IOM 4.4.10.5.

4.2.5.3 - Narcotic and Controlled Rx Drugs

Regulations of the Drug Enforcement Administration (DEA) impose strict controls and comprehensive record-keeping requirements on persons handling narcotics and controlled substances. As a result, an FDA 484 must be issued for all samples of such drugs collected by FDA.

Each dealer in narcotic and controlled drugs is assigned its own unique DEA registration number. Any time you collect a sample of a narcotic or controlled drug, be sure the Dealer's DEA Registration Number is entered in the appropriate block of the FDA 484. Double-check the number for accuracy. An error may result in possible investigation for drug shortages.

When samples of narcotic or controlled drugs are collected, the complete DEA Registration Number must be entered on the - RECEIPT FOR SAMPLES, given to the person from whom the samples were collected.

Concise completion of the FDA 484 for samples of narcotic or controlled drugs includes the trade and chemical name, strength, sample size, container size, lot, batch, or control number, manufacturer's name and address, division address and the sample number. See IOM 4.4.10.5. Use of the FDA 484 as a Receipt for Samples of these drugs has the approval of DEA. (See reverse of FDA 484).

4.2.5.4 - Prescription Drugs (Non-Controlled)

Issue an FDA 484, Receipt for Samples, when samples of prescription legend drugs are collected from dealers, individuals, or during inspections. Attach a copy of the FDA 484 to the FACTS Collection Record. See IOM 4.4.10.5.

4.2.5.5 - Preparation of FDA 484

Complete the blocks on the FDA 484 (Exhibit 4-5), Receipt for Samples, as follows:

Block 1 - Enter your Division address and telephone number including area code.

Block 2 - Enter the complete name and official title of the individual to whom you issue the FDA 484.

Block 3 - Enter date on which you finished collecting the sample. If you spent more than one day on the sample collection, enter the date you completed sampling.

Block 4 - Enter the complete Sample Number here. Be sure to include any prefixes such as "DI", "INV", etc.

Block 5 - Enter the firm's legal name.

Block 6 - If the firm is a dealer in narcotics or control drugs, enter their DEA Number here.

Block 7 and 8 - Enter the number, street, city, state, and zip code of firm.

Block 9 - Enter a brief description of the article collected, including the number and size of units collected, product name and any identifying brand and code marks.

Block 10 -. Check the appropriate box on the FDA 484.

Block 11 - Enter the amount paid for the sample (even if borrowed, the owner may ask rent for it) and check the appropriate box. If there is no charge (always offer payment except for Post Seizure Samples), enter N/C and leave boxes blank. If, as a last resort, it is necessary for you to use your personal check or credit card and this is acceptable to the person, enter amount and check "Credit Card." box.

NOTE: Older editions of the FDA 484 do not have a "Credit Card." box. If using older editions, write "Credit Card" following the sample amount.

Block 12 - In instances where payment is made for the Sample, whether actually purchased, borrowed or provided at no charge, and there is no Dealer's Affidavit, or any other document executed to show the owner's signature for receipt of payment, obtain the signature of the person receiving payment for the sample.

If Dealer's Affidavit, regular Affidavit or other document is used, the recipient's signature will be on that document, so it is not necessary for him to also sign the FDA 484. In this case insert an applicable statement such as "Dealers Affidavit signed" in this block.

Blocks 13, 14, and 15 - Enter your name, title and signature.

4.2.5.6 - Routing of FDA 484

Original - Give the signed original to the firm, preferably to the individual to whom you gave the FDA 482 and FDA 483. See IOM 4.2.5.3 regarding receipts for narcotics and controlled drug samples.

First Carbon - Accompanies the EIR. If no EIR is involved such as when collecting a sample and the dealer specifically requests a receipt, attach it to the original Collection Record. See IOM 4.2.5.2, 4.2.5.3, and 4.2.5.4.

Second Carbon - This is an extra copy for use as needed. If not filed in the factory file or attached to the C/R or not otherwise needed, it may be destroyed.

If exact copies are used instead of carbon copies, then route one exact copy with the EIR and a second as above.

When numerous subsamples are collected, the second carbon or exact copy may be attached to the original C/R to avoid repetition of the sub descriptions. When used for this purpose, be sure the numbers you assign to the physical subsamples matches those on the FDA 484, and that the subs are adequately described. See IOM Exhibit 4-5. If errors are noted after issuance, handle the same way as instructed under IOM 5.2.3.1.6.1 and IOM 5.2.3.1.6.2.

4.2.6 - DEALER IDENTIFICATION OF LOT AND RECORDS

Positive identification of sampled lots and the records covering their sales and shipment are essential to legal proceedings. The dealer's identification of a sampled lot and his identification of the records covering I.S. shipment should be factual and specific. If there is a question about accurate identification of the lot or records, determine all facts and establish identification as clearly as possible. Be alert to any identifying marks, which may later be used on the witness stand for positive identification.

4.2.6.1 - Private Individuals

When collecting Official Samples from private individuals, ask the individual to initial and date the label, wrappings, promotional literature, etc. This will aid in positively identifying the product and related documents in any court proceedings that may develop months, or even years later.

4.2.6.2 - Seriously Ill Individuals

If you collect samples from a person for contemplated regulatory action, and it is obvious the person is seriously ill, you should attempt to locate and obtain a corroborating statement and identification from someone else. This corroborating witness should have personal knowledge of the facts and be available if the principle witness cannot testify in a legal proceeding.

4.2.7 - SAMPLING FROM GOVERNMENT AGENCIES

See IOM Subchapter 3.2 for sampling information specific to Other Government Agencies (OGA).

4.2.8 - PAYMENT FOR SAMPLES

Payment for all samples, except those collected under authority of a Court Order or Decree, shall be offered to the person from whom the sample(s) were obtained regardless of the amount. See IOM 4.2.8.2.

An exception is import samples. FDA does not pay for Import samples at the time of collection. The importer should bill the Division Office. FDA will not pay for violative import samples. See 21 CFR 1.91.

4.2.8.1 - Post Seizure (P.S.) and Reconditioning Samples under Court Order

Do not pay for, or offer payment for, any Post Seizure (P.S) or other samples including those from reconditioned lots, if collected under authority of a Court Order or Decree. If the dealer insists on payment before permitting sampling, show him/her the Court Order. If he/she still refuses sampling, contact your supervisor immediately for further instructions. You may be instructed to notify the U.S. Attorney.

4.2.8.2 - Determining Sample Cost

If you are collecting samples from firms or representatives of firms who have Federal Supply, Veterans Administration or other contracts with the Federal Government, the cost of the sample should be determined by the scheduled price. Inquire of the firm if they are on contract for the item. If so, pay only the scheduled price.

Some dealers may wish to charge their regular selling price. However, if the cost of the sample seems excessive, try to persuade the dealer into charging a lower price that is more equitable. If asked, inform the dealer that the government considers a fair price to be the dealer's invoice cost plus a nominal charge (usually 10-15%) for freight, handling and storage.

If unable, through tactful discussion, to convince the dealer to lower the sample cost, do not haggle over the price to be paid. If the cost seems exorbitant, check with your supervisor to determine if the sample size can be reduced, or for further instructions. Whenever there is a disagreement over sample cost, ask the dealer to bill the division and report the circumstances in the Collection Remarks field on your FACTS collection record.

If divisions encounter requests for payment for method validation samples (either direct submission by firms to labs or during collection from responsible firms), they should contact the appropriate Office of New Drugs- CDER, or CVM, so that communication may take place with the application sponsor. If product is being collected from commercial distribution not in the control of the sponsor/manufacturer, then the division should expect to pay wholesale cost. Expenses for NDA method validation samples should be charged to a PDUFA reimbursable CAN.

4.2.8.3 - Method of Payment

There are two main ways to pay for samples. The sample costs may be billed to the division or cash may be used to pay for the sample. As a last resort, you can use your personal credit card to pay for the sample. Personal funds may be used to pay for samples when an ATM cash withdrawal is unavailable, or when otherwise authorized by division policy. See IOM 4.4.10.3.50 and 4.2.5.5.

4.2.8.3.1 - Costs Billed To Division

Billing sample costs to the division is, in many instances, the most practical method of payment. This is particularly true where substantial costs are involved due to large sample size, expensive samples, when samples are collected from third parties such as carriers and public storage warehouses, or when delivery followed by subsequent billing is the dealer's normal business practice. If available, obtain the dealer's invoice and submit it to the appropriate fiscal unit for your division.

Sampling from public storage warehouses and common carriers incurs costs, which are normally billed because the owner of the product is unavailable. Determine the identity of the owner or his agent and estimate the value of the goods sampled. Arrange with the owner or agent to bill the division.

4.2.8.3.2 - Cash Payment

If you have a government credit card and you need cash to pay for a sample, you are authorized to use your government credit card to withdraw an ATM advance to pay for your sample whether or not you are in travel status. The amount of the withdrawal should be limited to the cost of the sample. You should submit your itemized claim for samples along with the cash withdrawal fee by submitting a local voucher using electronic travel management system. Include the sample number and submit to your fiscal unit for payment. Any documentation should be provided. Sample costs cannot be charged directly to your government credit card.

4.2.8.4 - Sampling - Labor Charges

Additional labor, use of forklift, or other assistance may be required to move merchandise, skids, pallets, etc., to properly sample and restore the lot. Usually assistance will be available on the premises, or arrangements can be made with management to employ outside professional help.

There is usually little need to discuss payment when requesting nominal use of labor or equipment. However, if there is an indication management expects payment, attempt to reach a clear understanding of the charges before proceeding. If the charges to be incurred appear reasonable, and the cost is minor (about $25.00 or less), proceed with the work and add the charges to your sample cost. However, if substantial costs are involved, consult with your supervisor before making a commitment to pay.

Where the charges are substantial and have been authorized by your supervisor, arrange for the cost of labor and/or machinery to be billed to the division. Handle these charges separately from the actual cost of the sample. Determine the hourly rate and keep track of time, labor, or machinery actually used. Prepare a short memo outlining the charges and submit it to your division.

4.2.9 - VOLUNTARY EMBARGO

This section deals solely with a "voluntary" hold on regulated products. See IOM 2.7.1 for specific statutory authorities for detaining meat, poultry, egg products, and medical devices.

While there is no specific authority for requesting a voluntary embargo on a lot, voluntary embargoes by a dealer shall be encouraged where the lot sampled is clearly adulterated. By voluntarily holding, the dealer prevents further distribution of suspected violative goods until seizure or other appropriate action can be accomplished.

4.2.9.1 - Perishable Goods

Except in rare instances, it is generally not practical to hold highly perishable items unless the analysis can be completed within 24 hours. You should confer with your supervisor before requesting a voluntary embargo on perishable items.

4.2.9.2 - Obtaining a Voluntary Embargo

When the lot is clearly adulterated, or when instructed to do so by your supervisor, arrange for a voluntary embargo by the dealer. If possible, direct your conversation so that the dealer suggests the embargo. Call the dealer's attention to his/her responsibility under the law, and appeal to his/her sense of public service, integrity, or the health consequences that may be involved.

Always place a time limit on voluntary embargoes using your best estimate of how long it will take to complete the analysis and reach a division decision. Consider such factors as location of the examining lab, difficulty of the analysis required, turnover rate, storage conditions and the perishable nature of the merchandise. Note: Your division's compliance branch can request an extension of the voluntary embargo.

Since the action is voluntary, we cannot compel the dealer to do all the things we might ask him/her to do. While requests for voluntary holds are generally granted, a dealer may act or suggest an alternative approach.

If the dealer indicates a reluctance to voluntarily hold the lot, call his/her attention to Section 301(a) of the FD&C Act [21 U.S.C. 331(a)]. If the dealer still refuses, a state embargo may be the next action of choice. See IOM 3.3.1 and consult your supervisor.

If the dealer declines to hold the lot, but proposes returning it to the shipper, the dealer should be warned NOT to return the goods to the shipper and advised FDA does not condone shipping violative goods. Direct his/her attention to Section 301(a) of the FD&C Act [21 U.S.C. 331 (a)].

If the dealer offers to voluntarily denature or destroy the lot in lieu of voluntary embargo, provide or arrange for supervising the denaturing per IOM 2.8.1. If the dealer proposes to recondition the lot, refer him/her to your division compliance branch for approval of his/her method. See IOM Subchapter 2.6 and IOM 2.6.3.

SUBCHAPTER 4.3 - COLLECTION TECHNIQUE

Sampling operations must be carried out using techniques that ensure the sample is representative of the lot, the sample of the product is in the same condition as it was before sampling, and that the collection technique does not compromise the compliance status of the lot.

4.3.1 - RESPONSIBILITY

It is your responsibility to collect your own samples using techniques and methods which will provide the most ideal sample, yet not be objectionable to firm management. This subchapter and the sampling schedules that follow, contain many sampling techniques, but not all. Your training and experience will enable you to become proficient in most sampling operations. However, in new or unusual situations it is your responsibility to use imagination and ingenuity in getting the job done and, if necessary, to consult with your supervisor.

4.3.2 - LOT RESTORATION & IDENTIFICATION

4.3.2.1 - Restoring Lot(s) Sampled

Restore lots to their original condition. Do not leave partially filled shipping cases, short weight or short volume containers in the lot after sampling. Do not leave the lot in any condition, which might encourage pilferage, or make it unsalable.

When collecting from either full cases or bulk containers, replace sampled units by back filling from a container selected for that purpose. Avoid contaminating the back-filled units. If necessary, correct the contents declaration on the container(s) from which sampled to reflect the actual contents present. Refer to IOM 4.2.2 if the dealer objects to back filling because of company policy, different codes involved, or for other reasons. As a last resort, accede to the dealer's wishes and sample intact units, but record the facts in your regulatory notes and place a brief explanation on the C/R.

Carefully re-close all containers and shipping cases. (Commercially available glues in spray cans or plastic squeeze-type bottles are an effective means of re-gluing containers and cases without defacing with tape or other methods.) Re-cooper or reseal barrels and drums, re-sew bags, etc. If necessary, request use of the dealer's employees in helping to restore the lot or arrange through the dealer to employ outside help. See IOM 4.2.8.4.

4.3.2.2 - Identifying Lot(s) Sampled

Identify each container from which units are taken with the date, your initials and the sample number. **NOTE:** For import samples, identify each master container from which units are taken with the following: FDA, division abbreviation, sample date and the lead investigator's initials.

Should the dealer object to your identification procedure, attempt to reach a compromise (e.g., placing the ID in an obscure location, etc.). If the dealer still objects, accede to his wishes, but record the facts in your regulatory notes.

Positive identification of the containers sampled is important if it becomes necessary to resample the lot(s), or if an embargo, seizure, or other action ensues. It also aids the dealer to differentiate between containers that have been opened by FDA as opposed to those opened by pilferage or torn opened by rough handling. It may be necessary to mark more containers than sampled to assure proper identification of the lot. This can be done by using the Examination Label, a handwritten ID or by using a rubber stamp.

Do not use industrial or permanent type markers on sample containers which allow penetration by ink. Many inks will penetrate to the product and act as a contaminant, interfering with the analysis. Water base markers will run

when damp and must be covered with tape. See IOM 4.5.2.3 for identification techniques.

Do not permanently identify articles that are borrowed and will be returned to the dealer.

4.3.3 - SAMPLE SIZE

To determine sample size, first consult your assignment. If the assignment doesn't specify the sample size, follow the guidance in the applicable Compliance Program. The IOM SAMPLE SCHEDULE, should be used if the Compliance Program doesn't state the sample size. If none of these furnish the sample size, consult with your supervisor or the laboratory. Collect sufficient sample to allow for the 702(b) portion. See IOM 4.3.3.2 and 4.3.3.3.

4.3.3.1 - Medical Device Samples

The following table represents the devices for which there are sampling instructions in Compliance Policy Guides:

Device	CPG Reference
Clinical Thermometers	See CPG 335.800
Condoms	See CPG 345.100
Surgeons and Patient Exam Gloves	See CPG 335.700

In addition to providing instructions on sample size, these compliance policy guides provide guidance on criteria to determine adulteration and whether or not regulatory action should be recommended. See WEAC's webpage for additional guidance involving glove sampling.

4.3.3.2 - 702(b) Requirement

When the sample schedule, assignment or other instruction does not specifically provide for the 702(b) portion, collect a sufficient amount to provide this required portion and indicate duplicate availability in the FACTS CR by checking the 702(b) box. You are not required to obtain a 702(b) portion in the following instances exempted by statute or by regulation 21 CFR 2.10(b):

1. Devices and tobacco products are not included in the statutory requirement of Section 702(b).
2. The amount available for sampling is less than twice the quantity estimated to be sufficient for analysis, in which case, collect all that is available.
3. The cost of twice the quantity estimated to be sufficient for analysis exceeds $150.00. If the sample is critical, and the cost exceeds $150.00, check with your supervisor.
4. The sample cannot by diligent use of practicable preservation techniques available to the Food and Drug Administration be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as the Food and Drug Administration's analysis. If unclear consult with your Supervisor or servicing laboratory to confirm that practicable preservation techniques are not available before relying on this exception.
5. Import samples, collected from a shipment being imported or offered for entry into the United States.
6. The sample is collected from a person named on the label of the article or his agent, and such person is also owner of the article. For example, it is not necessary to obtain a 702(b) portion if the sample is collected from a lot owned by and in the possession of the manufacturer whose name appears on the label.
7. The sample is collected from the owner of the article or his agent, and the article bears no label, or if it bears a label, no person is named thereon.

In the remarks section of the CR, describe the specific circumstances and justification for not collecting the 702(b) portion. The documentation is not needed if the product is a device or tobacco product, or the assignment or compliance guide already states why the 702(b) portion is not needed.

Note: Regardless of the exemptions under 21 CFR 2.10(b) listed above, collect the 702(b) portion for filth samples unless your supervisor directs otherwise.

4.3.3.3 - Collecting the 702(b) Portion

Whenever possible, collect separate subsamples in order to provide the firm a portion as required by Section 702(b). Each duplicate subsample should be collected from the same bag, box, case, or container. The total sample should be at least twice the quantity estimated to be sufficient for analysis, including a reserve portion for FDA's laboratory. If unable to collect separate subsamples, assure that the total amount collected for each sample subsample, or the total amount collected from an undivided sample, is at least twice the amount estimated to be sufficient for analysis. See IOM 4.3.7.4 and 4.4.10.3.63.

4.3.4 - IN-TRANSIT SAMPLES

The exterior of any domestic package thought to contain an article subject to FDA regulation and in the possession, control, or custody of a common carrier may be examined (photographed, information on the outside copied, etc.) and records of the shipment may be obtained. Such package may not be opened either by an FDA employee or by an employee of the common carrier at the request of an FDA employee except as provided below.

4.3.4.1- Examination without a Warrant

The Office of Chief Counsel has advised FDA employees may, without a warrant, open, examine the contents and/or sample a package which is part of a domestic commercial interstate shipment in the possession, control, or custody of a common carrier only if:

1. The consignor or consignee affirmatively consents to examination and/or sampling of the contents; or
2. The Agency has reliable information the carrier regularly carries FDA regulated articles, and the facility where the sampling is contemplated is subject to FDA inspection.

Reliable information may come from agency files, the carrier itself, other customers of the carrier, etc. and

3. The Agency has reliable information a particular package sought to be examined is destined for, or received from another state, and contains an FDA regulated article. [Such information may be found on the exterior of the package and/or shipping documents in specific terms. Information may also come from reliable sources, which establish the consignor is in the business of manufacturing and/or shipping FDA regulated articles using a distinctive type of package (shipping container); and the package in question meets such description and shows the consignor to be such firm.]

4.3.4.2 - Examination with a Warrant

Confer with your supervisor on any question concerning the need for a warrant. However, headquarters approval must be obtained because such inspection and sampling may require a search warrant. Contact the Office of Operations (OO) to discuss the matter. They will coordinate as necessary with Office of Enforcement and Import Operations and the Office Chief Counsel and provide further instructions.

If a decision has already been made by the division office to obtain a warrant, follow the procedures outlined in the Regulatory Procedures Manual, Chapter 6-3.

If a common carrier reports a violative article which it discovers under its own package opening procedures, independent of any request by an FDA employee or any standing FDA cooperative program with the carrier, FDA may still need a warrant to examine the material. Unless all the conditions for independent sampling in IOM 4.3.4.1 1 or 2 exist, you must consult with your supervisor, who will arrange for headquarters consultation as outlined above.

Note: Where the identity of an Interstate product is known by virtue of it being visible in bulk or being in labeled containers or packages which are verified as to contents by shipping records, and where such product is under FDA jurisdiction at a given location, it may be sampled according to established IOM procedures.

4.3.4.3 - Resealing Conveyances

If it is necessary to break the commercial seal to enter a railcar or other conveyance, reseal the door with a numbered self-locking "U.S. Food and Drug" metal seal. Record in your regulatory notes (and on C/R if sample taken) the number of the car or conveyance, the identifying number on any car seals removed, and the number of the FDA metal seals applied.

4.3.5 - SPECIAL SAMPLING SITUATIONS

There will be situations that arise where the dealer may need to sample product for you due to safety and/or other concerns. After evaluation of the situation and prior to allowing dealer sampling, contact your supervisor for appropriate guidance and concurrence. If permissable, all dealer sampling must be done with your direct oversight. Note dealer sample collection in your CR.

Do not collect human or animal biological materials (urine, feces, sputum, blood, blood products, organs, tissue etc.) unless arrangements for special handling and special treatment have been made in advance. Most ORA servicing laboratories are not prepared or certified to handle these materials. In addition to guidance for special sampling situations provided below, sampling guidance may also be found in IOM Subchapter 1.5 – Safety under IOM 1.5.3 - Sampling.

Sampling Containers for Lemon Oil or Other essential oils - Plastic or paraffin-coated liners in caps of containers used to hold samples of this type of product are not satisfactory in that the plastic or paraffin is soluble in the oils and interferes with the analysis. Use glass, cork, foil covered, or non-plastic, non-paraffin closures.

Sampling medicinal and other gases - Gases represent a special sampling situation. Please contact your servicing lab to determine an appropriate sampling container and sample size.

4.3.5.1 - Complaints, Counterfeiting / Tampering, Foodborne Disease, Injury Illness

Detailed instructions for investigating and sampling products in connection with consumer complaints, tampering, foodborne outbreaks, injury and adverse reactions, etc. appear in the following subchapters and sections of the IOM:
IOM 8.2 - Complaints
IOM 8.2.7 - Sample Collection
IOM 8.3 - Investigation of Foodborne Outbreaks
IOM 8.3.3 - Sampling Procedure
IOM 8.4 - Investigation - Injury& Adverse Reaction
IOM 8.8 - Counterfeiting/Tampering
IOM 8.8.5.3 - Sampling

Be cognizant of conserving scarce resources when investigating consumer complaints that do not involve injury, illness, or product counterfeiting / tampering. Unnecessary samples waste both operational and administrative resources. Use judgment as to whether or not it is necessary to collect the consumer's portion in situations that do not involve injury, illness, or product tampering. For example, there is little need to collect a physical sample of an insect infested box of cereal from the complainant. Both you and the consumer can readily see it is insect infested. The laboratory would find it insect infested, and the division would merely report the same thing back to the complainant. No practical purpose would be served by either collecting or examining such a sample.

During consumer complaint investigations/follow-up when blood or body fluid contamination is suspected, and when there is no apparent illness or injury, samples should not be

collected without first contacting Emergency Operations due to the lack of confidence in the analytical methods and the results associated with certain samples. A decision to collect a sample will be made on a case by case basis, and after consulting with the Office of Regulatory Science, Emergency Operations, and the Office of Medical Products and Tobacco Operations.

4.3.5.2 - Recalls

See IOM 7.1 and 7.1.1.7.

4.3.5.3 - Natural Disasters

See IOM 8.5.

4.3.5.4 - Induced Samples

If this type sample is desired, your supervisor will provide specific instructions and procedures to be followed. This may involve:

1. Whether to use your correct name or an alias. Caution: if you use an alias, do not use a similar name or a name with initials the same as yours (e.g., Sidney H. Rogers should not use Samuel H. Right). In addition, do not use a division office or resident post as a return address when ordering products or literature.
2. Do not telephone your order in from the office or your home phone because the firm may have "Caller ID" and be able to identify your location by the phone number. For samples induced online, use a non-FDA network computer.
3. Whether to use order blanks contained in the promotional package, advertisement, or promotional activity; or whether false ones will be used.
4. Whether money orders, your credit card numbers, bank checks, or your personal checks should be used for payment. It depends on the situation, but money orders are preferred since these do not involve personal accounts.
5. Where the requested items are to be sent: rented P.O. Box, home address, General Delivery, or other address.
6. How the address and/or your name is to be recorded on the order blank. A code may be used either in your name or address, so any follow-up promotional material sent to that name and address can be keyed to your original order.

When it has been decided to induce a sample and you have discussed the procedures with your supervisor, prepare the order and obtain the money order, or payment document. When all documents for ordering the item(s) are prepared, photocopy all the material, including the addressed envelope, for your record and submit the order.

When the order is received, identify the sample item, all accompanying material such as pamphlets, brochures, etc. (including all wrappings containing any type of printing, identification, numbers, post marks, addresses, etc.), and submit the item and exhibits in the same manner as any other official sample. If payment of the item was by personal check or credit card number, attach a photocopy of the canceled check or credit card receipt if available. You may do this later, after clearance of the check or charge slip. Samples induced online should include a record of the purchase process including point of sale, relevant emails and documentation of where and how the sample was received and collected.

4.3.5.5 - Undercover Buy

See IOM 4.1.4.6.

4.3.5.6 - Collecting Surveillance Samples on Farms

Specific instructions have been developed for the collection of surveillance samples on farms or from on-farm packinghouses or processors, including pre-notification, interaction with the farm personnel, payment for samples collected on farms and sample size(s). Though these instructions only apply to surveillance samples, they may also be considered for illness investigations or for cause sampling but are not required.

On farm collections should be limited to instances where it is specifically mentioned in an assignment or is preferred by the industry or other sampling venues are not available. When an investigator is planning to collect surveillance samples on a farm, the investigator will call the farm at least 24 hours in advance to notify the farm of FDA's intent to collect samples and share the commodity of interest. There may be instances when responsible farm management will not be available on the planned date and time and the investigator will need to use his/her judgment in negotiating alternate dates as appropriate.

During the pre-notification call, the investigator should also determine an estimate of what the sample(s) will cost if the farm decides to charge for the samples. The investigator will take enough cash to cover the cost of the samples collected and not ask the farm to bill FDA as may be done in other sampling situations.

If the investigator collecting the sample is a PHS Commissioned Officer, the investigator will explain to the farm representative that he/she will be wearing his/her uniform. During this conversation, the officer will describe the uniform he/she will be wearing (e.g., blues, khakis) and also explain why the officer wears the uniform as a Commissioned Officer in the Public Health Service.

When on farm and viewing the inventory of product to be collected, the investigator will determine if the sample size needed will exhaust the farm's supply of the product or may cause the farm to not be able to meet customer needs. If so, consideration should be given to not collecting the sample or if possible modifying the sample collection. If the sample collection will exhaust the entire inventory, the investigator should discuss this with responsible farm

management and determine how soon inventory will be restored and if the responsible individual believes the sample collection will impose an economic disadvantage. If the responsible party states that it will cause an economic disadvantage, the investigator should not collect the sample at that time, but rather plan to return at another time when additional inventory will be available for sampling or consider selection of another site for collection.

4.3.5.7 - Collecting Feed Samples for BSE Analysis

If your work involves collecting samples for BSE analysis, please review Compliance Program 7371.009, BSE/Ruminant Feed Ban Inspections, specifically Part IV – Analytical, as well as Attachment E of that section for pertinent safety procedures.

Investigators need to be aware of proper safety procedures for collecting, packaging and shipping domestic and imported feed samples. The main objective of safety recommendations is to minimize exposure to feeds and feed dust at the time of sample collection and to minimize future exposure through feed dust on clothing or equipment.

Safety precautions listed should be followed for ALL sample collections for BSE analysis, both import and domestic. Use of these procedures will also minimize exposure risk to other potential pathogens and it is encouraged to follow these procedures whenever any dusty feed samples are collected.
In CP 7371.009, Part IV- Analytical, there are instructions regarding the collection of samples. The CP notes, "**CAUTION:** This material may be dusty and consist of fine particles, especially if the product is in bulk. Exercise appropriate precautions when collecting samples of dusty, loose material**.** Refer to "Safety Information for Imported Feeds Assignment - Collection and Analysis".

Minimizing dust exposure can be accomplished as follows:

1. **Recommended personal protective equipment (PPE) to be used by personnel collecting feed samples**:

   - Respiratory protection: minimum half-mask air-purifying respirator (face-sealing) with P100 filters (HEPA)
   - Ocular (eye) mucous membrane protection: goggles
   - Percutaneous (through skin openings such as cuts, abrasions- unbroken skin poses no known hazard) – waterproof gloves on hands; cover skin lesions, cuts, abrasions with waterproof dressing
   - Clothing contamination – disposable coveralls

2. Collection and bagging procedures:

Minimize dust as much as possible when collecting 16 – 1 oz subs and combining them into one sample. Wipe the outside of whirl-pak bag with a water-dampened paper towel in a clean area and place this bag into another whirl-pak bag **(double bag the sample).**

3. Cleanup and PPE removal:

When in a dust-free area, remove the disposable coveralls by turning inside-out, rolling up and placing in a plastic bag for disposal. Wipe shoes with water dampened paper towel. Remove goggles and respirator; wipe outside of goggles and respirator with water-dampened paper towel. Place goggles and respirator in clean carrying bag. Place all wipes in the disposal bag with the disposable coveralls. *Place the bag in a trash receptacle on site if the firm permits or carry out and dispose of properly at your FDA office.*

4.3.6 - ASEPTIC SAMPLE

Aseptic sampling is a technique used to prevent contamination by your sampling method. Aseptic sampling involves the use of sterile sampling implements and containers. Your sampling technique is where the lot or sample is contacted only by the sampling implements or the container. Samples collected using aseptic technique, will permit testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment. Aseptic sampling is critical to not only samples that will undergo microbiological analysis but also samples subject to chemical tests that might be altered by microbial activity. For chemotherapeutics, make sure that shipping conditions ensure that microbial populations remain inactive and do not have the opportunity to degrade the analyte. Whenever possible collect intact, unopened containers. Aseptic sampling is often used in the collection of in-line samples, environmental samples, product samples from bulk containers and collection of unpack-aged product that is being collected for microbial analysis.

Note: Products in 55-gallon drums, or similar large containers, either aseptically filled or heat processed, should not be sampled while the shipment is en route unless the owner accepts responsibility for the portion remaining after sampling. Try to arrange sampling of these products at the consignee (user) so the opened containers can be immediately used or stored under refrigerated conditions. Use ASEPTIC TECHNIQUE when sampling these products.

For more guidance on aseptic technique, you may consult the course *Food Microbiological Control 10: Aseptic Sampling*, which is available to FDA employees through the ORA U intranet site.

4.3.6.1 - General Procedures

If it is necessary to open containers, draw the sample and submit it under conditions, which will prevent multiplication

or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling technique. Take steps to minimize exposure of product, sampling equipment, and the interior of sampling containers to the environment.

4.3.6.1.1 - Sterilized Equipment

Use only sterilized equipment and containers. These should be obtained from the servicing laboratory or in an emergency, at local cooperating health agencies. Pre-sterilized plastic or metal tools should be used. However, if unavailable, the metal tools can be sterilized immediately before use with a propane torch. Permit the tool to cool in the air or inside a sterile container before using. Soaking with 70% alcohol and flaming off is an acceptable method of field sterilization and may be used as a last resort.

If it is necessary to drill, saw, or cut the item being sampled (such as large frozen fish, cheese wheels, frozen fruit, etc.), if at all possible, use stainless steel bits, blades, knives, etc. Wooden handled sampling instruments are particularly susceptible to bacterial contamination, are difficult to sterilize, and should be avoided.

4.3.6.1.2 - CAUTIONS

Be extremely careful when using a propane torch or other flame when sterilizing tools and equipment. Evaluate the conditions pertaining to explosive vapors, dusty air, flame-restricted areas, firm's policy or management's wishes. The use of supportive devices should be considered when torch is not being hand held. Also, be sure all flammable liquids, such as alcohol, in your filth kit are in metal safety cans and not in breakable containers.

If it is necessary to handle the items being sampled, use sterile disposable type gloves (rubber, vinyl, plastic, etc. - surgeon's gloves are good). Use a fresh glove for each sub and submit an unopened pair of gloves as a control. See IOM 4.3.6.5.

4.3.6.1.3 - Opening Sterile Sampling Containers

When opening sterile sampling containers, work rapidly. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid. (See IOM 4.3.5)

4.3.6.1.4 - Dusty Areas

Do not collect samples in areas where dust or atmospheric conditions may cause contamination of the sample, unless such contamination may be considered a part of the sample.

4.3.6.2 - Sampling Dried Powders

Cautions - The proper aseptic sampling of dried milk powder, dried eggs, dried yeast, and similar types of products is difficult because they are generally packed in multilayer poly-lined paper bags. These may be stitched across the entire top, may have filler spouts, or the top of the poly-liner may be closed or sealed with some type of "twists".

The practice of cutting an "X" or "V" or slitting the bag and folding the cut part back to expose the contents for sampling should not be used because it creates a resealing problem; the opening cannot be properly repaired.

The following procedures have been approved by the scientific units in Headquarters and should be used when sampling this type product.

4.3.6.2.1 - Bag And Poly-Liner Stitched Together Across Top Seam

1. Remove as much dust as possible from the seam end by brushing and then wiping with a cloth dampened with alcohol. Note: This does not sterilize the bag as porous paper cannot be sterilized.
2. Remove the seam stitching carefully (and dust cover, if any) and spread the walls of the bag and the poly-liner open enough to permit sampling being careful that no extraneous material such as dust, bits of twine, paper, etc., drops into the product.
3. Carefully scrape off the surface of the product with a sterile device and aseptically draw the sample from the material below.
4. Carefully reclose the bag and re-stitch by hand, or by machine if firm or FDA portable sewing machine is available.

4.3.6.2.2 - Bag Stitched Across Top And Poly-Liner Twist-Closed And Sealed With "Twist" Device - Wire, Plastic, Etc.

1. Brush, alcohol wipe, and remove stitching as described.
2. Remove "twist" seal and carefully open poly-liner using caution that no extraneous material drops into the product.
3. Draw aseptic sample in same manner as in step 3 above.
4. Carefully close the poly-liner with a twisting motion and reseal with "twist" seal arranging it so it will not puncture the poly-liner and re-sew bag as in step 4 above.

4.3.6.2.3 - Bags With Filling Spouts

The filling spout will be located at one side of the top stitching and will either pull out to form a top or side spout.

1. Brush and alcohol wipe the area around the spout and carefully pull it out to reveal the opening. It is better to have the bag on its side while pulling the spout so any dust in the opening falls outside the bag.
2. Carefully spread the sides of the spout apart and aseptically draw the sample. A trier or long handled device is

usually better for this type opening because of the limited opening.
3. Carefully close the spout with a firm twisting motion and be sure the opening is closed prior to pushing back into the bag.

4.3.6.3 - Collecting Water Samples

When it is necessary to collect water samples for bacteriological examination, use the following procedures:
1. Use sterile bottles. If dechlorination of sample is necessary, sodium thiosulfate sufficient to provide 100 mg/l should be placed in the clean bottles prior to sterilization. The sodium thiosulfate will prevent the chlorine from acting on the bacteria and assures, when the sample is analyzed, the bacterial load is the same as when collected.
2. Carefully inspect the outside of the faucet from which the sample will be drawn. Do not collect sample from a faucet with leaks around handle.
3. Clean and dry outside of faucet.
4. Let the water run from the fully open faucet for at least 1/2 minute or for 2 or 3 minutes if the faucet is on a long service line.
5. Partially close faucet to permit collecting sample without splashing. Carefully open sample bottle to prevent contamination, as for any other aseptic sampling operation.
6. Fill bottle carefully without splashing and be sure no water from your hands or other objects enters the bottle. Do not over fill but leave a small air bubble at top.
7. Unless otherwise instructed, minimum sample size for bacteriological examination is 100 ml.
8. Pack sample into an insulated shipping container with ice packs to keep sample cool in transit. Do not use wet ice to ship the sample to the lab.
9. Deliver sample to lab promptly. If sample is not examined within 24 hours after collection, the results may be inaccurate.

Note: When documenting specific situations in a plant, you may need to vary this procedure to mimic the actual conditions used by the firm.

4.3.6.4 - Sample Handling

For frozen samples, pre-chill sterile containers before use and keep frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration. See IOM 4.5.3.5, 4.5.3.6 and 8.3.3.3. Under normal circumstances dried products may be shipped unrefrigerated except in cases where they would be exposed to high temperatures, i.e., above 37.8°C (100°F).

Submit samples subject to rapid spoilage (specimens of foods involved in poisoning cases, etc.) by immediate personal delivery to the bacteriologist where feasible.

4.3.6.5 – Closed Controls

When collecting samples using aseptic technique and the subs are collected using pre-sterilized containers and equipment, collection and submission of unopened, closed controls is required. This includes finished product aseptic samples. See Field Bulletin #30 for more information on environmental samples.

Closed controls should be collected for each lot of control subs used for the sample.

List control subs on your C/R. Control subs should be identified with a different nomenclature than the physical sample, i.e., a, b, c versus 1, 2, 3. Provide control sub lot number(s) and expiration date(s), if applicable.

Examples of various control subs are:
1. Sterile Containers - Where sterile containers are used to collect aseptic samples, submit one unopened container, which was sterilized in the same manner as containers used for sampling.
2. Sterile Disposable Gloves - If sterile disposable gloves are used to handle the product, submit one unopened pair of gloves as a control.
3. Sterile Sampling Equipment -Where pre-sterilized sampling tools are used (e.g., spoons, spatulas, triers, etc.), submit at least one unopened sampling tool as a control.

4.3.7 - ADULTERATION VIOLATIONS

Since adulteration samples are collected to confirm the presence of filth or other deleterious material, they are generally either larger or more selective than samples collected for economic or misbranding purposes.

When widespread evidence of filth or other adulteration is present, 402(a)(4) conditions can be documented by selective sampling. See IOM 4.3.7.3. For adulteration with filth, you will need to field examine (See IOM 4.3.7.1) a number of lots of product to determine the extent of the adulteration and can collect an investigational (INV) sample (See IOM 4.1.6) of filth exhibits and take photographs to document the widespread nature of the evidence. Collect separate sub samples of filth from various areas of the firm to illustrate the extent of adulteration within the firm. Field examine various lots of regulated products and collect official selective samples to document filth or other adulteration. Filth found on the exterior of containers, on pallets containing regulated product, or on the floor adjacent to lots of regulated product you are selectively sampling can be considered subsamples of that official sample. Consult with your supervisor and be guided by the criteria in Compliance Policy Guide (CPG) 580.100 Food Storage and Warehousing - Adulteration - Filth (Domestic and Import). The criteria in the Compliance Policy Guide can be used to determine if a particular lot meets the minimum criteria for direct reference seizure. Documenting a number of lots which meet the criteria helps establish the widespread nature of the adulteration.

See IOM section 4.3.7.6 and 4.3.7.7 for instructions on how to selectively sample for microbiological samples, including pathogenic organisms to document adulteration.

When lots appear actionable, determine recent sales from the lot in question. Follow up may be necessary as directed by your supervisor.

4.3.7.1 - Field Examination

Some field examinations are also referred to as bag-by-bag exams or unit by unit exams. When you conduct such exams take care to describe observations of each unit of product examined, any physical subsamples collected which reflect the violative nature of the lot and exhibits which corroborate your report of observations.

Record in your regulatory notes, subsequently in C/R Collection Remarks field or Continuation Form, or on Analyst Worksheet FDA 431, the results of your unit by unit examination of the lot. Observations should be specific. Report the general storage conditions, the violative condition of the lot, the physical relationship of the violative lot to other lots in the area, how you conducted the examination and how many units you examined. Wherever possible, record quantitative observations.

Report the number and location of live and dead insects, rodent pellets, or other adulteration discovered inside the containers as well as on their exterior surface. Provide graphic measurements of areas of urine/chemical stains on each container and the extent of penetration. Correlate findings of the unit by unit examination with any photographs and physical subsamples collected.

Where the field examination is carefully described and documented, the sample collected from obviously violative lots may be reduced to carefully selected exhibits. The field examination and the report of findings will serve as the analysis.

4.3.7.2 - Random Sampling

The concept of random "blind" sampling is to yield information about the average composition of the lot. It is employed when you have no information or method of determining which units are violative. Usually the violation is concealed and must be found by laboratory methods.

Sample size is usually described in your assignment, IOM Sample Schedule, Compliance Program Guidance Manual, or the applicable schedules. If none of these furnish the sample size, a general rule is to collect samples from the square root of the number of cases or shipping containers but not less than 12 or more than 36 subs in duplicate. If there are less than 12 containers, all should be sampled. Discuss sample size and 702(b) requirements with your supervisor. See IOM 4.3.3.2.

4.3.7.3 - Selective Sampling

In some situations, random sampling is unnecessary or even undesirable. Under these conditions, examine the lot and select the portions which will demonstrate the violative nature of the lot.

In addition to the selective samples collected, exhibits should include diagrams and photographs to demonstrate the violative conditions reported, and which containers were sampled and photographed.

4.3.7.4 - Sample Criteria

The Agency has defined minimum direct reference seizure criteria to assist in assessing filth of individual lots. Criteria for rodent, insect, and bird filth are defined Compliance Policy Guide (CPG) 580.100, Food Storage and Warehousing - Adulteration - Filth (Domestic and Import) for human foods, and reiterated in IOM sections 4.3.7.2 - 4.3.7.4. When collecting selective samples of products to show adulteration by filth, be guided by this criteria.

When evidence of rodent, insect, bird, or other animal activity is encountered during an inspection it is your responsibility to assess the evidence you observe and determine and document whether the activity is:

1. Current or old
2. Isolated to one lot (possible FD&C 402(a)(3) charges - contain in whole or in part filth or is otherwise unfit for food).
3. Widespread, which requires evidence and documentation to illustrate all of the firm's susceptible products are potentially adulterated because they are being prepared, packed, or held under conditions whereby they may be contaminated. (possible FD&C 402(a)(4) charges)

Your assessment and documentation of the evidence observed (diagrams, photos and sample collections) will determine what actions may be required by either the establishment, the Agency, the Court, or all three to correct the problem. The evidence and documentation you collect and develop will be used to show, by a preponderance of evidence, that conditions at the firm have resulted, or could result in adulteration.

Your sample collection should be sufficient to document the extent of the violative conditions and not be limited to this minimum. Even where these minimum prerequisites are not met, you should collect samples as exhibits and evidence, particularly where adulteration under section 402(a)(4) of the FD&C Act [21 U.S.C. 342 (a)(4)] may be a factor. Your evidence may be used in a subsequent action against the firm, if corrections are not made.

Consult with your supervisor as soon as possible when you find evidence which meets the criteria set forth in CPG 580.100. If you are collecting several samples, the lab should be notified in advance that samples are on their way and should be analyzed expeditiously to facilitate regulatory

action. Your supervisor may also want to notify your compliance branch so evaluation of evidence for a possible mass seizure can commence.

4.3.7.4.1 - General

When Selective Sampling consists of an actual sample of a product, however small, as distinguished from bag cuttings, rodent pellets, insects, etc., a 702(b) portion must be obtained. In such cases, collect duplicate subs of the product to provide the 702(b) portion. This 702(b) portion is usually not an exact duplicate of the product collected for the Selective Sample, but should be collected from the same bag, box, or other container of product sampled. Whether collected from a container or bulk, the 702(b) portion should be taken as close as possible to that portion selectively sampled for analysis. Specify for each sub and duplicate collected, the origin, manner in which taken, and the examination to be made on your C/R. See IOM 4.3.3.3

Submit each portion of bagging or container portion, rodent pellets, material from beneath sampled area, control etc., in separate vial or subsample container.

It's important when collecting a selective sample for adulteration violations that you:

1. Use a coherent numbering/identification system for subsamples to avoid unnecessary confusion for the lab.
2. Provide a detailed listing of individual sub descriptions on the C/R.
3. If possible, provide a copy of any maps, photos or other additional documentation to the laboratory.
4. Be sure to obtain product labeling. Since samples of lots which are sampled selectively are official samples, complete labeling must be collected. See IOM 4.4.9.
5. Note: Whenever a portion of food is collected as part of a selective sample FD &C Act Section 704(d) applies and the CR should be marked as such.

4.3.7.4.2 - Rodent Contamination

The minimum direct reference seizure criteria to assist in assessing rodent adulteration of individual lots, as defined in Compliance Policy Guide (CPG) 580.100, are summarized as follows:

The storage facility is rodent infested and:

1. Three or more of the bags in the lot are rodent gnawed; or
2. At least five of the bags in the lot bear either rodent urine stains at least 1/4" in diameter, or two or more rodent pellets; or
3. The food in at least one container in the lot contains rodent gnawed material, or rodent excreta or urine.

Whether or not the warehouse is rodent infested; IF:

1. At least three bags bear rodent urine stains of at least 1/4" in diameter which penetrates to the product even though the product cannot be demonstrated to have been contaminated; or:
2. At least two bags are rodent-gnawed and at least five bags bear either rodent urine stains at least 1/4" in diameter, with or without penetration to the product, or two or more rodent pellets; or:
3. The food in at least one bag in the lot contains rodent-gnawed material or rodent excreta or rodent urine, and at least five bags bear either rodent stains at least 1/4" in diameter or two or more rodent pellets.

Additional regulatory guidance concerning rodent adulteration of pet foods can be found in CPG, 690.600 Rodent Contaminated Pet Foods.

4.3.7.4.2.1 - Examination and Documentation of Rodent Contamination

Examine the exterior of the containers looking for rodent hairs, urine stains, excreta pellets, gnaw marks, holes, nesting material and live rodents. Make a diagram of the entire lot and note your findings as you examine the individual containers. You will need to include these descriptions on your C/R.

Describe excreta pellets as carefully as possible, Note whether they appear dusty or shiny; soft or hard.

Examine suspected urine stains with ultra-violet light in as near total darkness as possible. A minimum of 15 minutes is normally required for the eyes to become properly adjusted to accurately differentiate between rodent stain fluorescence and normal fluorescence of rice and certain other commodities.

Wet, fresh or continually wetted runs may fluoresce poorly, but the odor of urine will usually be present and should be described on the C/R. Fresh dry urine stains will fluoresce blue-white, while older stains may be more yellowish/white. Rodent hairs will look like blue/white streaks. Look for the typical droplet pattern because rodents commonly urinate while in motion. Report the presence of droplet patterns on your C/R.

Urine stained areas may be photographed under ultra-violet light conditions. Check with your supervisor about the technical aspects of this procedure. Do not mark container surfaces to outline the stained areas when taking either ultra violet or normal photographs. This may contaminate the product by migration through the containers.

A number of things can interfere with the visual identification of urine stains. Many types of bagging and threading materials will fluoresce under U.V. light, however, the characteristic rodent stain fluorescence can be identified by its yellowish color and characteristic pattern. In addition, a number of products exhibit a natural fluorescence. The following products may be difficult to evaluate because of either natural fluorescence or "quenching" of UV rays, even if contaminated. ("Quenching" refers to a covering up or a decrease in the ability of a product to fluoresce.)

FOODS	NON-FOOD ITEMS
High Gluten Flour (Natural)	Burlap Bags (Quenching)

Nut Meats (Natural)
Bean Flours (Natural)
Brans (Natural)
Pop & Field Corn (Natural)
Wheat (Natural)
Starch (Natural)
Spices (Natural or Quenching)
Bleached Sacks (Natural-White Glow)
Lubricants (Oils & Greases) (Natural-Blue/White to yellow/brown glow)
Pitches & Tars (Natural-Yellow)
Detergents & Bleaches (Natural-White)
Sulfide Waste Matter (Natural-Blue/White)

Note clearly on your C/R if the product or package contains or is directly associated with any of the following:
1. Dried milk products (contain urea).
2. Whole grain wheat (contains urea and allantoin).
3. Animal feeds (urea is usually intentionally added).

4.3.7.4.2.2 - Collecting Exhibits or Subsamples

When sampling lots for rodent contamination, follow the safety precautions in IOM 1.5.5.4. Wear gloves and handle the exhibits with tweezers or forceps. Handle exhibits carefully to prevent loss of microscopic evidence. Where you separate, count, or identify the various elements of an exhibit, (e.g.: sieve and find X number of rodent pellets), maintain the counted portions separate from the other subs. Note on the C/R those subs that were counted, separated, etc.

Collect a representative number of rodent pellets for laboratory confirmation. Place the pellets in a vial or other rigid container to prevent crushing. One of the identifying characteristics the lab looks for is the presence of rodent hairs in the pellets. The more pellets examined increases the possibility of a good identification. However, do not collect all the evidence you see as this would recondition the lot.

Collect portions of urine stains or gnawed holes from containers using small scissors or a sharp knife. Leave a portion of the stain or gnawed hole intact but take a cutting large enough to provide good identification. Usually ½ inch around the stain is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) If possible, take stained cuttings from areas which have not been exposed for extended periods of time to light, in particular, ultraviolet light sources or to intense heat. If you have no alternative or cannot determine the stained areas' history, note the conditions on the C/R. Place cuttings and gnawed holes between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss of hairs or parasites due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as rodent hairs may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect a minimal amount of product from under the stained area or hole, preferably just clumped product as a separate subsample. This prevents dilution of the contaminated product with uncontaminated product. Whenever you collect product, regardless of amount, collect a separate subsample to provide a 702(b) portion. See IOM 4.3.7.4.1. and identify per IOM 4.5.2.1.

Collect nesting material with minimal handling. A half cup is enough for analysis. Do not collect any rodents.

Product Control: In addition, you need to collect product controls, in duplicate, to provide for the 702(b) portion. These subsamples should be collected from beneath unstained portions of the container. Collect control samples from 3 different containers.

Packaging Control: Collect a portion of unstained container, which does not fluoresce, as a separate subsample for a control. As a general guide, collect the controls from the opposite side of the bag or make the cutting large enough to separate the control area and the stain. Separate the controls from the stains and submit in separate containers. Collect at least 3 container controls for each sample. If the lot consists of different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

Submit each portion of bagging or container, pellets, material from beneath sampled area, control, etc., in separate vial or subsample container. Place the subsamples in a dark container, such as a cardboard box to protect them from light and protect the exhibits from being crushed.

4.3.7.4.2.3 - Summary of Sample for Rodent Evidence

The complete official sample will consist of:
1. Subsamples of rodent excreta pellets
2. Subsample of nesting material
3. Subsamples of stained bagging, or portions of the containers, and any adhering pellets.
4. Subsamples of unstained bagging, or portions of the containers, which do not fluoresce, for controls (minimum three required).
5. Subsamples of small portions of the product from directly beneath the stained areas. Do not dilute the contaminated product beneath the stain with the non-contaminated product.
6. Subsamples of small portions of product to serve as 702(b) portions
7. Subsamples of uncontaminated product from beneath the unstained bagging, or other container. These serve as controls and should be collected in duplicate to provide 702(b) portions. Collect control samples from 3 different containers.
8. Subsamples of cuttings from gnawed holes
9. Subsamples of small amounts of product collected from beneath the gnawed holes.
10. Subsamples of small portions of product to serve as 702(b) portions.
11. Product labeling.

12. Interstate documentation.

If conditions warrant, consider collecting an INV sample per IOM 4.1.6. to document widespread rodent activity.

4.3.7.4.3 - Insect Contamination

The criteria from CPG 580.100 below, involving dead insects only, will not be used for action against any food intended to undergo further processing that effectively removes all the dead insects, e.g. processing of cocoa beans.

1. The product contains:
   a. One live insect in each of two or more immediate containers; or, one dead insect in each of three or more immediate containers; or, three live or dead insects in one immediate container; plus
   b. Similar live or dead insect infestation present on, or in the immediate proximity of, the lot to show a 402(a)(4) [21 U.S.C. 342 (a)(4)] violation.
2. The product contains one or more live insects in each of three or more immediate containers.
3. The product contains two or more dead whole insects in at least five of the immediate containers. Note: a situation such as this may follow fumigation of the lot and vacuuming of the exteriors of the bags.
4. The product is in cloth or burlap bags and two or more live or dead insects are present on at least five of the containers. Note: Some live insects must be present. Product need not be shown to have become contaminated.

4.3.7.4.3.1 - Examination and Documentation of Insect Contamination

Examine the exterior of the containers (especially along seams or creases) looking for insects, larvae, webbing, nesting material, entrance or exit holes, and cast skins. Make a diagram of the entire lot and note your findings as you examine the individual containers. Describe insects or larvae carefully, noting if they are dead or alive. You will need to include these descriptions on your C/R.

4.3.7.4.3.2 - Collecting Exhibits or Subsamples

Collect a representative number of insects for laboratory confirmation. Consider the use of a moistened artist brush to collect subsamples. Place the specimens in a vial or other rigid container to prevent crushing. Collect all forms of insects you see, however do not collect all the evidence from the lot or you might recondition the product. If you collect live insects, be sure to note that on your C/R. However, you should not send live insects to the lab. Freeze the subsamples prior to shipment to ensure they are not alive when you ship them. Note the fact that the subsamples were frozen on the C/R.

Cut portions of bags or containers containing suspected insect entrance or exit holes from containers using small scissors. Usually ½ inch around the holes is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) Place cuttings between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss microscopic evidence due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as insect fragments may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting

Collect product from beneath holes which penetrate the packaging as a separate subsample. Whenever you collect product, regardless of amount, collect a separate subsample to provide a 702(b) portion. Note on the subsample itself and on your C/R which subsamples are the 702(b) portions.

4.3.7.4.3.3 - Summary of Sample for Insect Evidence

The complete official sample will consist of:

1. Subsamples of insects, larvae, webbing, etc.
2. Subsamples of portions of the containers with entrance or exit holes.
3. Subsamples of small portions of the product from directly beneath holes.
4. Subsamples of small portions of product serve as 702(b) portions See IOM 4.3.7.4.1.
5. Product labeling.
6. Interstate documentation.

If conditions warrant, consider collecting an INV sample per IOM 4.1.6. to document widespread insect activity.

4.3.7.4.4 - Bird Contamination

Per the criteria from CPG 580.100, if the product is in permeable containers (paper, cloth, burlap, etc.), and

1. The product contains bird excreta in one or more containers, and you feel the insanitary storage conditions will clearly support a 402(a)(4) [21 U.S.C. 342 (a)(4)] violation.
2. Bird excreta is present on the exteriors of at least five of the containers, and the product contains bird excreta in one.
3. At least 30% of the number of bags examined, but at least five bags, are contaminated with bird excreta; and at least three of the bags bear excreta stains which penetrate to the product, even though the product may not be contaminated.

Note: In all instances of bird excreta contamination the excreta must be confirmed by positive test for uric acid.

4.3.7.4.4.1 - Examination and Documentation of Bird Contamination

Examine the exterior of the containers looking for bird excreta. Make a diagram of the entire lot and note your findings as you examine the individual containers. You will need to include these descriptions on your C/R.

4.3.7.4.4.2 - Collecting Exhibits and Subsamples

Remove portions of bird excreta stains from containers using small scissors. Leave a portion of the stain intact but take a cutting large enough to provide good identification. Usually ½ inch around the stain is sufficient to allow manipulation during the lab exam. **Note:** The bag cutting should not be so large as to remove the entire contaminated portion, since this would recondition the product. For multilayer bags, be sure you cut through all layers of the bag and identify the layers with pencil. (Do not use ink as it often contains urea.) If possible, take stained cuttings from areas which have not been exposed for extended periods of time to light, in particular, ultraviolet light sources or to intense heat. If you have no alternative or cannot determine the stained areas' history, note the conditions on the C/R. Place cuttings between 2 pieces of white paper, and then fold, roll, or leave flat and place into a glass container or other suitable container. This will hold the evidence in place and prevent possible loss of microscopic evidence due to static charges. Do not separate a multilayer cutting. Avoid the use of polyethylene containers as bird excreta may adhere to containers made from this material. Put the cuttings in a large enough container to avoid excessive folding of the cutting.

Collect a minimal amount of product from under the stained area, preferably just the clumped product as a separate subsample. This prevents dilution of the contaminated product with uncontaminated product. Collect a separate subsample to provide a 702(b) portion (See IOM 4.3.7.4.1).

Product Control: In addition, you need to collect product controls, in duplicate, to provide for the 702(b) portion. These subsamples should be collected from beneath unstained portions of the container. Collect control samples from 3 different containers.

Identify the 702(b) subsamples, as such on subsample identification (See IOM 4.5.2.1.) Note on the subsample itself and on your C/R which subsamples are the 702(b) portions.

Packaging Control: Collect a portion of unstained container as a separate subsample for a control. As a general guide, collect the controls from the opposite side of the bag or make the cutting large enough to separate the control area and the stain. Separate the controls from the stains and submit in separate containers. Collect at least 3 container controls for each sample. If the lot consists of different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

4.3.7.4.4.3 - Summary of Sample for Bird Evidence

The complete official sample will consist of:

1. Subsamples of stained bagging, or portions of the containers.
2. Subsamples of unstained bagging, or portions of the containers for controls (minimum three required).
3. Subsamples of small portions of the product from directly beneath the stained areas. Do not dilute the contaminated product beneath the stain with the non-contaminated product.
4. Subsamples of small portions of product to serve as 702(b) portions.
5. Subsamples of uncontaminated product from beneath the unstained bagging, or other container. These serve as controls and should be collected in duplicate to provide 702(b) portions. Collect control samples from 3 different containers.
   Submit each portion of bagging or container portion, pellets, material from beneath sampled area, control, etc., in separate vial or subsample container.
6. Product labeling.
7. Interstate documentation.

4.3.7.4.5 - Chemical Contamination

Collect samples from lots suspected of dry chemical contamination in much the same manner as described for rodent urine. After collecting a sample of the contents from immediately beneath the suspected area, collect residues from the surface of the bag or container. In the case of infiltration of loosely woven bags, shake or tumble the bag over a large sheet of clean paper to collect the siftings as a sample.

4.3.7.4.6 - Mold Contamination

The USDA/FGIS has approved a number of commercial screening tests for detecting aflatoxin contaminated corn. However, these tests usually require a chemical extraction process and are therefore not amenable to FDA field examination procedures.

The black light test (also referred to as the Bright Greenish-Yellow Fluorescence (BGYF) test) is a presumptive test used to screen and identify corn lots that should be tested further for aflatoxins. The test is based on BGYF observed under long wave (366 nm) ultraviolet (UV) light produced by the molds *Aspergillus parasiticus* and *A. flavus* on "living" corn (i.e. corn that has been stored less than 3 months). The growth of these fungi may result in aflatoxin production. Aflatoxins per se do not produce BGYF under long wave UV light. It is thought the BGYF is produced by the reaction of kojic acid formed by the fungi and a peroxidase enzyme from living corn. Corn that has been in storage for a lengthy period of time (3 months or more) may

give false positive BGYF. Therefore, determine how long the corn being sampled has been in storage. If it has been in storage over three months, do not use the following field screening procedure.

Essential steps for this black light procedure are:

1. A 10 lb. sample representative of the corn lot must be obtained by probing, or by continuously sampling a grain stream.
2. Examine using a 366 nm UV light (portable black-lights meet this criteria).
3. Wear goggles or use a viewer that screens out UV light. Shine the light on the corn sample which has been spread in a single layer on a flat surface in a darkened room.
4. Use a 2 lb. portion, and carefully observe the entire corn surface one kernel at a time. Examine the entire sample using this procedure.
5. Count all BGYF glowers (kernels or particles that "glow" bright greenish-yellow). Compare the BGYF color with a fluorescent standard, if one is available. Remember normal corn, if it fluoresces, will fluoresce a bluish white.
6. If four (4) or more BGYF particles are detected in the 10 lb screening sample, collect a sample for laboratory analysis.

4.3.7.5 - Abnormal Containers

See IOM SAMPLE SCHEDULE CHART 2 - Sampling Schedule for Canned and Acidified Foods for listing can defects.

4.3.7.6 - Microbiological Samples

During inspections of firms producing products susceptible to microbial contamination (e.g., peanut butter, dried milk, dairy products, frozen ready-to-eat seafood, crème filled goods, breaded items, prepared salads, etc.), sampling may be warranted, based on observations or as directed in the Work Plan, Compliance Program, or assignment. Proof of adulteration with fecal organisms, elevated levels of non-pathogenic microorganisms, or presence of pathogenic microorganisms must be established. Follow instructions under IOM 4.3.7.7 when collecting microbiological samples to document manufacturing conditions conducive to adulteration.

4.3.7.6.1 – Collection Of Samples For Molds

Mold Samples - During inspections of manufacturers such as canneries, bottling plants, milling operations, etc., it may be necessary to collect scrapings or swabs of slime or other material to verify the presence of mold. The sample should represent the conditions observed at the time of collection and consist of sufficient material to confirm and identify mold growth on the equipment. If possible, take photographs and obtain scrapings or bits of suspect material. Describe the area scraped or swabbed, e.g., material was scraped or swabbed from a 2" x 12" area. Suspected filth, collected from ceilings, walls, and equipment, for mold examination must be kept moist by placing it in a container with a small amount of a 3-4% formalin solution. Large amounts of slime may be placed in a wide mouth glass jar with either a 1% formaldehyde solution or a 3-4% formalin. Note: Formalin is normally sold as a standard stock solution of 37%. To obtain the required 3-4% formalin solution, mix 10 ml of the 37% stock solution with 90 ml of distilled water. This will yield the appropriate strength solution necessary to fix the mold.

Although formaldehyde or formalin are the preservatives of choice you may preserve the subs in either a 50% alcohol solution or in acetic acid (full strength vinegar) if formaldehyde or formalin are not readily available.

Note that formaldehyde/formalin is a common sensitizing agent that that can trigger an allergic reaction in normal tissue after single or repeated exposures. It is also classified as a known human carcinogen (cancer-causing substance) by the International Agency for Research on Cancer and as a probable human carcinogen by the U.S. Environmental Protection Agency (EPA). Investigators must understand the hazardous properties of formaldehyde/formalin so that control measures can be taken to minimize exposure.

The above instructions apply to the collection of raw material, in-line and finished product samples for mold. However, in-line and finished product subs such as doughs, etc., which may be harmed by the formaldehyde, may be frozen. Check with your laboratory for its recommendation regarding preserving mold samples.

4.3.7.7 – Collection of Environmental and Product Samples for Food Susceptible to Contamination with Pathogenic Microorganisms

Sampling for products susceptible to microbial contamination and the environment in which they are produced may help identify the presence of pathogenic microorganisms before they can cause illness. With the recent increase in foodborne outbreaks and inspections identifying links between outbreaks and environmental (including non-food contact surface) contamination, there will be an increased focus on routine environmental sampling during inspections. Conduct environmental surface sampling as directed by the work plan, compliance program or assignment, or based on inspectional observations. If you are unsure of the circumstances under which to perform environmental sampling, consult with your supervisor. Also see IOM 5.4.7.2 for inspectional guidance for firms producing products susceptible to contamination with pathogenic microorganisms.

Collection of environmental and product samples for microbiological testing requires a thorough understanding of critical factors associated with the production of the specific product being inspected. To prove the establishment is being operated in an insanitary manner it is necessary to show the manufacturing operation or

conditions at the facility are likely to, or have contributed to the bacterial load of the product. When feasible, inspections should cover equipment condition before a day's production begins and the clean-up at the end of the day's production. For environmental *Salmonella* sampling, it is preferable to sample before the plant conducts a wet cleaning operation.

Environmental sampling should include sponges or swabs of food contact surfaces (particularly for *Listeria monocytogenes*) and non-food contact surfaces (particularly for *Salmonella* serotypes), based on observations, or as directed. Environmental monitoring supplies should be brought into the firm using precautions to prevent the transfer of foreign material into the processing area.

In-line sampling should be conducted based on observations or as directed. Collect finished product only after consultation with CFSAN, HFS 605 Division of Enforcement, or as directed in the compliance program or assignment.

When conducting environmental sampling or product sampling for microbiological testing, whenever applicable, an investigator/ microbiologist team approach should be used. For environmental sampling, a third person is recommended to assist with collection and/or recording of information.

4.3.7.7.1 - Environmental Sampling

CFSAN has developed guidance on the specific locations within a firm to collect environmental samples to increase the likelihood of detecting *Listeria monocytogenes* and *Salmonella*. See IOM Exhibit 4-20 and 4-21 and FIELD BULLETIN #30 – FOOD PROGRAM AREA INSTRUCTIONS FOR ENVIRONMENTAL SAMPLING for guidance on environmental sampling/locations for these microorganisms. In addition, please view the training video in Field Bulletin #30, "Environmental Sampling in Food Manufacturing FD148" which provides technical and procedural information on environmental sampling.

In most cases, it is preferable during discussion with the firm not to mention FDA's intent to collect environmental samples until immediately before sampling begins. Advance notice/pre-announcement of environmental swabbing may possibly provide the firm with the opportunity for unscheduled sanitation activities. Any such actions by the firm could potentially inhibit microbial recovery and compromise environmental sample(s).

During the initial phases of the inspection, the Investigator should conduct a walkthrough assessment observing and mapping operations, including the location of equipment, flow of the product, foot traffic of employees, forklift/mule traffic patterns, segregation of raw material versus finished products, and consider sampling areas where food is exposed and being processed, particularly post-treatment/pasteurization.

The "Zone Concept" identifies and prioritizes processing areas from highest risk and closest to the product to lowest risk and farthest from the product for potential contamination and harboring growth and niches for targeted pathogen and therefore should be implemented upon conducting environmental sampling as follows:

- Zone 1: Refers to all direct food contact surfaces such as slicers, mixers, conveyors, utensils, racks, work tables, etc. For inspections focusing on the presence of *Salmonellae*, such as firms producing peanut products and other dry product environments, food contact surfaces are normally not sampled unless specifically requested in the assignment or CP. In contrast, for inspections focusing on detection of *Listeria monocytogenes,* such as firms producing seafood or cheese products in a wet environment sampling of food contact surfaces is essential.
- Zone 2: Encompasses the areas directly adjacent to food contact surfaces (Zone 1). For investigations focusing on *Salmonellae*, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, Zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation and air handling equipment, and floors. In a much larger room (e.g. 20,000 square feet) Zone 2 is the area in the immediate vicinity of food contact surfaces, such as around the exposed product in which you could envision a pathway to product contamination either through the actions of man or machine.
- Zone 3: The area immediately surrounding Zone 2. Zone 3 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of humans or movement of machinery. Examples of Zone 3 areas include corridors and doorways leading into food production areas or areas in a large production room that are further away from food handling equipment than typical zone 2 areas. Walls, phones, forklifts and "mules", even if physically located in Zone 2, should be considered Zone 3 due to a decreased likelihood of cross-contamination.
- Zone 4: The area immediately surrounding Zone 3, generally considered a remote area. Zone 4 is an

area which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of humans or machinery. Examples of Zone 4 areas include an employee locker room if not immediately adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

Every effort should be made to conduct Listeria sampling when the facility has been in production for **at least four hours and before any wet cleaning is performed.** In instances with smaller firms that have short production periods, swabbing should be conducted during the mid to tail end of their production schedule.

In most cases, subsamples for *Salmonella* will be collected from the Zones 2 – 4 (see below), concentrating primarily on Zone 2. Samples should be collected from the equipment itself, particularly equipment mounting and support structures. When targeting *Listeria*, swabs will be collected primarily from Zones1 and 2. Perform most of the sampling for *Listeria* in, on, and around food contact equipment, focusing on areas where food is exposed and being processed, particularly post-treatment/pasteurization.

A large majority of the environmental samples collected should be taken from Zones 1 (when directed and depending on the organism in question) and 2, and to a lesser degree Zone 3 areas. Very few, if any, environmental samples should be taken from Zone 4 areas.

Swab subsample numbers for each organism are as follows:

- For *Salmonella* environmental swabbing, collect at least 100 swabs/subs and ideally 300 or more subs
- For *Listeria* environmental swabbing, collect at least 50 swabs/subs and ideally 100 or more subs.

Document the possible link between the source of an environmental sample and contamination of the food product using both written descriptions and photographs. Describe the location of the sample in relation to areas where food is exposed and any mechanical or human activities you observe that might cause an organism to be spread beyond this niche environment. The division's response to a positive swab will depend on the proximity of the sample location to the processing line and the likelihood of cross-contamination between the swabbed surface and food or food contact surfaces.

On occasion, firms may opt to collect their own swabs in conjunction with your sample. If this occurs, request the firm to provide their results when available.

4.3.7.7.2 - Environmental Sampling Equipment and Instructions For Large and Small Area Environmental Surface Sampling

These instructions should be followed in order to ensure standardization of FDA environmental sample technique across divisions.

For environmental sampling, the broth or buffer serves two purposes: 1) to neutralize sanitizer that may be on surfaces that you are sampling, and 2) to provide nutritional requirements for the organisms of interest to survive the transport to the laboratory.

Day and Engley (D/E) neutralizing broth or buffer (the terms broth or buffer are used interchangeably for this product) has been shown to be effective as a neutralizing agent against the widest range of sanitizing agents that may be in use by a firm and, per Office of Regulatory Science (ORS), is the one to be used for general purpose environmental sampling.

For large area environmental sampling, hand held sponges or sponges on a stick should be used. The sponges on a stick reduce manual contact with the sponge during the sampling procedure and are good for accessing tight spaces. Dacron tip swabs are recommended for small area environmental sampling (approximately 10cm x10 cm, or 4 x 4 inches).

Sampling Equipment:
If sources cannot be located for sponges or swabs pre-hydrated with D/E Neutralizing buffer or broth, use un-hydrated sponges and swabs along with single use tubes of D/E neutralizing broth. Do not add additional D/E buffer or broth to other types of hydrated sponges and swabs that contain either a neutralizing broth or an enrichment broth. Addition of D/E broth to these may dilute the concentrations of both components to the extent they will not be effective.

Hand held sponges or sponge on a stick pre-hydrated with D/E neutralizing broth if available, dry hand-held sponges or sponge on a stick, swabs pre-hydrated with D/E neutralizing broth, dry swab in swab tube with screw on cap or single use tubes of D/E Broth are recommended.

If you need sourcing information for equipment please contact the Division of Domestic Human and Animal Food Operations (DDHAFO) at (301) 796-0360.

Other general sampling supplies you will need for environmental sampling:

Sterile gloves (size 7 and 9 to include latex free styles)

Hand sanitizers (wash and sanitize hands often during sampling)
Cooling medium for samples
Boxes or coolers
Labels to ID samples
Permanent marker
Flashlight
Sterile metal spatulas (small) or other sterile implement to scrape debris out of cracks

It is important to use sponges or sponges on a stick for the large majority of samples since you can sample and "scrub" a larger area with a sponge compared to a swab. Swabs are only appropriate for areas that are inaccessible to sponges.

Sampling Method:

For large area environmental sampling, hand-held sponges or sponges on a stick should be used. The sponges on a stick reduce manual contact with the sponge during the sampling procedure and are good for accessing tight spaces. Dacron tip swabs are recommended for small area environmental sampling (approximately 10cm x10cm, or 4 x 4 inches) and for cracks and crevices.

Gloves:

For collection of environmental samples in Zones 2 - 4 and for firms targeted as part of *routine surveillance* inspections only, it is not necessary to change gloves between each sub provided that the CSO or analyst remains in the same zone and the integrity of the gloves is not compromised during the course of collecting the sub, (i.e. glove rips, or if it is brushed against a lab coat, etc.) For example, if 50 swabs are collected in Zone 2, the CSO or analyst would not need to change gloves between each of these subs until moving to another zone, another distinct processing room or area, or if the condition of the gloves warrants changing. However, gloves should be sanitized between each sub by applying a 70% solution of ethyl alcohol (preferred) or 70% isopropyl alcohol. It is expected that collection of a large number of subs in one area would necessitate several changes of gloves.

For swabs collected in Zone 1 and during "for-cause" inspections (such as those conducted in response to a current or previous outbreak, or an emergency), continue to follow the established policy and change gloves between each sub as described in the Environmental Sampling training video.

Sampling of Dry Surfaces:
Using a felt-tip black permanent marker, label the sterile bag containing the sponge with appropriate sample information.

1. Wash and sanitize your hands to the mid-forearm. Use clean disposable paper towels for drying your hands.

2. From the outside of the sponge bag manipulate the handle toward one side. Pull off the top of the whirl-pak bag holding the Sponge-stick along the perforation. Using the tabs on both sides of the wired band, pull gently to open the bag. Do not remove the Sponge-stick.

3. Pour into the Sponge-stick bag 9-10 ml or sufficient volume of DE neutralizing broth on the side away from the handle to hydrate the sponge (do not get broth on the handle). Be careful not to touch the opening of the broth container to any non-sterile surface before or during this transfer.

4. Massage the sponge through the outside of the bag to facilitate absorption. From the outside of the bag, push the Sponge-stick to the upper portion of the bag. While pushing the sponge-stick up from the bottom of the bag, squeeze excess D/E broth from the sponge back into the bag. The sponge should be moist but not dripping wet.

5. Using aseptic technique unwrap and place a sterile glove upon the hand you will use for swabbing. Do not touch any non-sterile surface (i.e. clothes, skin, counter tops, etc.) with the outside surface of the sterile glove. The other hand can be left ungloved for manipulation of non-sterile surfaces and materials if preferred.

6. Remove the Sponge-stick from the bag using your gloved hand. Using even and firm pressure push the sponge in one direction across the desired area of the environmental surface 10 times vertically, then 10 times horizontally. If visible soil or residue is present, sample the surface by vigorously rubbing the sponge over the designated area until the soil or residue is removed. Sampling of large flat surfaces (i.e. floor, table tops, and conveyor belts) should cover areas as referenced above, depending if the area is unclean, or has been cleaned and sanitized. It may be necessary to wet the sponge with additional neutralizing broth when sampling large and/or porous areas. Try to use only enough buffer to keep the sponge gliding smoothly over the surface. If there is excess buffer, squeeze it back into the whirl pack bag and continue until you have sampled the entire sampling site.

7. After sampling, return the sponge to original Whirl-Pak bag with any excess buffer, snap off the handle in accordance with the product instructions that accompany the Sponge-stick, and submit as a subsample.

8. Remove the used sterile glove and discard.

9. Squeeze as much air out of the bag as possible. Roll the top of the bag over several times until it is folded all the way down to the sponge. Fold in the tabs to lock the fold in place. Place the sponge bag inside another empty Whirl-Pak or equivalent bag and seal as before. Both bags must be tight enough to provide both a leak proof seal and minimal airspace during shipment of the moistened sponge.

10. As soon as possible, place the double-bagged sponge inside an insulated cooler, with pre-frozen gel packs to keep the samples cold, but not frozen, and transport/ship the sample to the servicing lab for analysis so it is received by

the lab within 24 hours of collection.

Sampling of Wet Surfaces:
Sample using aseptic techniques with a dry Sponge-stick following the general instructions above for removing the Sponge-stick from the bag, and for swabbing. After sampling, return the Sponge-stick to the original sterile Sponge-stick bag and using aseptic techniques add 10 ml of D/E neutralizing broth to the bag. Proceed as instructed in #5-10, above.

Small Area Environmental surface sampling procedure (approximately 10cm x10cm, or 4 x4 inches):

Swabs are suitable for sampling only very small areas that cannot be accessed any other way. For example, the swab can be used to sample the material in a hole in the floor such as might be encountered when a piece of floor mounted equipment is removed from an area and the floor has not been repaired to fill the bolt holes. Swabs may also be useful for sampling floor cracks or the inside of tubular equipment mounts.

Sampling of Dry Surfaces:
Collect samples using aseptic techniques with the swab pre-hydrated with D/E Neutralizing Solution. Using even and firm pressure, swab in one direction across the desired surface 10 times vertically, then 10 times horizontally, then 10 times diagonally. If visible soil or residue is present, sample the surface by vigorously rubbing the swab over the designated area until the soil or residue is removed. Return the swab to its vial, place in a Whirl-Pak bag, and as soon as possible place inside an insulated cooler with pre-frozen gel pack for transport/shipment to the laboratory.

Dust and debris scrapings may also be collected using a sterile implement from facilities producing dry products such as nuts and powders. A minimum of 5 to 10 grams should be collected with 100 grams being optimum. When sampling mops or brooms, swabbing with a sterile sponge pre-hydrated with D/E Neutralizing solution is an efficient method although mop strands and broom bristles may also be clipped and submitted.

Sampling of Wet Surfaces:
Collect sample using aseptic technique using the dry swab in the same manner as noted above. After swabbing, using aseptic technique add D/E neutralizing solution to the swab and transport to laboratory as noted above.

Collect debris on equipment and from floor defects, joints and gaps. Debris can be scraped out using a sterile implement, such as a small metal spatula. A minimum of 5 to 10 grams should be collected, with 100 grams being optimum.

Closed Controls:
For environmental samples only, collect one closed control for each distinct lot of sterile equipment used and submit with the final collection of subs on the last day of sampling.

Open Controls:
Open controls are not to be submitted for environmental sample collections.

Sample Numbering:
Often multiple days are required to collect an appropriate number of environmental swabs. If an environmental surface sample is collected on multiple days during an inspection, use a new sample number for each day, e.g., sample no. 100000 (first day) and sample no. 100001 (second day). The subs should be numbered sequentially, e.g., subs. 1-100 (first day) and subs 101-175 (second day). Link the sample numbers to the assignment for tracking purposes. Environmental swab subs should be numerical, i.e. 1, 2, 3, etc.; control subs should be alphabetic, i.e. a, b, c, etc.

Product codes have been created to allow for the tracking of environmental samples by commodity; Drugs and Foods/Feeds. When entering data into the FACTS systems for environmental samples, the collector of the sample will select the correct Sample Basis and enter the correct product code based upon the commodity.

All environmental samples, including swabs, soil, water, and animal scat, are to be identified as Investigational (INV). Use the following environmental sampling product codes: 52Y[][]07 for Farm Environmental Swabs/Samples; 52Y[][]08 for Process/Manufacturing Environmental Swabs/Samples; and 52Y[][]** for Animal Carcass Rinse/Swabs, where **= 01 (Beef), 02 (Chicken), 03 (Lamb), 04 (Pork), 05 Turkey), 06 (Other Animal Swabs). For Drug Environmental Swabs/Samples use product code 66Y[][]07. Do NOT use the product code of the covered product for environmental samples.

4.3.7.7.3 – In-Line Sampling/Factory Food Sample

In-line sampling should be conducted as directed or based on inspectional observations.

Each in-line subsample will consist of approximately 114 g (4 oz), in duplicate (702(b) portion), if that amount is available (Also see IOM 4.3.3.2 - 702(b) Requirement). All in-line samples must be collected aseptically.

Sampling Areas (this is not a comprehensive listing of areas to collect in-line samples, since each firm will be different, depending on processing/packaging techniques and the finished product produced:

"Raw" ingredients used in the manufacturing of finished foods (including those conveyed by bulk tankers) should be considered for sampling to determine the effect of subsequent processing on bacterial content. Of particular concern are raw materials which can support microbial growth, are not normally cooked or prepared in a manner lethal to pathogenic microorganisms (such as dairy, soy, corn or sugar syrup-based products), and adequate

controls to ensure the safety of the finished product are not in effect. Since the major portion of some finished food products are not homogeneously contaminated, it may be necessary to collect multiple subsamples of the raw material(s) to establish a reliable microbial base line.

Obtain sequential subsamples with the view of bracketing each step of the processing operation, in particular those steps suspected as routes of product contamination. A series of in-line samples should be collected during the first part of a shift, and a duplicate series during the latter part.

If products or components are heated (e.g., blanched, boiled, etc.) take subsamples immediately before and immediately after heating, before possible insanitary equipment and processing delays contribute to bacterial increases. Particular attention should be given to determine routes of cross-contamination from the raw product to the "heated" product, especially if this heating step is critical to the destruction of pathogenic organisms.

If a product is capable of supporting microbial growth and is not being handled expeditiously, sample before and after this particular processing step.

Take time and temperature measurements of cooking, freezing and cooling procedures. Sample when appropriate to demonstrate possible microbial growth. Large masses of ingredients may cool or warm slowly enough to permit microbial growth.

Improperly cleaned equipment may contaminate the product with bacteria. This may result in either a uniform or a spotty increase in bacterial numbers. If possible, scrapings of questionable material should be in sufficient quantity to be easily weighed and quantitatively diluted, if collected for analysis**.**

4.3.7.7.4 - Finished Product Sampling

Collect finished product as directed in the compliance program, assignment or by your supervisor. Collect product from production on the day of the inspection and from the previous day's run. Sampling multiple lots should be considered depending on the type of product and process used. The subsamples should consist of ten (10) retail size containers at least 114g (4 oz) each, in duplicate (702(b) portion).

If the finished product is also to be analyzed for Salmonella, collect samples in accordance with instructions in the IOM. See *Salmonella* Sampling Plan, Schedule Chart 1.

4.3.7.7.5 - Reporting Environmental Sampling Results On The FDA 483

Environmental sampling in the foods program has had increasing focus in assignments issued to the Field. FDA/ORA, with the concurrence of and in conjunction with Office of Chief Counsel (OCC) and the ACRA, has outlined criteria in order to implement a consistent policy for the reporting of positive environmental sample results on the FDA 483 as applicable to the foods program only. Current policy, going forward, is to report significant positive environmental sample results, from swabs collected at food firms, on the FDA 483, if the results are known prior to the conclusion/closeout of the inspection. In addition, divisions are not being asked to unnecessarily extend inspections to include these results. Reasoning behind the implementation of this policy includes:

- Informing the firm of positive results where food products are concerned
- Eliciting firm feedback in response to positive results
- The opportunity to provide relevant information to both regulators and the public when released under FOIA thereby potentially uncovering and linking other investigational information that can aid in the determination of root contamination cause(s)
- The responsibility to document positive environment sample results as significant observations that can contribute to potentially unsafe conditions as they pertain to the Public's health.

Positive environmental sampling results should be noted on the FDA 483 when the following conditions are met:

- Related to a current or future foods program inspection/investigation
- Inspection has not been closed (Note: it is not requested that the period of inspection be extended for the purpose of receiving analysis results)
- Positive sample finding(s) is/are a significant observation, i.e. a route of contamination from the environment to the product is clearly demonstrated, such as, for example, positive sample result(s) in Zones 1 and/or 2 for Listeria or positive sample result(s) in Zone 2 and/or 3 for Salmonella

Findings in Zone 3 (Listeria) and Zone 4 for either pathogen should not be reported on the 483 as they are normally not considered significant, except in combination with positive findings in Zones 1 or 2, when these would further strengthen regulatory action.

4.3.7.8 - Samples for Viral Analysis

Sample instructions will be issued by the appropriate Center on a case by case basis.

4.3.8 - ECONOMIC VIOLATIONS

4.3.8.1 - Net Weight

Field weighing for net weight is primarily to determine the likelihood of short weight units. The laboratory will confirm both tare and net weights.

Use a Gurley, Troemner, or equivalent balance. Check the accuracy of the balance before and after use. If this equipment is not available, or the units exceed their capacities, use commercial scales. If possible, have the

commercial scales checked in your presence by the local Sealer of Weights and Measures. If this is not possible, report the name, type of scale, style and capacity, minimum graduations, apparent sensitivity, and date of last sealing and by whom.

4.3.8.1.1 - Tare Determination

Whenever possible, determine a minimum of six tares selected at random. If empty containers are readily available, or if tares vary widely (e.g.; glass jars), determine at least 12 tares.

4.3.8.1.2 - Field Examination

Weigh 48 units, if that number is available, selected at random from the square root of the number of cases in the lot with a minimum of 6 and a maximum of 12. Where units are selected from the production line, do so in representative manner. Report the code weighed and if short weight, the quantity in the code. Unless otherwise instructed, do not weigh leaking containers. Identify each unit with the corresponding sub number on the Field Weight Sheet (FDA 485).

Submit the units indicated by the asterisks on the FDA 485 plus twelve additional weighed units for reserve if the average net is below that declared on the label.

4.3.8.1.3 - Field Weight Sheet

Record weights on Form FDA 485, Field Weight Sheet. See IOM Exhibit 4-6. Submit Field Weight Sheet with the printed FACTS Collection Record.

Individual Captions:

Block 1 Date - Enter the date weighed.

Block 2 Sample No.- Enter the sample number of the C/R.

Block 3 Product - Enter the specific name of the product, i.e., macaroni in cellophane, butter in aluminum wrappers, olive oil in glass, etc. Quote significant portions of the label including the declared net weight.

Block 4 Type of Balance - Enter the type of balance used i.e., Gurley, Troemner, etc. If balance used is not FDA equipment, give style, capacity, minimum graduations, etc.

Block 5 Responsible Firm and Address - Enter the name and address of the firm most likely responsible for the short weight violation.

Block 6 Address Where Weighed - Enter the name and address or location where weighed.

Block 7 Warehouse - Enter the type of warehouse where product is stored, i.e., cold storage, truck dock, production line, etc. Enter the temperature and estimate the humidity where possible.

Block 8 No. Of - Enter the number of cases, and number and size of units per case in the lot. Enter the number of cases from which subs were weighed and the number of subs weighed from each case. If the units are collected from a production line, estimate the number of units produced of the code weighed.

Block 9 Gross Weight - Arbitrarily assign and record the shipping case number from which each sub was weighed. Number each unit submitted to correspond with the sub number on the Field Weight Sheet. Record weights to second decimal place.

Block 10 Preliminary Tare - Determine and record tare weights as provided in IOM 4.3.8.1.1. Obtain the preliminary average tare by totaling preliminary tares and dividing by the number of tares weighed.

Block 11 Weighing Results - Determine the average gross weight by totaling gross weights and dividing by the number weighed; enter preliminary average tare from caption 10 in block 11b; determine average net weight by subtracting block 11b from 11a; enter the declared net weight as stated on the package weighed; determine the shortage by subtracting block 11c from 11d.

Block 12 Preliminary % Short - Enter the preliminary percent short, which is determined by dividing e by d.

Block 13 Remarks - Record any observations on the condition of the lot or storage facilities which might affect net weights, (faulty machine sealing of packages, extreme high temperature, extended length of storage, etc.)

Block 14 Division - Enter the name of the collecting division.

Block 15 Employee Signature – Sign the form.

Block 16 Employee Title – Enter your title.

4.3.8.2 - Volume Determination

Field determination of volume is a screening procedure to determine the likelihood of short volume units in the lot. The laboratory will confirm both tare and net volume.

4.3.8.2.1 - Free Flowing Liquids

The approximate volume of small containers of free flowing liquids may be obtained by direct measurement. Standardized graduated cylinders calibrated to "contain" a given volume can be obtained from the laboratory. Use the smallest graduate that will hold the volume to be measured. Under no circumstances use a graduate to measure a volume less than 25% of the maximum capacity of the graduate. Proceed as follows:

1. Select 8 units at random; one from each of 8 cases or otherwise representative of the lot.
2. Empty contents into calibrated graduate holding the container in a nearly vertical position but tipping so that the bottom of the container will drain. Allow to drain one minute after stream breaks into drops. Obtain an anti-

foaming agent from the laboratory if beer or other product likely to foam are measured.
3. Hold the graduate vertically with the surface of the liquid level with the eye. Place a shade of some dark material immediately below the meniscus and read volume from the lowest point of the meniscus. A convenient device for this purpose is a collar-shaped section of thick black rubber tubing cut open at one side and of such size as to clasp the graduate firmly.
4. If no units containing less than declared volume are found, no further determinations are required.
5. If one or more units containing less than declared volume are found, measure 4 additional units selected as above.
6. If the total of twelve determinations contains only one short volume unit, be guided by the significance of the average shortage as related to the individual program guideline.
7. If the total of twelve determinations contains more than one short volume unit, an Official Sample of 48 units should be collected regardless of the average shortage figure.

4.3.8.2.2 - Viscous Liquids

Direct measurement of viscous liquids or large containers is not practical. Field weigh 48 units as specified in IOM 4.3.8.1.3.

4.3.8.3 - Labeling

See "Industry Resources on the Changes to the Nutrition Facts Label" for guidance. See CFSAN's Office of Dietary Supplement Programs and Office of Nutrition and Food Labeling websites as well as FDA.gov for the most up-to-date information regarding claims in labeling.

Also, see CPGM 7321.005 to determine enforcement priorities for food labeling violations, including those related to the Food Allergen Labeling and Consumer Protection Act (FALCPA).

4.3.9 - ORGANOLEPTIC EXAMINATIONS

Examination of many products may be conducted on the spot without fixed laboratory equipment. These examinations vary from simple visual observations for gross filth, such as rodent pellets in wheat, to the detection of odors of decomposition in seafood. Organoleptic examinations for regulatory purposes shall be made only by those individuals qualified by training or experience to conduct such examinations.

If it is necessary to collect physical subsamples for organoleptic examination and they are collected from bulk, the subs must be packed in glass jars to prevent the product from picking up foreign odors.

Review your Compliance Program Guidance Manual and IOM 4.3.7.1 and 6.3.1 for field examination techniques which may be applicable to specific products or industry.

4.3.9.1 - Whole-Bag Screening

When making filth examination by screening shelled peanuts, dried bean, peas and similar products, packed in large containers (i.e., 50-125 lb. bags) use the portable folding whole-bag screens available in your division.

Conduct the examination in a well-lighted area. Set up screen and adjust height to permit opening the bags directly onto the high side of the screen. Place another bag or container on the screen's low side to catch the screened product.

Place a sheet of clean butcher or similar paper in screen body to catch screenings and insert screen wire over paper.

Open stitches of bag being examined to permit approximately ten to twenty-pound portions to enter onto high side of screen. Gradually work the product across the sieve to the low side and into the receiving container. Do not push large quantities rapidly across screen because insects, eggs, stones, excreta pellets, etc., will be carried along with the product and will not sift through the sieve openings.

Examine the screening from each bag and subjectively report live or dead insects, rodent excreta pellets, or other obvious filth. Submit screenings as separate subs if actionable.

SUBCHAPTER 4.4 - DOCUMENTATION & CR

4.4.1 - AUTHORITY

Section 703 of the FD&C Act [21 U.S.C. 373] describes FDA's authority to access and copy records of interstate shipment.

4.4.2 - OBJECTIVE

For FDA to initiate formal legal action, interstate jurisdiction must be established. Most often, this is done by documenting interstate movement of a product by copying records ("getting the records") of a shipment represented by an Official Sample. However, on occasion, jurisdiction can be fixed on a limited list of articles, e.g., counterfeit drugs, medical devices, oleomargarine, through other means.

4.4.3 - POLICY

Judicial Actions are defined as those actions that involve the judicial system. Judicial actions include seizures, injunctions, warrants, and prosecutions. Interstate commerce must be documented, and proper evidence attached to appropriate collection reports to support a judicial action. For Administrative Actions, such as Citation

or Suspension of Registration, follow the same procedure as with Judicial Actions.

Advisory Actions are defined as actions that do not include the judicial system. The actions may include those such as untitled or warning letters, regulatory meetings, etc.

Fully document every physical Official Sample at the time of collection unless instructed otherwise by the program or assignment. The type of interstate records (transportation records, freight bill, waybill, bills of lading. etc.) to be collected are outlined in IOM 4.4.7. The evidence required depends upon the violation and the type of judicial action proposed.

Documentary samples (see IOM 4.1.4.2) - not required to support administrative and/or advisory actions such as untitled letters, warning letters, suspension of registration, regulatory meetings, etc. There is usually no need to prepare a documentary sample in these cases, however, records of interstate commerce should be collected and incorporated into the establishment inspection report in order to document FDA jurisdiction over products suspected to be in violation. Additionally, an affidavit (see IOM 4.4.8) identifying the product(s) of concern, labeling, invoices, statement regarding interstate commerce and key evidence of violations may be prepared for signature by the appropriate party and attached to the inspection report in support of administrative and/or advisory actions. Documentary sample(s) are required for judicial actions such as seizure and injunction. In situations where potential further FDA judicial action is anticipated after an administrative and/or advisory action has been taken (i.e., seizure of products after suspension of registration) documentary samples should always be prepared.

4.4.3.1 - Collection Records

Sample Collections are recorded in the Field Accomplishments and Compliance Tracking System (FACTS). Individuals who may be assigned to collect samples should routinely obtain in advance, a supply of FACTS sample numbers, to be used by the collector to identify samples in the field, prior to accessing FACTS to prepare a sample collection record.

4.4.4 - RESPONSIBILITY

Document samples in accordance with procedures in this Subchapter being certain the copies of records obtained cover the product sampled.

Do not remove the dealer's only copy of records. Whenever possible, scan, photograph or photocopy, if duplicates are not available. Reproductions should be reviewed to ensure all relevant information is readable. Records should not be accepted by email from outside USFDA.

It is possible to enhance the clarity of photocopies from poor originals (e.g., second or third carbon copies, copies in blue ink, etc.) by overlaying the "original" document with one or two clear yellow plastic sheets. These clear yellow plastic sheets are available at most stationery stores.

If the above procedure does not enhance the copied document, pen and ink additions should be made. Records copied on FDA forms must be accurate and legible.

If you are documenting a shipper violation at a dealer, it is your responsibility to show the storage conditions did not contribute to the violation. Obtain an affidavit describing handling of the goods after receipt, and any other information which supports the violation.

In cases where the product does not move Interstate but is formulated from I.S. raw materials, government jurisdiction may be established by documenting the I.S. nature of the major raw materials. This is done by linking copies of records for the I.S. raw material with the production of the final product, by affidavit from a knowledgeable and responsible firm official. See IOM Exhibit 4-7.

Note: In the case of imported products which have been released to commerce, documentation of the sample should also include the port of entry and the importer of record to facilitate investigation by the home division if necessary.

4.4.5 - SAMPLE RECORDS IDENTIFICATION

Identify copies of all records obtained and attached to the collection report (except FDA forms) with the sample number (including the prefix if appropriate), collection date, and collector's handwritten name or initials (the person who signs the collection report, See IOM 4.5.2.5. If a document is more than one page in length, it must be numbered or attached in a manner that will allow further reviewers to determine if any pages are missing. See IOM 5.11.4.3.20.

If the firm maintains their records on film or electronically, see IOM 5.3.8.3.3, 5.3.8.3.1 and 5.3.8.3.2.

4.4.6 - EVIDENCE REQUIRED

When documenting violative situations, consider whether you have established FDA's jurisdiction, documented interstate commerce, shown a violation, and determined responsibility for the violation. The contemplated legal action determines the extent of documentation. A preponderance of evidence is required to prevail in a civil action, such as a contested seizure, as opposed to a criminal prosecution, which requires evidence establishing guilt beyond a reasonable doubt.

4.4.6.1 - Seizure

For a seizure action, FDA must establish jurisdiction over the product, show its interstate movement and document a violation.

Obtain copies of any document proving the article was introduced into or in interstate commerce or held for sale after shipment in interstate commerce. Collect copies of the

best records available, without extensive search or travel. See Section 304(a)(1) of the FD&C Act [21 U.S.C. 334].

4.4.6.2 - Injunction or Criminal Prosecution

The proof required depends on the violation of Section 301 of the FD&C Act [21 U.S.C. 331].

4.4.6.2.1 - Introduction Into Interstate Commerce

Proof is required showing introduction into interstate commerce on or about a certain day by a specific person of a specific consignment of the article. In addition, delivery for introduction into I.S. requires proof the seller had knowledge the purchaser intended to introduce the article into interstate commerce. See Section 301(a) or (d) of the FD&C Act [21 U.S.C. 331 (a) or (d)].

4.4.6.2.2 - Adulteration Or Misbranding In Interstate Commerce

Proof is required showing that a specific consignment was in interstate commerce and was rendered violative by a specific person on or about a certain date while therein. See Section 301(b) of the FD&C Act [21 U.S.C. 331 (b)].

4.4.6.2.3 - Receipt In Interstate Commerce

Proof is required showing receipt of a violative consignment in interstate commerce on or about a certain date, along with evidence to show specific delivery thereafter by a specific person. It is essential to show the violative condition of the shipment was known to the consignee before the delivery or proffered delivery. Whether it was sold or given away is immaterial. See Section 301(c) of the FD&C Act [21 U.S.C. 331 (c)].

4.4.6.2.4 - Manufacture Within A Territory

Proof is required of manufacture within any territory by a specific person on or about a certain date. See Section 301(g) of the FD&C Act [21 U.S.C. 331 (g)].

4.4.6.2.5 - False Guaranty

Proof of the giving on or about a certain date of a specific guaranty and proof of its falsity; usually a specific sale (and delivery) on or about a definite date to the holder of the guaranty. Interstate commerce is not required, except evidence the consignee normally engages in some interstate business. See Section 301(h) of the FD&C Act [21 U.S.C. 331(h)] and 21 CFR 7.13, 201.150 and 701.9.

4.4.6.2.6 - Dealer Violation

Proof of interstate origin of the article, and proof of a specific manipulation which adulterates or misbrands the article, on or about a certain date by a specific person. See FD&C Act 301(k) [21 U.S.C. 331 (k)].

4.4.6.3 - Complaint or Injury Samples

Generally, samples collected from complainants during investigation of injuries or foodborne out-breaks are investigational in nature and not documented. However, if the nature of the contamination or adulteration is such that regulatory action may be warranted, the interstate nature of the sample should be documented. Affidavits from the consumer, retailer, and wholesaler should be obtained.

At times, even though you may not be able to obtain physical portions of the involved item, a Documentary Sample can be collected by photographing the container, contents, labels, codes, etc., and obtaining necessary affidavits and interstate records. See IOM 4.1.6 for sample criteria on complaint samples.

During investigations of alleged tampering incidents, complainants must be advised of the provisions of the Federal Anti-Tampering Act (FATA). A general discussion of the FATA, its provisions for investigation, filing of false reports, and tampering can be useful and informative to those individuals.

Prior to concluding your interview of the complainant, obtain a signed affidavit attesting to the circumstances of the complaint. See IOM 8.8.5.4.

4.4.7 - DOCUMENTING INTERSTATE SHIPMENTS

The minimum set of records ordinarily submitted with a sample will consist of a copy of the invoice covering the sale of the lot to the dealer, the transportation record showing interstate commerce, and an affidavit signed by the dealer, which identifies both the lot sampled and the applicable records. See IOM 4.4.5 and 4.4.7.

Documentation obtained at a location other than the dealer where the sample was collected should be the subject of a memorandum to accompany the collection report.

4.4.7.1 - Sales Records

An invoice does not establish interstate commerce and thus federal jurisdiction. It does not prove actual movement. However, it may provide information as to the value of the goods, carrier, date of shipment, etc. and bear a Food and Drug type guarantee. Collect copies of the invoice to show the owner's intent to sell the product and tie other records to the sample. If the invoice covers numerous items, copy entries covering items sampled and indicate omissions by asterisks. Copy the invoice on the FDA 1662. See IOM Exhibit 4-8. If the invoice bears a Food and Drug guarantee, copy the guarantee on the back of the FDA 1662. Other records which may be substituted in the absence of an invoice are copies of purchase orders, receiving records, canceled checks, correspondence, etc.

Invoices covering in-transit shipments usually are not available. Document any available transportation record that establishes the lot to be in interstate commerce. Be sure to name the shipper and consignee if known. Where positive identification of a shipment cannot be made by personal observation, obtain a statement from the carrier's agent identifying the shipment sampled as having been delivered by the consignor on a certain day for delivery to the consignee. Include in this statement reference to the particular transportation record covering the shipment. The transportation record will generally be available after the shipment is delivered.

Where the sample is taken from a vehicle or dock as the vehicle is loaded, and there are no unusual circumstances which must be explained in a regular affidavit, use the FDA 1664b, Affidavit (In-Transit Sampling).

See IOM Exhibit 4-3.

4.4.7.2 - Transportation Records for Common Carrier Shipments

Section 703 of the FD&C Act [21 USC 373] provides for mandatory access to and copying of all records showing interstate movement of commodities subject to the Act. This is provided the request is in writing, and the records are in the possession of common carriers, or persons receiving or holding such commodities.

Section 704(a) of the FD&C Act [21 USC 374(a)] provides mandatory access, upon presenting your credentials and issuing a written notice of inspection, to documents covering the interstate movement of, non-prescription drugs for human use, prescription drugs and restricted devices. The authority applies to inspection of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs for human use, or restricted devices are manufactured, processed, packed or held.

Note: At times, you may have only the name of the carrier (trucking company), with no address or phone number. If you are unable to locate the trucking company, contact the local office of the U.S. Department of Transportation (DOT) Federal Motor Carrier Safety Administration (FMCSA). If you furnish this office the name of the trucking company, they will be able to provide the address and phone number. Division DIBs have the phone numbers of local offices of the FMCSA as part of a MOU between DOT and FDA; information can be found as well as on the FMCSA field office contact information website.

4.4.7.2.1 - Refusal To Permit Access To Records In Possession Of Common Carriers

Refusal to permit access to and copying of all records showing interstate movement of articles subject to FDA jurisdiction is unlawful provided the request for such permission is issued in writing. You cannot state that the law requires the records be furnished to FDA unless you also explain it is required only after a written request is issued. If refused, after providing a written request, politely explain the law requires the records to be furnished. You are more likely to get the records through courteous persuasion and tact than through stressing the force of law.

4.4.7.2.2 - Written Request For Records

If a carrier, consignee, or any other person refuses to supply I.S. records, and it is apparent he will not do so without a written request, report the facts to your supervisor. Do not routinely issue a written request for I.S. records since evidence so obtained may not be used in the criminal prosecution of the person from whom obtained.

If the request is being made of a carrier who has no responsibility for the violation, issue a written request only after approval by Division Management. When authorized by your supervisor to issue a written request, prepare a statement, using the following guidance, or as otherwise directed by your supervisor:

"Pursuant to Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) permission is hereby requested for access to and copying of all records showing quantity, shipper, and consignee, showing movement in interstate commerce and/ or the holding after interstate movement of_____."

Clearly identify the specific lots which are the subject of the request, the firm and the individual to whom the request is given.

4.4.7.2.3 - Bill Of Lading

The shipper who delivers the goods to the carrier for shipment, prepares The Bill of Lading. It is an order for the carrier to move the goods. When the carrier's agent signs the Bill of Lading he acknowledges receipt for the shipment. The carrier's office in city of origin of shipment maintains a copy of the Bill of Lading. Information normally included is the name and address of shipper, name and address of consignee, date of shipment, name of carrier, vehicle number, and a description of the goods. Copy Bill of Lading on Section II of the FDA 1662. See IOM Exhibit 4-8.
Create a memo to link the carrier's (e.g., UPS, FedEx, etc.) tracking number document to the actual shipment and delivery documentation and attach to the DOC sample CR with a memo explaining how the records were obtained.

4.4.7.2.4 - Freight Bill

This record is prepared by the transportation company for the purpose of collecting freight charges. It includes the same information found on the Bill of Lading, plus additional data about the carrier's handling of the shipment and cost involved. Railroads prepare Freight Bills at their destination offices, where copies can be made. Steamship and airlines combine the Bill of Lading and Freight Bill into one form. Copies are filed at both origin and destination offices of these carriers. Truck lines prepare Freight Bills at the origin office and both origin and destination offices should have

copies. The dealer should have a Freight Bill if he received the goods directly in interstate commerce.

Copy Freight Bills on Section II of the FDA 1662. Enter the type of shipping record in block 21. Section I and II may be executed together on one sheet. If only one section is used, leave the other section blank, and submit the entire page. (See IOM 4.4.7.2.4 and 4.4.7.3 for information on documenting carrier shipment records in CR.)

4.4.7.2.5 - Waybill

The transportation company uses the Waybill in its own operations, and it accompanies the shipment during transit. Copies are not given to the shipper or consignee but can be obtained from the carrier. Other transportation records are generally more readily available than Waybills. Air Freight Waybill numbers are designed so that the originating line and point of origin are encoded in the Waybill number itself. Each airline has a numerical code description, indicated by the first two digits of the number. The three letters, which next follow indicate the point of origin. For example, Waybill No. 01LGA, designates American Airlines (01) as the carrier, and La Guardia Field (LGA) as the point of origin. Most airline offices have a copy of "Official Air Freight Transmittal Manual", which lists the codes. Other express shipping companies, such as Federal Express, and United Parcel Service have their own codes.

4.4.7.3 - Mail or Parcel Service Shipments.

Always attempt to collect the original wrappings showing cancellation of origin office and address sticker. Record the facts obtained from the dealer on the FDA 463, Affidavit (Parcel Post/Service). See IOM Exhibit 4-9. Before the individual signs the statement he should be asked to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit.

To obtain documentation for USPS shipments, ask the dealer where the sample is being collected, to use the shipment label reference number to print the shipping documents from https://www.usps.com. If the article was shipped with Express Mail®, point-by-point tracking details are available. To obtain documentation for parcel service (e.g., UPS and Federal Express) shipments, ask the dealer to use the “tracking number” to print the shipping documents from the parcel service’s web-site. Prepare form FDA 463a.

If the shipment is not recent, the dealers may not have access to the records through their accounts. In this case, a visit must be made to a major parcel service/ parcel post office to obtain documentation. See IOM 4.4.7.2.2 and 4.4.7.2.3.

4.4.7.4 - Shipment by Privately-Owned Conveyance

Obtain on the FDA 463a, Affidavit, a dealer's statement setting forth the facts, including the date and manner of receipt. The affidavit by the dealer may not be evidence, since the dealer lacks personal knowledge of the point of origin. Ascertain the name and home address of the driver of the conveyance, vehicle license number, the name and address of the driver's employer or the owner of the conveyance and the driver's license number. Obtain an Affidavit, from the driver setting forth the facts of the shipment. See IOM Exhibit 4-10.

4.4.7.5 - In-Transit Sampling Affidavit

See IOM 4.1.4.3 and 4.3.4.3 for definition and sampling procedures. When obtaining samples from in-transit lots, if it is a straightforward uncomplicated sample requiring no unusual explanations, use the FDA 1664b, Affidavit (In-Transit Sampling). See IOM Exhibit 4-3. Otherwise, use the regular Affidavit, FDA 463a.

4.4.8 - AFFIDAVITS

Statements on various affidavit forms may be obtained from persons who have dealt somehow with the goods sampled, know material facts relating to the movement of the goods, and/or to events affecting their condition. Such facts, recorded in writing and signed by the person who can testify in court to those facts, can be used either to establish federal jurisdiction or fix the responsibility for a violation. The statement may identify documents proving I.S. movement of goods sampled; it may name the person who could testify to the identity of the goods sampled, and it may certify the sample collected is from the lot of goods covered by the records. See IOM 5.10.7 for additional requirements for Bioresearch Monitoring affidavits.

4.4.8.1 - General Considerations for all Affidavits

You should have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes, corrected and initialed by the affiant are an indication he/she has read and understood the statement. A handwritten statement by the affiant, declaring he/she read and understood the statement is a valuable tool to counter the possibility the affiant might later claim ignorance of what was signed.

Before the individual signs the statement, ask him/her to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit in the presence of and immediately after the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at ***" Subscribed, in this context means to attest by

signing. Thus, your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. If you provide a copy of the affidavit to the affiant, you should keep the original affidavit since the original is an official FDA document.

In cases where the affiant does not speak English, prepare the affidavit on form FDA 463a in the affiant's native language. If necessary, enlist the assistance of a translator. Having a qualified translator present is necessary to explain the statement and assist in discussion. The affiant will only sign the version in their native language, as that would be the one the affiant can attest to. After the affiant signs the affidavit that was written in their native language, you will sign the native language version as the affiant has sworn this statement to you.

A second affidavit should be created to translate the statement into English, with the translator as the affiant. This affidavit includes the translator's qualifications and the English translation of the statement. The translator will swear the translation of the native language affidavit is accurate. After the translator signs the second affidavit, the FDA employee will sign. The translator and witness to the second affidavit should not be the same individual. The translator's signature is placed following the written English translation and their credentials are written in the narrative section of the affidavit. The second affidavit should be appended to the original.

4.4.8.2 - Refusal to Sign the Affidavit

Prepare the statement as described above even if it is apparent the affiant will refuse to sign the affidavit. Have the affiant read the affidavit. If they decline, read it to them. Request the affiant correct and initial any errors in his/her own handwriting. Ask the affiant if the statement is true and correct. Ask him/her to write at the bottom of the statement "I have read this statement and it is true, but I am not signing it because..." in his/her own handwriting.

If the affiant still does not sign the affidavit, you should write a statement noting the refusal situation. Write this near the bottom and within the body of the affidavit. Include the actual situation, such as, you recorded the above facts as the affiant revealed them, the affiant read or refused to read the statement and avowed the statement to be true, and the affiant's reason for refusing to sign (e.g., "upon advice of corporate counsel", "per corporate policy", etc.). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit. Once the refusal is documented on the affidavit, it is not necessary to include any additional narrative under the "Refusals" heading of the EIR.

4.4.8.3 - Confidential Informants

You should take special precautions when obtaining an affidavit from a confidential informant. The affiant may be reluctant to sign a statement, which reveals his or her identity. See IOM 5.2.9 for guidance on interviewing confidential informants.

4.4.8.4 - Affidavit (Dealer/Warehouseman)

The Affidavit (Dealer/Warehouseman), FDA 1664, is used to document the dealer or warehouseman identification of the lot and related records. See IOM Exhibit 4-12.

Fill in all blanks on the form as applicable. There are sufficient blanks for listing up to three invoices and up to three shipping records covering the lot in question. Any unused blanks should be lined out and strike out the words or letters in parentheses which are not applicable.

Be certain the dealer knows what he is signing. Before the individual signs the statement, he/she should be asked to affirm the affidavit is true and accurate.

You should only sign the affidavit AFTER the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at ***" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. Also see IOM 4.4.8.5 for conditions not amenable to use of the FDA 1664.

4.4.8.5 - Affidavit (FDA 463a)

Unusual sampling situations may present circumstances that do not lend themselves to presentation on the FDA 1664 or 1664b. In these situations, record the facts on an FDA 463a, Affidavit.

There is no prescribed format for composing the statement. However, you should positively identify the affiant by name, title, and address at the beginning of the statement and show why he/she is qualified to make the statement. The facts should be arranged in an order roughly paralleling that of the FDA 1664. The most manageable narrative describes the events and circumstances chronologically. Whatever format is used, the recorded facts must be intelligible to the reader unfamiliar with the transaction. See IOM Exhibit 4-7, 4-10, 4-11, and 4-13.

Ascertain all the facts and record those which are material, relevant, and to which the affiant can affirm.

Narrate the facts in the words of the affiant, using the first-person singular. Do not use stilted terms such as, "that" as in the expression "that I am the president of..." If the statement is long and complex, break it down into logical paragraphs.

Have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes that have been corrected and initialed affiant are an indication he/she has read and understood the statement. A handwritten statement by the affiant declaring he/she read and understood the statement is a tool to counter the possibility the affiant might later claim ignorance of what was signed.

Before the individual signs the statement, he/she should be asked to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. Only sign in the signature block if the affiant signs the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit AFTER the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at ***" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. You and the affiant should sign all pages of a multi-page affidavit.

4.4.8.6 - Affidavit (Jobber)

Form FDA 1664a is used to document movement of goods from a jobber to a dealer. See IOM Exhibit 4-14. Complete all blanks as applicable. There are sufficient blanks to list up to three invoices and three shipping records. Line out any unused blanks and strike out all words and letters in parentheses, which are not applicable.

Be sure the jobber knows what he/she is signing. Before the individual signs, he/she should be asked to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit. Only sign in the signature block if the affiant signs the affidavit. See IOM Exhibit 4-11.

You should only sign the affidavit AFTER the affiant has signed it. The wording above your signature is, "Subscribed and sworn to before me at ***" Subscribed, in this context means to attest by signing. Thus, your signature is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. You MUST NOT sign an affidavit until after the affiant swears (affirms) to you the written statement he/she has signed is true. The dealer may be provided a copy of an affidavit if he/she requests it.

4.4.9 - LABELS AND LABELING

No sample documentation is complete without copies of the label and labeling. No special effort is needed to obtain copies of the label when it is on the individual units collected. However, the goods may be accompanied by labeling which is not affixed to the product. In this case, you must obtain copies of all labeling. Although your sample assignment may not specifically request the collection of accompanying labeling, determine if such labeling exists, and if it is present, collect it.

Collect copies of all labeling as directed by your assignment or Compliance Program (CP), when you are collecting labeling specifically to document labeling violations; otherwise, one copy is sufficient for routine review. The CP may require the collection of additional copies so that various offices can review the labeling simultaneously. Be sure to review the CP to ensure you collect enough original copies of labeling. Scan or mount as appropriate, individual copies of labeling so they can be reviewed by various individuals located in separate offices. If the labeling design prohibits effective scanning, multiple copies of the labeling may be necessary. Do not collect the actual labeling if only one copy is available. To do so may remove the offending literature and thus correct the misbranding or you may misbrand the product yourself, by removing legally mandated information. Photographs or other copies must be made in this case.

4.4.9.1 - Labels & Accompanying Labeling

These are defined as:

1. Label - A display of written, printed, or graphic matter upon the immediate container of an article.
2. Labeling - All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article. Labeling includes such material as circulars, booklets, placards, displays, window streamers, books, article reprints, websites, etc., that supplement or explain a product and /or are part of an integrated distribution system for the product. If the labeling and the product are in functional proximity at a point of sale, provide diagrams or photographs of this relationship. If the labeling and the product are found at a manufacturer or distributor, document the role that the labeling will play in the distribution of the product (e.g. to whom will it be sent and when).

Dealer Identification - Request the dealer (Note: a manufacturer may be considered a dealer if the product being sampled is located at the manufacturer) identify collected copies of accompanying labeling with his initials and the date. This will identify these copies of labeling if they are introduced in court later. Prepare a dealer's affidavit on the FDA 463a, covering the relationship of the labeling to the goods. This affidavit should include the following information.

1. Description of Labeling - Describe briefly each piece of literature by name of identifiable quote, i.e., Leaflet, "Do You Have Tired Blood" or Window Streamer, "Amazing New Tranquilizer". State the quantity of such labeling on hand.
2. Location of Labeling - Report the location of each different piece of literature and how much of each is at that location.
3. Method of Distribution - Determine how the labeling is made available to the public. Describe how it is displayed such as: for voluntary pick-up; mailed to prospective customers; distributed without being displayed, etc.

4. Source of Labeling - Describe whether the labeling was sent to the dealer by the shipper of the goods or if the dealer prepared the labeling himself or if it originated from another source. It is important to document this point to fix responsibility in the event the agency wishes to pursue action against that individual. It is not necessary to determine or fix responsibility in order to seize the goods. Document the shipment of the labeling if a source other than the dealer supplied the labeling.
5. Instructions to Dealer - The manufacturer or shipper often provide sales promotion instructions to the dealer. Obtain copies of such instructions if available.

4.4.9.2 - Bulk Shipments

Do not remove the label from bulk containers such as drums, barrels, and large bags, if this results in misbranding the article. Remove and submit an identical label from an empty container if available. Photograph or trace the label if none other is available.

Note: Besides using tracing paper, it is possible to trace a label on a piece of plastic, similar to a document protector, using either a ball point pen or stylus. If it is difficult to read, filling in the tracing with a marker, may highlight the tracing.

4.4.9.3 - Unlabeled or Partially Labeled Lot

The regulations provide for controlled shipment in IS commerce of unlabeled goods. It is a violation to ship unlabeled goods unless:

1. The shipper operates the establishment where the article is to be processed, labeled or repacked, or
2. If the shipper is not the operator of the establishment, he must first obtain from the owner a written agreement signed by the operator. The agreement must contain the post office addresses of both parties and describe the specifications and the processing, labeling, or repacking procedures, in sufficient detail to insure that the article will not be adulterated or misbranded within the meaning of the Act, upon completion of the processing, labeling or repacking.

Determine if there is a labeling agreement and obtain copies of pertinent correspondence. 21 CFR 101.100, 201.150, and 701.9.

4.4.9.3.1 - Documentation

Collect both un-labeled and re-labeled units or specimens of the label to be affixed. Collect specimens of any shipping case labels and any labeling which accompanied the original shipment.

Obtain evidence showing how the lot was labeled at the time of receipt; how the misbranding occurred, and who was responsible. Use photographs and diagrams if necessary to portray the present condition of the lot. If any of the lot has been resold, collect documentary evidence of the resale.

4.4.10 - REPORTING SAMPLE COLLECTIONS

See IOM 1.1 English language requirement. For each sample collected prepare a FACTS Sample Collection Record. Remember the collection report is the basis for most administrative and regulatory actions. The data entered into specific fields of the report are intended to provide information for the compliance officer to prepare documents for legal proceedings. While there may be more than one right way to describe the specific circumstances you are documenting, it is important to keep in mind the subsequent readers of your collection report. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples. Sample collection data may be entered either from an FDA office or from a remote location in the field using a laptop computer and modem. If change is needed to the data in the FACTS Firms table relating to the sample collection, e.g., the firm's name or address has changed; you (the collector) should notify your division's OEI coordinator, so the information can be updated in the FACTS firm table.

After collection data is entered into the FACTS system, you (the collector) must check the record for accuracy and completeness, send it to a supervisor for review, if appropriate, and then sign it electronically. The original data will be stored and permanently associated with this record. Any future changes to the FACTS database reference tables, such as the firm files, employee name, data codes, etc., will not alter the original data in the electronically-signed sample collection record.

Only the collector has editing privileges for the signed original sample collection record. You may modify the original record but must electronically sign each revision. All modifications of the original record are permanently retained as part of the original record. A permanent electronic record trail is created, capturing and retaining every change to original and subsequent records. If retrieval of the sample collection data is needed, the original record and all changes to the original record can be retrieved. See IOM 5.10.7 for additional information for Bioresearch Monitoring sample collections.

4.4.10.1 - Flag

The following situations require an entry in the Sample Flags screen in FACTS. See IOM Exhibit 4-15.

4.4.10.1.1 - 301(K) Sample

"301(k) Sample" - See IOM 4.1.4.4.

4.4.10.1.2 - Complaint Sample

Use this flag for any sample collected from a complainant during follow-up investigation.

4.4.10.1.3 - Dealer Voluntarily Holding

This flag alerts the reviewer the lot is being voluntarily held. Enter how long in the Flag Remarks field. This information will be important for the compliance officer to know when preparing a seizure or other regulatory action. This information needs to be entered as soon as the CR is created, in order for the laboratory to adequately prioritize sample analysis and provide a timely notification to the firm.

4.4.10.1.4 - Exhibit Sample

When sample is to be used exclusively for court exhibit without analysis.

4.4.10.1.5 - Factory Food Sample

Flag as "Factory Food Sample" when sample(s) of any item, used in the production of any food product, are taken during the EI. See IOM 4.1.6.

4.4.10.1.6 - Fumigated

Enter name of fumigant in Flag Remarks field.

4.4.10.1.7 - Inv. Samples Of Filth Exhibits

Enter the product code of the filth exhibits in the Product Code field of the FACTS Sample Collection Screen. **Note the product code for exhibits consists of the Industry Code followed by "YY-99" or "Y--99" as below.**

Example: Filth Exhibits of gnawings, pellets, wood splinters, etc.

In a food plant = 52YY-99
52 = Misc. food related items
Y = Exhibits
Y = Sub class - None
- = Dash
99 = Evidence exhibits n.e.c.

In a drug plant = 66Y--99
66 = Misc. drug related
Y = Exhibits
- = Dash
- = Dash
99 = Evidence exhibits n.e.c.

Other industries: Handled in same manner using applicable industry code(s).

4.4.10.1.8 - Pesticide Sample

After flagging a pesticide sample, the basis for sampling must be entered in the Flag Remarks field as either "Pesticide Compliance" or "Pesticide Surveillance". Additionally, the name of the county and state, or country where grown must be entered in the appropriate fields in the Collection Record.

Pesticide 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). The following examples are provided for clarification of this definition:

1. 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.
2. Grower Jones has violative residues of chlorothalonil on collards for which there is no tolerance. Field samples, I.S. samples, and packing shed, or warehouse samples of these collards would all be part of the same episode.
3. Grower Jones also has violative residues of omethoate on kohlrabi about two months later. This is a separate episode.
4. Along with the omethoate on kohlrabi, Grower Jones has violative residues of omethoate on beets. Normally this would be considered a separate episode from the previous episode. However, if information were available showing that both residues resulted from the same application of the pesticide or the residues were closely related in some other way, the beets might be considered as part of the kohlrabi episode.
5. Grower Smith has violative residues of disulfon and permethrin on kale. This would be considered as one episode because only one commodity is involved.

Note: The detention without physical examination procedures provide for recommending detention based on a single violative pesticide finding. See RPM Chapter 9-6. Under these procedures we may anticipate that the number of compliance samples collected in follow-up to a violative finding may diminish appreciably and, in most cases, will be limited to occasional audit samples. These samples should also be linked to the sample number (episode number) of the original violative sample that prompted the automatic detention. This episode number will be indicated in the applicable Import Alert.

The Episode Number will be the sample number of the first violative sample collected in a series of samples and is used to identify the other related samples within an episode. The division must assure that the Episode Number is used within the division and any other divisions which follow-up to the original violative sample. This number must appear in the Episode Number field of the FACTS CR.

4.4.10.1.9 - Reconditioned

When collected in connection with a reconditioning operation in accordance with a court order.

4.4.10.1.10 - Sampled In Transit

Use when the sample is collected from a carrier or while in transit. Indicate this flag in the Collection Remarks field. See IOM 4.1.4.3 and 4.3.4.

4.4.10.1.11 - Split Sample

Use this flag when a sample is divided between two or more laboratories.

4.4.10.1.12 - Survey Sample

Use this flag for any sample collected under a Compliance Program, which directs samples be collected as part of a survey, or if an assignment to collect the sample(s) indicates the sample(s) are "Survey" sample(s). Use this flag for any sample collected under the Drug Surveillance Program (CPGM 7356.008); enter the survey number in the flag remarks section.

4.4.10.1.13 - Under State Embargo

This flag alerts the compliance officer that the lot is being held under state embargo. Enter how long in the Flag Remarks field.

4.4.10.2 - Type Identification

When applicable, using the list of values, choose one of the following to complete the Sample Type field in FACTS. Identify any documents associated with the sample, and the sample itself, with the corresponding prefix, if noted followed by the FACTS sample number.

4.4.10.2.1 - Additional (ADD)

To identify a physical sample collected from a previously sampled lot. Do not report or document as an "ADD Sample" those instances when only additional records or documentation are obtained for the sample.

4.4.10.2.2 - Audit/Certification

To identify a physical sample collected to verify analytical results provided by a certificate of analysis or private laboratory analysis that purports to show the product complies with the Food, Drug and Cosmetic Act.

4.4.10.2.3 - Documentary (DOC)

To identify an official sample comprised of documents and photographs, collected without a physical portion. Do not use this designation to identify a physical sample for which you wish to delay analysis. See IOM 4.1.4.2 and Exhibits 4-1 and 4-2.

4.4.10.2.4 - Domestic Import (DI)

To identify samples collected of foreign products, which have passed through Customs and entered domestic commerce. The country of origin must be reported on the C/R. See IOM 4.1.4.8.

4.4.10.2.5 - Food Standards (FS)

To identify samples collected to provide information on which to base Food Standards. See IOM 4.1.5.

4.4.10.2.6 - Investigational (INV)

To identify samples collected to document observations and/or where interstate commerce does not exist or is not necessary. See IOM 4.1.6.

4.4.10.2.7 - Mail Entry

To identify a sample of an imported product that entered the United States through the U.S. Mail.

4.4.10.2.8 - Non-Regulatory

To identify a sample collected and analyzed by FDA for other federal, state or local agencies of products over which FDA has no jurisdiction.

4.4.10.2.9 - Official

To identify a sample which is representative of a lot of any product covered by the Food, Drug and Cosmetic Act for which interstate commerce can be documented.

4.4.10.2.10 - Post Seizure (PS)

To identify samples collected pursuant to a court order from a lot under seizure. See IOM 4.1.4.7.

4.4.10.2.11 - Regulatory

A sample collected or analyzed by non-FDA personnel, including samples submitted by industry.

4.4.10.3 - Preparation

The collection record (C/R) is the starting point and the basic reference for all actions and considerations based on the sample. It contains or bears direct reference to every important point about the sample and the lot from which it was collected. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples.

Individual Fields - Complete the individual fields on the FACTS Sample Collection Screen as indicated. The following fields must be completed to save the sample information; Sample Class; Sampling Division; Collector; Collection Date; Sample Basis; Sample Type; FIS Sample Number; Sample Description; Product Code; Product Description; Resp. Firm Type; Resp. Firm FEI Number; PAC; Sample Origin; and CR and Records Sent To. The fields described below are listed in alphabetical order to facilitate locating the instructions. Please note, when a collection report is generated, the field names may change on the report.

Any information that needs to be included regarding the sample and that cannot be documented via FACTS, should be documented on the C/R Continuation Sheet, FDA 464a. For example, pictorial descriptions of a field exam for a filth sample; or a description of relative documents and what they demonstrate regarding the subject lot of a documentary sample; etc.

4.4.10.3.1 - Accomplishment Hours

Enter the accomplishment data for every sample collected, by clicking on the "clock" icon at the FACTS task bar. In the Accomplishment hours screen, enter the PAC by selecting from the list of values and type in the number of hours spent collecting the sample. Also enter all PACs that were entered in the Collections PACs field on page 2 of the collection record. If another person is involved in the collection, add their time by clicking on the "Add" button. See IOM exhibit 4-16 page 2.

4.4.10.3.2 - Analytical Assignment

After saving a collection record, the system will prompt you for analytical assignment data. Enter lab analysis data (PAC and PAF) for your sample. The analytical PAC and PAF (Problem Area Flag) may be different from the collection PAC and PAF. Enter split sample data on separate lines. For DOC samples leave this field blank. Do not enter any data in this form if the sample is being delivered to a non-FACTS lab.

4.4.10.3.3 - Brand Name

Enter the Brand Name of the product. This is found on the labeling of the product. It is important to identify the product completely so the compliance officer can communicate accurate information to the court and the U.S. Marshal in the event of a seizure.

4.4.10.3.4 - Carrier Name

Enter name of the transportation company who transported the goods in interstate commerce if known at the time of preparation of the CR. You may need to obtain this later to fully document interstate commerce. In the case of a 301(k) sample, this is the transportation company who moved the component you are documenting across state lines. For a 301(a) sample documenting the shipment of a violative product in interstate commerce, enter the name of the carrier utilized by the manufacturer or distributor to carry the goods across state lines.

4.4.10.3.5 - Collection Date

Enter the date using the format - mm/dd/yyyy. **Note: the default date is today's date. Be careful not to use the default date if the sample was not collected on the date the CR is created. Only one date can be entered; if the sample collection was accomplished over several days, use one date. Be consistent. This date should be used to identify the physical sample and any records attached to the CR. This field is critical; be certain to verify the date.**

4.4.10.3.6 - Collection Method

Describe how you collected the sample and which subs are the 702(b) portion. Relate the number and size of the sampled units and subsamples to show how each was taken, e.g., "Two cans of product randomly collected from each of 12 previously unopened cases selected at random." Note any special sampling techniques used, e.g.: "Subs collected using aseptic technique and placed in sterile glass jars or whirl-packs" or "Subs 1-10 consist of approx. 1# of product. Subsamples 1-10 collected from bulk storage Bin #1 composited in unused, brown, paper bag." Completely describe the collection method of each sub of selective samples with multiple subsamples, including your observations of the conditions, e.g.: “Two live insects collected from seam of bag #2. Live insects were observed exiting bag and two were collected upon exit.” You will normally need to use a continuation sheet to describe collection of all subsamples and your description of the lot “bag-by-bag” examination. See IOM 4.5.2.1 regarding sub identification.

4.4.10.3.7 - Collection PACs

Enter the Program Assignment Code (PAC), which is most correct, from the list of values. If the PAC on your assignment is not listed, discuss with your supervisor or FACTS Lead User.

4.4.10.3.8 - Collection Reason

Enter the complete reason for collection giving the suspected violation, compliance program guidance manual, and analysis desired. Identify any inter-division, regional, headquarters initiated, assignment document(s) in sufficient detail so the document can be located, if necessary. If the sample was collected during an inspection to document violations found, state that and indicate the date of inspection. See IOM exhibits 4-1 and 4-16.

4.4.10.3.9 - Collection Remarks

Enter any remarks you feel are necessary. Describe any special circumstances. If a 704(d) [21 U.S.C. 374(d)] letter is indicated, include the name, title, E-mail address (if available) and the telephone/fax number of the most responsible person at the firm to which the letter should be addressed. If a 702(b) sample is not collected, describe the specific circumstance and justification for not collecting the 702(b) portion unless it is a device or tobacco product, or the assignment or guide already states why a 702(b) portion is not needed. If the sample is an in-transit sample, state the sample was collected in-transit, from whom sampled (e.g. driver and carrier firm), and where sampled. If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. You may

use a "CR Continuation Sheet", FDA 464a if you need more space.

Note: Confirmation of firm Email address and inclusion in collection remarks is integral in order to provide results in an efficient and timely manner. According to Field Management Directive (FMD) 147, if the firm has agreed to hold products pending FDA results or if the analytical results are laboratory classification 3, the Laboratory Director or their designee shall email the results of analysis to the collecting division's established email account for receipt of analytical results.

4.4.10.3.10 - Collector

Your name should appear here by default.

4.4.10.3.11 - Collector's Id On Package/Document

As the Sample Collector, quote your identification placed on the packages, labels, etc., e.g., "55563 12/5/05 SAR". Samples are to be quoted with the information in the order shown in the example without additional symbols, words, or characters. See IOM 4.5.2.3. When multiple units are collected, all or at least a portion should be labeled as subsamples. Subsample numbers need to be included on the C/R and in the EIR. You may include the sub numbers used in this block outside of the quotes, e.g., "55563 12/5/05 SAR" subs 1-30.

4.4.10.3.12 - Collector's Id On Seal

Quote your identification used on the Official Seal applied to the sample, e.g., "55563 12/5/05 Sylvia A. Rogers". See IOM 4.5.4.1 and exhibit 4-17. If you use the FDA metal seal, enter the words "Metal Seal" followed by the seal identification and number, e.g., "U.S. Food and Drug 233", entering the actual number of the seal used. Samples need to be kept under lock or in your possession, until sealed. The Collection Remarks field needs to describe any discrepancy between the date sealed and the date collected. Normally, the sample should be sealed on the same day as collected.

4.4.10.3.13 - Consumer Complaint Number

If the sample relates to a consumer complaint, enter the complaint number. This will allow your CR to be linked to the complaint and viewed by the Consumer Complaint Coordinator and other Division and Center personnel.

4.4.10.3.14 - Country Of Origin

Select the Country of Origin, if known. This field is of particular need when the sample is a Domestic Import Sample.

4.4.10.3.15 - County

Select the County where the sample was collected (or grown if appropriate, i.e. a pesticide sample of an agricultural product.) This field is not needed for many samples. Use for pesticide samples to aid in later communication with State officials in the event of a violative result.

4.4.10.3.16 - CR & Records Sent To

Enter the division which is most likely to initiate any regulatory action. This field requires some thought on the part of the collector and communication with the supervisor. For a 301(k) sample, where the dealer is responsible, this is the division where the sample was collected. Do not assume the address on the label is the location where follow-up to a violative sample will be initiated. Do not send the records to another division unless you know it is the division of the actual responsible firm. Per Staff Manual Guide f 2460.2, Field Office Filing System (or f:3291.2 as listed on the FDA internet site), field survey samples will be filed by the collecting division.

4.4.10.3.17 - CRX/DEA Schedule

Choose the appropriate schedule from the list of values, if applicable.

4.4.10.3.18 - Dairy Permit Number

Enter if applicable. If you are collecting samples from a dairy, obtain this number from the firm.

4.4.10.3.19 - Date Collected

See Collection Date IOM 4.4.10.3.5.

4.4.10.3.20 - Date Shipped

Enter date in the format, mm/dd/yyyy. This is the date of interstate shipment. Obtain it from the documentation you collected to document interstate movement of the product. Identify the document you used to determine this date in the "Documents Obtained" section.

4.4.10.3.21 - Documents Obtained

Click on the "Documents Obtained" button to enter Document Type, Document Number, Document Date and Remarks for any records collected to support a violation or show interstate movement of the product sampled. Enter an identifying number and date for invoices, freight bills, bills of lading, etc. Include the name and title of person signing any affidavits in the Remarks field. Be sure to describe the reason each document attached to the collection record was obtained. For example, when referring to a bill of lading, indicate that it was collected to document the interstate movement of the product. Also indicate which documents were collected to document specific violations encountered during inspections. State the number of pages for each document if it contains more than one page and

refer the reader to the appropriate section/page of the document which shows the deviation you are documenting. Indicate the number of photographs attached. Depending on the sample and what you are trying to document, you may use the document number to record the actual number of the document (i.e., invoice number or bill of lading number) or to order the documents attached. You should order your documents in a manner that allows easy review (be guided by your supervisor or Compliance Branch). This section may also be used to list C/R attachments including FDA generated forms. See IOM exhibit 4-1.

4.4.10.3.22 - Episode Number

Enter an episode number if applicable. See IOM 4.4.10.1.8.

4.4.10.3.23 - Estimated Value

Enter the estimated wholesale value of the lot remaining after sampling. Obtain this information from invoice or other records. (This is not the value to be used for seizure bond purposes; however, it may be used by the division to evaluate whether seizure is an appropriate action.) Estimate value if you have no documentary reference. For DOC samples (see Exhibits 4-1 and 4-2,), indicate the estimated value of the lot. If the DOC sample is collected to document a lot that has already been shipped, estimate the value, or obtain a figure from your documentation, which represents what was shipped. Many times, a DOC sample is collected merely to establish interstate commerce, in those situations, the value of the goods that traveled, or will travel, in interstate commerce is what is needed.

4.4.10.3.24 - FEI Number

The FEI number is a 10-digit unique identifier, which is used to identify firms associated with FDA regulated products. Use the Build button to query the database and find an FEI for firms associated with your sample. If one does not exist, FACTS will assign one to the firm. Take care in entering search criteria to avoid creating unnecessary FEI numbers. **You must enter an FEI for a dealer on every CR, unless you check the box indicating the dealer is a consumer.**

4.4.10.3.25 - Firm Name

This will be filled in by FACTS when you select an FEI.

4.4.10.3.26 - Firm Type

Using the list of values, select one of the following for each FEI entered, with respect to the product sampled:

4.4.10.3.26.1 - Dealer

This is always the firm from which the sample was collected. **There must be a dealer entered on every CR,** unless you check the box indicating the dealer is a consumer. **Note: this is not the same as the establishment type of the firm identified by the FEI. There are circumstances where you may identify the same firm as the dealer and another establishment type, such as when collecting a plant in-line sample.**

Note: If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. When the sample is an in-transit sample (see IOM 4.1.4.3), enter the consignee of the lot as the dealer and state in **collection remarks** the sample was collected in-transit, from whom sampled (e.g. driver and carrier firm), and where sampled.

4.4.10.3.26.2 - Grower

Select "Grower" if the FEI identifies a producer of a raw agricultural commodity.

4.4.10.3.26.3 - Harvester

Use "Harvester" for an FEI identifying the harvester of the product sampled.

4.4.10.3.26.4 - Ingredient Supplier

"Ingredient Supplier" should be used to identify a firm which supplied a raw material or component. For example, when documenting a 301(k) [21 U.S.C. 331(k)] situation.

4.4.10.3.26.5 - Manufacturer

Use "Manufacturer" with an FEI, which identifies the manufacturer of the product sampled. **Note: this may be the same as the dealer when a product is sampled at a manufacturer. In that case, you can enter the FEI twice and identify it as both the manufacturer and the dealer.**

4.4.10.3.26.6 - Shipper

The shipper is the firm responsible for causing the interstate movement of the product.

4.4.10.3.27 - FIS Sample Number

Enter the last two digits of the fiscal year. The remainder of the number will be assigned by FACTS. Note: FIS sample numbers will no longer be required when the FIS is turned off.

4.4.10.3.28 - Food Canning Establishment

Enter "Food Canning Establishment" if applicable.

4.4.10.3.29 - Hours

See Accomplishment Hours in IOM 4.4.10.3.1.

4.4.10.3.30 - How Prepared

Explain how the sample was prepared prior to submission to the laboratory; how you identified some or all the units;

and how you wrapped and sealed the sample. Note any special preparation methods such as fumigation, frozen, kept under refrigeration, etc., and the form in which the sample was delivered to the laboratory, e.g. in paper bags, original container, etc. If coolants or dry ice were used, indicate so here. It is important to be specific as to how you protected the integrity of the sample and the chain of custody, e.g., “Subs identified as noted (describe how 702(b) portion was prepared/handled- see IOM 4.5.2.1), placed in unused, brown paper bag; bag taped shut and FDA seal completed (as noted) and applied, bag identified as noted in pen/ink. FDA 525 attached to sealed bag, placed in brown, cardboard box and prepared for shipment, then delivered to division security guard desk for UPS pick-up”.

4.4.10.3.31 - Lot Size

Enter the amount of goods on hand before sampling as determined by your inventory of the lot. Include the number of shipping cases and the size of the components, e.g., 75 (48/12 oz.) cases, 250/100 lb. burlap bags, 4/100,000 tab drums, 24 cases containing 48/12/3 oz. tins. If accompanying literature is involved, describe and state the amount on hand. For DOC samples (see Exhibit 4-1 and 4-2), also indicate the lot size, e.g. "one x-ray machine" or "50000 syringes and 1000 promotional brochures."

4.4.10.3.32 - Manufacturing Codes

Click on the "Manufacturing Codes" button to enter and identify all codes, lot numbers, batch control codes, etc., and how they are displayed on labels, containers and shipping containers. Enclose the code in quotes, e.g. "code". For example, code embossed on can cover, "87657888" or code applied in ink on side of container, "0987878". Also indicate the manufacturing codes used on products for which a DOC sample was collected, for example, "serial number "ABC" stamped on metal plate." See IOM Exhibit 4-2.

Enter any expiration dates in the Exp. Date field.

4.4.10.3.33 - Method of Collection

See Collection Method in IOM 4.4.10.3.6.

4.4.10.3.34 - National Drug Code (NDC)

Enter if applicable

4.4.10.3.35 - Orig CR & Records To

See CR and Records Sent To in IOM 4.4.10.3.16.

4.4.10.3.36 - Payment Method

Select one of the following from the from the list of values: "Billed"; "Borrowed"; "Cash"; "Credit Card"; "No Charge"; "Voucher". The “Credit Card” option means you used your personal credit card as a last resort.

4.4.10.3.37 - Permit Number

See Dairy Permit Number in IOM 4.4.10.3.18.

4.4.10.3.38 - Product Code

Enter the 7-digit product code. Use the Product Code Builder for guidance. When 301(k) samples are collected, the full product code of the finished product must be entered. See IOM exhibit 4-1. See IOM 4.4.10.1.7 for product codes for filth or evidence exhibits. Special product code considerations include environmental samples. See environmental sample identification instructions under IOM 4.3.7.7.2.

4.4.10.3.39 - Product Description

Enter a complete description of the product including the common or usual name and the product packaging/container system. For example, aspirin tablets packed in clear, non-flexible plastic bottle with white screw on top with yellow stick-on label and black printing. Bottles packed in white, paperboard boxes with black printing. Paperboard boxes packed in brown cardboard boxes with black printing. If you need additional space, continue the description in remarks. See IOM exhibit 4-1.

4.4.10.3.40 - Product Label

Quote pertinent portions of the label such as brand name, generic name, quantity of contents, name and address of manufacturer or distributor, code, etc. In the case of drugs, quote the potency, active ingredients and indicate whether Rx or non-Rx. Quote sufficiently from accompanying literature to identify. In the case of a Documentary Sample, sufficiently describe the article to identify what is sampled.

NOTE: When the product sampled is packaged in a container, shipping case or similar container, quote the pertinent labeling from the container.

When quoting from a label, or labeling, use exact spelling, capitalization, punctuation, arrangement, etc., as found on the original label(ing). Use asterisks to indicate any omissions.

4.4.10.3.41 - Product Name

Product Name field is completed by FACTS when you select the product code.

4.4.10.3.42 - Reason For Collection

See Collection Reason in IOM 4.4.10.3.8.

4.4.10.3.43 - Recall Number

If the sample was collected as part of a recall investigation where the recall number is already known, enter the recall number.

4.4.10.3.44 - Receipt Issued

Select "FDA472", "FDA484", or "None" from the list of values.

4.4.10.3.45 - Receipt Type

See Receipt Issued in IOM 4.4.10.3.44.

4.4.10.3.46 - Related Samples

This field is used to identify a sample number to which other sample information can be linked. When you collect more than one sample from a single shipment or there is more than one sample relating to a possible regulatory action, designate one sample as the "lead" sample. Enter that sample number in this field of the collection record for each related sample. Other related sample numbers should be listed in the Collection Remarks field.

4.4.10.3.47 - Resp. Firm Type

Choose the appropriate type from the list of values for the firm most likely to be responsible for a violation. For a 301(k) [21 U.S.C. 331(k)] sample the responsible firm should be "Dealer". You should only enter one firm with the firm type you designate as the responsible firm type.

4.4.10.3.48 - Sample Basis

Select from the two choices on the list of values.

"Compliance" means the sample was collected on a selective basis as the result of an inspection, complaint or other evidence of a problem with the product. "Surveillance" means the sample was collected on an objective basis where there is no inspectional or other evidence of a problem with the product.

Please note official samples can be either compliance or surveillance, and INV samples can also be either. See IOM Exhibit 4-16 for more information.

4.4.10.3.49 - Sample Class

Make a selection from the following list of values: "Collaborative Study"; "Criminal Investigation"; "Division Use Sample"; "Normal Everyday Sample"; "Petition Validation"; "Quality Assurance"; "State Partnership"; "Total Diet".

4.4.10.3.50 - Sample Cost

Enter the cost of the sample. If no charge, enter 0. If, as a last resort, you use your personal credit card to pay for the sample, enter the amount paid in this field and select "Credit. Card" in the Payment Method field. If you are unable to determine the cost of the sample and the firm states they will bill you later, enter the estimated cost in this field and state that it is an estimate in the Collection Remarks field.

4.4.10.3.51 - Sample Delivered Date

Enter the date on which the sample was delivered to the laboratory or for shipment. For DOC samples, you must leave this field blank. If you make an entry, you must enter a laboratory.

4.4.10.3.52 - Sample Delivered To

Enter to whom you delivered the physical sample. If delivered to your own sample custodian under seal, show delivery to servicing laboratory or sample custodian. If delivered to an analyst, report e.g., "In person to Analyst Richard R. Doe." If you shipped the sample, enter the name of the carrier to whom the sampled was delivered. Enter the carrier shipment tracking number. If the sample is shipped by air, enter the air waybill number. If shipment is by parcel post, give the location of the post office, e.g., "P.P., Austin, TX." For a DOC sample, this field may be left blank. If the sample is being sent to a non-FACTS laboratory, enter the laboratory here.

4.4.10.3.53 - Sample Description

Briefly describe what the sample consists of, i.e., three unopened, 200 tablet bottles; 20 lb case of iceberg lettuce; or documentary sample consisting of records, literature and photographs, etc.

4.4.10.3.54 - Sample Flags

Click on the "Sample Flags" button to choose an appropriate flag using the list of values. See IOM 4.4.10.1 and exhibit 4-15.

4.4.10.3.55 - Sample Number

Select a pre-assigned sample number, using the list of values button, or the system will enter a sample number when the record is saved.

4.4.10.3.56 - Sample Origin

Choose "Domestic" or "Domestic/Import" from the list of values.

4.4.10.3.57 - Sample Sent To

Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORS Sample Distribution site. See IOM 4.4.10.5. If you are splitting the sample among multiple laboratories for various analyses, enter each laboratory separately. Generally, in that case you will have more than one PAC code. If, because of your assignment, you are aware the sample should be forwarded to a second laboratory after the first analysis is complete, include that information in the Collection Remarks field. However, you should only enter a laboratory in this field if you are sending the sample there, not if the laboratory will be expected to

forward it. For a DOC sample, leave this blank. If the sample is to be sent to a non-FACTS lab, leave this field blank, enter the lab in the Sample Delivered To field, print a copy of the collection record and enclose it in the FDA 525 attached to the sample.

4.4.10.3.58 - Sample Type

Make a selection from the list of values. You can enter only one value. If more than one type applies, choose one and indicate the other in remarks. If the sample is a domestic import, be sure to enter "DI", so that you can enter the foreign manufacturer. See IOM 4.4.10.2.4.

4.4.10.3.59 – Sampling Organization

Make a selection from the list of values. This is the division that actually collects the sample.

4.4.10.3.60 - State

Select the State where the sample was collected. This field is optional for many samples. Always use it for pesticide samples.

4.4.10.3.61 - Status

This field is pre-filled by the system as "In-Progress". Select "Ready for Review", from the list of values, when you are ready to send the record to your supervisor for review, if you are required to do so. After supervisory review, if appropriate, change the status to "Complete". This will cause the electronic signature form to be activated.

4.4.10.3.62 - Storage Requirements

Select from the following list of values: Ambient; Frozen; Refrigerated, Dry Ice, Fresh, Uncontrolled and Flashpoint.

- D=Dry Ice – used to indicate the product is cooled using dry ice (frozen CO2)
- H=Fresh – used to indicate the product is an unprocessed or raw agricultural commodity and stored accordingly
- U=Uncontrolled – used to indicate product is stored under conditions in which the temperature is not controlled (this would be considered a non-temperature regulated warehouse/facility, conveyance not under temperature control, etc.)
- P=Flashpoint – used to designate the flashpoint of a flammable substance (Identify the flash point in °F or °C in the 'Remarks' section)

4.4.10.3.63 - 702(b) Portion Collected

Check this box if the sample you collected contains a 702(b) Portion of any food, drug or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. This includes samples where 1) the sample schedule already accounts for the 702(b), 2) you collected in duplicate and separated the duplicate out and 3) you collected in duplicate and did not separate the duplicate out. If you did not separate the 702(b) portion, note this in the remarks so the laboratory can separate the 702(b) portion. If no 702(b) portion was collected, do not check this box and provide reason for non-collection in the Collection Remarks section (4.4.10.3.9).

4.4.10.3.64 - 704(d) Sample

Check this box if the sample is collected during an inspection (e.g., a FDA 482 has been issued) of a food manufacturer, processor or packer, and the firm is entitled to a copy of the analytical results. See FMD 147. Include in Collection Remarks name, title, E-mail address (if available) and telephone/fax number of the most responsible person at the firm. See also IOM 4.1.1.4 and 4.4.10.3.9.

4.4.10.4 –Lab Servicing Table (LST) Dashboard

The National Sample Distributor (NSD), implemented in October 2007, has been phased out completely with the implementation of Program Alignment.

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

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

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

4.4.10.4.1 – Other Information

The Office of Regulatory Science intranet website maintains current documents related to the Laboratory PAF managers Contact List and the Division Compliance Contacts. Questions on sample analyses, assignments, laboratory capability, or otherwise can be directed to the Office of Regulatory Science contacts listed at that site.

Additional information on sample collections/laboratories, including assignments, SCOPE and contacts, can be found at

Field Guidance-
http://inside.fda.gov:9003/ProgramsInitiatives/FieldOperations/FieldGuidance/default.htm

Field Programs-
http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/default.htm

Also reference 4.5.5.2 - Routing of Samples.

4.4.10.5 - Routing

Anyone who has user access to the FACTS system has access to the electronic records contained therein, including sample collection records. Individuals requiring sample collection data can query the system and retrieve data, based on the query parameters. In those cases where an individual needs to receive immediate notification of a sample collection, the collector may communicate the sample number via E-mail, telephone, or another means to a user, and the user may then query the system and obtain the desired data. It is not always necessary to print paper copies of FACTS sample collection records for those who have access to FACTS.

Routing Records Accompanying Sample Collection Record - Forward Collection Record from FACTS and original records through your supervisor to the division office compliance branch most likely to take regulatory action.

When a sample is to be billed, route a copy of the FDA 484, if issued, annotated with the FACTS sample number to the appropriate fiscal unit for your division. If possible at the time of collection, provide the FACTS sample number to the firm and request that this number be placed on the billing invoice. If no sample number is available, ask the firm to identify the bill with your name as the collector to help the fiscal unit match the bill to the sample record in FACTS. The fiscal unit will have access to the sample collection record in FACTS to obtain detailed sample information.

SUBCHAPTER 4.5 - SAMPLING: PREPARATION, HANDLING, SHIPPING

4.5.1 - OBJECTIVE

The preparation, handling, and shipping of samples is your responsibility, and must be carried out in a manner which assures the sample's integrity and supports testimony that the sample examined was the same sample you collected from the documented shipment.

As few persons as possible should handle the sample to reduce the likelihood of compromising sample integrity. In order to maintain “chain of custody”, it is important that properly packaged and identified samples be opened only by the sample custodian(s). See ORA Lab Manual, Volume II, Section 5.8 for information about relinquishing samples.

4.5.2 - IDENTIFYING MARKS

4.5.2.1 - Subsamples

Identify a representative number of subsamples (subs) with the sample number (including prefix, if appropriate), collection date and your handwritten initials. If individual sub identity must be maintained, assign and mark each sub with a separate Arabic numeral. In some comprehensive inspections or investigations it may be important to correlate the manufacturing control code with the sub number.

When a variety of articles are included under one sample number, fully identify each sub and describe them on the C/R. Factory exhibits should be fully identified and, where appropriate, correlated with inspectional observations, manufacturing procedures, and/or routes of contamination. See IOM 4.2.5.6 for using the FDA 484 - Receipt for Samples as a memo to accompany C/R to describe subs collected.

When multiple subs are taken from cases, bales, boxes, etc. in the lot, Arabic numerals and letters in combination may be used for identification. For example: if two cans are taken from each case in the lot, the cans may be marked as subs 1a, 1b, 2a, 2b, etc. to identify the subs as coming from case #1, case #2, etc. If the second can or container taken from each case is the 702(b) [21 U.S.C. 372(b)] portion, it is desirable that all duplicate portions be sealed separately from the FDA portion. This fact should be so noted on the cases and C/R.

If multiple subsamples are to be collected, it may be advantageous to place identifying information such as sub number, sample number, and collection date on peel-off labels, tape, etc. in advance of sampling to save valuable time. Your initials must be in your own handwriting.

Do not place peel-off labels directly on cans for ACD samples collected for cause as these can interfere with the analysis.

4.5.2.2 - Borrowed Samples

Although most samples are purchased, some may be borrowed, non-destructively examined, and returned to the owner. These samples must be handled carefully to avoid defacing or damaging the product.

Identify borrowed samples so the identification can be removed with no damage to the product, i.e. a sticker label that can be peeled off.

4.5.2.3 - Identification Techniques

Mark a representative number of subsamples with the sample number, collection date and your handwritten initials. Similarly identify any outer packaging, labels or circulars. If more than one person is involved in collecting the sample, the person preparing and signing the C/R

initials the subs. Reinsert circulars removed from packages. See IOM 4.3.2.2 for procedures on identifying lots from which sampled.

Transparent tape such as Scotch Magic Transparent tape accepts ball point ink and may be used on glossy items such as glass, plastic, tin, etc. Glass, such as bottles, vials and ampoules, may be identified by using a very fine pointed felt or nylon marking pen and covering the identification with transparent tape for protection.

Do not use tape on very small containers such as ampoules, which must be snapped or broken to remove the contents for analysis. Tape wrapped around the container may interfere with assay.

Do not use permanent type markers when identifying subs in absorbent containers if the ink may penetrate into the product thus contaminating the sample.

Diamond or carbide tipped stylus pencils may be used to mark tin, glass, etc. Do not use diamond or carbide tipped stylus to mark products in glass under pressure (i.e., carbonated beverages).

4.5.2.4 - Photographs

Unless they are part of a DOC Sample, photographs are exhibits, to an EIR, report of investigation, or complaint. They are not samples. Photos taken during inspections and investigations are not described on a C/R, but are submitted as exhibits with the EIR. Photographs related to DOC Samples, e.g., labeling, records, and product, are identified with the sample number, collection date, and handwritten initials on the border or backside. See IOM 4.4.5 Attach the photos to the FACTS Collection Record.

In describing photographs, do not mark the face of the print. Narrative descriptions may be placed on the mounting paper next to the print or, if explanatory graphics are required, use a plastic overlay. See IOM 5.3.4.2.3 for negative identification and submission procedures and IOM 5.3.4.3 for digital photos.

IMPORTS: See IOM 6.2.8– Photographs: Identification and Storage.

4.5.2.5 - Records - Accompanying Literature and Exhibits

Identify all copies of sample records, accompanying literature, and attached documents with the sample number (including prefix, if applicable), collection date and your handwritten initials as described in IOM 4.5.2.1. If an attached document is more than one page in length, it must be numbered or attached in a manner that will always allow further reviewers to determine if any pages are missing.

4.5.3 - SAMPLE HANDLING

All samples must be handled, packaged, and shipped to prevent compromising the identity or integrity of the sample. Samples must be packed with shock absorbing materials to protect against breakage of containers or damage to Official Seals. Frozen samples must remain frozen; perishable products may be frozen, if freezing doesn't interfere with the planned analysis, products requiring refrigeration (e.g., fresh crabmeat for bacteriological analysis) should be shipped in ice. Use your experience and knowledge (and that of your supervisor, if necessary) to determine the most appropriate packing and shipping method.

4.5.3.1 - Fumigation

See IOM 1.5.3.1 for safety precautions.

General - As soon as possible, freeze any sample containing, or suspected to contain live insects, as long as freezing will not change or damage the product or break the container. If freezing is inappropriate to maintaining the integrity of the sample, fumigation may be carried out using air tight containers (such as a mason-type jar with inner ring, or a polypropylene container with air tight lid), with sufficient fumigant to kill the insect infestation. Contact your servicing laboratory for alternative fumigants.

Moth crystals, containing paradichlorobenzene (PDB), is an alternative fumigant. Do not use mothballs or moth flakes containing naphtha or naphthalene. Do not use moth crystals in or near plastics, particularly Styrofoam/ polystyrenes as crazing or melting may occur. Other alternative fumigants include: liquid household ammonia or ethyl acetate, either of which can be used to dampen a cotton ball and placed in an appropriate container; or cut small portions of commercial pesticide strips.

4.5.3.1.1 - FUMIGATION SAFETY PRECAUTIONS

Follow safety precautions when fumigating samples. **Contact your local servicing laboratory or MSDS for the appropriate protective gear and handling of fumigants.** Guidance is as follows:

1. Carry all alcohols, fumigants, and other hazardous liquids in approved safety containers.
2. When fumigants or preservatives are used, limit your exposure to these chemicals. Minimize transfer and exposure time. Avoid getting chemicals on hands or clothing. DO NOT MIX CHEMICALS.
3. Insure DOT regulations and guidance and International Air Transport Association (IATA) guidelines are followed when mailing or shipping samples containing fumigant or preservative. Exceptions for small quantities are listed in 49 CFR 173.4.
4. The sample identification data on your packaging, the FDA-525 and C/R, must always identify the fumigant and method of fumigation, and/or preservative used.
5. Material Safety Data Sheets (MSDS) for each chemical fumigant or preservative used must be available at each duty site and enclosed with the shipped sample. Read and follow all instructions and precautions listed on the MSDS.

4.5.3.1.2 - Procedures For Fumigation

Place a small amount of fumigant, in an airtight container. Separate the fumigant from the sample with a piece of paper, paper napkin, or unscented facial tissue. Put specimen or product into container and seal tightly. Do not re-open container unless absolutely necessary. If possible, use a glass container with a lined screw lid. A mason-type jar with inner ring is also acceptable.

4.5.3.1.3 - Exceptions To Fumigation

When submitting samples or exhibits to show live infestation, do not fumigate. Consult with your supervisor or your servicing laboratory PRIOR to sending or bringing a live infestation into the laboratory to permit preparation for proper handling and storage. Do not fumigate sample when submitting samples for pesticide residue analysis.

4.5.3.1.4 - Preservation Liquids

Insects may be killed and preserved in 70% ethyl alcohol or a 1:1 mixture of 70% ethyl alcohol and glycerin (may be labeled glycerol). These chemicals can be obtained from your servicing laboratory. Do not collect rodents or animal tissues unless specifically instructed. Insure all vials or bottles of preservation liquids are tightly sealed to avoid leakage. Identification labels may be placed in containers,but must be written in India ink or 2H pencil only. Keep all preservation liquids away from excessive heat or open flame.

Identify preservative used on FDA 525, C/R, and on sample container. Enclose a copy of the MSDS with the shipped sample. Follow DOT and IATA guidelines when shipping or mailing samples with preservatives as stated under fumigants.

4.5.3.2 - Labeling

Samples collected for label review only should be officially sealed in clear plastic bags. This will permit cursory review and, if necessary, photocopying of the container label and reduce the need to break the seal each time the label is examined.

4.5.3.3 - Samples for Pathological Examination

Tissue samples are not routinely collected for microscopic or pathological examination. Authorization must be obtained from the appropriate Center before collecting samples of this material.

When assigned to collect tissue samples, unless directed otherwise by the program, the assignment, or your supervisor, cut the tissue into 1/4 inch pieces and preserve in 10% buffered formalin, or in other suitable preservatives as directed. Do not freeze the sample since frozen tissue is not suitable for pathological studies.

4.5.3.4 - Small Sample Items

Samples in small vials, bottles, boxes and similar type containers may be placed inside the FDA 525 envelope after identification. When the envelope is used as the sample package, place the official seal across the glued flap and the blank face of the form.

If the sample container (vial, bottle, etc.) is officially sealed, it may be placed in the same FDA 525 together with copies of the assignment.

4.5.3.5 - Frozen Samples

Containers - Pre-chill sterile containers before collecting frozen samples. Transfer liquids in glass to expandable containers before freezing. If the liquid must be frozen in glass, leave sufficient headspace to allow expansion. If freezer facilities are not available or if the sample is to be shipped, pack with dry ice in insulated containers.

Dry ice and insulated containers may be obtained from ice cream or dry ice dealers, and economical polystyrene (Styrofoam) containers are available at most variety stores. However, while Styrofoam containers have excellent insulating qualities, they will not withstand shipping abuse unless protected by sturdy outer cartons.

Note: If your division desires the return of Styrofoam freezer chests or ice packs used in shipping samples, note this fact on the C/R and FDA 525.

Dry Ice - Caution: Dry ice is potentially dangerous and requires caution in handling and shipping. Do not handle with unprotected hands; transport in your car without adequate ventilation; or place inside tightly closed metal, plastic, or similar type containers that do not breathe. If it is necessary to use this type container, adequately vent to prevent pressure build up. Do not use glass containers for packaging or storing dry ice. (Note: Failure to adequately vent a container containing dry ice may cause a dangerous pressure build up, resulting in serious risks to sample integrity and personal safety for those handling the container).

Note: If a sample is to be analyzed for ammonia contamination, it must not be shipped frozen in dry ice. Use other methods of freezing, if frozen shipment is necessary.

4.5.3.5.1 - Shipping Frozen Samples

If using a U.S. Government Bill of Lading, it is important to give a full and accurate description of the sample for rate purposes. If more than one commodity is in the shipment, describe and enter each separately.

In all packages where dry ice is used, distribute the dry ice equally on all sides of the sample package using pieces as large as possible. Be sure the container is insulated on all six sides and tape all edges securely to assist in insulating the carton. Do not place dry ice inside officially sealed packages.

Freezing by dry ice is not effective for more than forty-eight hours. For overnight shipments, use at least one pound of dry ice per pound of sample. Increase the amount for longer hauls or unusually warm weather. (Note: When samples are in plastic type containers, the dry ice must be wrapped in paper to prevent direct contact with the plastic. The extreme cold generated by the dry ice may cause plastic to become brittle and rupture.)

Shipments made via FedEx Corporation, Priority I, Purolator, Airborne or by other fast air express carriers, will be delivered to consignees early the next business day. Tests have shown the following amounts of dry ice will be adequate when this method is used:

For samples already in frozen state: five to ten pounds of dry ice depending on sample size is normally sufficient. For samples requiring only to be refrigerated: A minimum of ten pounds of dry ice is sufficient.

According to current policy and practices for shipping dry ice with respect to CFR 49, the International Air Transport Association (IATA) regulations and the UPS Dangerous Goods Agreement:

For non-medical, non-hazardous U.S. domestic air packages with 2.5 kg (5.5 pounds) or less of dry ice, mark the outer carton with (prominently and visibly in 1'' block letters):

- "Dry Ice" or "Carbon Dioxide, Solid"
- If dry ice, then also "DRY ICE; 9; UN1845."
- A general description of the non-hazardous contents (e.g. food, meat)
- The amount of the dry ice contained in the package at the time of packaging or a statement that there is 2.5 kg [5.5 pounds] or less in the package
- Use the dedicated Dry Ice Label (available from the carrier, for an example see IOM Exhibit 4-19.) Complete the bottom portion of the sticker and note the amount of dry ice in kilograms.

For non-medical U.S. domestic packages with greater than 2.5 kg (5.5 pounds) of dry ice:

- Indicate in Campus Ship that you will be shipping dry ice, or attach Hazardous Materials shipping papers available from the carrier ($5 per package dry ice fee applies)
- The package must be prominently and visibly marked, in 1'' block letters, as containing "Dry Ice" or "Carbon Dioxide, Solid", UN1845 (See: IOM Exhibit 4-19).
- A label identifying dry ice contents is available from the carrier, for an example see IOM Exhibit 4-19
- The net weight of dry ice at the time of packaging must be indicated on the shipping papers and can also be marked on the outer package (prominently and visibly marked in 1'' block letters)
- UPS Dangerous Goods Agreement required (Note: A UPS Dangerous Goods Agreement, available from the shipper, is required to be filled out and provided to the shipper at time of shipment).

Note: The dry ice may freeze the edges of the product, so if it is imperative no part of the sample becomes frozen, use coolants other than dry ice. Mark the FDA 525 that dry ice was used.

See IOM 4.5.5.8.6 when shipping sample packages containing hazardous or toxic items by air.

4.5.3.5.2 - Control

To prove the shipment did not thaw in transit, place a jar or leak-proof plastic bag of chipped ice in the shipment adjacent to the sample package, but not within the officially sealed package.

4.5.3.6 - Refrigerated (Not Frozen) Samples

Maintain refrigerated (not frozen) samples in a refrigerator at 4.4°C (40°F) or below. Use either wet ice or some type of "Ice Pak", "Liquid Ice", "Sno-Gel", "Kool-It", or similar products to maintain the required temperature range.

Place Ice Paks, etc., in sealed plastic bags to protect samples from possible contamination should the container break, the ice melt, or the refrigerant penetrate the sample. Use insulated shipping containers for shipping samples to the laboratory.

4.5.3.6.1 - Control

If it is necessary to show the sample temperature did not go above the desired or specified temperature, you can use one of several methods, such as including a pre-chilled, shaken down, maximum reading thermometer or commercially available indicators. Take care to place the thermometer outside of the sealed sample package and attempt to place in an area anticipated to be likely to reach the highest temperature. Describe the method used on your C/R.

4.5.4 - OFFICIAL SEALS

Domestic samples, regardless of type, shall be sealed with form FDA 415a, Official Seal, or, in some situations with the FDA "Metal Seal". See IOM 4.5.4.6 for use of metal seals. See also IOM 4.1.4.2.

Note: With the approval of your supervisor and laboratory, it is not necessary to affix an official seal to a sample that will be in the sample collector's continuous personal custody until it is submitted personally to an analyst. This procedure should be reserved for emergencies and high

priority situations. The sample should be submitted the same day it is collected with the subs properly identified. The C/R must state you personally delivered the sample to "Analyst _____"or other appropriate staff member.

Make every effort to prepare and submit your samples on the date collected so the C/R, sub identification, and the final official seal bear the same date, and thus enhance sample integrity. However, if you cannot finish the sample preparation on the same day collected, you must explain in the C/R Collection Remarks field what steps you took to protect the integrity of the sample, e.g., officially sealed and locked in supply cabinet, locked in safe, etc.

Never place more than one sample in the same officially sealed package.

Official seals may be used up to five years beyond the expiration date indicated by the manufacturer of the seal. Field offices should periodically monitor their official seal inventory and discard or destroy any official seals that are more than 5 years beyond the expiration date indicated by the manufacturer of the seal.

4.5.4.1 - Preparation

Inscribe FDA 415a, official seal, with the division office name, sample number (with the appropriate prefix), the date applied, your signature, printed name and title. See IOM Exhibit 4-17. The seal must bear only one signature. If more than one person is involved in collecting the sample, the person preparing and signing the collection record must sign the seal.

4.5.4.2 - Application

Seal the sample package so that it cannot be opened at any point without evidence of tampering. If the surface of the sample container is of such construction or condition that the FDA-415a, official seal, will not adhere (e.g., waxed container, frosted over, sweating, etc.), wrap or place sample in a container to which the official seal will hold. See IOM 4.5.4.6.

To ensure the sample package cannot be opened at any point without evidence of tampering, wrap clear packing tape around the package that the seal is adhered to and across at least two sides of the official seal. The clear packing tape should not cover any text on the official seal.

When using the self-adhering seals, the surface on which the seal is to be placed must be clean and dry. The seal must be rubbed when affixed to generate heat and help it bond.

4.5.4.3 - Sealing Method

There are many acceptable methods of officially sealing samples. Because of the wide variety of shapes and sizes of samples, and the ingenuity you may have to apply to package and packaging situations, explicit methodology will not be detailed here. If you are unsure of a sealing method, consult your supervisor.

4.5.4.4 - Protecting the Official Seal

Protect the sealed surface by wrapping the package securely with heavy wrapping paper for mailing or shipment. If your officially sealed package is not further wrapped for shipping and the tape(s) and official seal are thus exposed, you must protect the Official Seal from damage during shipment by:

1. Covering the official seal with a sheet of heavy wrapping paper or heavy clear plastic (e.g. from a document protector) of sufficient size to cover the surface of the official seal.
2. Tape the protective paper or heavy clear plastic securely around the edges so it cannot come loose and expose the official seal. Do not paste or glue the paper or plastic to the face of the official seal since this will obliterate the official seal when removed.
3. When you protect the official seal by heavy paper, write "FDA Seal Underneath", or similar wording across the protective paper. This alerts the receiving custodian the official seal is underneath, and to take care when removing the protective paper. If you cover and protect the seal with heavy clear plastic, the sample custodian will be able to copy the necessary information off the seal without removing the protective cover.

4.5.4.5 - Broken Official Seals

Reseal the sample whenever you break the official seal. Each seal used on the sample will be submitted with the records associated with the collection record, properly initialed and dated, to provide a continuous history.

There is only one class of seal: an "official seal". Anytime a sample is sealed with the FDA 415a, or with the FDA Metal Seal, the item is "officially sealed". An officially sealed sample must sometimes be reopened to prepare it for submission to the laboratory, or for some other legitimate reason. In that situation, the original seal must show the date it was broken. When the sample is ready to be resealed the new seal must show the date it is applied. This procedure must be followed each time the official seal on a sample is broken. Each seal will show the history of the date it was applied and broken. See instructions in Exhibit 4-17. Indicate in the collection remarks field of the FACTS C/R the fact that the seal was broken and reapplied and attach the broken seal to the FACTS C/R. This provides an unbroken, documented chain of custody.

4.5.4.6 - Metal Seals

Where it is impossible to use the paper official seal, the numbered self-locking "U.S. Food and Drug" metal seal may be used. This seal is effective for use on wooden crates, drums, baskets, etc., where the FDA 415a cannot be used. Record the number of the metal seal used on the CR. See IOM 4.3.4.3 for instructions on the use of the metal seal to reseal railroad cars or conveyances. When a supply

of these seals is needed by your division, contact the Division of Domestic Human and Animal Food Operations (DDHAFO) at (301) 796-0360.

4.5.4.7 - Sealing Non-Sample Items

Although the primary purpose of the official seal is for sealing samples, there are times when the official seal may be used to officially seal items other than samples. The FDA metal seal is often used to seal rail cars or vehicles as indicated in IOM 4.3.4.3.

When directed by your supervisor, you may use an official seal to seal questionable or suspicious bioresearch records encountered during an inspection or investigation to prevent tampering or to preserve their integrity. As explained in the applicable compliance program, the procedure must have the approval of the bioresearch monitoring staff (HFC-230) prior to implementation.

4.5.5 - SAMPLE SHIPMENT

When you cannot personally deliver a sample to the examining laboratory, ship it by the most economical means commensurate with the need for rapid handling. See IOM 4.5.5.2 and 4.5.5.6 for special information on shipments to FDA Headquarters' laboratories.

FDA collects a wide variety of samples, many of which are unstable, toxic or hazardous material, e.g., etiological agents, radiation products, chemical, hard swells, etc. Use safety precautions in handling and shipping commensurate with the hazard. See IOM 4.5.5.8.7.

If there is any concern regarding the contents of the package the sample custodian may verify in FACTs the identity of the collector and the product collected prior to opening the package.

4.5.5.1 - FDA 525 - Sample Package Identification

Form FDA 525 - Place the FDA 525, sample package identification, near the official seal. For small containers or surfaces that will not accommodate the FDA 525, you can tie it to the sample package by using twine through the eyelet. Do not affix the FDA 525 on the outside of the shipping container or under the official seal. Enclose a copy of the assignment document in the FDA 525 envelope and provide the following information on the FDA 525:

1. Division or Headquarters' laboratory to which the sample is directed, City, State, and unit symbol (e.g., SRL, HFD-400, HFS-300, etc.).
2. Date.
3. Your division and symbol.
4. Sample Number.
5. Name of dealer.
6. Product Identification.
7. Address of dealer.
8. Enter the reason for collection. (Copy from C/R.) Provide reference to any sampling assignment.
9. Provide information as to the analysis to be made.
10. When entering information for "Package___of___Packages"- number of packages should be the number of sample packages. Also enter any pertinent remarks. Note if your division desires the return of any freezer chests, ice packs, or maximum/minimum thermometers used.
11. Provide any special storage instructions. Mark appropriate block and enter suggested refrigeration temperature if necessary. Elaborate in Remarks if necessary.
12. Print your name.

See IOM 4.5.3.4 when using the FDA 525 as a sample package. See IOM 4.5.5.3.6 for information to include with the FDA 525 for medical device samples.

Outer Wrapper or shipping container - Always place the words, "SAMPLE NO. _____" followed by the actual FACTS or OASIS sample number(s)(with appropriate prefix) on the outside of the package near the address label. This alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

4.5.5.2 - Routing of Samples

In general, samples will be submitted to an appropriate servicing laboratory with available capacity via the Lab Servicing Table (LST) Dashboard, except as directed by the Compliance Program Guidance Manual, assignment or your supervisor. The following provides general procedures for sample submission.

1. Vitamin and Nutritional Labeling - Submit to FDA, Science Branch (HFR-SE680), 60 Eighth St. N.E., Atlanta, GA 30309.
2. Radiopharmaceuticals for Sterility - Submit samples to WEAC.
3. Drug Residues - Submit to the Denver District Tissue Residue Lab.

4.5.5.3 - Samples to Administration Laboratories

When shipping samples to headquarters or other special laboratories follow the procedures for each laboratory.

4.5.5.3.1 - Split Samples

Where the sample examination is split between a Headquarters Division, the National Center for Drug Analysis, and a division lab:

1. Follow the above procedures on the portion sent to a Headquarters' laboratory or NCDA.
2. Submit Original C/R and records to the servicing laboratory, whether or not the home division.

4.5.5.3.2 - National Center for Drug Analysis or Headquarters' Division

National Center for Drug Analysis or Headquarters' Division analysis alone.

1. Do not forward original C/R and records.
2. Enclose a copy of the assignment memorandum in the FDA 525 envelope.
3. Affix the FDA 525 to the officially sealed sample package.
4. Submit the Original C/R and records to the home division, or forward to the home division if other than the collecting division.

4.5.5.3.3 - Center For Food Safety and Applied Nutrition (CFSAN)

Submit samples to CFSAN as directed by a Compliance Program, Field Assignment or with approval of the Office of Compliance, Division of Field Programs and Guidance Compliance Programs Branch (HFS-615).

The Compliance Program, Field Assignment, or approval will provide sample information and instructions for shipping to the appropriate CFSAN laboratory. CFSAN laboratory locations are:

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

FDA Gulf Coast Seafood Laboratory
Iberville Drive
Dauphin Island, AL 36528

1. Office of Regulatory Science
   a. Division of Bioanalytical Chemistry (HFS-715) - Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins, nutrients in food, ingredients in dietary supplements, and ingredients of cosmetics.
   b. Division of Analytical Chemistry (HFS-705) - Conducts laboratory investigations in the broad areas of food additives, allergens, pesticides, dietary supplements, seafood toxins, food defense threat agents, and industrial chemicals that may contaminate CFSAN regulated products.
   c. Division of Microbiology (HFS-710) - Develops, optimizes, and validates methods for recovery, detection, identification, and quantitation of pathogens and toxins from foods and cosmetics, and the processing environment. Maintains FDA's food-related gateway to the PulseNet System. Develops and applies subtyping methods to further enhance data generated for Pulsenet, strain identification, and molecular epidemiological investigations.
2. Office of Applied Research and Safety Assessment
   a. Division of Molecular Biology (HFS-025) - Analyzes foods when the chemical methodology is under development or unusual equipment or skills are required, such as radioactivity analysis and migration of food additives from food packaging materials. Microbiologically examines samples for potential food pathogens by rapid molecular biological testing using DNA probes, PCR, and DNA fingerprint analysis.
3. Office of Cosmetics and Colors
   a. Division of Color Certification and Technology (HFS-105) - Conducts analyses of color additive samples submitted to FDA for certification, assigns certification lot numbers to compliant lots, and denies certification to non-compliant lots. Develops, optimizes, and validates methods for the determination of components and impurities in certifiable color additives. Develops, optimizes, and validates methods for the determination of color additives in foods and cosmetics. Conducts analyses of foods and cosmetics for color additive content when special skills and expertise are not available in the field.
4. Office of Food Safety
   a. Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory (HFS-400) - Conducts microbiological and chemical investigation of seafood, including bacterial and viral pathogen, natural marine toxins, aquaculture drugs, products of decomposition, and other contaminants when special skills or equipment required for analysis are not available in the field.

4.5.5.3.4 - Center For Drug Evaluation And Research Division Of Pharmaceutical Analysis (DPA)

Examines surveillance drug samples collected and shipped under current program directives. Analyzes all heparin and insulin samples.

CDER-OPS-OTR
Division of Pharmaceutical Analysis (DPA)
645 S. Newstead, Ave.
St. Louis, MO 63110

4.5.5.3.5 - Center For Biologics Evaluation And Research (CBER)

Center for Biologics Evaluation and Research
Sample Custodian (ATTN: HFM-672)
Building NLRC, Room 113
Kensington, MD 20895

Examines and reviews biological products not covered by a Compliance Program. Prior to shipping a sample, the division should notify either the Sample Custodian, 301-594-6517, or the Regulations and Policy Branch, 301-827-6210, who in turn will notify the Sample Custodian.

4.5.5.3.6 - Center For Devices And Radiological Health (CDRH)

WEAC (see 1. below) is the primary laboratory for devices and radiation-emitting products. The CDRH Office of Science and Engineering Laboratories accepts medical devices and radiation-emitting products for testing, but only after assignment or approval from CDRH, Office Health Technology. Note: Include in the FDA 525 envelope a copy of the manufacturers finished device specifications test methods and acceptance/rejection criteria.

1. Send samples for sterility analysis to: Winchester Engineering and Analytical Center (WEAC)
   109 Holton Street (HFR-NE400)
   Winchester, MA 01890-1197
   Patrick Regan, Director, Analytical
   Telephone: 781-756-9707
   FAX: 781-756-9757
2. Send bioburden analysis samples to WEAC.
3. Send bioindicator analysis samples to WEAC.
4. Send device and GWQAP device samples for physical and engineering analysis to WEAC.
5. Send in-vitro diagnostic device samples to WEAC.
6. Send devices used for antibiotic susceptibility testing (including discs) requiring performance testing to WEAC.
7. Send Southwest and Pacific Region condom and glove samples to the Pacific Regional Laboratory (PRS)
8. Send all other condom and glove samples to WEAC.
9. Send radiological health samples to:
   CDRH/OSEL Sample Custodian HFZ-105
   WO62, 10903 New Hampshire Ave,, Room 4126
   Silver Spring, MD 20993
   Telephone: 301-796-2558
   FAX: 301-796-9795 Note: Contact Office of Science and Engineering Laboratories, 301-796-2558 prior to collection and shipment of any radiological product sample.

4.5.5.3.7 - Center For Veterinary Medicine (CVM)

Center for Veterinary Medicine
Division of Compliance (HFV-230)
7500 Standish Place (MPN II)
Rockville, MD 20855
240-276-9200

Samples of veterinary products, not specifically covered by one or more of the CVM Compliance Programs, can be sent to the above address for review, evaluation, and comment. This includes documentary samples, and labels/ labeling and advertising materials. There are no laboratory facilities at MPN II. If you have questions about sampling or sample destinations, contact HFV-230 and/or the applicable program contact.

4.5.5.3.8 - Center For Tobacco Products (CTP)

Do not collect samples of tobacco products unless directed by an assignment, approved by the Center for Tobacco Products, Office of Compliance and Enforcement, or by Division Management.

Send compliance and surveillance samples to: Southeast Regional Laboratory (SRL), Atlanta Center for Tobacco Analysis. Contact information on Atlanta Center for Tobacco Analysis website.

4.5.5.4 - Sample Shipment to Outside Agencies

Do not ship any samples outside FDA unless your assignment, applicable program, or your supervisor specifically instructs you to do so.

4.5.5.5 - Notifying Receiving Laboratories

When frozen, perishable, or high priority items are shipped, notify the receiving division or lab by telephone, or e-mail, that you have shipped the sample. Provide the following information:

1. Sample Number
2. Name of Product
3. Number of Parcels in Shipment
4. Carrier's Name
5. Carrier's Waybill Number
6. Carrier's Train, Truck, Bus, or Flight Number
7. Estimated Time and Date of Arrival
8. Relevant Remarks, i.e., "Sufficient Dry Ice to maintain frozen until 8:00 AM, (date)"
9. Place the name and telephone number of the person that is to receive the sample on the outer shipping container near the address with instructions to the carrier to contact the above-named individual upon arrival of the package.

4.5.5.6 - Method of Shipment

Note: If samples are shipped to headquarters laboratories by bus lines, delivery of the sample must be specified on the bus bill. Use the most economical method of shipment consistent with the need for special handling. Shipping costs may be reduced by packing samples addressed to the same consignee into a larger container or by "piggy-backing" (taping a number of larger boxes together and shipping them as one package). Make sure the total package is within the carrier's weight and size limits.

4.5.5.7 - Parcel Post

When samples are shipped by parcel post, do not exceed the parcel post limits as to size and weight.

1. Package Limits
   a. From a first-class post office to a first-class post office:
      Weight - 40 lbs.
      Size - 84 in. length and girth combined.
   b. Mailed at or addressed to a second or lower-class post office:
      Weight - 70 lbs.
      Size - 100 in. length and girth combined.
2. Address Labels - The use of franked labels and envelopes is no longer allowed. Affix proper postage to envelope or address label after using division or resident post postal scale and meter. If no postal meter is available, use the resident post postage scale to weigh the envelope or package and add the proper postage using postage stamps. If no stamps are available purchase them from the post office and claim reimbursement on your voucher. Obtain a receipt for the stamps or postage, if required by your Division Office.

If the package is addressed to an FDA unit, show the FDA routing symbol following the name of the FDA unit.

Note: Wrap parcels shipped "Registered Mail" in kraft paper because the postal service must affix an ink stamp seal to each closure point. Do not wrap the outer package with tape that has a shiny or glossy surface (e.g., masking tape, filament tape, scotch type tape, etc.).

Some items cannot be mailed or can be mailed only in small quantities for safety and legal reasons. Call 1-800-ASK-USPS or visit your Post Office if you have questions.

4.5.5.8 - Common Carrier

Certain Department of Transportation (DOT) regulations exist pertaining to carrier inspection of packages. Instruct the carrier to contact the shipper (FDA) prior to any package inspection requires breaking the official seal. Carriers have broken FDA official seals for package inspection during transit, thereby compromising the sample integrity.

If an FDA 3082 - Shippers Declaration for Dangerous Goods is executed for shipments of restricted items, place a statement in the special handling section that breaking an FDA official seal is not authorized, and to contact the shipper (FDA) if there are any questions regarding the shipment. See IOM Exhibit 4-18.

4.5.5.8.1 - Shipment

You must decide how your samples are shipped. The judgment must be based on your knowledge of the practices and performance of the transportation firms in your area. As a general rule, Parcel Post, United Parcel Service, or current GSA contract carrier should be used for small packages and other express or comparable carriers for packages too large for PP, UPS, or current GSA contract carrier. Before using motor express lines and passenger bus lines determine that their schedules and delivery practices are satisfactory and reliable. Bus lines must not be used for shipments to Washington, DC offices unless delivery at the destination address is specified.

Air express or air freight shall be used only for samples requiring extremely rapid handling or where more economical means of shipment are not available or feasible.

Air freight service is offered by the individual air lines and, although usually not as convenient as express, is more economical and should be used especially for shipments of 50 lbs. or more.

4.5.5.8.2 - Designated Carriers

You may ship by any carrier you wish with the objective of obtaining the best possible service at the most economical rate.

Always indicate on the carrier's shipping document that the shipment is a U.S. Government shipment.

4.5.5.8.3 - Government Bill Of Lading

Prepare Form SF-1103, Government Bill of Lading (GBL), for shipments made by common carrier except as described below. Distribute GBL as follows:
Give the Carrier:

1. Original (White) Form SF-1103
2. Shipping Order (Pink) Form SF-1104
3. Freight Waybill Original (White) Form SF-1105
4. Freight Waybill Carriers Copy (White) Form SF-1106
   Submit the remaining 4 copies "Memoranda Copy" (Yellow), Form SF-1103a, and the "Memorandum Copy" (Blue), Form SF-1103b, to your division.
   If available, obtain the transportation costs or the rate from the carrier and enter it in pencil on the copies submitted to the division.

4.5.5.8.4 - Commercial Bill Of Lading

The use of commercial forms (in lieu of GBL's) and procedures for small shipments is subject to the limitations and instructions set forth in the following paragraphs. The use of commercial forms shall be limited to those carriers that have a letter of agreement with FDA or GSA.
The use of commercial forms is to be applied only to the following types of shipments:

1. Shipments for which the transportation charges ordinarily do not exceed $100.00 per shipment and the occasional exception does not exceed that monetary limitation by an unreasonable amount.
2. Single-parcel shipments via express, courier, small package, or similar carriers, without regard to shipping cost, if the parcel shipped weighs 70 lbs. or less and does not exceed 108 inches in length and girth combined.

3. Multi-parcel shipments via express, courier, small package or similar carriers for which transportation charges do not exceed $250.00 per shipment.

4.5.5.8.5 - Address Labels

Form HHS-409, address and sample number identification label, is no longer available. Until a new standardized label is issued, investigators need to use the street address of the receiving laboratory or office. Do not use the post office box number as contract carriers may not deliver to PO Box numbers.

Place the words "SAMPLE NO", followed by the appropriate FACTS or OASIS sample number(s) (with appropriate prefix), on the outside of the shipping package(s) near the address label. The package(s) should be properly identified with the FDA office shipping the sample and the receiving laboratory or other office. This alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

4.5.5.8.6 - Shipment Of Hazardous Or Toxic Items

The Department of Transportation (DOT) regulations require certain packaging, forms, certifications, declarations, and/or statements covering shipment of hazardous or toxic items. Except for dry ice, most of the samples of hazardous or toxic materials we ship are classified as "ORM-D, Consumer commodity". Both dry ice classified as "9", and ORM-D classifications require a certification/declaration for shipment by air but not for shipment by surface transportation.

Shipments containing dry ice - use the dedicated Dry Ice Label (available from the carrier - for an example see IOM Exhibit 4-19). Complete the bottom portion of the sticker and note the amount of dry ice in kilograms. In addition to the label, the package itself must be clearly marked in 1" block letters: "DRY ICE; 9; UN1845".

Contact the carrier involved to execute the necessary forms, certification/declarations, packaging, marking, etc. required for the particular shipment or hazardous or toxic items.

For further information, contact your district Safety Officer or Industrial Hygienist.

4.5.5.8.7 - PRECAUTIONS

The following precautions should be observed when shipping samples:

1. Always pack liquid products in sufficient cushioning and absorbent material to absorb any breakage which might occur. Check with the Post Office or other carriers regarding shipment of liquids.
2. Hard swells may explode. Wrap them heavily in paper and cushioning material for shipment and submit promptly.
3. Observe special precautions when shipping products in pressurized containers to avoid exposure to excessive heat. Air shippers who ship in non-pressurized planes may also have special requirements for this type container. Check Post Office and carrier for regulations, precautions, or restrictions before shipping products in this type container.
4. Special precautions for both packaging and shipping radioactive substances must be observed. If necessary, consult your supervisor, the regional radiological health representative, WEAC or the applicable program.

Note: The compliance program for radioactive drugs directs the manufacturer to ship samples via their normal mode of transportation to WEAC. The Nuclear Regulatory Commission (NRC) requires that firms manufacturing radioactive drugs ship only to NRC licensed consignees. WEAC's NRC license number is 20-08361-01 Exp. Date 11/30/2026. This license number should be used for any shipments of radioactive products to WEAC.

4.5.5.9 - Certified and First Class Mail

Where speed is essential and a record of receipt of the sample is desired, small samples may be sent by express mail or certified air mail, or, in situations where speed is a factor but the receipt is not necessary, by first class air mail. Where other methods of shipment do not suffice, larger samples may be shipped certified or first class as a last resort. Normally do not use certified or first class for routine samples.

4.5.6 - Payment Of Shipping Charges

1. Cash Payment - Agencies have authority to use imprest funds (pay cash) for Cash On Delivery (COD) payment of transportation charges. See IOM 4.5.5.8.1 and 4.5.5.8.2.
   a. Shipments between divisions may be shipped COD when the conditions cited above are met.
   b. Shipments to headquarters may be shipped COD but you must enter on the firm's commercial bill of lading that the FDA billing unit is as follows:

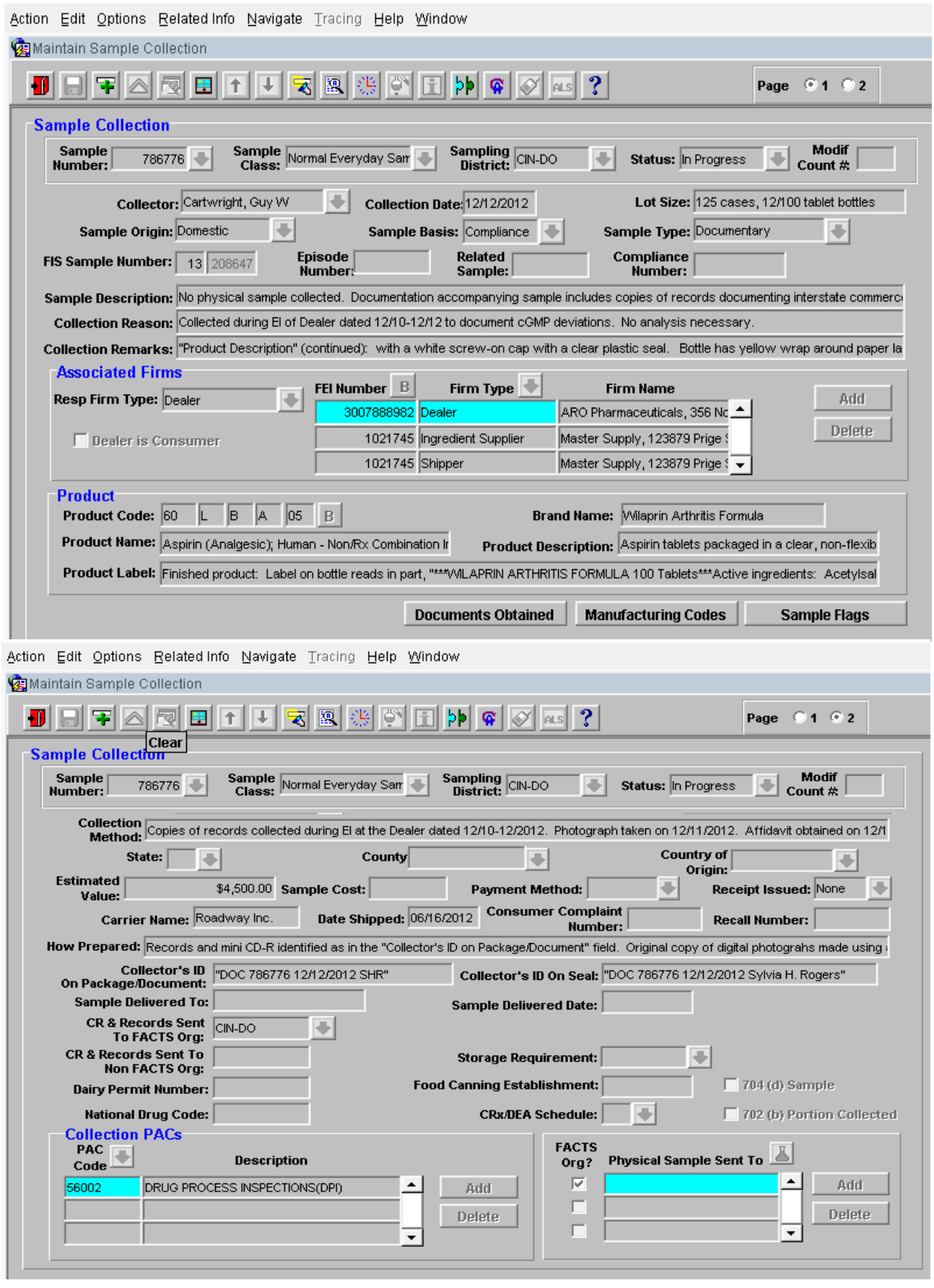
      Food and Drug Administration
      Division of Accounting (HFA-120)
      1350 Piccard Dr.
      Rockville, MD 20850

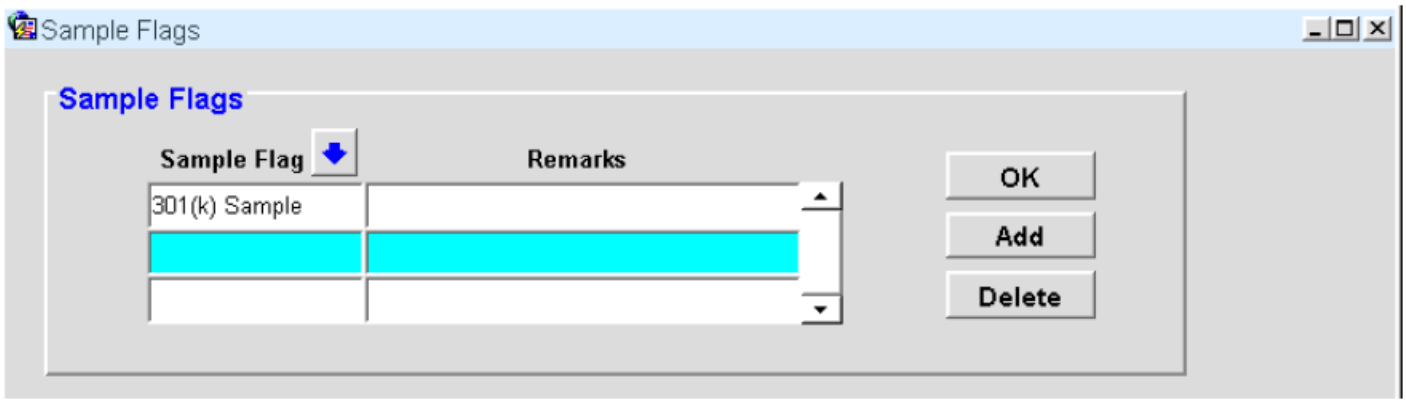
2. Other Means of Payment - If you do not pay cash or the shipping cost exceeds those circumstances in IOM 4.5.5.8.4, you must use one of the following payment methods:
   a. Postal meter or postage stamps - You can use these for shipments under 70 lbs/ when it is cost effective.
   b. Billed shipments - Those shipments meeting the criteria in IOM 4.5.5.8.1 and IOM 4.5.5.8.4 and are billed by an invoice from the carrier.

c. Government Bill of Lading (GBL) - If the other methods discussed above are not appropriate, a GBL must be issued at the time of the shipment.
d. In an emergency, if you are without a GBL or the carrier refuses to accept a GBL at the time of shipment, you can convert the carrier's invoice to a GBL after the completion of the shipment. Avoid this procedure if at all possible.

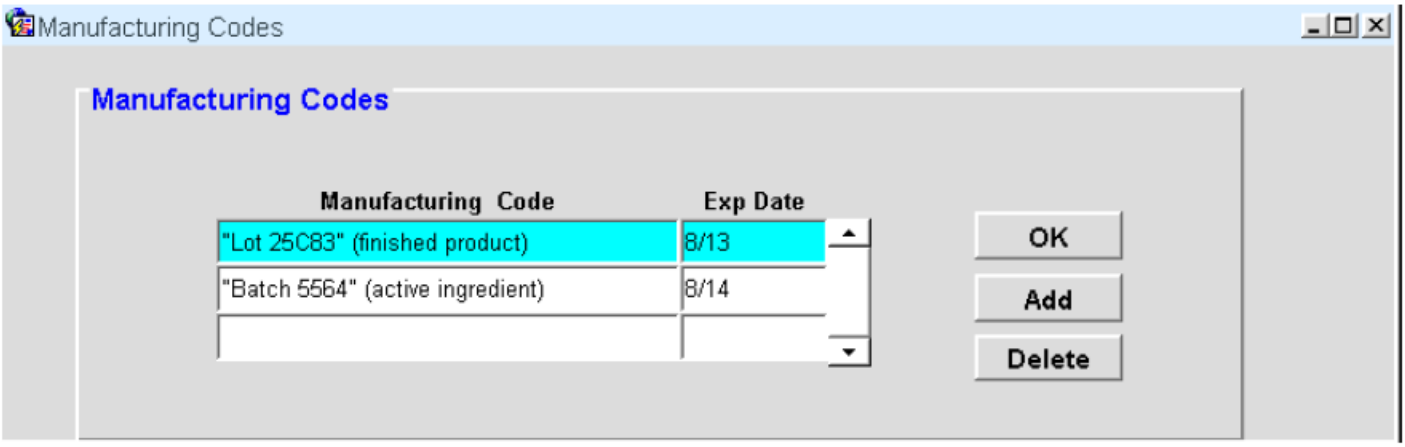
CHAPTER 4 EXHIBITS AND SAMPLE SCHEDULES

4-1 FACTS SAMPLE COLLECTION SCREEN




Sample Flags
Sample Flags
Sample Flag
Remarks
301(k) Sample
OK
Add
Delete


Documents Obtained
Document Type
Document Number
Document Date
Remarks
Affidavit
1.
12/12/2012
Signed by Nicholas I. Herkimer, President.
Invoice
2.
06/06/2012
Invoice no. 2346 documenting Master Supp
Bill of Lading
3.
06/16/2012
Bill of lading no. 124679 documenting inter
OK
Add
Delete


Manufacturing Codes
Manufacturing Codes
Manufacturing Code
Exp Date
"Lot 25C83" (finished product)
8/13
"Batch 5564" (active ingredient)
8/14
OK
Add
Delete

Food and Drug Administration Office of Regulatory Affairs
Collection Report
For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 01/30/2015

Flag	Flag Remarks
301(k) Sample	

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Documentary	13208647	In Progress

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3007888982	12/12/2012	60LBA05	Dealer	56002	.5

Compliance Num	Country of Origin

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	CIN-DO			

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
No				Wilaprin Arthritis Formula

Product Description
Aspirin tablets packaged in a clear, non-flexible plastic bottle (See "Remarks")

Product Label
See continuation.

Reason for Collection	MFG Codes	Expiration Date
Collected during EI of Dealer dated 12/10-12/12 to document cGMP deviations. No analysis necessary.	"Lot 25C83" (finished product) "Batch 5564" (active ingredient)	8/13 8/14

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
ARO Pharmaceuticals	356 Northview Dr Powell, OH 43065-9479 US	Dealer	3007888982	
Master Supply	123879 Prige Street Henderson, KY 42420 US	Ingredient Supplier	1021745	
Master Supply	123879 Prige Street Henderson, KY 42420 US	Shipper	1021745	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
125 cases, 12/100 tablet bottles	$ 4,500.00	None	Roadway Inc.	06/16/2012

Description of Sample
See continuation.

Method of Collection
Copies of records collected during EI at the Dealer dated 12/10-12/2012. Photograph taken on 12/11/2012. Affidavit obtained on 12/12/2012.

How Prepared
See continuation.

Collector's Identification on Package and/or Label	Collector's Identification on Seal
"DOC 786776 12/12/2012 SHR"	"DOC 786776 12/12/2012 Sylvia H. Rogers"

Sample Delivered To	Date Delivered	Orig C/R & Records To
		CIN-DO
	Lab w/Split Sample	Lab

Document Number	Document Date	Document Type	Document Remarks
1.	12/12/2012	Affidavit	Signed by Nicholas I. Herkimer, President. (1 page.)
2.	06/06/2012	Invoice	Invoice no. 2346 documenting Master Supply's sale

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 12/12/2012

			of 1 - 250 lb. drum of acetylsalicylic acid batch no. 5564 to the Dealer. (1 page.)
3.	06/16/2012	Bill of Lading	Bill of lading no. 124679 documenting interstate shipment of 1 - 250 lb. drum of acetylsalicylic acid from Master Supply, Henderson, KY to the Dealer via Roadway Inc. (2 pages.)
4.	06/16/2012	Other	"Raw Material Inventory Record" documenting the receipt of acetylsalicylic acid batch no. 5564. (1 page.)
5.	11/21/2012	Other	"ARO Pharmaceuticals Batch Record" for Wilaprin Arthritis Formula lot 25C83 documenting the manufacturing, packaging and labeling of the finished product and the related quality records. (20 pages.)

Remarks
See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
		No	No	Sylvia H. Rogers

Name of Signer	Date & Time of Signature	Meaning
Sylvia H. Rogers		12/12/2012 12:40 PM ET Collector

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 12/12/2012

Continuation:

Product Label
Finished product: Label on bottle reads in part, "***WILAPRIN ARTHRITIS FORMULA 100 Tablets***Active ingredients: Acetylsalicylic acid 500 mg.***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." Paperboard carton reads in part, "WILAPRIN ARTHRITIS FORMULA 100 Tablets***Active ingredients: Acetylsalicylic acid 500 mg.***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." Printing on cardboard box reads in part, "***WILAPRIN ARTHRITIS FORMULA***12/100 Tablet Bottles***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." (Labeling attached as part of the "Master Pharmaceuticals Batch Record" on pages 13 - 15.)

Active ingredient: Label on drum reads in part, "***Acetylsalicylic Acid UPS***Batch No. 5564***Use by 8/14***Net Weight 250 lbs.***Master Supply Henderson, KY 42420***." (Photograph attached on page 26.)

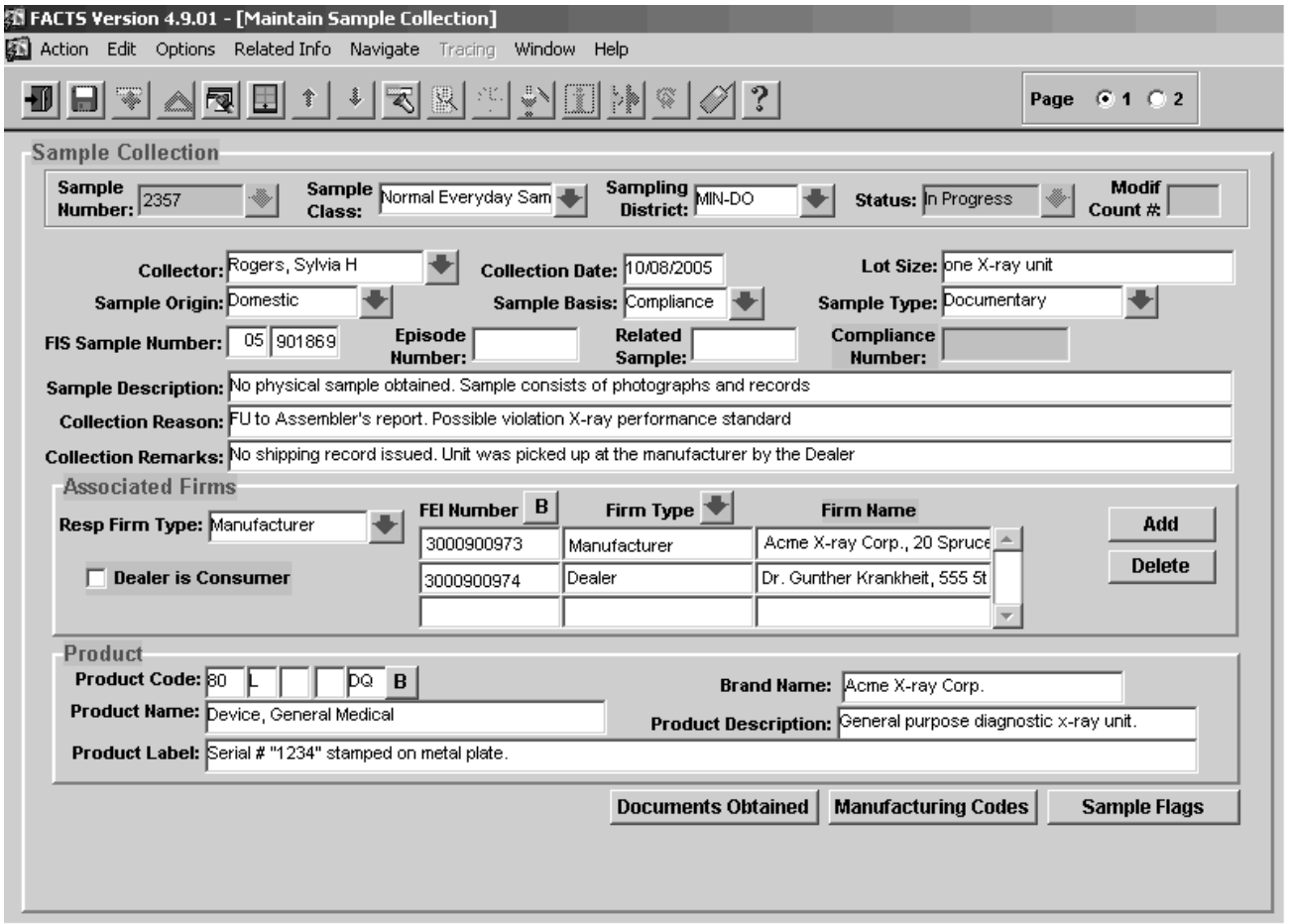
Description of Sample
No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce and cGMP deviations, one photograph and an affidavit.

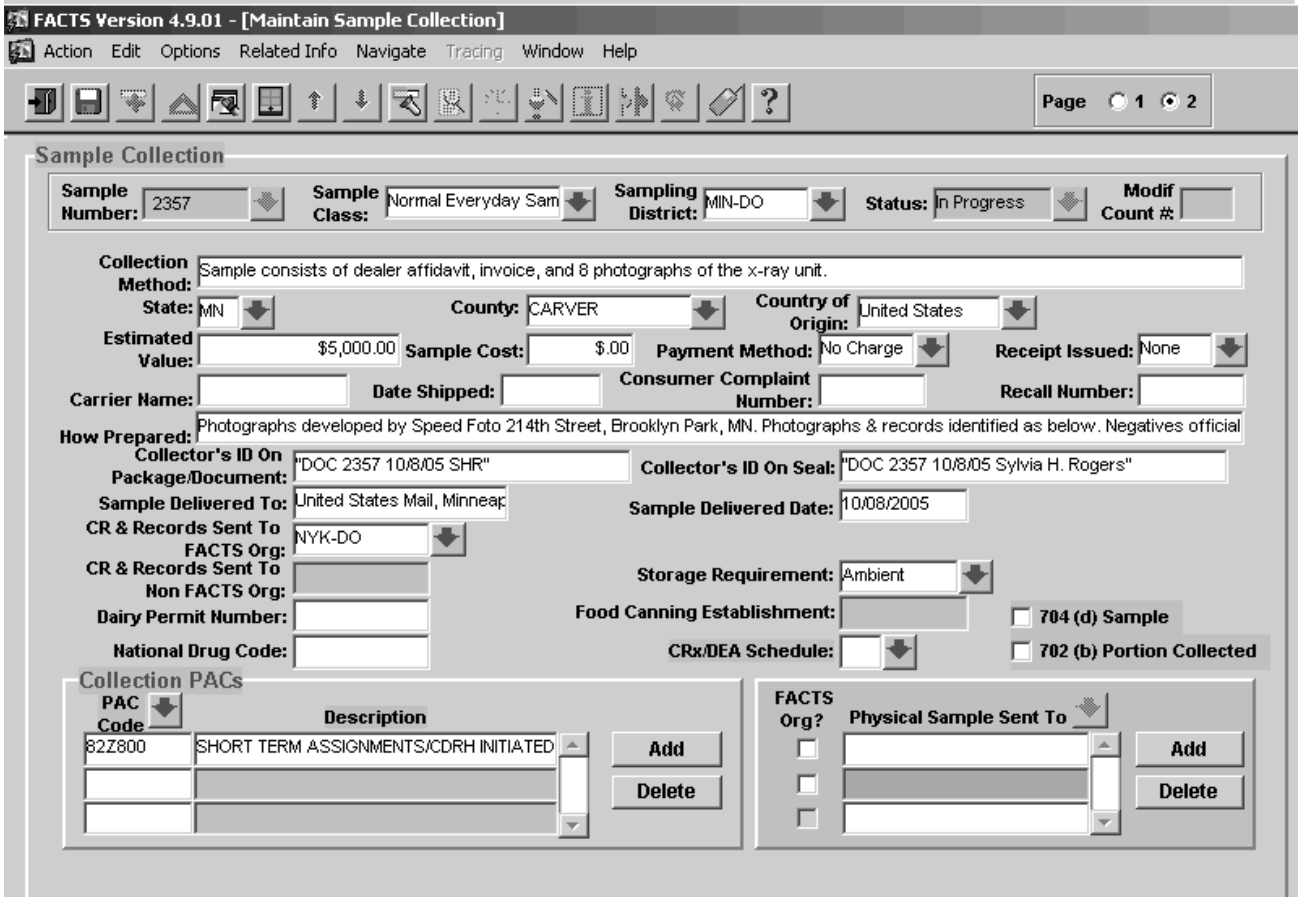
How Prepared
Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photograhs made using a mini CD-R, which was officially sealed In a FDA 525 envelope as in the "Collector's ID on Seal" field.

Remarks
"Product Description" (continued): with a white screw-on cap with a clear plastic seal. Bottle has yellow wrap around paper label with black printing. Bottle packaged in a white paperboard carton with black printing. Packed 12 cartons per box in a brown corrugated cardboard box with black printing.

Refer to EIR of Dealer dated 12/10-12/2012. FDA 483 dated 12/12/12 observation nos. 1 through 5 are cGMP observations related to this product.

4-2 FACTS SAMPLE COLLECTION SCREEN





4-3 AFFIDAVIT (IN-TRANSIT) – FDA 1664b

AFFIDAVIT *(In-transit Sampling)*

SAMPLE NO. 55522

STATE OF: UTAH

COUNTY OF: UINTAH

Before me, Sylvia 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 Wayne J. Ellmore.

_____, in the county and State aforesaid, who, being duly sworn, deposes and says: I am employed by

Trans-National Truck Lines, Tulsa, OK,
(Carrier or firm name, city & state)

_____ as Driver.
(Title of position)

On October 14, 2001, *(Date)* at Vernal, Utah. *(City & state where sampled)*

The above named FDA employee collected a sample consisting of two crates (48 heads per crate) of Polar brand Iceberg lettuce packed by Delbert Brothers Lettuce Suppliers, Fresno, CA.
(Description and number of units sampled)

from Tractor Trailer #321, Oklahoma Lic. #3672TR, 2001.
(Enter type and number & License number of truck, bus, RR car, airplane, etc. or Firm name and shipping dock

_____, from shipment(s) of goods consigned to or being shipped to
address if from dock)

Mid Central Distributors, 33 Front St., Minneapolis, Minnesota.
(Consignee name and address)

The aforesaid sampled shipment(s) was (were) identified to the FDA collector by Wayne J. Ellmore,
(Name of individual

_____, Truck Driver.
making identification) *(Title of person making identification)*

(Copy of) Shipping Record(s) F/B, number A-32196,
(Type record – B/L, Waybill, etc.)

dated 10/14/01, issued by Trans-National Truck Lines,

_____, which were identified by Wayne J. Ellmore, Driver,
(Name & title of individual

_____, and furnished to the FDA collector cover this (these) shipment(s).
identifying records)

AFFIANT'S SIGNATURE

Wayne J. Ellmore

Subscribed and sworn to before me at Vernal, Utah.
(City and State)

this 14th day of October, 2001.

Sylvia H. Rogers.
(Employee's Signature)

FORM FDA 1664b (8/01) PREVIOUS EDITIONS MAY BE USED Created by PSC Media Arts (301) 443-2454 XTF

4-4 CARRIER'S RECEIPT FOR SAMPLE - FDA 472

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NO. 300 S. Riverside Plaza, Suite 550 South Chicago, IL 60606
TO	NAME AND TITLE OF INDIVIDUAL John B. Carr, Driver	DATE 11-6-04
	NAME AND ADDRESS OF CARRIER Transcontinental Trucking, 10 Front St. Dallas, TX 75204	SAMPLE NUMBER 27269
CONSIGNEE AND ADDRESS *(Street, City, State and ZIP Code)* XYZ Wholesale 111 S. Water Market Chicago, IL 60601		CONSIGNOR AND ADDRESS *(Street, City, State and ZIP Code)* Best Yet Packing Co. 3 First St. Young Town, TX 75002

SAMPLE(S) REMOVED FOR EXAMINATION		WAYBILL OR FREIGHT BILL NUMBER
AMOUNT OF SAMPLE	**PRODUCT**	
2 cases (48 ct)	Lettuce – Best Yet Brand	A-23764

SAMPLE COLLECTOR'S NAME	TITLE	SIGNATURE
Sylvia H. Rogers	Investigator	*Sylvia H. Rogers*

FORM FDA 472 (10/01) PREVIOUS EDITION MAY BE USED UNTIL **CARRIER'S RECEIPT FOR SAMPLE**

SUPPLY IS EXHAUSTED.

4-5 RECEIPT FOR SAMPLES - FDA 484

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT ADDRESS & PHONE NUMBER 850 Third Avenue Brooklyn, NY 11232 718-340-7000

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Richard A. Frost, General Manager	12-4-06	25563

5. FIRM NAME	6. FIRM'S DEA NUMBER
Quality Wholesale Drug Co.	AB3632918
7. NUMBER AND STREET	8. CITY AND STATE *(Include Zip Code)*
3146 Front Street	Brooklyn, NY 11232

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(**NOTE**: *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.*)

One Box of 25 - 1 cc ampoules, Dilaudid HCl (hydromorphine) 2 mg/cc, lot # 0103213 manufactured by Knoll Pharmaceutical Co., Orange NJ.

10. SAMPLES WERE	11. AMOUNT RECEIVED FOR SAMPLE	12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)*
☐ PROVIDED AT NO CHARGE ☒ PURCHASED ☐ BORROWED *(To be returned)*	☒ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD $15.00	Richard A. Frost

13. COLLECTOR'S NAME *(Print or Type)*	14. COLLECTOR'S TITLE *(Print or Type)*	15. COLLECTOR'S SIGNATURE
Sylvia H. Rogers	Investigator	Sylvia H. Rogers

FORM FDA 484 (3/06) PREVIOUS EDITION MAY BE USED RECEIPT FOR SAMPLES PAGE 1 OF 1 PAGES

PSC Media Arts (301) 443-1090 EF

FORM FDA 484 (3/06) BACK

Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-
(1) ****
(2) ****
(3) ****
(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise
dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.
Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form FDA 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

4-6 FIELD WEIGHT SHEET - FDA 485

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DATE: 9-16-05
2. SAMPLE NUMBER: 55532
3. PRODUCT: Spaghetti in plastic bags: "Genoa Semolina Vermicelli***Delmonico Foods, Inc. San Francisco, Calif.***Net Weight 12 ozs."
4. TYPE OF BALANCE: Gurley

5. RESPONSIBLE FIRM AND ADDRESS *(Zip Code)*	6. ADDRESS WHERE WEIGHED
Delmonico Foods, Inc. 4701 Canal Street San Francisco, California	Medicine Bow Wholesalers 23 Railroad Ave. Cheyenne, Wyoming

7. WAREHOUSE	a. TYPE	b. TEMPERATURE	d. HUMIDITY
	Wholesale Grocery Warehouse	80° F	est. 20%

8. NO. OF	a. CASES IN LOT	b. CASES SAMPLED	c. SUBS WEIGHED FROM EACH CASE
	325 48/12 oz.	12	4 from each of 12 cases

9. GROSS WEIGHT *(Submit a minimum of 12 subs with at least one from each case examined. Submit the subs indicated by the asterisks adding others where necessary to identify additional subs submitted. Determine six tares. Where tares may vary widely, determine up to 12 where practical.)*

CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT	CASE NO.	SUB NO.	GROSS WEIGHT
1	1	11.40	4	13	12.08	7	25	11.32	10	37	12.00
1	2	11.72	4	14	11.68	7	26	12.00	10	38	12.04
1	3*	11.60	4	15*	11.42	7	27*	11.34	10	39*	11.64
1	4	11.30	4	16	12.40	7	28	11.34	10	40	11.72
2	5	11.32	5	17	11.32	8	29	11.34	11	41	12.10
2	6	11.40	5	18	11.34	8	30	11.40	11	42	11.70
2	7*	12.00	5	19*	11.40	8	31*	11.40	11	43*	11.40
2	8	11.38	5	20	11.42	8	32	11.36	11	44	11.50
3	9	11.34	6	21	12.02	9	33	12.04	12	45	11.32
3	10	11.40	6	22	11.70	9	34	12.00	12	46	11.30
3	11*	11.42	6	23*	12.08	9	35*	11.38	12	47*	11.24
3	12	12.02	6	24	12.10	9	36	11.36	12	48	11.36
TOTAL		138.30			140.96			138.28			139.32
										GRAND TOTAL	556.86

10. PRELIMINARY TARE				11. WEIGHING RESULTS	
TARE NO.	WEIGHT	TARE NO.	WEIGHT	a. AVERAGE GROSS	11.60
1	0.22	4	0.23	b. PRELIMINARY AVERAGE TARE	.22
2	0.22	5	0.21	c. AVERAGE NET	11.38
3	0.21	6	0.22	d. DECLARED NET	12.00
TOTAL	0.65	**TOTAL**	0.66	e. SHORTAGE	.62
		GRAND TOTAL	1.31	12. PRELIMINARY % SHORT	5.2%
*NUMBER OF TARES WEIGHED			6	13. REMARKS *(List observations of lot or storage conditions affecting net weights)*	
PRELIMINARY AVERAGE TARE			0.22	Lot has been in storage since 9-1-05.	

14. DISTRICT	15. EMPLOYEE SIGNATURE	16. EMPLOYEE TITLE
DEN-DO	*Sidney H. Rogers*	Investigator

FD FORM 485 (5/85) PREVIOUS EDITION MAY NOT BE USED FIELD WEIGHT SHEET

4-7 AFFIDAVIT - "301(k) Sample" - FDA 463a

AFFIDAVIT	SAMPLE NO. 55533
STATE OF Kansas	COUNTY OF Sedgwick

Before me, Sidney 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. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Joseph H. Roe in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Vice President in charge of production of the Doe Bottling Co., Inc., 123 Main, Thistown, Kansas 67201; and as such I have knowledge of the raw material receiving and use, and carbonated beverage production at this firm.

The sample consisting of two cases, 48- 10 ounce bottles, of Kola Cola, coded ABCD, collected by Investigator Rogers on November 15, 1999 was from a lot of 2668 cases produced by this firm on October 7, 1999. The copies of our production records for October 7, 1999 consist of a Syrup Room Report dated 10-6-99, a two-page Production Report dated 10-7-99, an undated in-line Control record, and a Finished Drink Control Record dated 10-7-99. Copies of these records were provided to the investigator and cover our production of this lot.

The above described lot was made in part from a portion of a lot of bulk liquid sugar received October 3, 1999 from the Sweet Sugar Co., Boise, Idaho, in railroad tank car ATSF 98765, unloaded October 6, 1999. The copies of the Sweet Sugar Co. invoice number 468 dated Sept. 26, 1999; freight waybill number UP-3579 dated Sept. 27, 1999 issued by the Union Pacific Railroad Co.; and our receiving report number 01-23 dated October 3, 1999 were provided to the investigator and cover this shipment.

The above described lot was also made in part from a portion of a lot of Kola Cola syrup base received September 23, 1999 from the Kola Cola Co., Thattown, Texas. The copies of Kola Cola Co. invoice number KCO1928 dated Sept. 20, 1999; freight bill number X-98125 dated Sept. 21, 1999 issued by Speedy Truck Line Co.; and our receiving report number 01-01 dated Sept. 23, 1999 were provide to the investigator and cover this shipment.

The above described lot of Kola Cola was identified to the investigator by William S. Doe, Production Supervisor. I identified and provided copies of the records to the investigator.

AFFIANT'S SIGNATURE AND TITLE

Joseph H. Roe, Production Vice President

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

Doe Bottling Co., Inc. 123 Main, Thistown, Kansas, 67201

Subscribed and sworn to before me at Thistown, Kansas this 15th day of November, 1999.

Sidney H. Rogers

(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-8 COPY OF INVOICE/SHIPPING RECORD - FD 1662

1. LOCATION	2. NAME OF SAMPLE COLLECTOR	3. DATE COLLECTED	4. SAMPLE NUMBER
Pine Bluff, Arkansas	Sylvia H. Rogers	10-8-05	55566

SECTION I - COPY OF INVOICE

5. CONSIGNOR *(Name, Street, City, and State)*	6. CONSIGNEE *(Name, Street, City, and State)*
Captain Sam Seafood, Inc. 719 Butler Ave. New Orleans, LA	Razor Back Super Market 1207 Little Rock Dr. Pine Bluff, AR

7. GUARANTEE	8. INVOICE NUMBER	9. INVOICE DATE
-----see reverse-----	477	9-20-05

10 QUANTITY	11 UNIT SIZE	12 DESCRIPTION OF ARTICLE(S)	13 UNIT PRICE		14 TOTAL	
10 cs.	24/4.5 oz.	Horseshoe Brand Canned Medium Shrimp	2	84	56	80
5 cs.	10/5 lb.	Frozen Green Hills 21-25 Shrimp	1	10	275	00
		**********				
5cs.	24/8 oz.	Horseshoe Brand Canned Cove Oysters	5	25	52	50
		**********				
2 cs.	6/4 lb.	Frozen C&P Small Shrimp	1	50	72	00
			15. **TOTAL**		642	80

SECTION II - COPY OF SHIPPING RECORD

16. SHIPPER *(Name, Street,, City, and State)*	17. CONSIGNEE *(Name, Street, City, and State)*
Captain Sam Seafood, Inc. NOLA	Razor Back Super Market 1207 Little Rock Dr. Pine bluff, AR

18. CARRIER *(Name, City, and State)*

Sea Breeze Trucking, Inc. NOLA

19. CAR OR EQUIPMENT NUMBER	20. WAYBILL DATE & NUMBER	21. TYPE OF RECORD *(Specify)*	22. RECORD NO.	23. RECORD DATE
Van 109	N/A	F/B	06641	9-20-05

24. SHIPPED FROM *(City and State)*	25. ROUTE	26. DATE SHIPPED
NOLA	N/A	9-20-05

27 DESCRIPTION OF ARTICLE(S)	28 NO. PKGS.	29 WEIGHT	30 RATE	31 CHANGES
Canned Food	20	300	172	5.16
Frozen Seafood	8	350	224	7.84

32. RECEIVED BY	33. DATE REC'D	34. **TOTAL**				
P. Monteux s/s	9-26-05		28	650		13.00

FORM FDA 1662 (4/86) PREVIOUS EDITION MAY BE USED **COPY OF INVOICE AND SHIPPING RECORD**

4-9 AFFIDAVIT (PARCEL POST) - FDA 463

AFFIDAVIT *(Parcel Post/Parcel Service)*	SAMPLE NO. 2358
STATE OF Colorado	COUNTY OF Pueblo

Before me, Sidney 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 (20U.S.C.3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Joseph D. Bullard in the county and state aforesaid, who, being duly sworn, deposes and says: (I) (My firm) received on or about the day of July 10th, 2005, in response to an order previously given by me, two (packages, containers, etc.) consisting in whole or in part of a product designated "4 ounces NET***Johnson's Eye Ease***Reservation Special" via: (parcel post, United States mail) (United Parcel Service) from Old Indian Herb Co. 294 N. Blackfoot St., Boise, Idaho 30854 and covered by attached copy of invoice number C-20 dated 7-2-05; after unpacking the goods the (parcel post) (parcel service) wrapper was destroyed; and on the 12th day of July, 2005, Inspector/Investigator Rogers obtained from me a sample consisting of 10-4 oz. bottles of Johnson's Eye Ease coded "J-638" on the bottle label, shipped and described as aforesaid and for which he paid me the sum of $25.00 in (cash) (voucher) (billed).

Remarks: I first learned of this product while reading the January 2005 issue of "The Retired Engineer." I use it to relieve the burning and itching in my eyes after working in the heat and dryness.

AFFIANT'S SIGNATURE AND TITLE

Joseph D. Bullard

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

Subscribed and sworn to before me at Crow, Colorado *(City & State)* this 13th day of July, 2005.

Sidney 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 463(4/83) PREVIOUS EDITIONS ARE OBSOLETE

4-10 AFFIDAVIT - FDA 463a

AFFIDAVIT	SAMPLE NO. 55555
STATE OF Oregon	COUNTY OF Klamath

Before me, Sidney 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. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared George W. Hughes in the county and State aforesaid, who, being duly sworn, deposes and says:

I live at 482 Abricia Ave., Klamath Falls, Oregon. On October 18, 1999, my neighbor, Dr. Samuel Thompson, asked me to pick up some medical instruments from a firm in Santa Rosa, California for him. Later that same day I drove to Santa Rosa in my 1997 Dodge Ram pick-up truck which has Oregon license plates, number FAS 682. My Oregon driver's license number is OR0123-45-6789.

The next morning, October 19, 1999, I drove to Charles Brown & Associates at 920 Grape St., Santa Rosa, California and picked up 4 containers bearing the label: "Fancy Medical Device, quantity 1." Each container contained a medical device.

I drove back to Klamath Falls, Oregon after picking up a load of wine for my wine cellar, and arrived home on or about 11:00 PM.

The next morning, October 20, 1999, I delivered the 4 containers to Dr. Samuel Thompson at his office, 2209 Timberline Ave., Klamath Falls, Oregon.

I did not charge Dr. Thompson for the pick-up and delivery because I make regular trips to pick up wine in Santa Rosa for my wine cellar.

AFFIANT'S SIGNATURE AND TITLE

George W. Hughes, Owner

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

Hughes Wine Cellar, 483 Abrecia Ave., Klamath Falls, 97210

Subscribed and sworn to before me at Klamath Falls, Oregon this 4th day of November, **1999** .

Sidney H. Rogers

(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-11 AFFIDAVIT - FDA 463a

AFFIDAVIT	SAMPLE NO. 166455
STATE OF Florida	COUNTY OF Orange

Before me, Paul A. Revere, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Nicholas I. Herkimer in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Warehouse Manager at ABC Distribution Company, 200 Harding Street, Orlando, FL 32806 and have held this position for 3 months. Previously, I held the position of Traffic Manager here for 10 years. As such, I am familiar with and can identify records associated with the receipt, storage and shipment of goods at my firm.

On or about 3/1/01, my firm received a shipment of 500 cases, 24-½ fl. oz. bottles/case of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops from Sawyer Corporation, 51 Summer Street, Andover, MA 01810. This shipment was delivered to my firm by Yellow Freight Company, 1553 Fairlawn Street, St. Louis, MO 63126 and is covered by Sawyer Corporation invoice number 1500 dated 3/1/01 and bill of lading number 2000 dated 3/1/01.

On 4/1/01, I identified and provided Investigator Revere copies of the documents described in this statement. On 4/1/01, Investigator Revere collected a sample consisting of 96 - ½ fl. oz. bottles of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops, lot number 020101, from the shipment described above. This sample was provided to the FDA at a cost of $192.00, which will be billed.

I read this statement and agree it is true.

AFFIANT'S SIGNATURE AND TITLE Nicholas I. Herkimer, **Warehouse Manager**

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

ABC Distribution Company, 200 Harding Street, Orlando, FL 32806

Subscribed and sworn to before me at Orlando, FL this 1st day of April, 2001.

Paul A. Revere

(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-12 AFFIDAVIT - (Dealer/Warehouseman) - FDA 1664

AFFIDAVIT *(Dealer/Warehouseman)*

SAMPLE NO. 55563

STATE OF: Arkansas

COUNTY OF: Jefferson

Before me, Sidney 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 Henry O'Rourke, in the county and State aforesaid, who, being duly sworn, deposes and says: The sample consisting of Two Cases (24/8 oz. Each) Horseshoe Brand Canned Cove Oysters collected by the above FDA employee on 3-10-99 was from shipment(s) received by us from Captain Sam Seafood, Inc. New Orleans, LA on 3-7-99 and so identified to the collector:

That the copy of invoice(s):

NUMBER	DATE	NUMBER	DATE	NUMBER	DATE
1) 06641	3/6/99	2) 06643	3/7/99	3)	

and (copy of) shipping record(s):

TYPE: *(B/L, F/B)*	NUMBER	DATE	ISSUING FIRM OR CARRIER
1) F/B	4778	3/6/99	Acme Freight Lines, Inc. NOLA
2) F/B	A-9321	3/7/99	Thru-Fast Lines, Little Rock, AR
3)			

which were identified and furnished the collector, cover this (these) shipment(s):

That said shipment(s) was (were) entered for the account of N/A

under Lot no. _____.

The collector paid me the sum of $ 21.32 (in cash) ~~(by voucher)(to be billed)~~ for the sample.

REMARKS

AFFIANT'S SIGNATURE & TITLE

Henry O. O'Rourke, Warehouse Manager Plant #12

FIRM *(Name and address, include ZIP Code)*

Southeastern Seafood Distributors, Inc.
#4 Canal Street Dock Red River Basin Area, Little Rock, AR 72901

Subscribed and sworn to before me at Little Rock, AR

(City and State)

this 10th day of March, 1999

Sidney 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 1664(4/83) PREVIOUS EDITIONS ARE OBSOLETE

4-13 AFFIDAVIT - FDA 463a

AFFIDAVIT	SAMPLE NO. 55545
STATE OF Tennessee	COUNTY OF Shelby

Before me, Sidney 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. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared George R. Applegate in the county and State aforesaid, who, being duly sworn, deposes and says:

I am manager of John's Curb Market, 342 East Johnson St., Memphis, Tennessee. As such, I have knowledge of purchasing and receipt of products at the market.

On September 2, 1999, FDA Investigator Sidney H. Rogers collected from my firm a sample consisting of six - 4 pound cans of Red River Brand Pure Sorghum. This sorghum was collected from a lot of six cases, each containing 4 - 4 pound buckets (cans) purchased by me from Ted Buymore who regularly sells sorghum in this area. Ted delivered this lot of six cases to my market on August 28, 1999 in a red panel GM truck with Alabama license plates. I do not know the license number.

AFFIANT'S SIGNATURE AND TITLE

George R. Applegate, Manager

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

John's Curb Market, 342 East Johnson St., Memphis, TN 38110

Subscribed and sworn to before me at Memphis, Tennessee this 2nd day of September 1999.

Sidney H. Rogers

(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-14 AFFIDAVIT - (Jobber) - FDA 1664a

AFFIDAVIT *(Jobber)*

SAMPLE NO. 55563

STATE OF Arkansas

COUNTY OF Jefferson

Before me, Sylvia 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 Patrick T. Palmer, in the county and State aforesaid, who, being duly sworn, deposes and says: The lot of The lot of 325 cases, (24/ 4 ½ oz. cans) of Jolly Miller Canned Mushrooms.

which we invoiced and sold to Patriot Markets, Inc. Frankford, Pennsylvania, on 4-12-99.

was a portion/all of a parcel shipped to us by Northern Light Foods, Inc. Duluth, Minnesota.

and is covered by submitted (copy of) invoice(s):

	NUMBER	DATE	NUMBER	DATE	NUMBER	DATE
1)	3914	4/4/99	2)		3)	

and (copy of) shipping record(s):

TYPE: *(B/L, F/B)*	NUMBER	DATE	ISSUING FIRM OR CARRIER
1) B/L	20018	4/5/99	Northern Freight Carriers
2)			
3)			

REMARKS

AFFIANT'S SIGNATURE & TITLE

Patrick T. Palmer, Warehouse Manager Plant #12

FIRM *(Name and address, include ZIP Code)*

Liberty Wholesale Grocers
3210 11th Ave. Frankford, PA 19105

Subscribed and sworn to before me at Frankford, PA
(City and State)

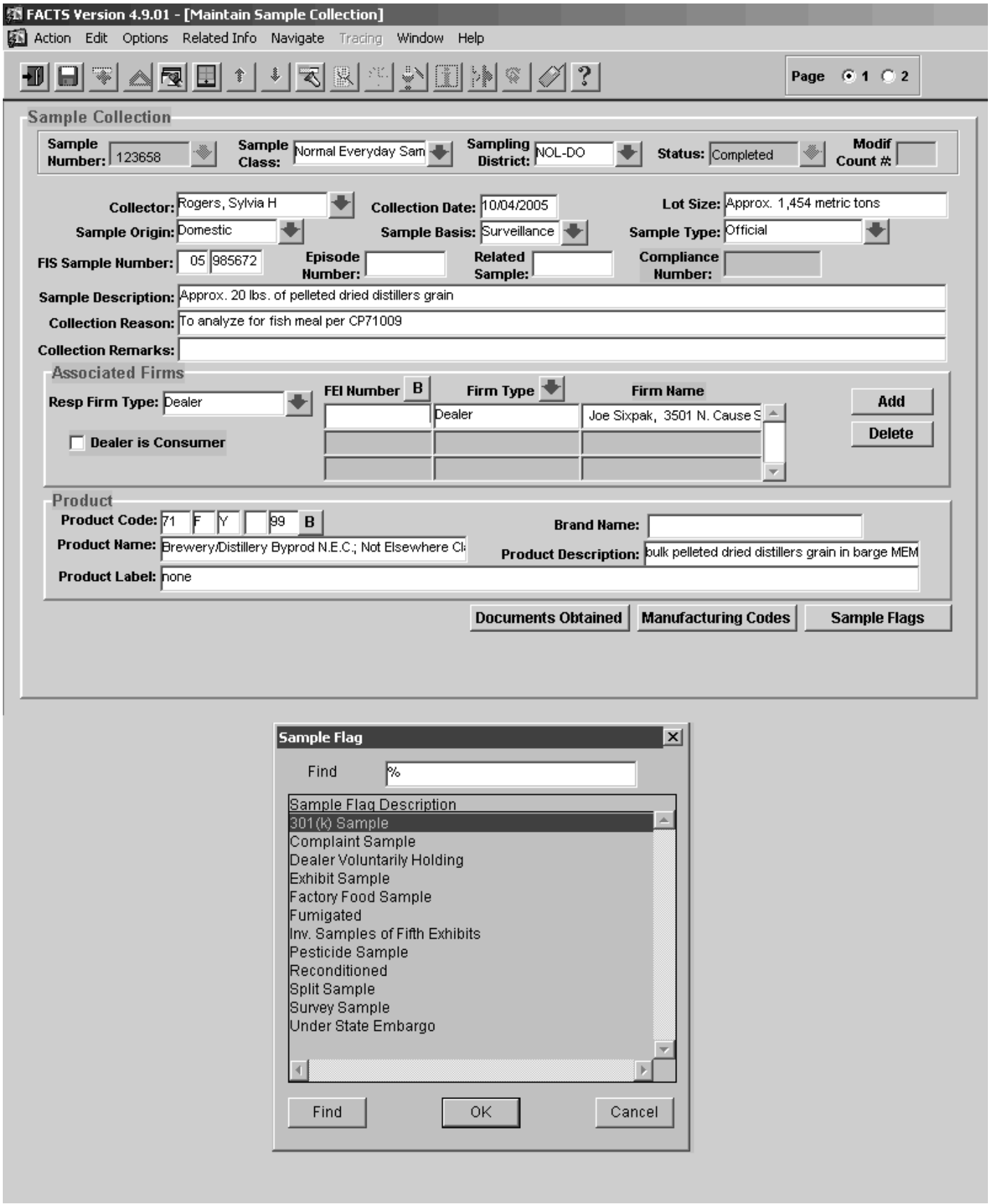
this 28th day of April, 1999

Sylvia H. Rogers
(Employee's Signature)

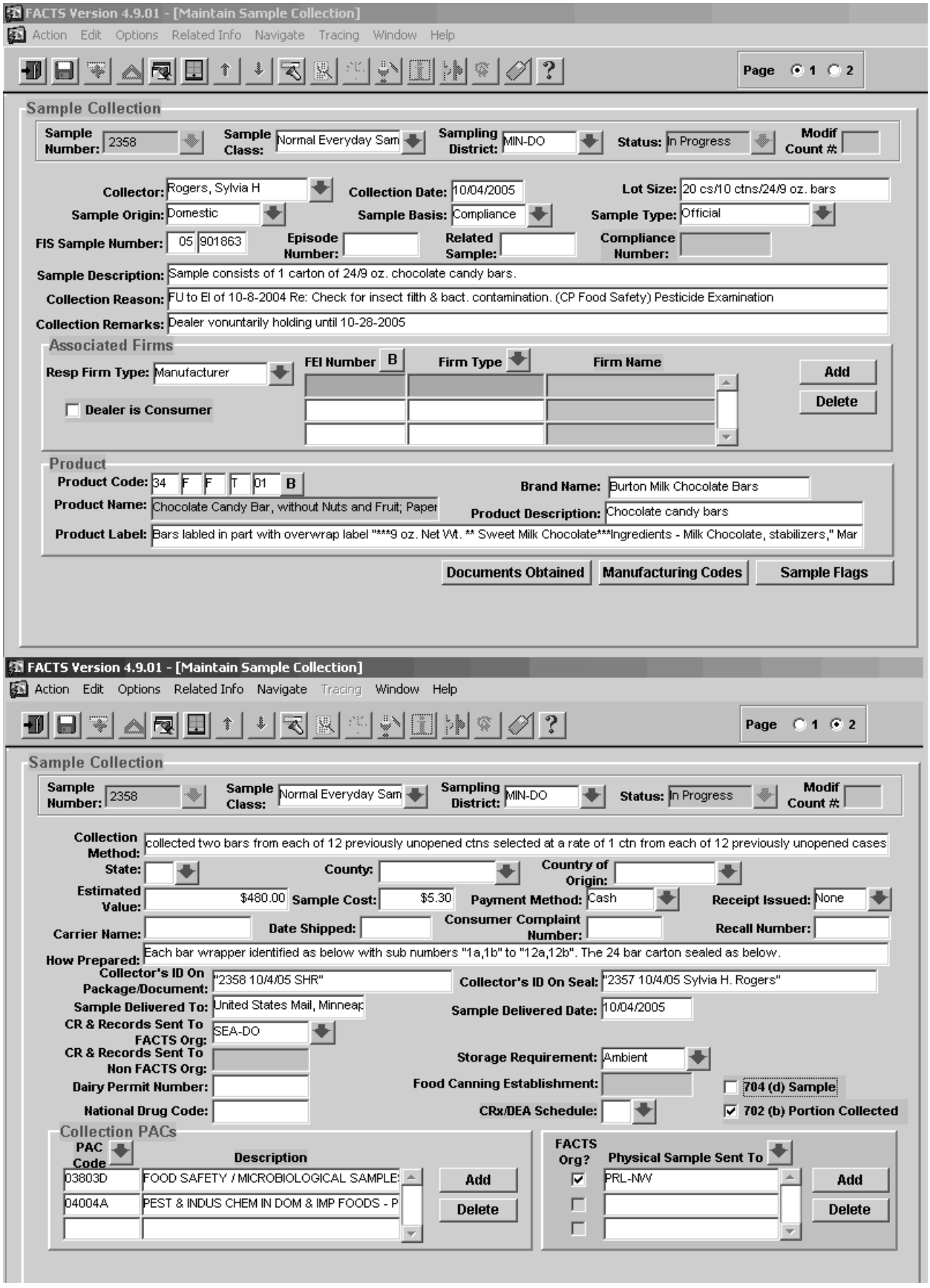
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953;and P.L. 96-88, effective May 4, 1980.

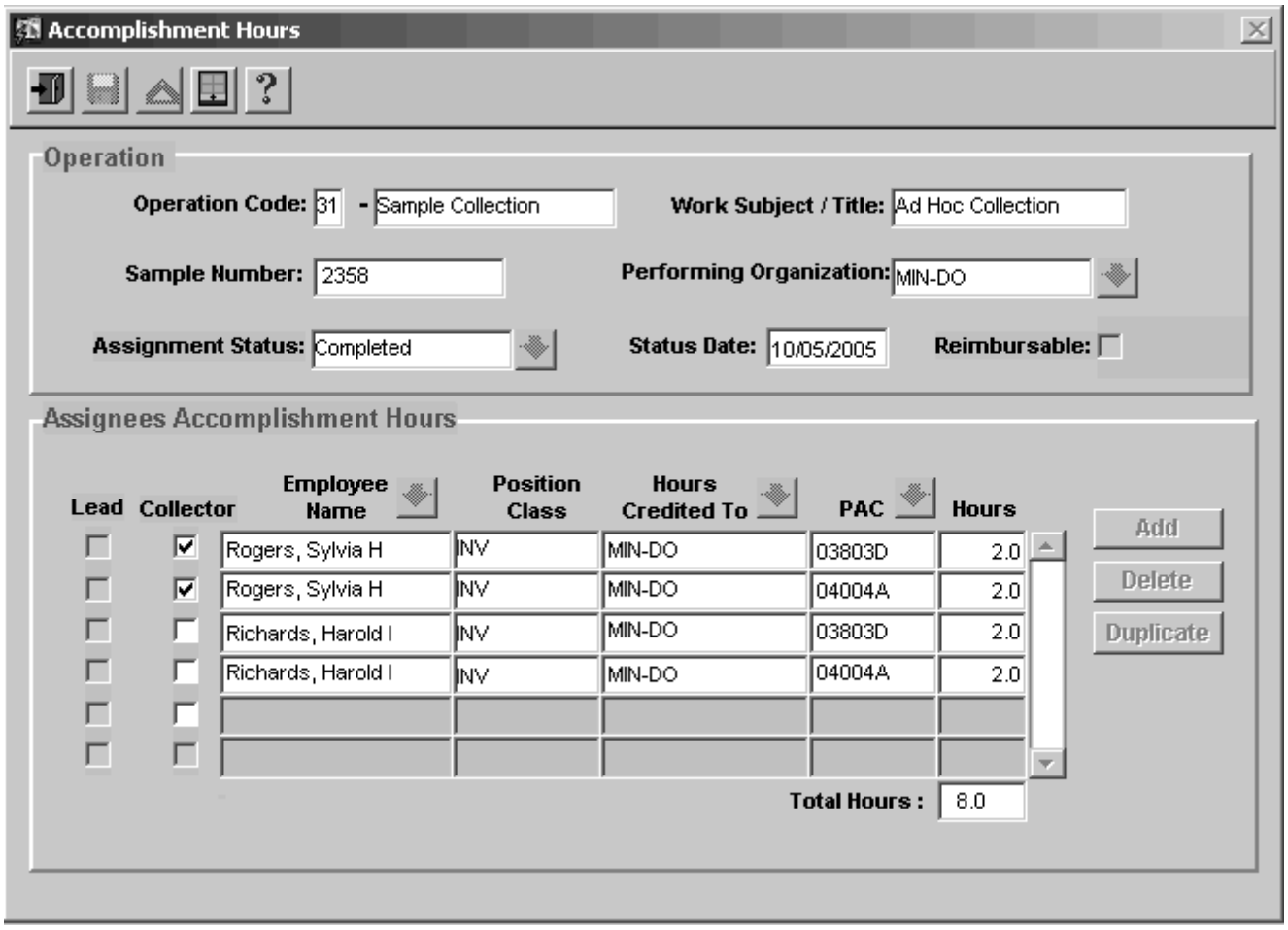
FORM FDA 1664a (7/01) PREVIOUS EDITIONS ARE OBSOLETE

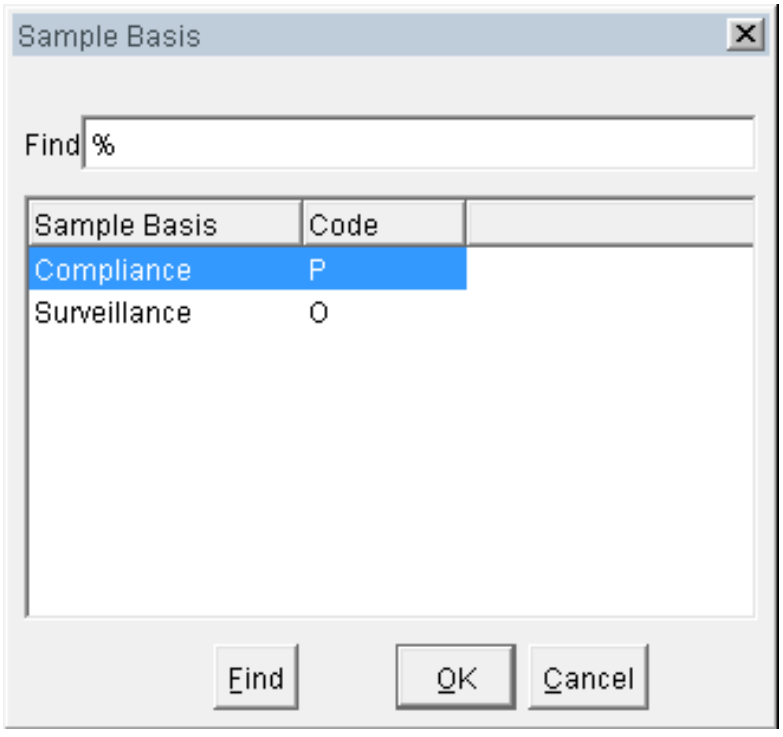
4-15 FACTS SAMPLE COLLECTION SCREEN



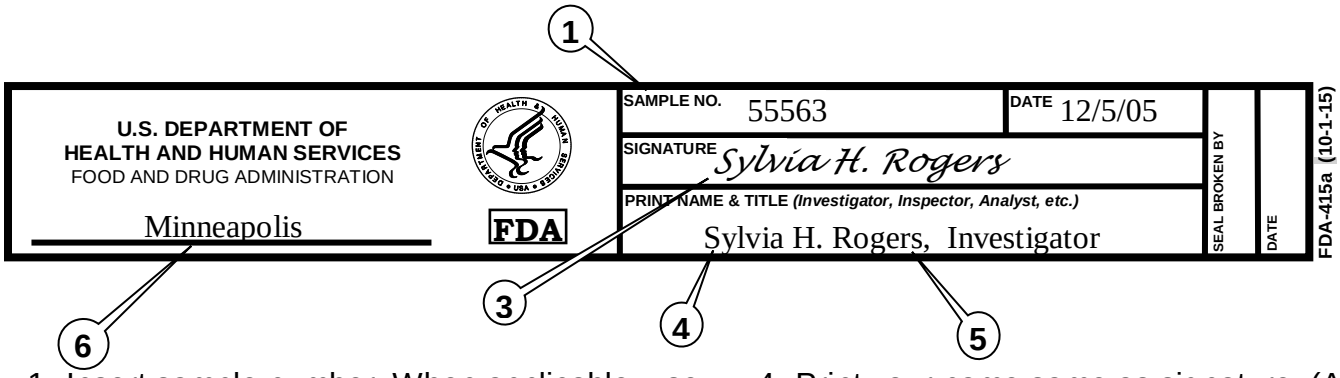
4-16 FACTS SAMPLE COLLECTION SCREEN




Accomplishment Hours
Operation
Operation Code: 31 - Sample Collection
Work Subject / Title: Ad Hoc Collection
Sample Number: 2358
Performing Organization: MIN-DO
Assignment Status: Completed
Status Date: 10/05/2005
Reimbursable:
Assignees Accomplishment Hours
Lead
Collector
Employee Name
Position Class
Hours Credited To
PAC
Hours
Rogers, Sylvia H INV MIN-DO 03803D 2.0
Rogers, Sylvia H INV MIN-DO 04004A 2.0
Richards, Harold I INV MIN-DO 03803D 2.0
Richards, Harold I INV MIN-DO 04004A 2.0
Total Hours : 8.0
Add
Delete
Duplicate


Sample Basis
Find %
Sample Basis
Code
Compliance P
Surveillance O
Find
OK
Cancel

4-17 OFFICIAL SEAL - FDA 415a



1 Insert sample number. When applicable, use prefix, e.g. “INV”, “FS”, “DOC”, “PS”, etc. (See IOM 4.4.10.2)

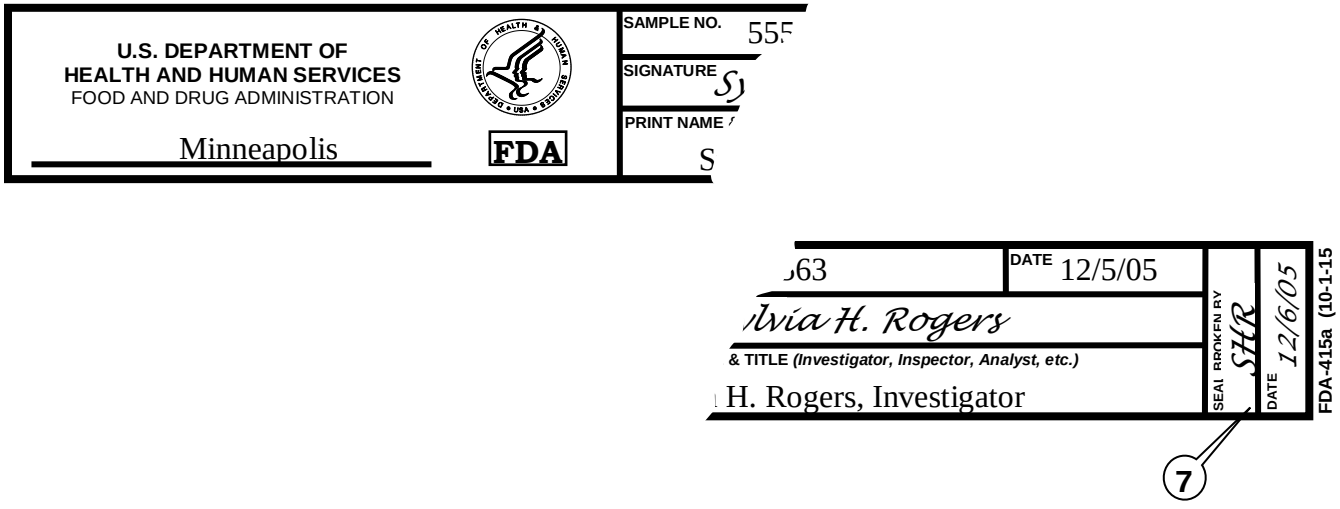
2 Insert date sealed. Use figures, month, day, year. (See # 7 below when seal is broken for any purpose.)

3 Sign your signature.

4 Print your name same as signature. (A rubber name stamp may be used if desired but use it carefully and do not smear.)

5 Print your title.

6 Print your division- spell out - do not use abbreviations or symbols. (A rubber stamp may be used.)



7 When seal is broken for any purpose, initial here and enter the date broken. Submit broken seal with sample records.

4-18 DECLARATION FOR DANGEROUS GOODS

Shipper

U. S. FOOD & DRUG ADMINISTRATION
6601 N.W. 25th St. Room 236
Miami, FL 33122

Air Waybill No.
Delta 7012-6140

Page 1 of 1 Pages

Collection Report Number
2555

Consignee

Food and Drug Administration
60 Eighth Street
Atlanta, GA 30309

U.S. GOVERNMENT SHIPMENT

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORTATION DETAILS

This shipment is within the limitations prescribed for *(delete non-applicable)*

~~**PASSENGER AND CARGO AIRCRAFT**~~ **CARGO AIRCRAFT ONLY**

Airport of Departure
Miami, FL

Airport of Destination
Atlanta, GA

Shipment type *(Delete non-applicable)*

NON-RADIOACTIVE ~~**RADIOACTIVE**~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and Type of packing	Packing Inst.	Authorization
PROPER SHIPPING NAME OF ARTICLE as listed in the Restricted Articles Tariff Federal Aviation Regulations or IATA Restricted Articles Regulations,	Class Or Divi-sion	UN Or ID No.	Subsi-diary Risk			
DRY ICE (CARBON DIOXIDE SOLID)	ORM A OR 9	UN 1845	N/A	5 Fiberboard containers net weight 20 lbs. dry ice each container	173.615 or 615	
	Note: Include these notations on all Dry Ice shipments.					

Additional handling Information

DO NOT OPEN THIS PACKAGE, IF PROBLEMS ARISE, CONTACT SHIPPER AT (305)555-3344

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked and labeled, and are in all respects in the proper con-dition for transport by air according to the applicable International and National Government Regulations

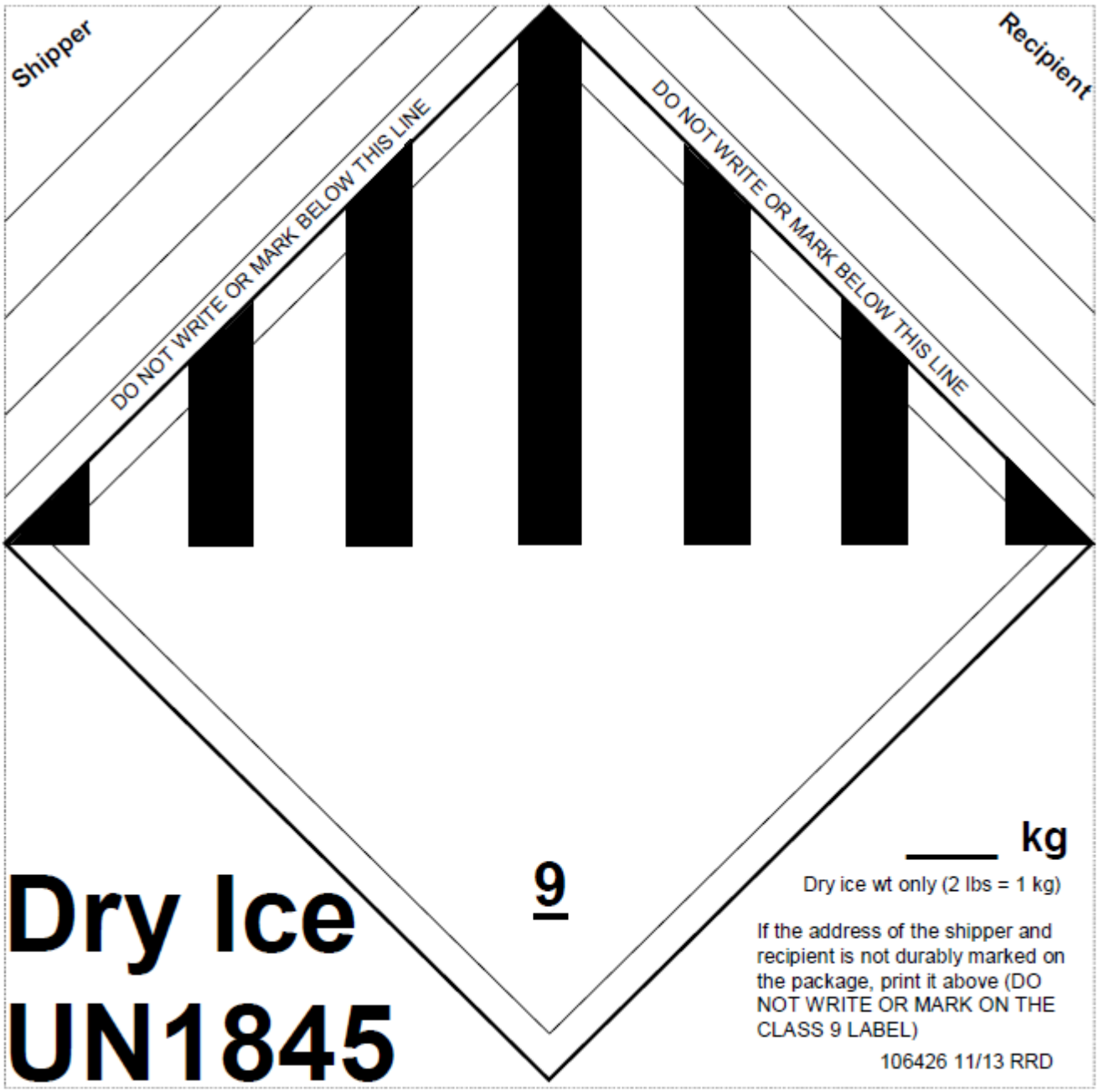
Name/Title of Person Signing
Sidney H. Rogers
Investigator

Place and Date
Miami, FL (9-8-99)

Signature *(See warning above)*
Sidney H. Rogers

FORM FDA 3082 (3/83) PREVIOUS EDITION IS OBSOLETE

4-19 DRY ICE LABEL



4-20 Environmental Sampling for Detection of Listeria monocytogenes, CFSAN Guidance

BACKGROUND

Listeria monocytogenes has been associated with such foods as raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 0°C permits multiplication in refrigerated foods.[4] Listeriosis is a foodborne illness of major public health concern because of the severity of the disease (meningitis, septicemia, and pregnancy complications such as miscarriage or stillbirth), a high case-fatality rate, and a long incubation period. *Listeria monocytogenes* differs from most other food-borne pathogens because it is widely distributed, resistant to diverse environmental conditions, including low pH and high NaCl concentrations, and is microaerobic. The multitude of ways it can easily enter food processing plants and its ability to grow and survive for long periods of time (in the environment, in/on foods, and in food processing plants) under adverse conditions have made it a major concern for many manufacturing industries in recent decades.[2]

SAMPLE COLLECTION

DO Collect Samples From:	**DON'T Collect Samples From**:
Moist/wet areas with standing water	Dry, clean areas
Direct food contact surfaces	Employees – work shoes, hands etc
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Hand wash or eyewash stations
Sanitizing foot mats – if disinfectant is not maintained this can be a good harboring source and point of transfer to other areas of the facility	Packaging materials – jars, lids, etc
Cleaning Equipment – automated floor cleaning equipment, brooms, mops, waste containers especially underside, etc	Raw agricultural products – raw peanuts etc or any food contact surface used exclusively for raw foods.
Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators and evaporator condensate pans	Outside the plant – roof, parking lot, walkways, etc.
Product conveyors – cables, belts, joints, where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product	Zone 4
Motor and Electrical Housings – that are not cleaned and/ or sanitized.	
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks, etc.	
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies.	
Doorways - floor area leading directly into production areas	
Drains – Not during production	
Ice Makers – inside, scoops, underside of top of ice chamber	
Ceilings and Walls – in production areas coolers and freezers	
Door gaskets to coolers and freezers; damp insulation around pipes	

References:

1. FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling
2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs 383-403.
3. Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs 55 – 67
4. Bad Bug Book. *Listeria monocytogenes* , Page 100
5. Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready to Eat Foods Draft Guidance.

4-21 Environmental Sampling for Detection of Salmonellae, CFSAN Guidance

BACKGROUND

Salmonellosis has been known to be a food-borne disease since the late 1800s. It still remains a major food safety concern throughout the world, is the major cause of bacterial foodborne illness in the U.S and is a pathogen of significant interest to FDA. The major reservoirs for Salmonellae are raw meats, poultry and eggs; the organism is also isolated from aquaculture products and fruits, vegetable and nut meats. Salmonellosis outbreaks have been associated with a variety of foods, including raw seafood, fresh produce, egg products, cake mixes, unpasteurized milk, peanut butter, chocolate and salad dressings. Salmonellae are known to survive and grow in the natural environment, including water sources. It is ubiquitous and has been recovered from some insects and nearly all vertebrates and invertebrates. This makes the recovery and identification of Salmonellae critical as an environmental contaminant.

SAMPLE COLLECTION

DO Collect Samples From:	DON'T Collect Samples From:
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Employees – work shoes, hands etc.
Sanitizing foot mats – if dry	Hand wash or eyewash stations
Cleaning Equipment – central vacuum systems, automated floor cleaning equipment (e.g., Tenent type walk-behind or riding sweepers, brooms, mops, etc.) Pay particular attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks.	Packaging materials – jars, lids, etc.
Air conveying equipment – air filters; air ducts and intake and exhaust vents; food residue on equipment and floors if old and dry	Direct food contact surfaces –cleaned often, would be unlikely to have residual organism growth.
Product conveyors – cables, belts, joints, where product residue accumulates, if the residue is old and dry	Raw ingredients– raw peanuts refined sugar, etc.
Unsealed control and drive chambers; electrical/ mechanical service boxes that are not cleaned and/ or sanitized. Look for dry dust and residue in these boxes.	Outside the plant – roof, parking lot, etc
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	Areas with running water and very wet areas
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks etc.	Zone 4
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies if dry.	
Doorways - floor area in doorways leading into or out of the production facility or onto the roof	
Pallets – Floor under wooden or plastic pallets and pallets themselves	
Floor drains - use a sponge to scrub dry residue from floor drain grids and walls	

References:

1.FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling
2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs 141-178.
Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs 55 – 67

1- SALMONELLA SAMPLING PLAN

PURPOSE:

To determine the presence of *Salmonella* in processed foods and soils/water used for the growth of foods intended for human consumption.

APPLICABILITY:

This sampling plan is applicable to the inspection of either a continuing series of production lots or to isolated lots consisting of an identifiable collection of process units (cans, bags, packages, or similar units). Additionally, the soil plan is for use during on-farm investigations requiring the sampling of soil for the presence of *Salmonella*. This plan is for use by FDA for regulatory purposes.

FOOD CATEGORIES:

Foods are listed in three categories based on the number of *Salmonella* hazards and whether a food is to be consumed by infants, the aged, or infirm.

The three defined *Salmonella* Hazards of foods are:
1. The food or an ingredient of the food is a significant potential source of *Salmonella*;
2. The manufacturing process does not include a controlled step that destroys *Salmonella*; and
3. The food has significant potential for microbiological growth if "abused" in distribution or by consumers.

Classification of Foods:

Foods have been classified into three food Categories for regulatory sampling purposes. The foods are listed in the Categories by Product Code sequence.

NOTE: For products not listed, check with your supervisor. The Division will request categorization from the Office of Field Programs/Center for Food Safety and Applied Nutrition (HFS-600), or, when time is of essence, the Division will make the categorization and obtain later concurrence from CFSAN.

Category I

This includes all foods that would normally be in Category II except that they are intended for consumption by the aged, the infirm, and infants.

Category II

This includes the foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
03	Bread, rolls, buns, sugared breads, crackers, custard and cream filled sweet goods
05	Breakfast cereals, ready to eat
07	Pretzels, chips and specialty items
09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and Cheese products
13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption.
14	Pasteurized and unpasteurized imitation dairy products for consumption

15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish and crustacean products; smoked fish, shellfish and crustaceans for consumption
17	Unflavored gelatin
20-22	Fresh, frozen and canned fruits and juices, concentrates and nectars; dried fruit for consumption; jams, jellies, preserves and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing and oleomargarine
27	Dressings and condiments (including mayonnaise) salad dressing and vinegar
28	Spices including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Chewing gum and candy
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products
36	Syrups, sugars and honey
38	Soups
39	Prepared salads

Category III

This includes the following foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
02	Whole grain, processed grain and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products normally cooked before consumption
26	Vegetable oils, oil stock and vegetable shortening
35	Dry dessert and pudding mixes that are cooked prior to consumption
37	Frozen dinners, multiple food dinners
45-46	Food chemicals (direct additives)

SAMPLE COLLECTION

Each sub will consist of a minimum of 100 g (approx. 3.53 oz). The usual subsample is a consumer size container of a product. Subsamples should be obtained at random to ensure that the total sample is representative of the lot. When a lot consists of identifiable subsamples (e.g., different codes), sub samples should be obtained from subsamples in the proportion that the subsamples are to the whole lot.

More than one subsample may be collected from large institutional or bulk containers when the number of sub samples required exceeds the number of containers in the lot. A subsample will consist of more than one container when the lot consists of containers smaller than 100 g (e.g., 4 - 25 g containers is a subsample).

When a sample is collected by transferring it to sample containers, a sample control must be submitted which consists of an empty sample container that is exposed to the same conditions under which the sample is collected. See IOM 4.3.6.2 and 4.3.6.5 on controls. Use aseptic technique when sampling from bulk containers.

SAMPLE SIZE

The following sample sizes also apply to the finished product portion of in-line samples when analyzed for Salmonella. Each subsample will consist of at least 100 gm (approx 3.5 oz).

The 702(b) [21 U.S.C. 372(b)] portion is included in these subsamples, however all subs must be collected for proper analysis. Do not reduce the number of subsamples when collecting import samples.

FOOD CATEGORY	**NUMBER OF SAMPLE UNITS (SUBS)**
I	60
II	30
III	15

SAMPLE SUBMISSION

Submit all samples collected to your division's microbiological servicing laboratory unless directed otherwise by your supervisor or assignment. See IOM 4.5.5.2.

FARM INVESTIGATIONS – SOIL AND WATER SAMPLES

Soil Samples

When conducting an investigation at a farm that was implicated as the source of produce contaminated with Salmonella, and the crop is exposed to soil or water splash from the soil, such as leafy greens, cantaloupes, or cucumbers, soil samples may yield important information as to how the produce was contaminated, especially if a soil amendment such as animal manure or compost was used, or if the crops on that field were rotated and animals grazed on the land previously.

Unless specific instructions were provided by the office issuing the assignment, generally 5 sub samples are collected per field, one from the growing area on each corner, and one near the center. Additional samples may be collected based on observations, such as animal incursion, areas where water may drain, portions of the field susceptible to road dust or runoff, etc. Each field should be issued a separate sample number for ease of identification and review of data. A 1000 ml whirlpack should be filled with soil from a depth of 1 to 3 inches using a sterile scoop and double bagged. Take a photograph of each area where samples are collected and indicate the location and subsample number on a diagram of the field.

Soil samples should be submitted to the lab at 4°C (39°F) or below.

Water Samples

If specialized equipment such as a peristaltic pump are not available, collect water in a sterile, 1000 ml Nalgene sample bottle from wells and surface water. When collecting a surface water sample, a sterile pipette with a re-usable suction bulb is recommended. Using the end of the pipette, stir the surface of the sediment until the water becomes cloudy and then collect this water. *Salmonella* may form a biofilm or colonize sediments and be recovered well past the outbreak period.

Water samples should be submitted to the lab at 4 °C (39 °F) or below.

Environmental samples will be submitted as Investigational Samples (INV).

2- SAMPLING SCHEDULE FOR LOW-ACID CANNED AND ACIDIFIED FOODS

Low Acid Canned Foods

Field Examination

1. At the beginning of the inspection, conduct visual exams of warehouse stock/product offered for import for evidence of abnormal cans including swollen and leaking cans, wet cases, swarms of fruit flies around isolated pallets, etc.
2. If the visual exam or inspectional evidence indicates possible problems, such as under processed lots, lots with questionable seam integrity, or abnormal cans, exam the affected lots. Preferably field examine lots that have been warehoused at least 14 days.
3. A lot to be examined will be one production code.
4. Follow the chart below for the field examination**.** If abnormal containers are found, always collect an official sample of the lot, if possible. For lots with abnormal cans collect an investigational sample ONLY when there is not enough product available to collect an official sample. In all cases, include on the collection report: the lot size, the number of containers examined, and the number of abnormal containers found by type (e.g., hard swells).
5. The chart provides instructions on the number of cans/cases to examine depending on the size of the lot. **When the maximum number of containers / cases have been examined for the specified lot size, collect a sample if one or more abnormal containers are found.** The exam can be discontinued early based on the number of abnormal containers found. For example, if examining a lot consisting of 3409 or more cans, if 11 abnormal cans are found after examining 1000 cans, discontinue the exam and collect a sample
   a. Flippers. Only one end is slack or slightly bulged and the end remains flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.
   b. Springers. One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge, but only one will remain flat when pressed, the can is a springer. Springers result from moderate positive pressure in the can. Buckling or extensive denting of the side wall may produce a springer.
   c. Swells. Both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can
   be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

NOTE: Other abnormalities or defects, such as visibly leaking cans, severe dents around seams, gross seam defects, severely rusted containers should be reported on C/R, (with numbers of cans defective cans observed) but not counted as "abnormal containers" for the purposes of the sequential field examination. Do not collect leakers, but report the number observed. It may be necessary to collect samples of other defects (e.g. seam defects) to support observations and document the severity of the defects. In some cases, photographs may be a suitable substitute for collection of physical samples.

If a sample is collected, identify on the C/R, by sub-sample number, the condition of each container in the sample (e.g., sub-sample 1 - flipper; sub-sample 2 - hard swell; - sub-sample x - normal). Report the results of the warehouse stock examination in the EIR and in FACTS. See IOM 5.1.5.3

Special Sample Handling: If you are shipping swollen cans, double bag and ground ship the sample. If the cans are moderately swollen or worse you should ship the sample with ice packs.

When the 'Reason for Collection' on the Collection Report includes can seam analysis, the CSO shall collect the can seam specifications for the cans in the sample. This is specific to the can manufacturer and can size collected in the sample. The can seam specifications will be submitted in the FD-525 along with the Collection Report for the servicing laboratory.

		PACKED 48/CASE		PACKED 24/CASE		PACKED 12/CASE		PACKED 6/CASE		*Number Abnormal Containers to Discontinue Examination Early
Lot Size Contain	Number to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	
192 or less	All	1 - 4	all	1 - 8	All	1 - 16	All	1 - 32	all	3
193 - 288	192	4 - 6	4	8 - 12	8	16 - 24	16	32 - 48	32	5
289 - 384	all for≤ 298 298 if greater	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all ≤ 50 50 if greater	6
385 - 576	363	8 - 12	8	16 -24	15	32 - 48	30	64 - 96	61	7
577 - 912	433	12 - 19	9	24 - 38	18	48 - 76	36	96 - 152	72	8
913 - 1488	480	19 - 31	10	38 - 62	20	76 - 124	40	152 - 248	80	9
1489 - 3408	529	31 - 71	11	62 - 142	22	124 - 284	44	248 - 568	88	10
3409 or more	576	71 or more	12	142 or more	24	284 or more	48	568 or more	96	11

1. Sample Size for Samples Collected as a Result of a Field Exam:
   a. Official Sample
      The sample will consist of all abnormal containers and the number of normal cans specified under "2. Official Samples" below (e.g., if 8 abnormal containers are observed during the examination of a lot containing 696/ 2 lb. cans the sample will consist of the 8 abnormal cans and 48 normal cans, collected 2 cans from each of 24 cases). Open additional cases, if necessary to meet this requirement. This will provide enough product for complete analysis, including: can seam, incubation, aerobic and anaerobic growth, pH and water. Note that the sample size given for normal cans includes the 702(b) portion.
   b. Investigational Sample and Import Sample.
      Samples for laboratory examination will consist of all abnormal and 12 normal containers.
2. Other Sampling
   Official Samples
   a. Filth, Micro, etc. (Includes 702(b) [21U.S.C.372 (b)] portion)

Collect each subsample to duplicate from a separate case, if possible. Mark subs 1a, 1b, 2a, 2b, etc. Collect as follows:

NET WEIGHT	SIZE OF LOT	MIN TOTAL CANS	CANS/CASE
795 gr (28 oz) and smaller	Up to 50 cases	48	2 from 24
	More than 50 cases	96	2 from 48
Over 795 gr (28 oz)	Up to 600 cases	48	2 from 24
	More than 600 cases	72	2 from 36

   b. Standards Assay (Includes 702(b) portion)
      NOTE: Sample sizes listed below are based upon the requirements of the Standards (21 CFR 145.3). When sampling products which are likely to be non-uniform throughout the lot because of variations from standards of quality, identity, fill-of-container, grade, etc., collect each subsample in triplicate from a separate case. Mark subs 1a, 1b, 1c, 2a, 2b, 2c, etc. Collect as follows:

NET WEIGHT	NUMBER OF CANS OR PACKAGES	MIN TOTAL CANS	CANS/CASE
1 kg (2.2 lbs) or less	4800 or less	48	3 from 16
	4801 to 24,000	72	3 from 24
	24,001 to 48,000	96	3 from 32
	48,001 to 84,000	144	3 from 48
	84,001 to 144,000	264	3 from 88
	144,001 to 240,000	384	3 from 128
	Over 240,000	600	3 from 200
Greater than 1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2400 or less	48	3 from 16
	2401 to 15000	72	3 from 24
	15001 to 24000	96	3 from 32
	24001 to 42000	144	3 from 48
	42001 to 72000	252	3 from 88
	72001 to 120,000	384	3 from 128
	Over 120,000	600	3 from 200
Greater than 4.5 kg (10 lbs)	600 or less	48	3 from 16
	601 to 2000	72	3 from 24
	2001 to 7200	96	3 from 32
	7201 to 15000	144	3 from 48
	15001 to 24000	252	3 from 88
	24001 to 42000	384	3 from 128
	Over 42000	600	3 from 200

Acidified Foods

A lot is defined as one production code.

Field Examination

Conduct a reconciliation examination and check for damaged or destructive container closures. For example, during a visual examination the following may be observed: 1) glass containers with obvious closure defects such as excessive torque on the lid and/or insufficient security, 2) plastic and semi-rigid containers with obvious defects such as leakers and poorly sealed lids, or 3) metal containers with damage or obvious container defects to the double seam.

Conduct a field examination if abnormal containers are observed during the reconciliation examination. Follow the applicable instructions provided above (see Low-Acid Canned Food “Field Examination” section, including chart) when performing a field examination.

Sample Collection

For acidified products, the equilibrium pH determines whether the product will support organisms of public health significance. Spoilage in such products is usually due to inadequate heat treatment to kill spoilage organisms. Spoilage may be significant because high numbers of microorganisms may affect the adequacy of the thermal process. Molds and some bacteria can grow in an acid environment and actually utilize acid as one of their nutrients; and thus, raise the pH to a level above 4.6 where *Clostridium botulinum* or other toxin-producing microorganisms can grow.

Microbial spoilage can be detected by observing swollen lids on jars or swollen can ends. The liquid may be turbid and a whitish deposit may be visible on the product or in the bottom of the jar. See the Guide to Inspection of Acidified Food Manufacturers for additional information: http://www.fda.gov/ora/inspect_ref/igs/iglist.htmlCollect samples for pH testing. Samples must be collected randomly from the entire lot. **Sample size does not include 702(b) portion**.

1. # 10 cans – Use the following sample size for containers larger than 795 gr (28 oz): Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot. Sample size is 12 containers.
2. # 2 half (1/2) cans – Use the following sample size for containers equal to 795 gr (28 oz) or smaller: Randomly select 2 normal containers from each of 12 randomly selected cases (if available) in the lot. Sample size is 24 containers.

If abnormal containers are encountered, collect all abnormal containers (up to a maximum of 24) in addition to the normal containers collected for pH testing (referenced above). Indicate on the C/R the total number of containers examined and the number of each type of abnormality and defect observed. Also indicate the estimated percentage of abnormal containers in the lot.

3- PESTICIDE SAMPLES

(includes 702(b) portion)
DO NOT FUMIGATE PESTICIDE SAMPLES

INTRODUCTION
The objectives of FDA's pesticide monitoring program are to gather information on levels and incidences of pesticide residues in the nation's food supply and to initiate enforcement actions against shipments of foods and feeds found to contain illegal pesticide residues. To meet both objectives, it is necessary to collect samples of foods and feeds for pesticide residue analysis. This section describes procedures for the collection of raw agricultural and processed commodity samples. These procedures apply to both domestic and import arenas. Additionally, a separate set of procedures for collecting samples in conjunction with special investigations, such as samples collected to determine levels of pesticide residues in soil, water, and growing crops, is included.

For pesticide samples, the laboratory will maintain a portion of the composited sample as the 702(b) [21 U.S.C.372(b)] portion.

Pesticide sample sizes no longer differentiate between Surveillance and Compliance Samples. All pesticide samples will be collected as directed below. Remember to include the state and county or country of origin in the Flag. See IOM 4.4.10.1.8.

For appraisal purposes, you must Flag each Domestic as to the basis for sampling in accordance with the definitions below.

Pesticide Compliance Sample. Collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a "Pesticide Surveillance Sample" that was found to contain actionable levels of pesticide residues. Flag "Pesticide Compliance".

Pesticide Surveillance Sample. Collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. Flag "Pesticide Surveillance".

Divisions have the option to collect 1 intact shipping case of fresh produce from packing sheds or large produce warehouses. The one case must meet the minimum sample size specified below. This "one case" option may be used on any import sample or on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the samples according to the instructions below. This "one case" sampling does not apply to large items such as melons.

NOTE: If "one case" option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

Plant products: description of primary samples and minimum size of laboratory samples (total weight of all subs or units collected).

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
1. PRIMARY FOOD COMMODITIES OF PLANT ORIGIN			
All fresh fruits, All fresh vegetables, Frozen bulk produce (not retail) except dry pulses			
Small sized products units generally < 25 g	Berries, peas, olives	whole units, or packages, or units taken with sampling device	1 kg (2.2 lbs)
Medium sized products units generally 25 - 250 g	Apples, oranges, corn on the cob, potatoes	whole units, or units taken with sampling device	1 kg (2.2 lbs) (at least 10 units)
Large sized products units generally > 250 g	Cabbages, lettuce, cucumbers, grapes (bunches, except for sulfites), sweet potatoes	whole units, units taken with sampling device	2 kg(4.4 lbs) (at least 5 units)
Pulses, Cereal grains	soy beans, peas, lentils, rice, wheat (except from rail carloads)		1 kg (2.2 lbs) 1 kg (2.2 lbs)
Tree nuts	(except coconuts)		1 kg (2.2 lbs)
	coconuts		5 units
Oilseeds	peanuts		0.5 kg (1.1 lb)
Seeds for beverages and sweets	See CP 7304.004		0.5 kg (1.1 lb)
Herbs (*for dried herbs see section 3 of this Table*)	fresh parsley others, fresh	whole units or units taken with sampling device	0.5 kg (1.1 lb) 0.2 kg (0.5 lb)
Spices	dried	whole units or units taken with sampling device	0.1 kg (0.25 lb)
2. PRIMARY ANIMAL FEED COMMODITIES			
Primary feed commodities of plant origin			
Legume animal feeds, and other forages and fodders		whole units, or units taken with sampling device	1 kg (2.2 lbs) (from at least 10 units)
Straw, hay and other dried products		whole units, or units taken with sampling device	1 kg (2.2 lbs) (from at least 10 units)
Note. See IOM Sample Schedule Chart 4, Wheat Carload Sampling for guidance in the collection of samples by trier from railcars and trucks.			
3. PROCESSED FOODS OF PLANT ORIGIN			
Secondary food commodities of plant origin, dried fruits, vegetables, herbs, milled cereal products **Derived products of plant origin**, teas, vegetable oils, juices, by-products for animal feed and miscellaneous products **Manufactured foods (single ingredient) of plant origin**, **Manufactured foods (multi-ingredient) of plant origin**, including products with ingredients of animal origin where the ingredient(s) of plant origin predominate(s), and breads			
Products of high unit value		packages or units taken with a sampling device	0.1 kg* (0.25 lb)
Solid products of low bulk density	Hops, Tea	packaged units, or units taken with a sampling device	0.2 kg (0.5 lbs)
Other solid products	bread, flour, apple pomace, dried fruit	packages or other whole units, or units taken with a sampling device	0.5 kg (1.1 lbs)
Liquid products	vegetable oils, juices	packaged units, or units taken with a sampling device	0.5 L or 0.5 kg
** A smaller laboratory sample may be taken from a product of exceptionally high value but the reason for doing so should be noted in the collection report.*			
4. EGGS AND DAIRY PRODUCTS			
Poultry eggs			
Eggs, except quail and similar		whole eggs	12 whole chicken eggs, 6 whole goose or duck eggs
Eggs, quail and similar		whole eggs	24 whole eggs
Milks		whole unit(s), or unit(s) taken with a sampling device	0.5 L
5. PROCESSED FOODS OF ANIMAL ORIGIN			
Secondary food commodities of animal origin, skimmed milks, evaporated milks and milk powders **Derived edible products of animal origin**, milk fats, butters, butter oils, creams, cream powders, caseins, etc.			

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
Manufactured food (single ingredient) of animal origin, **Manufactured food (multi-ingredient) of animal origin**, (including products with ingredients of plant origin where the ingredient(s) of animal origin predominates(s))			
Liquid milk, milk powders, evaporated milk and cream, cream, dairy ice cream, yogurt		packaged unit(s), or unit(s) taken with a sampling device	0.5 L (liquid) or 0.5 kg(solid)
Notes. (i) Evaporated milks and evaporated cream in bulk must be mixed thoroughly before sampling aseptically. (ii) Milk powder in bulk should be sampled aseptically, passing a dry borer tube through the powder at an even rate. (iii) Creams in bulk should be mixed thoroughly with a plunger before sampling but foaming, whipping and churning must be avoided.			
Butter and butter oils (butter, whey butter, low fat spreads containing butter fat, anhydrous butter oil, anhydrous milk fat)		whole or parts of packaged unit(s), **or** unit(s) taken with a sampling device	0.2 kg or 0.2 L
Cheeses, including processed cheeses	units 0.3 kg or greater	whole unit(s) or units taken aseptically with a sampling device	0.5 kg
	units < 0.3 kg	whole unit(s)	0.3 kg
Note. Cheeses with a circular base should be sampled by making two cuts radiating from the center. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides.			
Liquid, frozen or dried egg products		unit(s) taken aseptically with a sampling device	0.5 kg

9. GRAPES FOR SULFITES

Collect approximately 900 - 1800 g (2 - 4 lbs) of grapes [10/100 - 200 g (1/4 to 1/2 lb) subs]. Each subsample will consist of individual grapes, not bunches, and will be collected from different lugs (cases) on as many different pallets in the lot as possible. No grapes that are damaged during the sampling procedure should be included in the sample. However, grapes with damage prior to sampling may be included in the sample.

If sulfiting pads are present, grapes sampled should be selected from areas closest to and directly under the pad.

Monitoring activities should be focused upon lots of grapes with the highest potential for violative sulfite residues.

Direct efforts to lots of grapes sulfited through fumigation or to lots with multiple fumigations especially towards the end of the harvesting season and also to lots with significant numbers of damaged grapes (split, crushed, or unusually wet, if such damage is apparent).

Sample lots of grapes sulfited through the use of sulfiting pads, with or without additional fumigation. If at all possible, sample lots subjected to the following conditions, which could cause high sulfite residues:

- Lots subjected to un-refrigerated storage of 2 or more hours during warm weather.
- Unusual shipping conditions (ships at sea during heavy storms).
- Lots with significant numbers of damaged grapes.
- Lots containing evidence of sulfite pad damage sufficient to cause spilling of sulfiting agent onto grapes.

Special Sample Handling

Place sample in tightly closed airtight glass mason jar(s) or sealed plastic bag(s). Although no effort should be made to commingle subsamples, more than one subsample may be placed in the same container for shipping convenience.

Appropriate cooling procedures are:
Place samples in shipping container or cooler with sufficient ice or other refrigerant to keep sample refrigerated until arrival at the laboratory. Sample should be placed immediately in a refrigerator at or below 7 degrees C. If sample is not to be analyzed within a few hours, the sample should be placed in a freezer, which is maintained at or below -20 degrees C.

Or, if the sample is frozen, place the sample in a container with sufficient dry ice to keep the sample frozen until arrival at the lab. The sample should then be placed in freezer upon arrival at the laboratory.

1. **FISH AND SHELLFISH PRODUCTS**

NOTE: THIS SAMPLE SIZE FURNISHES SUFFICIENT FISH FOR HEAVY METAL ANALYSIS.

Packaged Fish, fresh, frozen, smoked, cured, or shellfish (except oysters)
Collect 12 subs - minimum sub size is 453 g (1 lb)

Bulk Fish - .453 - 1.35 kg (1 - 3 lb)/fish
Collect 12 subs, each sub to consist of 453 g (1 lb) of edible fish

Bulk Shellfish (except oysters)
Collect 12 - 453 g (1 lb) subs

Canned Fish and Shellfish Products (except oysters)
Collect 12 subs - 5 cans per sub

Other Fish and Shellfish Products
Oysters - Collect 12 1 pint subs

Fish Flour and Meal
Follow the guidance in section 5 above.

SWORDFISH FOR HEAVY METALS

These sample sizes must be used whenever sampling swordfish, either for audit, surveillance, or compliance purposes.

Whole Fish (dressed, head removed)
Characterize lot in terms of fish sizes, i.e., small, medium, and large. The following dressed weight ranges are used for classification:

Small Fish - Weighs less than 36.4 kg (80 lbs)

Medium Fish - Weighs 36.4 - 54.5 kg (80 - 120 lbs)

Large Fish - Weighs more than 54.5 kg (120 lbs)

For lots consisting of 12 or more fish, the representative sample to be collected will be determined by the following formula:

ns = (n) (Ns)/N
ns = the number of fish in a given weight range from which subsamples must be taken
n = total number of subsamples to be collected from the lot. (In using this formula n will always equal 12)
Ns = the number of fish in a given weight range in the lot
N = the total number of fish in the lot

Example: If a lot consists of 25 fish and is characterized as: 5 small fish [less than 36.4 kg (80 lbs)], 15 medium fish [36.4 - 54.5 kg (80 - 120 lbs)], and 5 large fish [greater than 54.5 kg (129 lbs)], the sample should be collected as follows:

small fish $\frac{(12)(5)}{25} = 2.4 = 2$

medium fish $\frac{(12)(15)}{25} = 7.2 = 7$

large fish $\frac{(12)(5)}{25} = 2.4 = 2$

TOTAL SAMPLE: 11 sub samples

Usually, the total sample will consist of 12 subsamples. However, due to rounding numbers of subsamples determined by the formula may be 11 or 13 in some instances. The total sample should consist of the specific number of sub samples determined by the formula in all cases.

Each sub sample should consist of approximately a 0.5 kg (1 lb) steak cut from just below the nape of the fish. Care should be taken to avoid mutilation of fish. The sub must consist of edible flesh. If a private laboratory is conducting the analysis, individual fish from which the sub sample is taken should be identified with a tag or other suitable method. This will permit FDA to take audit samples from the same fish sampled by the private laboratories.

For lots consisting of 12 or less fish, collect 1 sub from each fish.

Swordfish Loins (slabs or sides cut from dressed whole fish which has been boned or trimmed).

Use the same formula stipulated for whole fish, with the exception that the following weight ranges should be used to characterize the lot:

Small fish loins = weighs 9.1 - 18.2 kg (20 - 40 lbs)
Medium fish loins) = weighs 18.2 - 36.4 kg (40 - 80 lbs)
Large fish loins = weighs over 36.4 kg (80 lbs)

Swordfish Steaks

Collect 12 sub samples, i.e., 12 steaks, at random from different containers in the lot (as many as possible)

Canned Swordfish

Collect 12/453 g (1 lb) sub samples at random

11. RETAIL CONTAINERS CANNED, FROZEN AND DRIED FOODS

Collect retail containers equal to the number of primary units specified above.

12. SPECIAL INVESTIGATIONS

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

For leafy vegetables, such as lettuce, cabbage, etc.: INV Samples collected in the growing field should be representative of local commercial harvesting practices If the local practice is to strip outer leaves at the time of harvest, this practice should be followed when collecting field samples. In head lettuce, for example, the lettuce may be packed directly into shipping cartons in the field, in which case 6 or 8 outer leaves are left on the head to be removed at the retail outlet. In other instances, each head is stripped of 2 or 3 outer leaves and individually wrapped in plastic, placed in shipping cartons, and the consumer receives the produce in this condition. Describe sampling method on C/R and describe how packing shed handles produce prior to shipping (e.g., washing, waxing, stripping, etc.).

Soil Samples

Collect soil samples from fields according to the following 3x3 grid diagram:

	a	b	c
1	o	o	o
2	o	o	o
3	o	o	o

Sample at the 9 locations indicated by the "o". If the field being sampled is very large, you may have to sample it using a 4x4, 5x5, or even larger grid pattern.

Subs are to be placed in clean quart glass jars, which have been washed in water, rinsed in methanol, and air dried. If methanol is not available, use washed, air dried jars and submit an empty jar as a control. Note on CR that jars were or were not rinsed with methanol.

Obtain two "6 in" deep plugs (1-2 in. in diameter from each sampling location. Place two plugs from each location in cleaned glass jars, place clean aluminum foil over top of jar and seal with screw cap.

Soil samples should be submitted to the lab at 4° C (39° F) or below.

Water Samples - Collect 3 quarts of water from the same sampling source (e.g., faucet, stream, lake, etc.) and place in cleaned, washed and methanol rinsed jars as described under "Soil Samples".

Submit water samples to lab at 4° C (39 ° F) or below.

GENERAL

Official Samples shall be collected whenever feasible unless they are not required to accomplish the objective of the assignment. Investigational Samples shall be collected only when Official Samples are not readily available.

Consult with your supervisor in cases of doubt as to sample cost, size, or collection technique.

When collecting samples in glass jars, line the lids with aluminum foil which has been certified by the laboratory as contaminant free or use Teflon lined lids.

If shipment of shell eggs is required and breakage may result during transit, subs may be broken, shells discarded, and liquid magma collected in clean glass jars. Each sub jar should be properly identified.

Samples collected at Packing Sheds should be representative of the produce as shipped in commerce. DO NOT strip outer leaves from subs collected at packing sheds from bulk lots, shipping cartons ready for shipment, in-transit lots or at final destination. If the packing shed practice is to strip outer leaves prior to shipment, follow this practice when collecting the samples. Describe the sampling method on the C/R.

DO NOT USE magic markers, etc. to identify sub bags, because the ink may affect assay results. Use stick on labels to identify sub bags.

Collect samples in the container in which the dealer is packaging the product. If the dealer is packaging the product in plastic bags, collect sample in these bags. If the firm is not packing the product, collect the samples in paper bags, cardboard cartons, etc. Do not use plastic bags as this may interfere with the analysis, unless the bags are certified as contaminant free by your division laboratory.

Samples must be delivered as promptly as possible to the laboratory if regulatory action is to be taken against actionable lots.

Hold samples in cold storage until ready to be shipped or delivered to the laboratory. If the sample is of a hard fruit or vegetable (such as apples, pears, butternut squash), and is shipped overnight delivery, it can be shipped to the laboratory unrefrigerated, but the FDA 525 should direct refrigeration upon receipt.

Use aseptic technique, where applicable, when collecting samples of finished products from bulk containers.

4- WHEAT CARLOAD SAMPLING

I. SAMPLING NORMALCARS
CAUTION: WHEN USING A GRAIN PROBE, BE CAREFUL NOT TO CLOSE THE TRIER COMPARTMENT DOORS ON YOUR FINGERS.
Collect samples only of specific assignment.

A. Equipment
1. Double tube compartmented trier, 60 in. long
2. Sampling cloth at least 60 in. long
3. 1000 ml plastic graduate
4. Paper bags or other suitable containers capable of holding more than one quart of sample and do not use canvas bags.
5. FDA Metal Car Seals for resealing railroad cars
6. Aluminum ladder
7. Block and tackle to open railcar door

B. Drawing Sample
Principal sources of grain samples are railcars, barges, and trucks. Draw 5 probes (in duplicate) for each sample taken as described below. However, if the sample is to be Field Examined, an initial sample of 5 probes drawn as indicated below will be sufficient.

Probe samples from railcars and trucks as follows:

Probe #1 - From Center of car

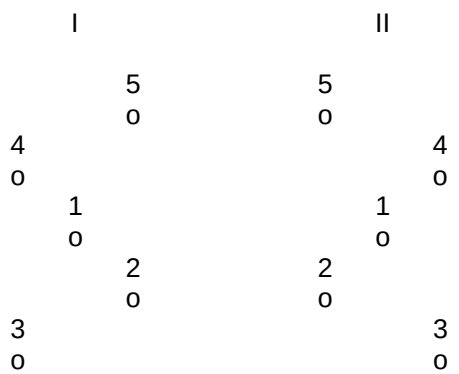
Probe #2 - From 3-5 feet back from door post toward end of the car and approximately 2 feet from the side of the car.

Probe #3 - From 3-5 feet from the same end of the car, but approximately 2 feet from the opposite side of car as Probe #2.

Probe #4 - Same as Probe #2, but opposite end of car.

Probe #5 - Same as Probe #3, but opposite end of car.

Sketches I and II below are alternatives showing the approximate sampling locations.



Insert trier in the grain at an angle of about 10° from the vertical, with the slot up and closed. Open slots. Give trier 2 or 3 short up and down motions, so that the openings will fill. Close slots (SEE CAUTION AT BEGINNING OF SCHEDULE), withdraw trier and carefully empty over sampling cloth. The cloth should be long enough to catch product from each compartment separately when you open the trier compartment doors; e.g. about 6 feet long.

C. Field Examination

Examine each pocket of the probe separately, looking for evidence of pink wheat, rodent pellets, insect damage and uneven loading or plugging. Note any insect infestation and record types of insects and whether live or dead. Count and report for each probe the number of rodent pellets, or rodent pellet fragments. Follow procedure in I.C.2 below. Count as pellets any that are sufficiently large to be readily identified by size, shape, surface coating, and/or presence of rodent hairs. Report the number of rodent pellets per sub. Measure the volume of each sub (probe) in quarts and calculate the average number of pellets per quart per I.C.2.a below. Place pellets from each sub in separate vials and submit with each wheat sub. Place each of the wheat subs in clean, paper bags.

Do not use canvas bags or take glass jars into railcars.

Substantially larger loads will require additional probing or larger samples taken from falling grain during loading or unloading operations.

Submit all suspect samples to laboratory for confirmatory analysis.
1. **Non-Violative Samples**. When field examination shows sample as non-violative, return grain to the car, unless collected for pesticide analysis. Report results in the Remarks Section of the C/R.
2. **Violative Samples**
   a. **Rodent Pellet Contamination**. The guideline for determining whether wheat is violative due to rodent contamination is: "9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per kg of wheat."

NOTE: Since it is impractical to weigh rodent pellets and wheat in the field, the following estimations can be used. Mouse pellets average approximately 8.7 mg each and a kilogram of wheat about 2.35 pints. This translates roughly as 1 pellet per quart of wheat or 1/2 pellet per pint.
Where your field examination reveals one or more rodent pellets (or you can estimate that sufficient fragments of rodent pellets exist to equal one pellet) in a quart of wheat, take duplicate probes to furnish the claimants portion. Take the duplicate probes from the same locations as the original probes. Place the duplicates in separate containers and identify these to correspond with the original probes.

   b. **Pink Wheat**. Where evidence of pink wheat or other fungicide treated wheat is found, collect 15 probe samples. Take 5 probes from each end of the car and 5 probes from the center of the car. Submit the three 5-probe portions separately, using new clean containers.

c. **Insect Damaged Kernels**. The violative status of these samples should be established by laboratory analysis. When any evidence of insect damage is revealed by cursory examination, collect duplicate samples and submit for laboratory analysis.

3. **Resealing Cars** See IOM 4.3.4.
4. **Procedures for Actionable Cars.** If field examination reveals an average of one or more rodent pellets per quart or gross evidence of insect-damaged kernels, evidence of plugging, or "pink wheat" contamination, determine any movement of the car or other disposition of the grain and notify your supervisor immediately.
5. **Preparation of Sample for Laboratory Analysis**. If a sample can be delivered to the laboratory promptly and confirmatory analysis handled expeditiously, freezing of the FDA subsamples is not necessary. The claimant's (702(b)) portion of the sample, however, must be frozen. It is preferable to freeze the subsamples in paper bags. If a freezer is not available, the subsamples (in paper bags) can be placed in a cooler box with dry ice. Do not use glass jars with dry ice. Officially seal all subsamples. If dry ice is used, you must label the shipping container as described in IOM 4.5.5.8.6. See Exhibit 4-19. Indicate frozen storage on the FDA 525.

D. Special Reporting

Submit an Analyst Worksheet (FDA-431) for each sample analyzed and found in compliance. See IOM 4.3.7.1. If field examination shows the sample is possibly actionable, report analytical results in Remarks Section of the C/R.

II. <u>SAMPLING PLUGGED CAR</u>

If uneven loading, layering or "plugging" is suspected, contact your supervisor as to whether to sample or not. A 'plugged" car is a railcar, truck, or barge load of grain where the contamination is suspected of being in only one portion or layer of grain. Plugging is usually the deliberate mixing of violative grain below the surface or in isolated pockets of grain.

A. Equipment

Equipment needed is the same as in 1.A. above except:

1. Double tube grain probe must have individual compartments permanently separated.
2. Small containers of sufficient size to hold the contents of each compartment of each grain probe.

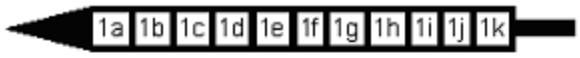
B. Procedure

1. In the Remarks Section of the C/R, draw a diagram showing actual "plugging" pattern suspected.
2. Each sample consists of thirty probes of grain with each probe compartment maintained as a separate sub. Each sample thus consists of 300-330 subs depending on whether a 10 or 11 compartment probe is used and if grain depth is sufficient to insert the probe to fully cover all compartments of the probe.
3. Probe each load and number the probes as follows:

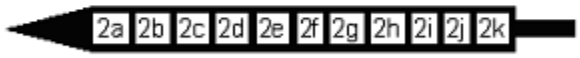
   1 4 7 10 13 16 19 22 25 28
   2 5 8 11 14 17 20 23 26 29
   3 6 9 12 15 18 21 24 27 30

4. Identify the subs by probe number plus compartment letter starting with small "a" as the compartment nearest the tip of the probe.

Example:



Probe #1



Probe #2

5. Submit sample to your division's servicing laboratory. See IOM 4.5.5.2.

5- IMPORTED WHITEFISH SAMPLING SCHEDULE

GENERAL

This Sample Schedule objective is to maintain import lot integrity from time of importation thru FDA inspection or examination and final action.

Shipments will be special manifested from non-lab ports to DO cities and other cities designated by the DD as FDA inspection points. These shipments will arrive in Customs bonded trucks under seal applied by Customs at the port of entry. Customs Entry documents and commercial invoice will accompany each shipment. The commercial invoice contains a description of the lots in the shipment and will serve as a guide in the selection of the lots to be sampled.

1. Special Manifested Shipments:
   a. Determine if seals are intact and record seal number.
   b. FDA metal seals may be broken and lots checked against invoice.
   c. Customs seals may be broken only if authorized by Customs.
   d. Lots which are not to be examined will be released by completing the "MAY PROCEED" block of the FDA-701.
   e. Sample lots to be examined by using either the Single or Sequential Sampling Plan depending on whether examination is made at the DO Lab or at the dock. The Sequential Plan can only be used where additional fish are immediately available for cutting.
2. Definition of a Lot & Selection for Examination.
   a. A lot is defined as "Each group of fish of a distinct size, listed in the invoice as from a distinct lake, will be considered as a separate lot. Where an invoice does not list lakes of origin of boxes of fish in a shipment, fish of the same size and kind will be considered to comprise a single lot. When the size of the fish or lakes of origin in a shipment are not specified, the shipment will be treated as a single lot."
   b. Limit sampling to lots containing 5 or more boxes unless deliberate splitting up of lots is suspected.
   c. Basis for Sampling. Select lots for sampling on either a "selective" or "objective" (random) basis. The criteria in selective sampling may be prior knowledge or suspicion that fish listed as from a given lake are likely to have excess cysts; that the shipper has been known to manipulate shipments; etc. Regardless of the reason for selective sampling, record the basis for sampling each lot in your examination report. Simply list the basis as "selective" or "objective" next to the results of each lot sampled.
   d. Normally, select boxes in a lot for sampling at random. However, where there's evidence of layering, selectively sample the suspect boxes.
3. Sampling Schedule.
   a. Imported samples of whitefish & related fish for parasites. The sampling schedules estimate lot quality more precisely, thereby reducing the likelihood of passing a lot which should be detained, or vice versa, due to an inadequate sample.
      SCHEDULE A below is a single sample plan for use in collecting samples for examination in the division lab or other location where it is impossible or undesirable to return and obtain additional fish.
      SCHEDULE B below contains sequential sampling plans for use when the exam is made at a customs office or a carrier's dock where you have immediate access to the lot and can obtain additional fish, if necessary.
      The sequential plan for lots of 20 to 100 boxes is presented in tabular form. The sequential sample plan for lots of 100 or more boxes is presented in a sampling chart. For small lots of 5-20 boxes, a sequential sample plan is not feasible. All import sampling plans are based on lot size and the sizes of the fish in the lot. When lots are very good or very poor quality, in terms of cyst infestation, double sample plans require a smaller sample size on the average than single sampling plans, to reach a decision.
   b. Domestic Samples for Parasites.
      i. For Laboratory Examination. Lots of 11 or more boxes; Collect at least 25 fish from a representative number of boxes. For small lots, under 11 boxes; Collect 12 fish from a representative number of boxes.
      ii. For Examination in Other Than Laboratory. Cut a preliminary sample in accordance with the appropriate double sampling plan, Schedule B. Cut the additional sample where indicated or bring the additional sample to the laboratory for examination.

SCHEDULE A - SINGLE SAMPLE PLAN

Number of Boxes in Lots	NUMBER OF KG'S (POUNDS) IN A SAMPLE 1/		
	Jumbo or Large 2/	Medium 2/	Small 2/
5 - 19 boxes	12.7 kg (28lbs)	10.5 kg (23lbs)	7.3 kg (16lbs)
20 - 100 boxes	24 kg (73lbs)	20.5 kg (45lbs)	15 kg (33lbs)
100 or over	32 kg (70lbs)	25.5 kg (56lbs)	17.8 kg (39lbs)

1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.

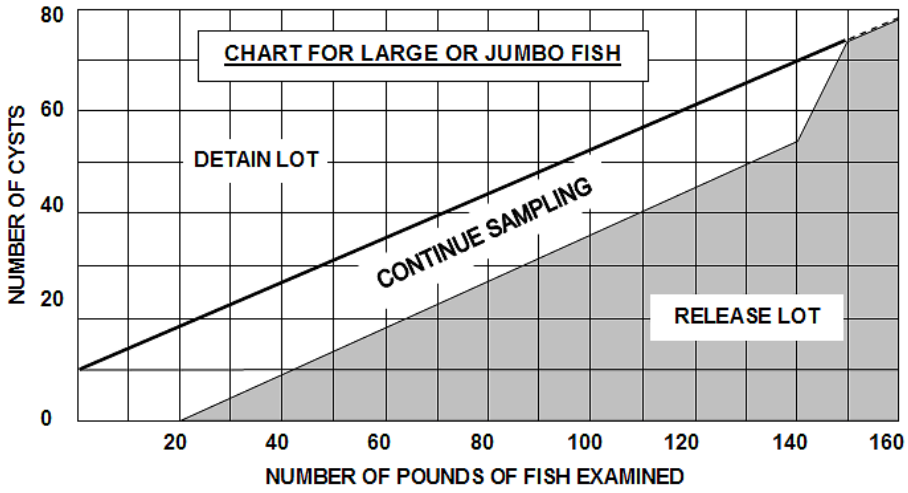
2/ RANGE OF WEIGHT OF FISH IN EACH SIZE CLASS:
SMALL Under 675 g (1 1/2lbs)
MEDIUM 675 g (1 1/2lbs) & under 1.4 kg (3lbs)
LARGE 1.4 kg (3lbs) & under 1.8 kg (4lbs)
JUMBO Over 1.8 kg (4lbs)

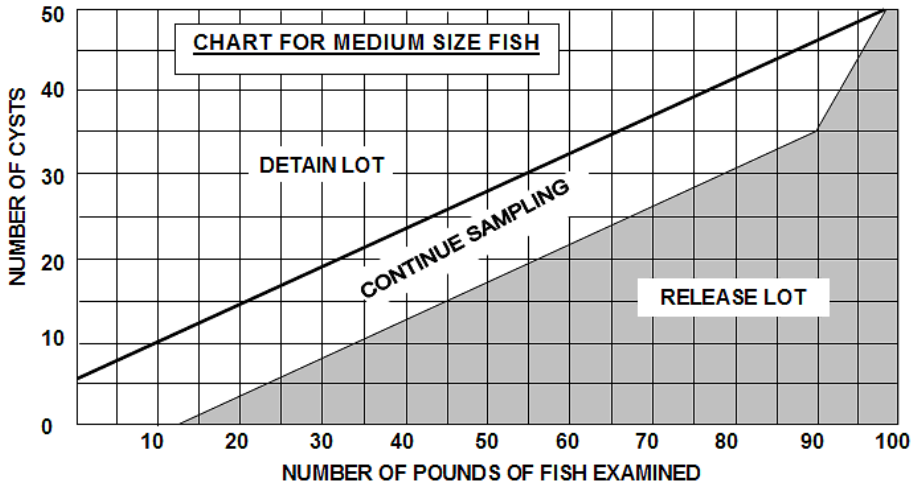
SCHEDULE B - SEQUENTIAL SAMPLE PLAN
1. Limited to lots of 20 - 100 boxes. 454 kg (1000lbs) to 2272 kg (5000lbs)

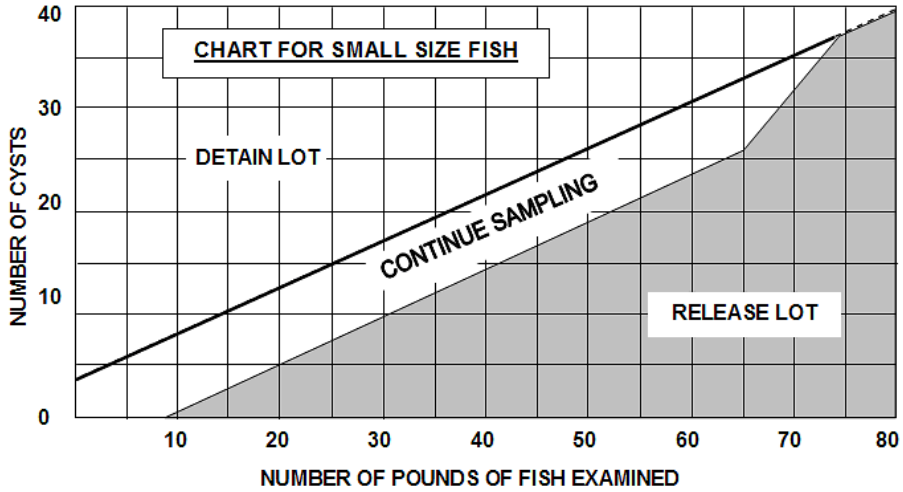
Size of Fish 1/	Size of preliminary Sample	Cysts/45.5 Kg (100lbs) in Preliminary Sample			Size of ADD'L SMPL	Cysts/45.5 Kg (100lbs) in sample	
		PASS	DETAIN	TAKE ADD'L SMPL		PASS	DETAIN
Large & Jumbo	16 kg (35lbs)	30 or less	70 or more	31-69	28.6kg (63lbs)	49 or less	50 or more
Medium	12.3 kg (27lbs)	26 or less	67 or more	27-66	19.5 kg (43lbs)	49 or less	50 or more
Small	8.2 kg (18lbs)	38 or less	61 or more	39-61	11.8kg (26lbs)	49 or less	50 or more

1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.
2/ For lots of 100 boxes or over, use the Sequential Sampling Chart for the particular size fish in the lot.

WHITEFISH SEQUENTIAL SAMPLING PLAN (WHEN LOT SIZE EXCEEDS 100 BOX







6- AFLATOXIN SAMPLE SIZES

Sample sizes of human food samples for all other mycotoxins can be found in CP7307.001 Domestic & Import Mycotoxin Compliance Program

Use “Commodity particles relatively small” for Sample sizes of complete feed and pet food for all other mycotoxins.

PRODUCT SAMPLE SIZES FOR AFLATOXIN ANALYSIS

(Includes 702(b) [21U.S.C. 372(b)] portion - each sample unit, contains product for the reserve portion, no duplicate subs are necessary)

NOTE: COMPLIANCE SAMPLE SIZES MAY DIFFER FROM SURVEILLANCE SAMPLE SIZES.

COMPLIANCE SAMPLE COLLECTION ONLY

PRODUCT	PACKAGE TYPE	LOT SIZE	NUMBER OF SAMPLE UNITS*	UNIT SIZE (minimum)	TOTAL SAMPLE SIZE (minimum)
Peanut Butter (smooth)	Consumer or	NA	24	225 gm (8 oz)	5.4 Kg (12 lbs)
	bulk		12	454 gm (1 lb)	5.4 kg (12 lbs)
Tree nuts - paste			12	454 gm (1 lb)	5.4 kg (12 lbs)
Brazil Nuts in-shell (in import status)	Bulk	< 200 bags	20	454 gm (1 lb)	9 kg(20 lbs)
		201-800"	40	454 gm (1 lb)	18 kg (40 lbs)
		801-2000"	60	454 gm (1 lb)	27 kg (60 lbs)
Pistachio nuts in-shell (in import status)	Bulk	multiples of 34,100 kg (75,000 lbs.)	20 % of units	---	50 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Pistachio nuts shelled (in import status)		multiples of 34,100 kg (75,000 lbs.)	20 % of units	---	25 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Corn - shelled, meal flour or grits	Consumer or bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Oil seed meals - Peanut meal, cottonseed meal	Bulk	NA	20	454 gm (1 lb)	9 kg (20 lbs)
Ginger Root dried whole	Bulk	"n" units	Sq root "n"	---	6.8 kg (15 lbs)
	Consumer	NA	16	160-280 gm (1 oz)	4.5 kg (10 lbs)
Milk - whole, skim low fat	Consumer or bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Small grains - wheat sorghum, barley, etc	Bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Mixtures containing commodities susceptible to mycotoxin contamination	Consumer	NA			
Commodity particles relatively large			50	454 gm (1 lb)	22.7 kg (50 lbs)
Commodity particles relatively small***			10	454 gm (1 lb)	4.5 kg (10 lbs

Surveillance and follow-up COMPLIANCE SAMPLE COLLECTION

Peanut Butter (Crunchy) Peanuts shelled roasted, or unroasted, Peanuts ground for topping	Consumer or bulk	NA		**SURVEILLANCE SAMPLE**	
			10	454 gm (1 lb)	4.5 kg (10 lb)
				COMPLIANCE SAMPLE	
			48	454 gm (1 lb)	21.8 kg (48 lbs)
Peanuts, roasted in shell (only for domestic runner variety)	Consumer or bulk	NA		**SURVEILLANCE SAMPLE**	
			15	454 gm (1 lb)	6.8 kg (15 lbs)
				COMPLIANCE SAMPLE	
			75	454 gm (1 lb)	34 kg (75 lbs)

Tree nuts (except in-shell Brazil Nuts and all pistachio nuts in import status) shelled, in-shell slices, pieces, or flour	Consumer or bulk	NA	**SURVEILLANCE SAMPLE**		
			10	454 gm (lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
			50	454 gm (1 lb)	22.7 kg (50 lbs)
Edible seeds** melon pumpkin, sesame, etc	Bulk	NA	**SURVEILLANCE SAMPLE**		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
			50	454 gm (1 lb)	22.7 kg (50 lb)
Dried fruit** - e.g.: Figs	Consumer or bulk	NA	**SURVEILLANCE SAMPLE**		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
			50	454 gm (1 lb)	22.7 kg (50 lb)

NOTE: Containers for samples of unprocessed, intact nuts, seeds, or grains must be sufficiently porous to provide for dissipation of moisture produced by respiration of the nut, seed, or grain.
* To be collected from as many random sites in the lot as possible. For surveillance samples, you may combine subs prior to shipping to the laboratory. For compliance samples, you must maintain sub integrity.

** Optional sampling program for seeds or dried fruit with a low incidence of contamination. Take initial 10 x 454 g (1 lb) sample. If any aflatoxin is detected, resample 50 x 454 g (1 lb) sample for determination of contamination level on which to base regulatory judgment.
*** CVM Classifies complete feed and pet food as a “commodity particles relatively small”

7- CANNED FRUIT - FILL OF CONTAINER - AUTHENTIC PACK

Collect samples only on a specific assignment or during inspections when it appears that the firm is not filling the containers to capacity.

1. INVESTIGATIONAL SAMPLES: Authentic Pack Preparation. Procedure for preparing authentic factory packs.
   a. Remove 72 cans, 3 at a time, from packing line after fruit has been added and before syruping.
   b. Mark 24 cans with the sub numbers A-1, A-2, A-3, etc.; 24 cans with sub numbers B-1, B-2, B-3; and 24 cans with sub numbers C-1, C-2, C-3, etc. See IOM 4.5.2.3.
   c. Drain water from the "B" subs by inverting each can for 10 seconds, holding the fruit so it doesn't fall out.
   d. Obtain gross weight of each can and record data for each series of sub on 3 separate FDA-485 - Field Weight Sheets.
   e. Add additional fruit of the same kind and style to the "C" subs until the cans are filled to capacity. Do not tamp the contents or crush the fruit.
   f. Record the number of fruit pieces added where the size of the fruit makes the procedure reasonable. Do not make time consuming counts of small pieces of fruit or berries.
   g. Obtain the gross weight of the "C" subs after additional fruit is added and record on "C" series Field Weight Sheet.
   h. Return all 72 cans to the filling line for syruping, exhausting, sealing, etc. in normal cannery operation.
   i. Remove cans after cooking and cooling.
   j. Identify cans with a single INV Sample number.
   k. Attach FDA-485 - Field Weight Sheets to C/R.

2. OFFICIAL SAMPLES
   See Sample Schedule Chart 2 for sample size.

3. SPECIAL REPORTING AND PRECAUTIONS
   a. Report coding of cans and shipping cases.
   b. Obtain label specimen(s) for the slack filled products.
   c. Report shipments made before the inspection or since previous inspection in the same canning season.
   d. Do not prepare Authentic Factory Samples when the cannery is packing for USDA fill-of-container certification unless:
      i. USDA inspection is not continuous.
      ii. USDA Certification is for quality only.
      iii. USDA recommendations for weights are not being followed.

4. SAMPLE SUBMISSION
   Submit samples to your division's designated workplan servicing laboratory

8- IMPORTS - COFFEE, DATES AND DATE MATERIAL

1. Coffee - Import Field Examination - Note: Examine a minimum of six bags of coffee beans regardless of lot size. If a significant number of defective beans or significant contamination is found during the examination of these six bags, continue the examination using the following schedule, which applies for both Import Field Examination and samples for laboratory analysis:

LOT SIZE	NO. BAGS TO BE SAMPLED
100 or less	6 bags
101 - 200	10 bags
201 - 1000	15 bags
over 1000	20 bags

   a. Sample each bag with a trier, collecting 1/2 pt. of beans from the top and 1/2 pt. from the bottom of the bag. The total quantity of beans taken from each bag must be the same, since both wharf and laboratory examinations are to be performed on a composite sample of all beans collected. Shake each sub on a #8 sieve nested in a pan. Dump the sifted beans from each sub into a bag of sufficient size to hold and permit mixing all of the subs collected from the lot. Composite the subs. Do not maintain individually.
   b. Macroscopic Filth Examine the siftings for macroscopic filth (live and dead whole insects, excreta pellets, extraneous material and sweepings), reporting findings for each sub separately. See IOM 4.3.7.4. Transfer macroscopic filth, including all sifted material to a second bag and submit to the laboratory for confirmation. If live insect infestation is encountered, freeze the filth portion containing the insects and the composite coffee bean sample. The lot will be detained if a live insect infestation is encountered, however, proceed with the defect bean examination since the reconditioning process will depend on the results.
   c. Defect Bean Examination Thoroughly mix the composite sample of coffee beans and remove three-hundred beans at random. Examine each individual bean visually (or at a 5X magnification) for insect tunneling and mold damage. Count as moldy only those beans with 1/4 or more of the surface being moldy. Note: Each division office has examples of the various types of reject beans.
   Accept the lot if twenty or less rejects are found and discard the sample. Report your wharf examination into FACTS or OASIS, depending on your assignment; no Sample Collection Report is necessary.
   d. If twenty-one or more rejects are detected, return beans examined to the composite and submit to the laboratory. You may discontinue the examination when twenty-one rejects are detected. When a sample is submitted to the laboratory, all import field examination time is reported as a field exam in FACTS and the sample collection time is reported as an import sample collection. All necessary documents for an import sample collection must be completed.

2. Dates & Date Material - Filth

In the laboratory, dates, like in-shell nuts are sampled in accordance with a sequential sampling program, i.e. all subsamples are composited, and 100 dates are sampled at a time, repetitively, until such time they either exceed or fall under certain reject numbers. It is not uncommon to have to examine 3 to 6 (100 date) repetitions. It is therefore important for each subsample to contain at least 200-300 dates or 2 lbs of date material. Sample according to the following schedule:

NUMBER OF SUBSAMPLES REQUIRED

NO. CONTAINERS IN LOT*	WHOLE DATES	DATE MATERIAL
100 or less	3	4
101 - 600	8	6
601 - 1200	14	8
1201 - 2000	26	10
2001 - 2800	36	12
2801 - 6000	44	14
6001 - 9600	56	16
9601 - 15000	68	18
Over 15000	82	22

* Schedule is based upon unit containers weighing between twenty and one-hundred pounds. For containers exceeding one-hundred pounds each, consider as two or more containers. For example, a one-hundred and fifty-pound container is considered as two containers; a three-hundred pound container as three containers, etc.

   a. Identify each subsample separately.
   b. Each lot will be a separate sample. Reconditioning, if possible, will be based on lot numbers.
   c. Jujube sampling – collect according to the above schedule for dates and date material. Do not identify jujube samples as dates, *Phoenix dactyllifera*. Jujubes, *Zizphus jujube*, are usually labeled as Chinese Red Dates, Dried Red Dates, or Honey Dates and are not misbranded when labeled as such due to long standing use of these names.
   d. If live insects are noted, include these as part of the sample collected and report on the C.R. which subs contained the insects and how many insects, adult or larvae, were noted. If live infestation is noted, place all subs from the lot sampled in large plastic whirl-pak bags and freeze or place in a cooler on dry ice.

9- SAMPLING SCHEDULE FOR COLOR CONTAINING PRODUCTS & COLOR ADDITIVES

The following schedule provides general guidance for collecting samples of foods and cosmetics to determine whether non-permitted colors are present, rather than to determine the actual level of a particular color. This schedule was developed with the assumption that color distribution in the lot will be homogeneous. In the case of heterogeneous products, your supervisor should contact Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement (HFS-605) to determine sample size.

INDUSTRY CODE		SAMPLE SIZE (DO NOT COMMINGLE CODES) (Min. 225 g (8 oz)/pkg Unless otherwise specified)
GRAIN AND BAKING		
02	Whole grains, Milled Grain Products and Starch	2 retail packages
03	Bakery Products, Doughs, Bakery Mixes, and Icings	2 retail packages
04	Macaroni and Noodle Products	2 retail packages
05	Cereal Preparations Breakfast Foods	2 retail packages
07	Snack Food Items (Flour, Meal, or Vegetable Base)	2 retail packages
DAIRY		
09	Milk, Butter, and Dried Milk Pdts	Liquid Pdts: 2 pts where possible Solid: 2 packages
12	Cheese and Cheese Products	2 retail packages
13	Ice Cream and Related Products	6 items per sample (If item is single serving; i.e., cup, popsicle, bar, etc.) 2 pt containers where possible, or 1 quart or 1/2 gal
14	Filled Milk and Imitation Milk Products	2 pints
EGGS		
15	Egg and Egg Pdts	2 dozen whole eggs (e.g. colored hard-boiled Easter eggs) 2 retail pkg of egg pdts
FISH		
16	Fishery/Seafood Pdts	2 retail packages. Any collection of smoked salmon should be selective, based on inspectional evidence
MEAT & SIMULATED MEAT PRODUCTS		
17	Meat, Meat Products and Poultry	2 retail packages
18	Vegetable Protein Pdts	2 retail packages
FRUIT, NUT AND VEGETABLE PRODUCTS		
20-22	Fruit & Fruit Pdts	2 retail packages canned or glazed. 12 fresh fruit (e.g., oranges, etc.).
23	Nuts & Edible Seeds	2 retail packages
24-25	Vegetable & Vegetable Products	2 retail packages
26	Vegetable Oils & Olive Oil	Liquids - 2 pints Solids - 2 retail packages
DRESSINGS AND SPICES		
27	Dressings & Condiments	2 retail packages
28	Spices, Flavors, & Salts	Extracts - 2 pints Solids - 2 retail packages
BEVERAGES		
29	Soft Drinks & Waters	6 Retail Units (Cans, Bottles, Packets)
30	Beverage Bases, Concentrates, and Nectars	Liquids - 1 pint Solids (Powder mix, packets) - 6 Consumer Pkg Solids - 2/225 g (8 oz) or larger containers
31	Coffee and Tea	2 retail packages
32	Alcoholic Beverages	2 pints or 1 quart
CONFECTIONS AND DESSERTS		
33	Candy w/o chocolate, Candy Specialties, and Chewing Gum	2 retail packages
34	Chocolate & Cocoa Pdts	2 retail packages
35	Gelatin, Rennet, Pudding Mixes,	6 pkgs - smallest consumer size

	& Pie Fillings	
36	Food Sweeteners (Nutritive)	2 pints
MULTIPLE FOODS, SOUPS, SALADS, BABY FOOD AND DIETARY		
37	Multiple Food Dinners Gravies, Sauces and Specialties	Single Serving Dinners, etc - 4 pkgs Two Consumer Pkgs when 1 pkg serves more than 2
38	Soups	Same as 37 Above
39	Prepared Salad Products	Same as 37 Above
40	Baby (Infant and Junior) Food Pdts	Sufficient retail pkgs to total at least 454 g (1 lb) of food
41	Dietary Conventional Foods and Meal Replacements	Same as 37 Above
COLORS AND COSMETICS		
50	Color Additives for Foods Drugs, and Cosmetics	1. Straight Color 28 g (1 oz) powder. 2. Color Mixtures 110 g (4 oz) Liq, paste or powder. If mixture contains over 50% pure dye, 55 g (2 oz) is sufficient
53	Cosmetics	Four retail packages of the same lot code for each shade (color) in the product line, if the product is strongly colored. (e.g., Lipsticks, hair coloring products, eye mascara, eye liners, make up pencils of all types) Sufficient number of retail packages to equal 1 lb or 1 pt of sample if the product is lightly colored. (e.g., creams, lotions, shampoos, bath products, shaving preparations, and perfumes.) Note: Always collect a minimum of two retail units of each product.
MISCELLANEOUS		
	Bulk Items (Any bulk food or cosmetic)	Dry - 454 g (1 lb) Liquid - Min 36 fl oz

10- DRUG SAMPLING SCHEDULES

(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size[1]	
	INV Sample[2]	Official [702(b) & Check][3]
DRUGS	36	86
DEVICES	46	106

LEGEND:
[1]Double sample size requirements when individual containers are 2 ml (2 g) or smaller.
[2]INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.
[3]Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) [21 U.S.C. 372(b)] and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting division lab, plus a separate 100 tab portion to be split for dissolution testing.

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	MINIMUM SAMPLE SIZE (Includes 702(b) portion)	
	Sub Size	Nos. of Subsamples
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 g or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your division for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 4.3.6 through 4.3.6.5.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your division unless directed otherwise.

11- VETERINARY PRODUCTS, FEEDS, & BY- PRODUCTS FOR ANIMAL FEEDS

1. GENERAL

This sampling schedule may be used as a guide in the collection of surveillance or compliance samples resulting from division assignments or as a follow-up to violative inspections and/or investigations. Before collecting follow-up samples to violative inspections or investigations, contact your supervisor since it may be necessary for your division to consult with the Atlanta Center for Nutrient Analysis (HFR-SE680) when unscheduled compliance sampling is contemplated.

2. SAMPLE PRODUCT, SIZE, & SPECIAL INSTRUCTIONS

Vitamin-mineral testing, sampling instructions and information. Sample size includes 702(b) portion.

Unless excessive cost is a factor, collect at least 3 intact containers from each lot or control number. When sampling from bulk lots, collect appropriate subs from a minimum of 3 different bulk containers in the lot.

DOSAGE FORM VITAMIN-MINERAL PREPARATIONS (Single/Multiple Ingredients)

PRODUCT	NO. SUBSAMPLES	MINIMUM TOTAL SAMPLE SIZE	REMARKS
Injectables	3 vials/amps	30 ml	Split samples for sterility testing (60 vials/amps)
Tabs/Caps	3 retail units	300 Tabs/Caps	Split sample for micro tests (10/50 tab/cap subs)
Liquids	3 retail units	4 fl. oz.	Split sample for micro tests (10/2 fl. oz. subs)
Powders	3 retail units	112 g (4 oz)	Same as above

FEEDS & BY-PRODUCTS FOR ANIMAL FEEDS (Vitamin-Mineral Claims)

Vitamin A & D Concentrates, Supplements & (A&D feeding	3 retail units(1/2 gal or less)	3 lbs (1.4 kg) 3 pints	Limit samples to those products containing at least 800 units/g Vit A and/or 80 Feeds units/g Vit D
Vitamin B2 (Riboflavin) Concentrates, Supplements, & feeds	Same	Same	Limit samples to those products containing at least 20 mg/lb
Vitamin B12 (Cyanocobalamin) Concentrates, Supplements & feeds	Same	Same	Limit samples to those products containing at least 1 mg/lb
Multiple Vitamins Concentrates, Supplements, & feeds.	Same	Same	Limit samples to those products meeting vitamin levels listed above.

3. SAMPLE SUBMISSION

Submit all samples for Vitamin Potency analysis to the Atlanta Center for Nutrient Analysis (HFR-SE680). Submit samples for filth analysis, microbiological examination, sterility, etc. to your division servicing laboratory.

12- MEDICATED ANIMAL FEEDS SAMPLING

Medicated Premixes

1. Investigational Samples (INV Samples)
   To demonstrate suspected drug carryover or other chemical contamination during manufacturing, collect 1-900 g (2 lbs) of static residual material in the equipment, and the finished product premixes.
2. Official Physical Samples 702(b) [21U.S.C.372(b)] Portion Included
   For expensive premixes or components, collect a total of 3/170 gm(6 oz) subs; One sub from each of 3 containers. In the case of premixes packaged in plastic; e.g., mini-packs, follow instructions under bagged premixes.
   a. Bagged Premixes
      Collect 10 - 454 g (1 lb) subs from each lot. Sample all bags in lots under 10 bags, for a total of 10 subs from the lot.
      Collect 454 g (1 lb) subs from at least 10 different bags selected at random in lots of more than 10 bags.
   b. Bulk Premixes
      Collect at least 10 - 454 g (l lb) subs, from different locations in the lot providing a minimum total sample of 4.5 Kg (10 lbs).
3. Documentary Samples (DOC Sample) - Refer to IOM 4.1.4.2 for guidance on the collection of DOC Samples.

Medicated Feeds

1. Investigational Samples (INV Sample)
   Collect 1 - 900 g (2 lb) of static residual material in the equipment and correlate with finished feed samples to show that residues are being carried over into the finished product.
2. Official Samples (Includes 702(b) portion)
   a. Bagged Complete Feed
      Collect a total sample of not less than 2.3 kg (5 lbs) from each lot. Collect 454 g (1 lb) subs sampling all available bags from lots of 10 bags or less. If lot size is greater than 10 bags, collect 454 g (1 lb) from each of 10 bags selected at random.
   b. Bulk Complete Feed
      Collect at least 10 - 454 g (1 lb) subs from different points in the bulk lot to obtain a minimum total sample of 4.5 kg (10 lbs).
   c. Concentrates/Supplements
      If the concentrate or supplement is relatively inexpensive, follow the sampling procedures for complete feeds. Limit sampling of more expensive drug materials, concentrates, or supplements to no more than 3 containers taking a 170 g (6 oz) or 6 fl. oz. sub from each of the 3 containers.
3. Documentary Samples (DOC Sample)
   a. Feed Subject to MFA Approval - Collect DOC Samples of products processed without required MFA approval. Where the plant does not ship in IS commerce, but ingredients are received from IS sources, document the IS nature of drug ingredients and the "Held For Sale" status of the finished feed. Labeling of drug ingredients must be submitted.
   b. Misbranded Products - Collect a DOC Sample for misbranding or labeling deficiencies. The failure to provide warning and/or withdrawal statements which could present danger to animals or man, or gross evidence of false and misleading therapeutic claims, are factors for consideration.

Sampling Precautions (See IOM Sample Schedule Chart 4)

1. Insert the trier the full length of the bag when sampling bagged premixes, or complete feeds.
2. Clean trier between sampling the different lots of premixes or complete feeds.
3. Place subs in a clean, airtight container, preferably clean glass jars.
4. Do not fumigate samples intended for potency analysis, drug carryover or cross-contamination.

Sample Submission

Submit samples to your division's servicing laboratory or as directed by your assignment or supervisor. See IOM 4.5.5.2.

13- SAMPLE SIZES WITH APPLICATION TO FOOD PRODUCTS FOR ALLERGENS

(Listed below is the sample size needed for lab analysis. Collect all samples in duplicate, with the duplicate serving as the 702 (b) reserve sample)

Product	Package type	Number of sample units	Unit size	Total sample
Non-liquefied foods, i.e., cereals, cookies	Consumer	20	1 lb	20 lbs
Pre-liquefied foods, i.e., ice cream, chocolates	Consumer	10	1 lb	10 lbs
Paste or slurry type	Consumer	24 12	8 oz 1 lb	12 lbs 12 lbs
Fluid, i.e., beverages	Consumer	10	16 fl. oz	160 fl. oz

MPORTANT! WHEN TO SAMPLE: At the time of submission of this table to the IOM, only “for cause” allergen samples for peanut contamination should be collected. Test methods for additional allergens are under development and the field will be notified when they are available for regulatory purposes. The allergen compliance program, when issued, will provide additional sampling guidance. “For cause” sampling should be limited to instances where there is a reasonable probability that a product may contain an allergen and the labeling of the suspect product does not indicate the presence of the allergen. This probability may result from a consumer complaint, a downstream consignee laboratory analysis, or other evidence of the presence of the allergen. Also reference IOM Chapter 8, 8.4.7.5, Allergen Samples, which indicates that allergen samples are to be collected after consultation with OCM/OEIO and CFSAN.

[a] See Laboratory Information Bulletin (LIB) # 4341, Application of Validated, Multiple Laboratory *Performance Test Methods*SM for the Detection of Peanuts in Food, Vol 21(2) 2005 for details regarding the analysis and quantitation of analytical samples.

Note: To be collected from random sites. May combine subs or maintain sub integrity depending on purpose of sampling

Note: Prepare composite following proper grinding and mixing procedures. Separate four 1-lb portions from composite.

Adapted from U.S. Food and Drug Administration, Office of Regulatory Affairs, Investigations Operations Manual, Chapter 4, Sample Schedule 6, Mycotoxin Sample Sizes

4-22 PRODUCT LABELING EXAMPLE

WILAPRIN ARTHRITIS FORMULA

100 Tablets

Fever Reducer and Pain Reliever

Active Ingredients: Acetylsalcylic acid 500 mg.

Inactive Ingredients: Corn Starch, powdered cellulose

LOT 25C83 Manufactured in an approved facility

EXP 8/2013

ARO Pharmaceutical

100 Main Street

Powell, OH 43065

See Carton for Complete Labeling

INTENTIONALLY BLANK