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. FD&C Act, Section 702(a) [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 - Use of Notice of Inspection to the driver or agent when it is necessary to inspect vehicles. See IOM 5.2.2.1.
2. Manufacturers, etc. - An FDA 482. A Notice of Inspection should be issued 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)]. Reports of analysis are not required for non-food items examined (rodent pellets, etc.). The servicing laboratory is responsible for furnishing the report of analysis.

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 Sections 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. Interstate documentation is not required, see CPG manual section 110.200 and 110.600. Import Samples need not be sealed, unless District policy dictates, as long as the integrity of the sample is maintained.

Normally, 702(b) of the FD&C Act [21 U.S.C. 374 (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 by policy 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.

4.1.4.2 - Documentary Samples

In a "Documentary" (or "DOC") sample, no actual physical sample of the product is taken. 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 samples 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 there is little need for laboratory examination. A single piece of life support equipment, 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 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 copies of records obtained to 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 photos are taken as part of DOC samples, the rolls of exposed film should - unless developed by yourself - be sent to established commercial film dealers or color processors for developing. Report identity of film processor on the FDA 525. Also see IOM 5.3.4.

See IOM 4.5.2.5 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 Exhibit 4-1 and 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.

4.1.4.3 - In-Transit Samples

In-Transit samples are those collected from lots held on loading/receiving docks of steamships, trucklines, 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.
3. 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)] is a prohibited act, which can result in any 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". In an "undercover buy", however, the solicitation is made in person, usually under an alias. Pre-arranged explanations or cover stories are necessary to dispel any suspicions about the requester that may surface in face-to-face discussions. "Undercover buys" are frequently used in investigating complaints of illegal activity where the information cannot be substantiated or refuted through more conventional means.

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 subdivisions he collects 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, it enters domestic commerce and any sample collected is 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 writing the sample number on physical samples of Domestic Import products, documents related to the sample, and the seals, preface the sample number with prefix "DI" in the same manner other sample types are used, such as, "DOC", "FS", "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 4.1.7.1, 4.1.7.2, and chapter 6.

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.

4.1.5 - FOOD STANDARDS SAMPLE

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

Note: Samples of standardized foods are not FS Samples.

4.1.6 - GWQAP SAMPLES

As part of the Government-Wide Quality Assurance Program (GWQAP), FDA may determine the need for testing samples of medical products procured on Government contracts in order to assure compliance with Federal specifications and the applicable requirements of the FD&C Act.

Whenever FDA determines samples are desired, Office of Enforcement's Division of Compliance Information and Quality Assurance (DCIQA) advises the home district GWQAP coordinator if a sample is to be collected, and provides written background and testing instructions. DCIQA normally arranges for DOD/VA/HRSA to ship GWQAP drug samples directly to the home district for processing and analysis. Most device samples are shipped directly to WEAC by DOD/VA/HRSA. District investigators will rarely be requested to collect GWQAP or "GQA" Samples from DOD/VA/HRSA facilities. However, they may occasionally complete a C/R and prepare a "GQA" Sample for the laboratory upon its arrival from DOD/VA/HRSA.

For more information about GWQAP Samples, contact Terry Zuch, DCIQA at 240-632-2816.

4.1.7 - 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. Factory Samples - Raw materials, in-process and finished products to demonstrate manufacturing conditions. Note: Photographs taken in a firm are not samples. They are exhibits except when they are part of a DOC Sample. See IOM 4.5.2.4, 5.3.3, and 5.3.4.
2. Exhibits - Filth exhibits and other articles taken for exhibit purposes during inspections to demonstrate manufacturing or storage conditions, employee practices, and the like. 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. An example of an INV filth sample would be rodent excreta pellets, apparent nesting or other rodent gnawed material, and other evidence of rodent activity collected from the perimeter and at multiple locations throughout a manufacturing facility or warehouse in order to document widespread rodent infestation.
3. 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, rather than INV.
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 writing the sample number on sub samples, documents related to the sample, and the seals, preface the sample number with "INV" in the same manner as other sample types are used (e.g. "DOC", "DI").

4.1.7.1 - 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.

4.1.7.2 - 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.

4.1.7.3 - 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, 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 you will make every effort to restore the lot to its original state, you are prepared to purchase a whole unit to avoid leaving broken cases, and we 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

A challenge of FDA authority to collect samples may be raised by a dealer who, for varied reasons, both 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(b) of the FD&C Act [21 U.S.C. 372(b)]. If you have not already done so, issue an FDA 482 - Notice of Inspection 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), 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 5.2.4 and Compliance Policy Guide manual section 130.100 for further discussions on resolving the impasse.

4.2.4 - NOTICE OF INSPECTION

See IOM 4.1.1.2, 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 printed FACTS Collection Record. See IOM 4.4.10.5.

4.2.4.2 - Refusals

See IOM 4.2.2. An FDA 482 must be issued in all sample refusal situations to invoke the applicable provisions of the FD&C Act. The copy of the FDA 482 is to accompany the EIR; a memorandum outlining the facts of the refusal if no EIR is prepared.

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, and the only regulatory sanctions possible are against the product itself or parties other than the carrier (e.g., manufacturer, shipper, etc.), furnish the carrier or his agent an FDA 482 modified to read "Notice of Inspection to Collect Samples Only...". See exhibit 5-4. Attach a copy to the printed 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 modified to read "Notice of Inspection to Collect Samples Only..." See Exhibit 5-4. Attach a copy to the printed 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 district. 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 it's 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.

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

Complete the FDA 484 carefully and completely. Include the trade and chemical name, strength, sample size, container size, lot, batch, or control number, manufacturer's name and address, district address and the sample number on the FDA 484 Receipt for Samples. 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 printed 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 District 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 complete Sample Number here. Be sure to include any prefixes such as "DI", "INV", etc.

Block 5 - Enter 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 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 - In certain situations such as for large or expensive device samples, the owner of the article may not want to part with the item. In these instances, FDA may borrow the item and return it later. If the item is borrowed and to be returned, check this box on the FDA 484. Otherwise, check the purchased block even if there is "no charge".

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 "Cr. Cd." box.

NOTE: Older editions of the FDA 484 do not have a "Cr. Cd." box. If not, write in "Cr. Cd." following the amount.

Block 12 - In instances where payment is made for the Sample, whether actually purchased, borrowed or pro-

vided 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 14, 15, and 17 - Enter your name and 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.

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 proceeding 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 3.2.3.4 for information.

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 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 District 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 a lower price is more fair. If asked, tell the dealer 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 district and report the circumstances in the Collection Remarks field on your FACTS collection record.

If districts 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 responsible Office of New Drug Chemistry review division, 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 district 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 ways to pay for samples. The sample costs may be billed to the district or cash may be used to pay for the sample.

4.2.8.3.1 - COSTS BILLED TO DISTRICT

Billing sample costs to the district is, in many instances, the most practical method of payment. This is particularly true where substantial costs are involved due to large numbers or 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 dealers normal business practice. If available, obtain the dealer's invoice and submit it to the appropriate fiscal unit for your district.

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 district.

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 ATM fee by submitting a local voucher using Travel Manager. 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 district. 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 district.

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 district 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 district's compliance branch can ask for 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 district compliance branch for approval of his/her method. See IOM 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 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 backfilled 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 cartons 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, or you may complete and affix an FDA 2426, Examination Label, to each shipping case or bulk container sampled. For burlap or woven bags, the FDA 2426 may be glued to tags, and the tags attached to the bags.

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 FDA reserve portion and 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.

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. 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 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. (Currently 21 CFR 2.10 uses $50.00 as the amount. However, ORA policy sets a limit of $150.00. If the sample is critical, and the cost exceeds $150.00, check with your supervisor.
4. Import samples, collected from a shipment being imported or offered for entry into the United States.
5. 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.
6. 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.

Note: Regardless of the exemptions under 21 CFR 2.10(b) listed above, a good rule of thumb to follow for most filth samples, is to collect the 702(b) portion.

4.3.3.3 - Collecting the 702(b) Portion

Whenever possible, collect separate subdivisions in order to provide the firm a portion as required by Section 702(b). Each duplicate subdivision 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 subdivisions, assure that the total amount collected for each sample subdivision, 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.

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 Division of Field Investigations (DFI) (HFC-130) at 301-827-5653 to discuss the matter. They will coordinate as necessary with Office of Enforcement (HFC-200) and Chief Counsel (GCF-1) and provide further instructions.

If a decision has already been made by the district 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 1 or 2 above 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

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 these areas of the IOM:
IOM 1.5. - Safety
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 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 gasses - Gasses 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 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 and Illness Reactions
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 district would merely report the same thing back to the complainant. No practical purpose would be served by either collecting or examining such a sample.

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 district 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.
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 charge plate 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.

4.3.5.5 - Undercover Buy

See IOM 4.1.4.6.

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 are 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. 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 emergency, at local cooperating health agencies. Presterilized 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

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. Submit one empty sterile container similarly opened and closed as a control. See IOM 4.3.6.5.

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 type 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 restitch 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 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 resew bag as in 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. 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 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^{o}C (100^{o}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 - Controls

When collecting samples using aseptic technique and the subs are collected using presterilized containers and equipment, submit a number of control subs. If the sampling covers a long period of time you should submit controls which show environmental conditions during the time of sampling. The controls should be collected at the start, during, and at the end of the sampling period. List control subs on your C/R.

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. Also submit at least one empty sterile container which has been opened and closed in the sampling area.
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 presterilized 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 se-

lective sampling. See IOM 4.3.7.3. 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 of filth exhibits and take photographs to document the widespread nature of the evidence. See IOM 4.1.7. 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.

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 in 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 you observe by 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.

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:

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

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.

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.

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

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.

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

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.

Handle exhibits carefully to prevent loss of microscopic evidence.

Submit each portion of bagging or container portion, 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. Subsamples of stained bagging, or portions of the containers, and any adhering pellets.
3. Subsamples of unstained bagging, or portions of the containers, which do not fluoresce, for controls (minimum three required).
4. 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.
5. Subsamples of small portions of product to serve as 702(b) portions
6. 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. Subsamples of cuttings from gnawed holes
7. Subsamples of small amounts of product collected from beneath the gnawed holes.
8. Subsamples of small portions of product to serve as 702(b) portions.
9. Product labeling.
10. Interstate documentation.

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. 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.

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 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, 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).

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 702b 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.

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 blacklight 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 blacklight 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 - LACF for listing can defects.

4.3.7.6 - In-Line Samples

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% formalin solution. Large amounts of slime may be placed in a wide mouth glass jar with either a 1% formaldehyde solution or a 3% formalin. Note: Formalin is normally sold as a standard stock solution of 37%. To obtain the required 3-4% formalin solution, mix 5 ml of the 37% stock solution with 95 ml of distilled water. This will furnish the 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 (vinegar).

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.

Bacteriological Samples - During inspections of firms producing products susceptible to microbial contamination (e.g., frozen precooked; ready to eat seafood, creme filled goods, breaded items, egg rolls, prepared salads, etc.), proof of adulteration, with fecal organisms, or elevated levels of non-pathogenic microorganisms, must be established. Sampling of raw materials, in-line and finished product is warranted. Follow instructions under IOM 4.3.7.7 - Products Susceptible to Contamination with Pathogenic Microorganisms, Sampling During Inspection.

4.3.7.7 - Products Susceptible to Contamination with Pathogenic Microorganisms

A top priority of the agency and CFSAN is to decrease foodborne illness caused by microbial contamination. With the rise of foodborne outbreaks detailed guidance was developed for sample collections and inspections dealing with microbial contamination.

Note: This guidance is intended to augment guidance found in the Compliance Programs listed below. Instructions in current compliance programs and ongoing assignments supersede this guidance. Before conducting inspections under these programs, investigator/analyst teams should be thoroughly familiar with the guidance provided in the appropriate Compliance Program.

For the following Compliance Programs collect samples for microbiological analyses only if:

1. Directed to do so in the current compliance program or ongoing assignments.
2. The firm has a previous history of microbiological contamination (e.g., follow up to illness or injury complaint, recalled/seized product, previous inspectional history, etc.) or
3. Sampling is conducted 'for cause' during an inspection (e.g., inspectional observations warrants collection for microbiological analyses):
   a. Domestic and Imported Cheese and Cheese Products (7303.037)
   b. Domestic Food Safety (7303.803)
   c. Domestic Acidified and Low-Acid Canned Foods (7303.803A)
   d. Domestic Fish and Fishery Products (7303.842) and
   e. Juice HACCP Inspection Program (7303.847). Except as directed by the compliance program, you should not conduct any in-line, environmental, or finished product sampling, for microbiological concerns, during the inspection. Instead, fully document the lack of HACCP control(s) without physical sampling. If in the investigator's judgment the firm's HACCP plan is extremely inadequate and therefore sampling is warranted, contact CFSAN/OC/Division of Enforcement/Domestic Branch HFS-607 to determine what in-line sampling will be performed and the type of regulatory action that may be warranted for the situation at hand.

During inspections of these types of firms, or where inspectional observations indicate there may be a microbial contamination problem, whenever possible an investigator/ microbiologist team approach should be used.

A bacteriological inspection 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 all inspections at firms meeting the criteria previously referenced, environmental swabs, in-line and finished product samples must be collected to document possible or actual routes of contamination of the finished product. Other environmental swabs (e.g., floor drains, walls, etc.) will be collected based upon the investigator's observations of extensive insanitary conditions.

4.3.7.7.1 - IN-LINE SAMPLING

In-Line Sampling During Inspection:

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).

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

"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.

4.3.7.7.2 - ENVIRONMENTAL SAMPLING

"Environmental" swab sampling does not give quantitative results. Because a swab takes a very small sample, microorganisms of significance are often missed. It is important to keep in mind a negative result on a swab will often negate an inspectional observation unless the observation is fully documented. A positive finding will give more support to a fully documented observation.

Environmental swabs from food contact surfaces are to be collected initially (See IOM 4.3.7.6). Other environmental swabs (e.g., floor drains, walls, etc.) will be collected based upon the investigator's observations of extensive insanitary conditions.

Document the possible link between the source of an environmental sample and contamination of the food product. For example, if a swab was taken from:

A floor drain - Did cleaning procedures provide "back splash" to the food contact surfaces or product? Were employees observed walking through the area of the floor drain and back to the processing area (how many and when)? Was product dropped on the floor and placed back on the processing line (how many times and when)?

A wall - Did insects (e.g., flies and number) land on the wall and have subsequent contact on the food contact surface or product (how many and when)?

The ceiling area - Is condensate, flaking paint, etc., located over the processing area? Did you observe the condensate dripping on the food surfaces of the processing equipment and/or product?

4.3.7.7.3 - FINISHED PRODUCT SAMPLING

Collect finished 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 (702b portion).

If the finished product is also to be analyzed for Salmonella, the number of finished product subs should be 15, 30 or 60, depending upon product classification. See Salmonella Sampling Plan, Schedule Chart 1.

See IOM 5.4.7.2 for inspectional guidance for firms producing products susceptible to contamination with pathogenic/non-pathogenic microorganisms.

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 either 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.

Bloch 3 Product - Enter the specific name of the product, i.e., macaroni in cellophane, print 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 District - Enter the name of the collecting district.

Block 15 Employee Signature

Block 16 Employee 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 the document "Guide to Nutritional Labeling and Education Act (NLEA) Requirements" for guidance. See Office Nutrition, Labeling, and Dietary Supplements (ONLDS) website (http://www.cfsan.fda.gov/~dms/lab-hlth.html) for the most up-to-date information regarding claims in labeling.

Also, see CPGM 7321.005 to determine enforcement priorities for food labeling violations, including those related to the Food Allergen Labeling and Consumer Protection Act (FALCPA) http://www.cfsan.fda.gov/~dms/alrgact.html.

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 district.

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

Fully document every Official Sample at the time of collection unless instructed otherwise by the program, the assignment or your supervisor. Current agency policy does not require the collection of records of interstate movement for the issuance of a Warning Letter. Also, the FDA Modernization Act expanded the (rebuttable) presumption of interstate commerce for medical devices to all commodities regulated by FDA. Nevertheless, in any situations where you think a formal legal action may occur, make sure you collect copies of interstate records.

The decision to collect copies of records of interstate commerce in situations involving warning letters may be further covered by District policies or situations. As an example, in cases where the records are readily available and the site is located a long distance from an FDA office, it may be better to collect copies of the records at the time the sample is collected. This will ensure FDA has the records in the event a different action is chosen and you will have saved resources in their collection.

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, photocopy or mechanically copy records, if duplicates are not available. Reproductions should be reviewed to ensure all relevant information is readable.

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 stationary 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 district 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. 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 always allow further reviewers to determine if any pages are missing.

If the firm maintains their records on film or electronically, see IOM 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 I.S.

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 I.S.

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 Section 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 4.1.7 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 4.3.3 and 4.4.5.

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 Office of Motor Carrier Safety, Federal Highway Administration, Department of Transportation. If you furnish this office the name of the trucking company, they will be able to provide the address and phone number. The DIB has the phone number of the local offices of the OMCS as part of a MOU between DOT and FDA.

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 District 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.

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.

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). 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. See IOM Exhibit 4-9.

Note: Shipments made by "Express Mail" do have a shipping record maintained. These are:

1. Express Mail - Form A - used for Post Office to Post Office service.
2. Express Mail - Form B - used for Post Office to Addressee service.
3. Express Mail - Form C - used for Airport to Airport service.

Obtain copies of the Postal Service record from the consignee, if possible, or from the Post Office to document shipments using Express Mail Service.

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.

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 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.

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.

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, 4-11, 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 and it has been signed.

See IOM Exhibit 4-14.

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 at least three copies of all labeling. When you are collecting labeling specifically to document labeling violations, the Compliance Program Guidance Manual may require the collection of additional copies so that various offices can review the labeling simultaneously (for example, CPGM 7321.005 requires the investigator collect 4 copies). Be sure to review the CPGM to ensure you collect

enough original copies of labeling. Mount individual copies or sets of labeling so they can be reviewed by various individuals located in separate offices. 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, 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. See 21 CFR 101.100, 201.150, and 701.9.

4.4.9.3.1 - DOCUMENTATION

Collect both unlabeled and relabeled 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 district'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 you (the collector) have 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.

4.4.10.1 - Flag

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

See the Other Codes Section of the Data Codes Manual for an explanation of the flags.

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.

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 4.1.7.

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 (obtained from the Data Codes Manual) 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 from the Data Codes Manual.

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 district must assure that the Episode Number is used within the district and any other districts 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 4.1.7.

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 AWARD (GQA)

To identify samples collected as part of the Government Wide Quality Assurance Program administered by ORA/OE/Division of Compliance Information and Quality Assurance. See IOM 4.1.6.

4.4.10.2.11 - POST SEIZURE (PS)

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

4.4.10.2.12 - 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 District; 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 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. Marshall 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 assign-

ment 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 interdistrict, 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 and title of the most responsible person at the firm to which the letter should be addressed. 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.

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". 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 District 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 or district office to which you will send the CR and records. This should be the office 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 district 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 district unless you know it is the district 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 intranet site), field survey samples will be filed by the collecting district.

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 collec-

tion record was obtained. For example, when referring to a bill of lading, indicate 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 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) and attach the documents to the printed C/R in the order they were entered into FACTS. 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 district 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 with 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 carton, 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 ID’d as noted in pen/ink. FDA 525 attached to sealed bag, placed in brown, cardboard box and prepared for shipment, then delivered to district security guard desk for FEDEX 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, cartons 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 carton, "0987878". Also indicate the manufacturing codes used on products for which a DOC sample was collected, for example, "serial number "ABC" stamped on metal ID 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

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 build feature or your data codes manual. 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.

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.

When the product sampled is packaged in a carton, 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

Choose "Compliance" if the sample was collected on a selective basis as the result of an inspection, complaint or other evidence there may be a problem with the product. Select "Surveillance" if 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 4-15.

4.4.10.3.49 - SAMPLE CLASS

Make a selection from the following list of values: "Collaborative Study"; "Criminal Investigation"; "District 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 Government Bill of Lading Number, if used. 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, leave this field 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

Choose appropriate lab from the list of values. Select the laboratory to which you are sending the sample. 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 DISTRICT

Make a selection from the list of values. This is the district 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.

4.4.10.3.63 - 702(B) PORTION COLLECTED

Check this box if you collected the duplicate portion of food, drug or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. Note: for routine surveillance samples, collected per a sample schedule, the sample size already includes the 702(b) portion.

4.4.10.3.64 - 704(D) SAMPLE

Check this box if the sample is collected during an inspection, i.e., a FDA 482 has been issued, from a food manufacturer, processor or packer, the firm is entitled to a copy of the analytical results. Include in Collection Remarks name and title of the individual to receive at the firm. This only pertains to when you collect the sample **at** the manufacturing/processing/packing firm.

4.4.10.4 – National Sample Distributor (NSD)

The NSD system was implemented in October 2007. NSD automates the FACTS lab selection function, directing the flow of samples to ORA laboratories which can best conduct sample analysis work at specific times. NSD will identify/suggest an appropriate lab for the Problem Area Flag (PAF), PAC, and district information provided in FACTS. The suggested lab information will then be transmitted back to FACTS for further processing. NSD consists of three modules: Routing module, Lab Capacity module and Lab Contacts module.

The Routing module automatically determines the appropriate lab(s) that can best handle the work for the PAC/PAF combination provided by the user. The NSD Routing module consists of three screens: Questionnaire Screen, Confirm/Override Selections Screen and Print Laboratory Information Screen. The NSD questionnaire screen allows the user to enter additional information that is used to determine the routing of the sample.

The Lab Capacity module allows the users to view/update the capacity of the lab for the upcoming week(s) depending on the user role and affiliation. The NSD Lab Capacity screen allows the Sample Manager to set the capacity for laboratory work by PAF and track the number of samples assigned by NSD to a given laboratory on a weekly basis.

The Lab Contacts modules allow the PAF manager to enter any number of contacts for each PAF, as well as any number of sample custodians. The NSD Lab Contact screen allows the PAF manager to enter contact information for the laboratory, names and phone numbers for a number of Sample Monitors and Sample Custodians for each PAF for which the lab has capacity. This information can be accessed by the collectors from the Confirm/Override Selections screen.

4.4.10.4.1 – NSD AND ASSIGNMENTS

Existing Import Alert and Domestic Assignments issued before NSD – use NSD to choose the servicing laboratory and disregard the servicing laboratories referenced in the assignments. Be alert for specific guidance issued in which NSD is manually overridden.

Assignments and alerts issued after 10/15/07 will have a NSD section with instructions when to override the system.

4.4.10.4.2 – OVERRIDING NSD

Do not override NSD unless specific guidance is distributed. Examples of when NSD may be overridden are:

1. Follow-up samples – send these samples to the original lab which analyzed the initial sample.
2. For-Cause Samples – when collected as part of a violative inspection should go to the servicing lab, especially when the lab is co-located with the responsible Compliance branch.
3. Sample Shipping Cost Prohibitive – the collecting district makes this decision.

Communication – when you override the NSD lab selection, contact the servicing lab prior to shipping the sample. The servicing lab will determine if adequate resources and capacity are available to conduct the analysis in a timely manner.

4.4.10.4.3 OTHER INFORMATION

The Division of Field Science intranet website maintains current documents related to the Laboratory PAF managers Contact List and the District Compliance Contacts.

Sample collectors should complete NSD training on the ORA intranet; this site includes the National Sample distributor tutorial and user manual.

Questions on sample analyses, assignments, laboratory capability, or otherwise can be directed to the Division of Field Science the Scientific Compliance and Regulatory Review branch manager (George Salem 301-827-1031) or Laboratory Operations Branch manager (Todd Bozicevich 301-827-9552).

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 - Print a copy of the Collection Record in FACTS. Attach original records to the printed FACTS Collection Record and route, through your supervisor, to the district office compliance unit most likely to take regulatory action. When requested, additional copies should be routed, attached to a routing slip, marked "records to accompany CR _____(number), as requested." Include a copy of the printed FACTS Collection Record in the FDA 525 if it is available at the time of sample shipment.

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 district. 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 shipment you documented.

As few persons as possible should handle the sample to reduce the likelihood of compromising sample integrity. See the Laboratory Procedures Manual (LPM), Chapter 4, 4.1 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.

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 written 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 4.2.9.2 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, i.e., labeling, records, product, etc. are identified with the sample number, collection date, and handwritten initials on the border or backside. See IOM 5.3.4.2.1 Attach the photos to the printed FACTS Collection Record. See IOM 4.4.10.5.

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.

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 guidelines are followed when mailing or shipping samples containing fumigant or preservative. Exceptions for small quantities are listed in 49 CFR 173.4. If the samples are sent via Federal Express, the International Air Transport Association (IATA) dangerous goods regulations must be met. (Call 1-800-238-5355, extension 922-1666 for specific instructions for shipment.)
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 cartons.

Dry ice and insulated cartons 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 district 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, glass, 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.

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.

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, including dry ice, 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 Styrofoam insulated shipping cartons 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 prechilled, 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.

4.5.4.1 - Preparation

Inscribe FDA 415a, official seal, with the district 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 carton, frosted over, sweating, etc.), wrap or place sample in a container to which the official seal will hold. See IOM 4.5.4.6.

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. Your supervisor, your on-the-job training, and your developing experience will familiarize you with the most effective methods.

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 and "Temporary 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 printed 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 are needed by your district, contact the Division of Field Investigations (DFI) (HFC-130) at 301-827-5653.

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.

4.5.5.1 - 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 carton 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. District 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 district 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. Enter any pertinent remarks. Note if your district 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 - 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 your district's designated servicing laboratory, except as directed by the Compliance Program Guidance Manual, assignment or your supervisor. The following provides general guidance 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. Tissue Residues - Submit to the Denver District Tissue Residue Lab.

A complete, current listing of designated servicing laboratories can be found in the current ORA Field Workplan as Appendix III. This appendix is comprised of a table designating the servicing laboratories for each collecting district and for each compliance program or subpart.

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 Headquarter's Division, the National Center for Drug Analysis, and a district lab:

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

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 district, or forward to the home district if other than the collecting district.

4.5.5.3.3 - CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

Unless specifically directed by a Compliance Program or an assignment, do not submit samples to the CFSAN without approval of the Office of Compliance, Division of Field Programs, Compliance Programs Branch, HFS-636 at 301-436-2061. Send samples to CFSAN at the following address:

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

CFSAN Laboratories are as follows:

1. Office of Cosmetics and Colors
   a. Division of Cosmetics and Compliance (HFS-125) - Conducts chemical and/or toxicological analyses of all cosmetic complaint samples needed for medical evaluation.
   b. Division of Colors Certification and Technology (HFS-105) - Conducts color analysis of foods/drugs/cosmetics.
2. Office of Nutritional Products, Labeling, and Dietary Supplements
   Division of Research and Applied Technology (HFS-840) - Conducts examinations related to food standards and food technology. Analyzes conventional foods for requirements of nutritional properties where special skills and expertise are not available in the field.
3. Office of Applied Research and Safety Assessment
   Division of Molecular Biology (HFS-025) - Analyses foods when the chemical methodology is under development or unusual equipment or skills are required, such as radioactivity analysis/migration of food additives from blood packaging materials. Microbiologically examines samples for potential food pathogens by rapid molecular biological testing using DNA probes, PCR and DNA fingerprint analysis.
4. Office of Plant and Dairy Foods
   a. Division of Natural Products, Microanalytical Branch (HFS-315) - Examines foods for bacterial contamination if field laboratory facilities are not available.
   b. Division of Natural Products (HFS-345) - Analyzes foods for non-nutritive components, including toxins.
   c. Division of Pesticides and Industrial Chemicals - (HFS-335) - Conducts examinations related to industrial chemicals contamination, including pesticides, toxic elements and radionuclides.
   d. Division of Microbiological Studies (HFS-515) - Conducts examinations related to Food Standards and food technology investigations, including the intended effect of food additives and the integrity of packaging.
5. Office of Seafood
   Division of Science and Applied Technology (HFS-425)
   Conducts decomposition, toxicity and parasite analysis of seafood where special skills or equipment required for analysis are not available in the field.
6. Office of Food Additive Safety
   Division of Chemistry Research and Environmental Review (HFS-245) - Analyses foods and food packaging materials for direct and indirect food additives where special skills and expertise are not available in the field.

4.5.5.3.4 - CENTER FOR DRUG EVALUATION AND RESEARCH DIVISION OF PHARMACEUTICAL ANALYSIS (DPA)

Center for Drug Evaluation and Research Division of Pharmaceutical Analysis (DPA)

Center for Drug Analysis (HFH-300)
Division of Pharmaceutical Analysis (DPA)
US Courthouse and Customhouse Bldg.
1114 Market Street, Room 1002
St. Louis, MO 63101

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

4.5.5.3.5 - CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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 district should notify either the Sample Custodian, 301-594-6517, or the Surveillance and Policy Branch, 301-594-1070, 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 OST laboratory accepts medical devices and radiation-emitting products for testing, but only after assignment or approval from CDRH, Office of Compliance. 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
   Pamela MacKill Director, Analytical
   Telephone: 781-729-5700 ext. 748
   FAX: 781-729-3593
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/OST Sample Custodian HFZ-105
   12725 Twinbrook Parkway, Room 210
   Rockville, MD 20852
   Telephone: 301-827-4723
   FAX: 301-827-4731 Note: Contact Electronic Products Branch, HFZ-342, 301-594-4654 prior to collection and shipment of any radiological product sample.

4.5.5.3.7 - CENTER FOR VETERINARY MEDICINE

Center for Veterinary Medicine
Division of Compliance (HFV-230)
7500 Standish Place (MPN II)
Rockville, MD 20855
301-827-1168
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.

4.5.5.4 - 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 district 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 carton 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 carton 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 district 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 District 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.).

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 district. If available, obtain the transportation costs or the rate from the carrier and enter it in pencil on the copies submitted to the district.

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

Affix a completed address label, form HHS-409, U.S. Government shipment to each shipping carton. Use the street address of the consignee, do not use the post office box numbers, since carriers usually will not deliver to PO box numbers. If the package is going to an FDA unit, include the FDA routing symbol in the consignee address. If shipment is made under the GSA-Carrier Agreement, strike out the information on GBLS in the lower left corner of the form since a GBL is not used.

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 Sticker (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.

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.

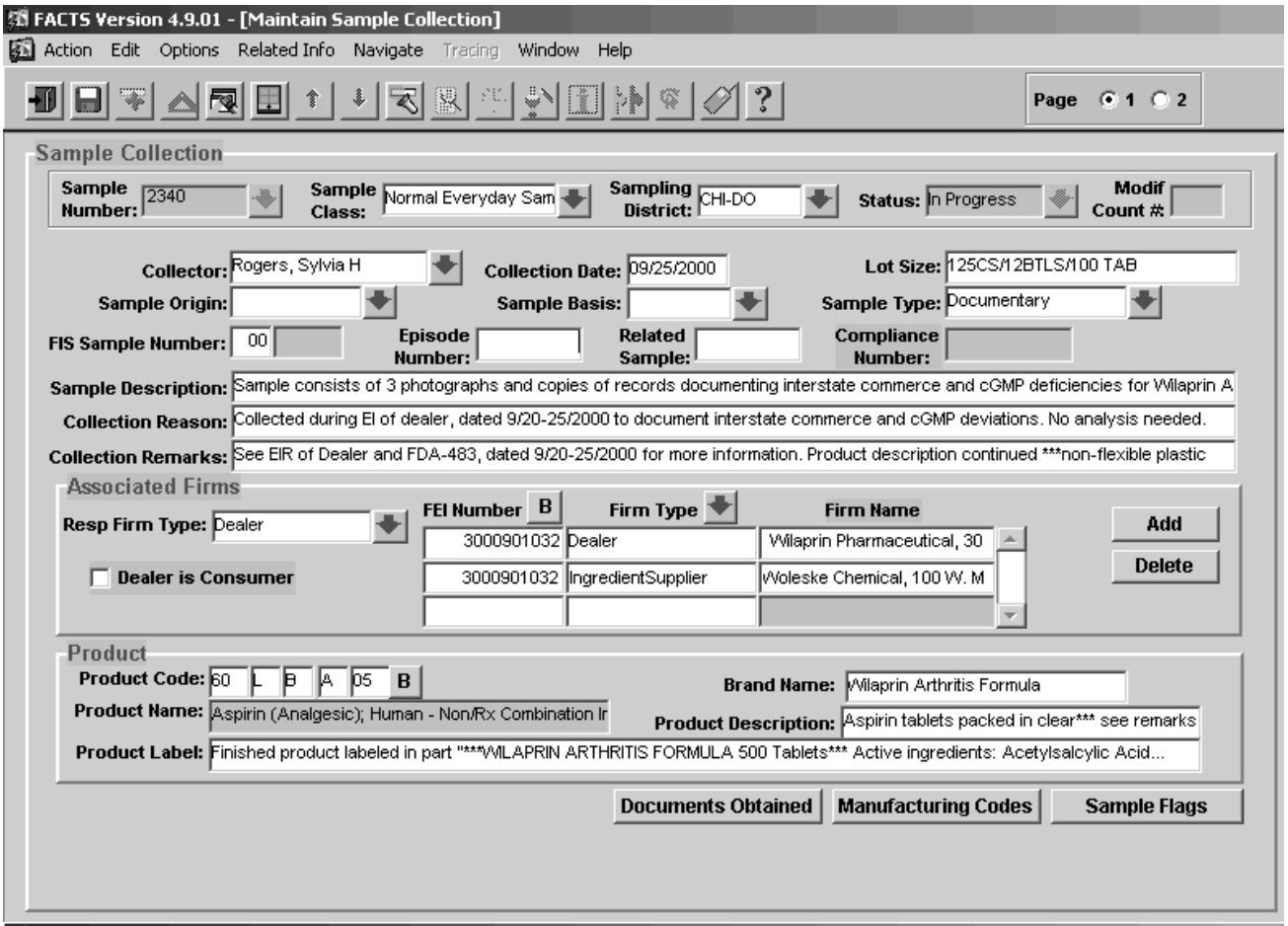
Note: The compliance program for radioactive drugs directs the manufacturer to ship samples via their normal mode of transportation to WEAC. The Nuclear Regulatory Commission (NRC) requires that firms manufacturing radioactive drugs ship only to NRC licensed consignees. WEAC's NRC license number is 20-08361-01 Exp. Date 2-28-2006. This license number should be used for any shipments of radioactive products to WEAC.

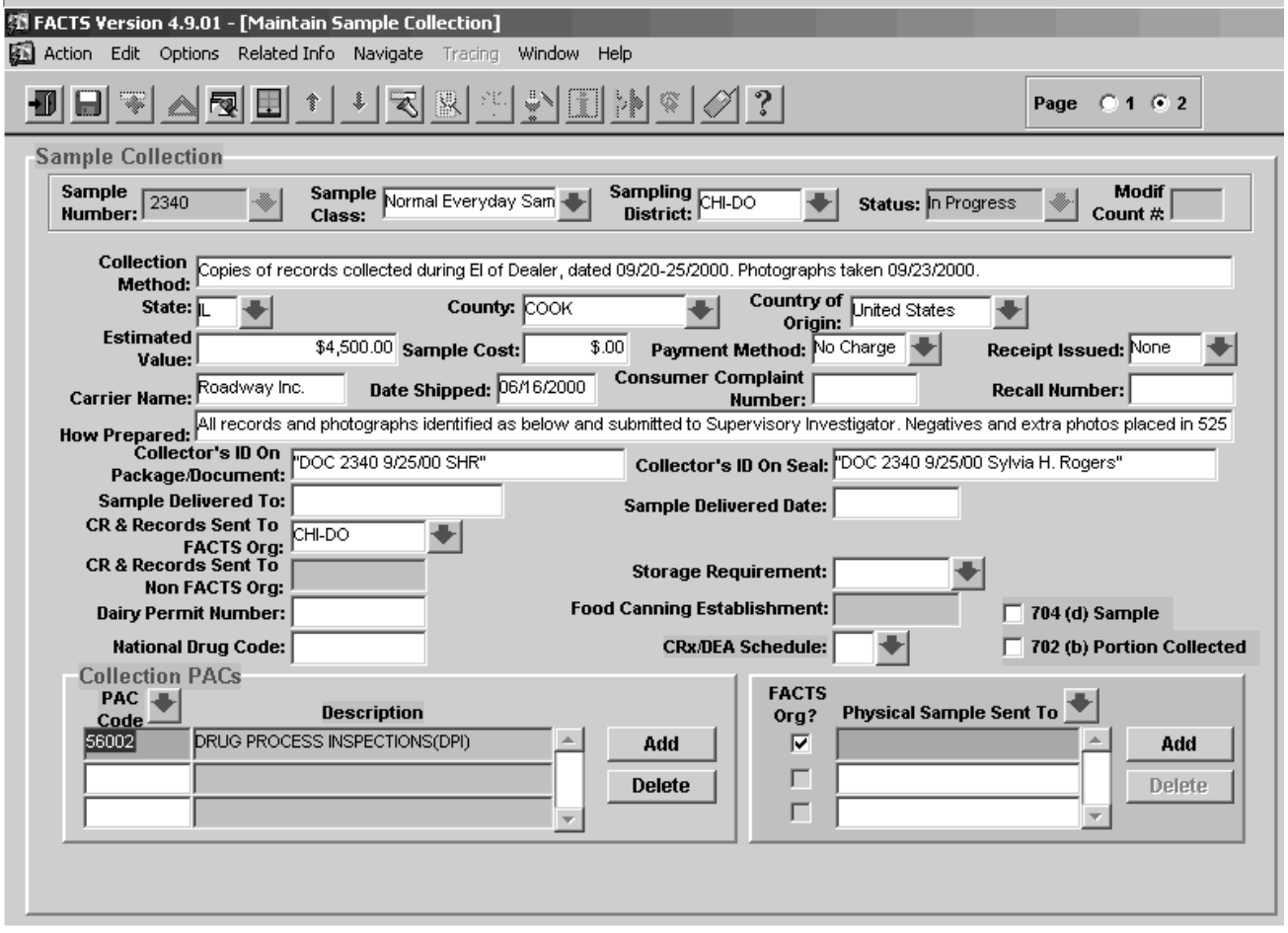
4.5.5.9 - Certified and First Class Mail

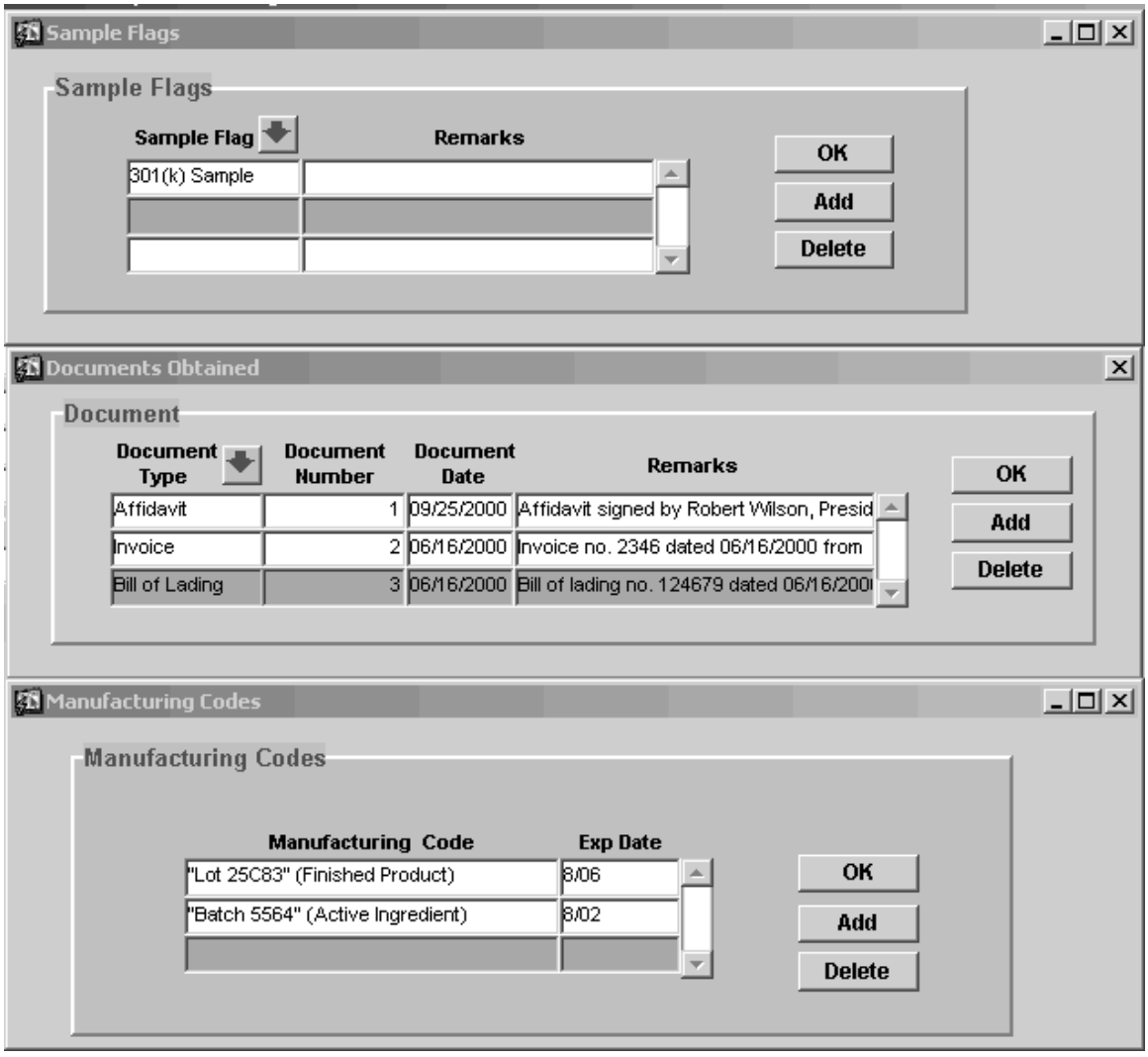
Where speed is essential and a record of receipt of the sample is desired, small samples may be sent by express mail or certified air mail, or, in situations where speed is a factor but the receipt is not necessary, by first class air mail. Where other methods of shipment do not suffice, larger samples 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 districts 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
      Accounting Branch (HFA-120)
      5600 Fishers Lane
      Rockville, MD 20857
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.


FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 2340
Sample Class: Normal Everyday Sam
Sampling District: CHI-DO
Status: In Progress
Modif Count #:
Collector: Rogers, Sylvia H
Collection Date: 09/25/2000
Lot Size: 125CS/12BTLS/100 TAB
Sample Origin:
Sample Basis:
Sample Type: Documentary
FIS Sample Number: 00
Episode Number:
Related Sample:
Compliance Number:
Sample Description: Sample consists of 3 photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wilaprin A
Collection Reason: Collected during EI of dealer, dated 9/20-25/2000 to document interstate commerce and cGMP deviations. No analysis needed.
Collection Remarks: See EIR of Dealer and FDA-483, dated 9/20-25/2000 for more information. Product description continued ***non-flexible plastic
Associated Firms
Resp Firm Type: Dealer
Dealer is Consumer
FEI Number B
Firm Type
Firm Name
3000901032 Dealer Wilaprin Pharmaceutical, 30
3000901032 IngredientSupplier Woleske Chemical, 100 W. M
Add
Delete
Product
Product Code: 60 L B A 05 B
Brand Name: Wilaprin Arthritis Formula
Product Name: Aspirin (Analgesic); Human - Non/Rx Combination Ir
Product Description: Aspirin tablets packed in clear*** see remarks
Product Label: Finished product labeled in part "***WILAPRIN ARTHRITIS FORMULA 500 Tablets*** Active ingredients: Acetylsalcylic Acid...
Documents Obtained
Manufacturing Codes
Sample Flags


FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 2340
Sample Class: Normal Everyday Sam
Sampling District: CHI-DO
Status: In Progress
Modif Count #:
Collection Method: Copies of records collected during EI of Dealer, dated 09/20-25/2000. Photographs taken 09/23/2000.
State: IL
County: COOK
Country of Origin: United States
Estimated Value: $4,500.00
Sample Cost: $.00
Payment Method: No Charge
Receipt Issued: None
Carrier Name: Roadway Inc.
Date Shipped: 06/16/2000
Consumer Complaint Number:
Recall Number:
How Prepared: All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525
Collector's ID On Package/Document: "DOC 2340 9/25/00 SHR"
Collector's ID On Seal: "DOC 2340 9/25/00 Sylvia H. Rogers"
Sample Delivered To:
Sample Delivered Date:
CR & Records Sent To FACTS Org: CHI-DO
CR & Records Sent To Non FACTS Org:
Storage Requirement:
Dairy Permit Number:
Food Canning Establishment:
704 (d) Sample
National Drug Code:
CRx/DEA Schedule:
702 (b) Portion Collected
Collection PACs
PAC Code
Description
56002 DRUG PROCESS INSPECTIONS(DPI)
Add
Delete
FACTS Org?
Physical Sample Sent To
Add
Delete


Sample Flags
Sample Flags
Sample Flag
Remarks
301(k) Sample
OK
Add
Delete
Documents Obtained
Document
Document Type
Document Number
Document Date
Remarks
Affidavit
1
09/25/2000
Affidavit signed by Robert Wilson, Presid
Invoice
2
06/16/2000
Invoice no. 2346 dated 06/16/2000 from
Bill of Lading
3
06/16/2000
Bill of lading no. 124679 dated 06/16/200
OK
Add
Delete
Manufacturing Codes
Manufacturing Codes
Manufacturing Code
Exp Date
"Lot 25C83" (Finished Product)
8/06
"Batch 5564" (Active Ingredient)
8/02
OK
Add
Delete

United States Food and Drug Administration
Collection Report
For Sample Number: 2340

This is an accurate reproduction of the original electronic record as of 11/07/2003

Flag	Flag Remarks
301(k) Sample	

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Documentary	00908358	In Progress

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3000901032	09/25/2000	60LBA05	Dealer	56002	8

Compliance Num	Country of Origin

Related Smpl Number	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt
	2	CHI-DO			

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

Product Description
Aspirin Non-Rx Combination Tablet

Product Label
See continuation

Reason for Collection	MFG Codes	Expiration Date
Collected during EI of dealer, dated 9/20-25/2000 to document Interstate commerce and cGMP deviations. No analysis needed	"Lot 25C83" (Finished Product) "Batch 5564" (Active Ingredient)	8/06 8/02

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Wilson Pharmaceutical	300 Riverside Chicago, IL 60606 US	Dealer	3000901032	
Woleske Chemical	100 W. Main Kansas City, MO 64111 US	Ingredient Supplier	3000901033	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
125 CS/12 BTLS/100 TAB	$4,500	None	Roadway	06/06/1999

Description of Sample
Sample consists of 3 photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wilaprin Arthritis Formula

Method of Collection
Copies of records collected during EI of dealer, dated 09/20-25/2000. Photographs taken 09/23/2000.

How Prepared
See continuation.

Collector's Identification on Package and/or Label	Collector's Identification on Seal
"DOC 2340 9/25/00 SHR"	"DOC 2340 9/25/00 Sylvia H. Rogers"

Samples Delivered To	Date Delivered	Orig C/R & Records To
		CHI-DO

United States Food and Drug Administration
Collection Report
For Sample Number: 2340

This is an accurate reproduction of the original electronic record as of 11/07/2003

Lab w/Split Sample **Lab**

Document Number	Document Date	Document Type	Document Remarks
1.	09/25/2000	Affidavit	Affidavit signed by Robert Wilson, President
2.	06/16/2000	Invoice	Invoice no. 2346 dated 06/16/2000 from Woleske Chemical, Kansas, MO for 1-250 lb drum of Acetylsalicylic Acid, batch 5564
3.	06/16/2000	Bill of Lading	Bill of Lading no. 124679 dated 06/16/2000 from Roadway Inc. Smith Center Kansas for shipment of 250 lbs of Acetylsalicylic Acid from Woleske Chemical, Kansas City, MO to Wilson Pharmaceutical, Inc. Chicago, IL
4.		Other	Raw Material Inventory Card for Acetylsalicylic Acid Batch no. 5564
5.		Other	Photographs 1-3 of labeling for bulk 250 lb. Drum of Acetylsalicylic Acid, Batch 5564
6.		Other	Wilson Pharmaceuticals Batch Record for Wilaprin Arthritis Formula, lot 25C83 (25 pages) (Page 13, 14 and 15 contain copies of all labeling distributed with lot 25C83)

Remarks
See EIR of dealer and FDA-483, dated 9/20-25/2000 for more information. FDA-483 points 1-12 discuss deviations specific to this product.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
$0.00	No Charge	No	No	Silvia H. Rogers

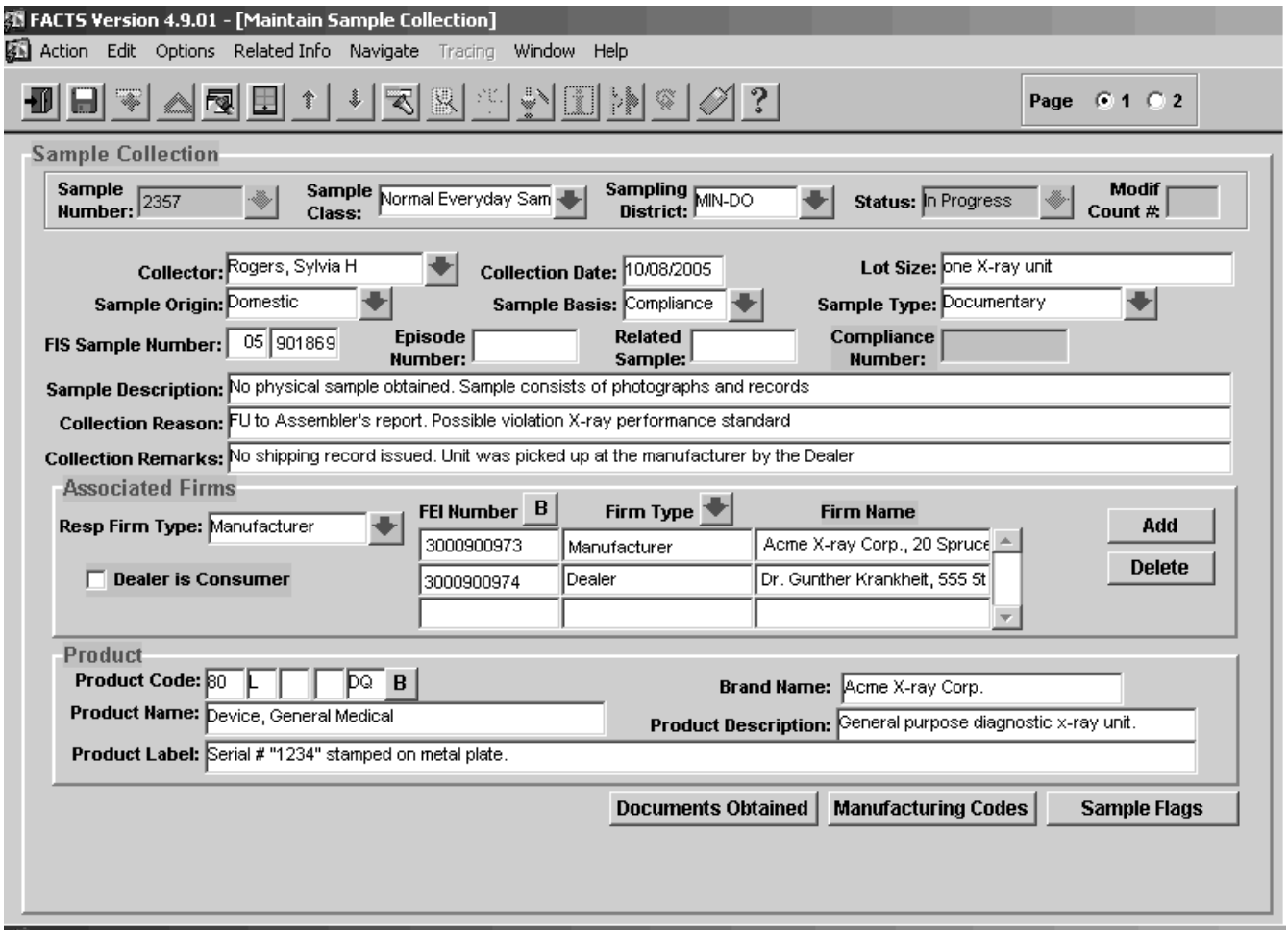
Name of Signer **Date & Time of Signature** **Meaning**

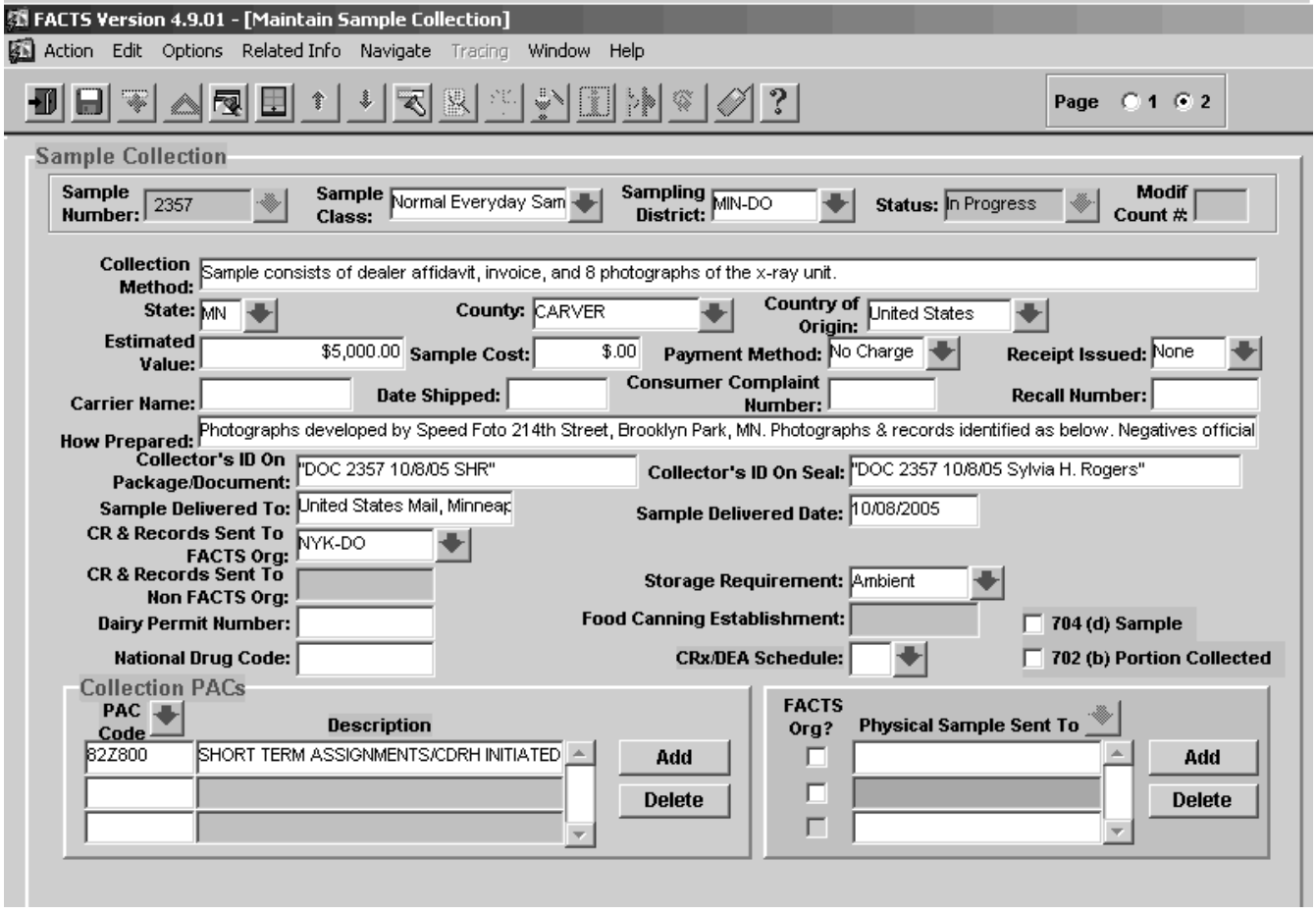
United States Food and Drug Administration
Collection Report
For Sample Number: 2340

This is an accurate reproduction of the original electronic record as of 11/07/2003

Product Label
Finished product is labeled in part: "***WILAPRIN ARTHRITIS FORMULA 500 Tablets***Active Ingredients: Acetylsalicylic Acid…5000mg, Caffeine…32mg.***100 Tablets***Lot 25C83***EXP 8/06***Wilson Pharmaceuticals, Chicago, IL 60606". Each bottle is placed in a white, paperboard box labeled in part, "*** WILAPRIN ARTHRITIS FORMULA *** 100 Tablets Active ingredients: Acetylsalicylic Acid…5000mg, Caffeine…32mg. ***Lot #25C83 Expires 8/06 *** Wilson Pharmaceuticals, ***". White paperboard boxes are placed in brown cardboard cartons labeled in part, "*** WILAPRIN ARTHRITIS FORMULA***Wilson Pharmaceuticals***Lot 25C83***EXP8/06***"
Active ingredient documented is Acetylsalicylic Acid packaged in 250 lb drum, labeled in part: "***Acetylsalicylic Acid, USP***Batch No 5564***Use by 8/02**Woleske Chemical, Kansas City, MO 64111***"

How Prepared
All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525, sealed as below and submitted to Supervisor.


FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 2357
Sample Class: Normal Everyday Sam
Sampling District: MIN-DO
Status: In Progress
Modif Count #:
Collector: Rogers, Sylvia H
Collection Date: 10/08/2005
Lot Size: one X-ray unit
Sample Origin: Domestic
Sample Basis: Compliance
Sample Type: Documentary
FIS Sample Number: 05 901869
Episode Number:
Related Sample:
Compliance Number:
Sample Description: No physical sample obtained. Sample consists of photographs and records
Collection Reason: FU to Assembler's report. Possible violation X-ray performance standard
Collection Remarks: No shipping record issued. Unit was picked up at the manufacturer by the Dealer
Associated Firms
Resp Firm Type: Manufacturer
Dealer is Consumer
FEI Number B
Firm Type
Firm Name
3000900973 Manufacturer Acme X-ray Corp., 20 Spruce
3000900974 Dealer Dr. Gunther Krankheit, 555 St
Add
Delete
Product
Product Code: 80 L DQ B
Brand Name: Acme X-ray Corp.
Product Name: Device, General Medical
Product Description: General purpose diagnostic x-ray unit.
Product Label: Serial # "1234" stamped on metal plate.
Documents Obtained
Manufacturing Codes
Sample Flags


FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 2357
Sample Class: Normal Everyday Sam
Sampling District: MIN-DO
Status: In Progress
Modif Count #:
Collection Method: Sample consists of dealer affidavit, invoice, and 8 photographs of the x-ray unit.
State: MN
County: CARVER
Country of Origin: United States
Estimated Value: $5,000.00
Sample Cost: $.00
Payment Method: No Charge
Receipt Issued: None
Carrier Name:
Date Shipped:
Consumer Complaint Number:
Recall Number:
How Prepared: Photographs developed by Speed Foto 214th Street, Brooklyn Park, MN. Photographs & records identified as below. Negatives official
Collector's ID On Package/Document: "DOC 2357 10/8/05 SHR"
Collector's ID On Seal: "DOC 2357 10/8/05 Sylvia H. Rogers"
Sample Delivered To: United States Mail, Minneap
Sample Delivered Date: 10/08/2005
CR & Records Sent To FACTS Org: NYK-DO
CR & Records Sent To Non FACTS Org:
Storage Requirement: Ambient
Dairy Permit Number:
Food Canning Establishment:
704 (d) Sample
National Drug Code:
CRx/DEA Schedule:
702 (b) Portion Collected
Collection PACs
PAC Code
Description
82Z800 SHORT TERM ASSIGNMENTS/CDRH INITIATED
Add
Delete
FACTS Org?
Physical Sample Sent To
Add
Delete

AFFIDAVIT *(In-transit Sampling)*

SAMPLE NO. 55522

STATE OF UTAH

COUNTY OF UINTAH

Before me, Sylvia A. 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, personnally 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 A. Roger
(Employee's Signature)

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

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

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 A. Rogers*

FORM FDA 472 (10/01) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. **CARRIER'S RECEIPT FOR SAMPLE**

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 ampules, Diloudid 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 A. Rogers	Investigator	Sylvia A. 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

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."

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

TARE NO.	WEIGHT	TARE NO.	WEIGHT
1	0.22	4	0.23
2	0.22	5	0.21
3	0.21	6	0.22
TOTAL	0.65	**TOTAL**	0.66
		GRAND TOTAL	1.31
*NUMBER OF TARES WEIGHED			6
PRELIMINARY AVERAGE TARE			0.22

11. WEIGHING RESULTS

a. AVERAGE GROSS	11.60
b. PRELIMINARY AVERAGE TARE	.22
c. AVERAGE NET	11.38
d. DECLARED NET	12.00
e. SHORTAGE	.62
12. PRELIMINARY % SHORT	5.2%

13. REMARKS *(List observations of lot or storage conditions affecting net weights)*: 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 PREVIOUS EDITION MAY NOT BE USED **FIELD WEIGHT SHEET**

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.

1. LOCATION	2. NAME OF SAMPLE COLLECTOR	3. DATE COLLECTED	4. SAMPLE NUMBER
Pine Bluff, Arkansas	Sylvia A. 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.				
P. Monteux s/s	9-26-05	**TOTAL**	28	650		13.00

FORM FDA 1662 (4/86) PREVIOUS EDITION MAY BE USED **COPY OF INVOICE AND SHIPPING RECORD**

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, cartons, 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

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.

The next morning, October 19, 1999, I drove to Charles Brown & Associates at 920 Grape St., Santa Rosa, California and picked up 4 cartons bearing the label: "Fancy Medical Device, quantity 1." Each carton 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 cartons 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.

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 (4/83) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

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'Rourk, 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

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 Sydney 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 (4/83) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

AFFIDAVIT *(Jobber)*

SAMPLE NO. 55563

STATE OF: Arkansas

COUNTY OF: Jefferson

Before me, Sylvia A. 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

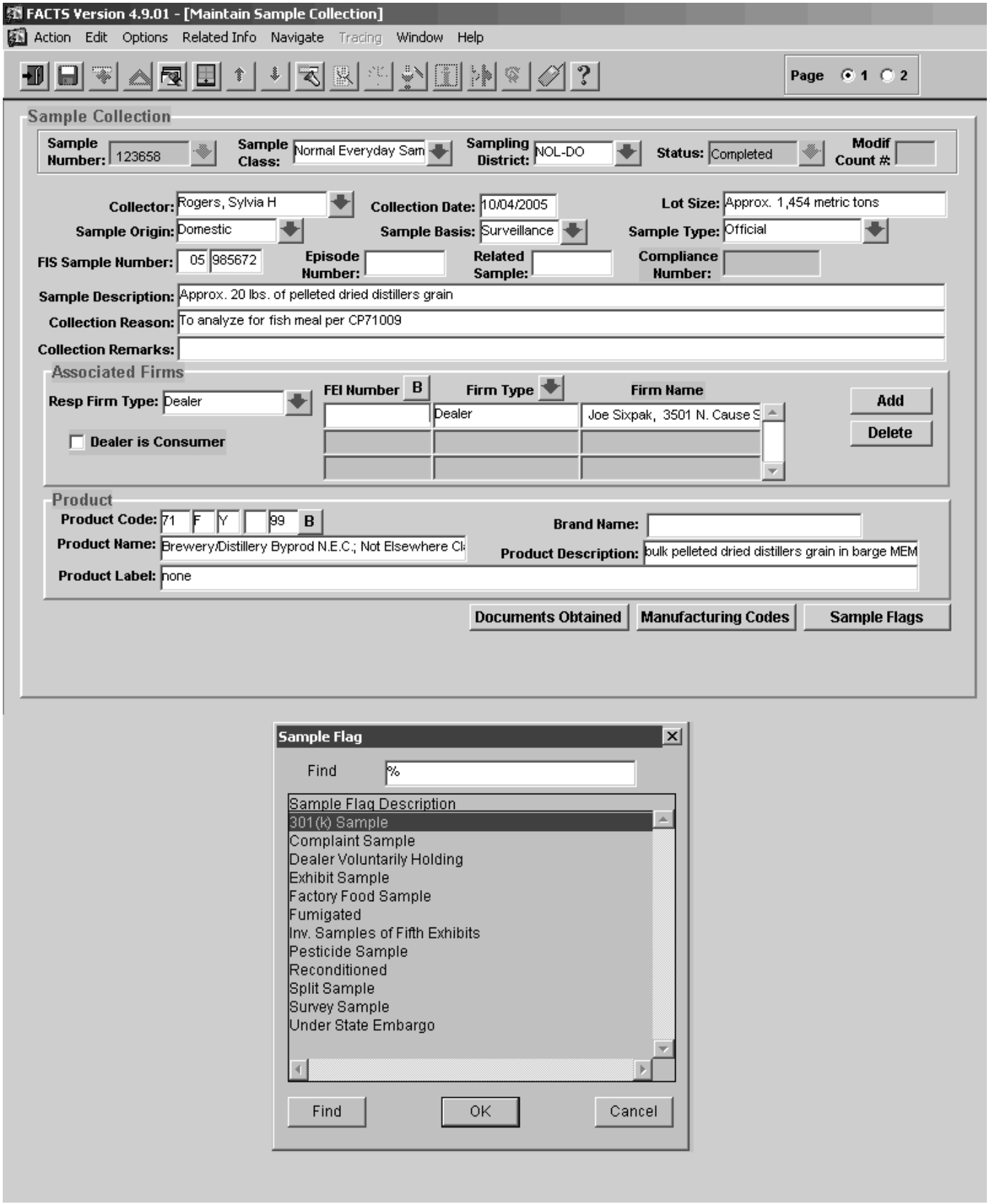
Subscribed and sworn to before me at Frankford, PA
(City and State)

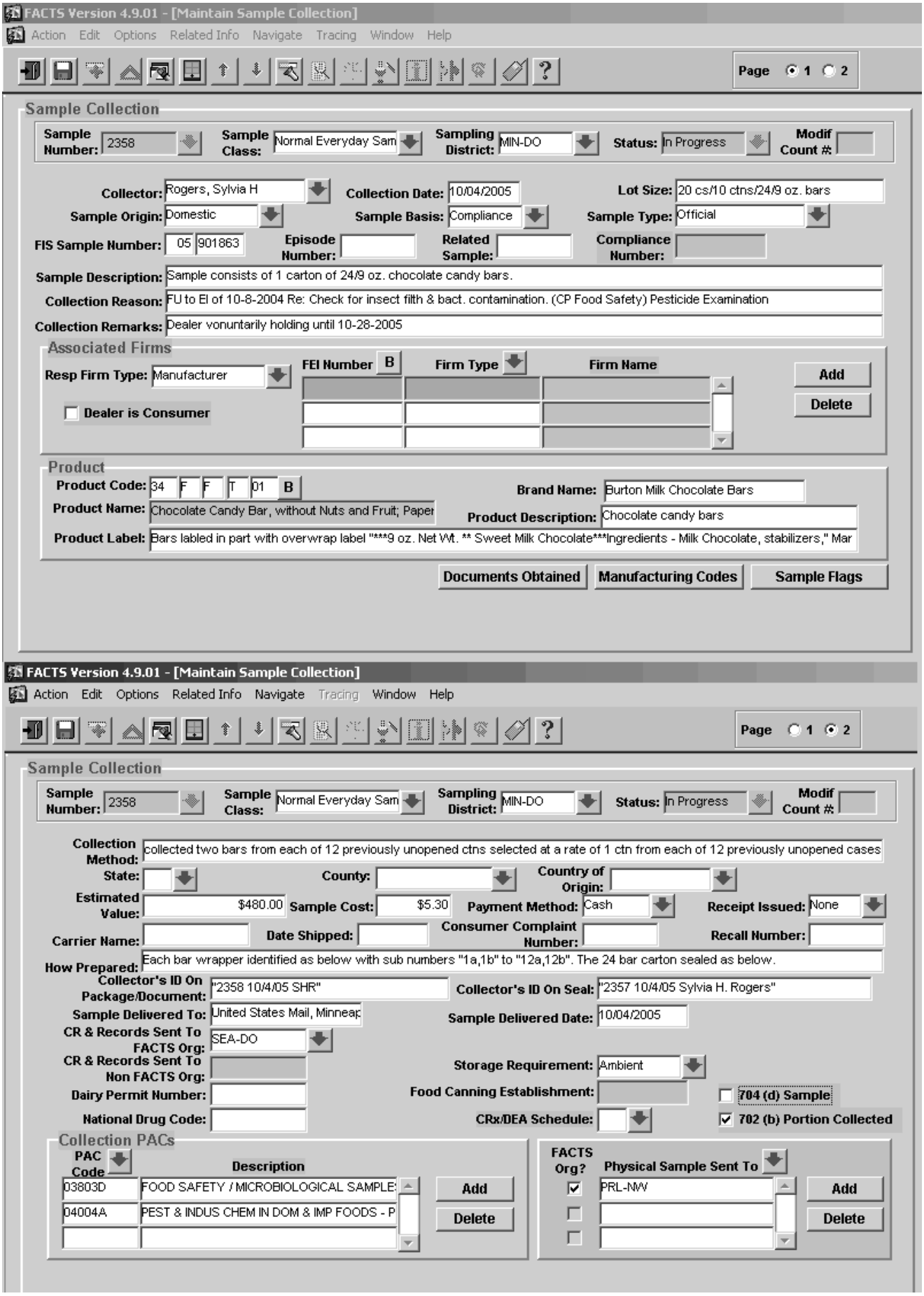
this 28th day of April, 1999

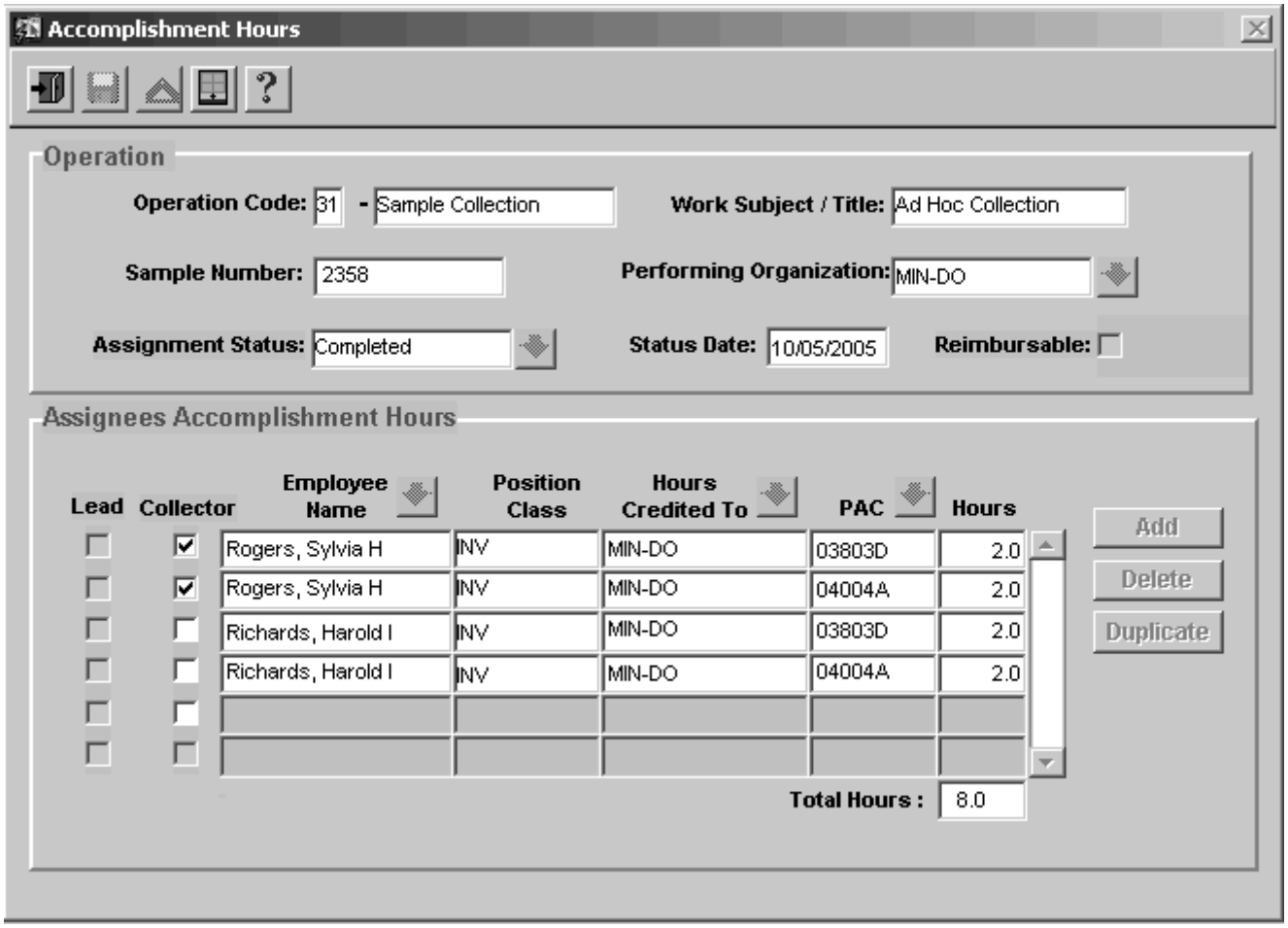
Sylvia A. Rogers
(Employee's Signature)

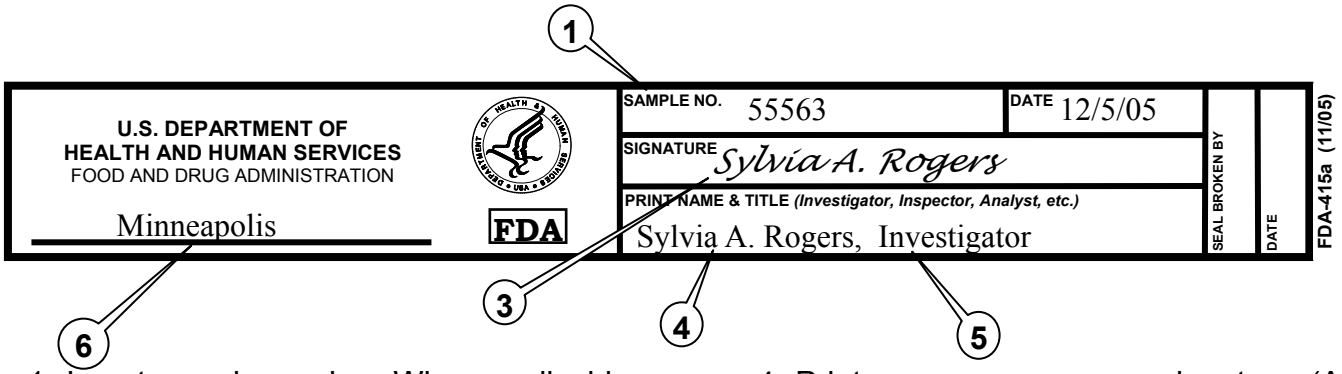
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953;and P.L. 96-88, effective May 4, 1980.

FORM FDA 1664a (4/83) PREVIOUS EDITIONS ARE OBSOLETE


FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 123658
Sample Class: Normal Everyday Sam
Sampling District: NOL-DO
Status: Completed
Modif Count #:
Collector: Rogers, Sylvia H
Collection Date: 10/04/2005
Lot Size: Approx. 1,454 metric tons
Sample Origin: Domestic
Sample Basis: Surveillance
Sample Type: Official
FIS Sample Number: 05 985672
Episode Number:
Related Sample:
Compliance Number:
Sample Description: Approx. 20 lbs. of pelleted dried distillers grain
Collection Reason: To analyze for fish meal per CP71009
Collection Remarks:
Associated Firms
Resp Firm Type: Dealer
Dealer is Consumer
FEI Number B
Firm Type
Firm Name
Dealer
Joe Sixpak, 3501 N. Cause S
Add
Delete
Product
Product Code: 71 F Y 99 B
Brand Name:
Product Name: Brewery/Distillery Byprod N.E.C.; Not Elsewhere Cl
Product Description: bulk pelleted dried distillers grain in barge MEM
Product Label: none
Documents Obtained
Manufacturing Codes
Sample Flags
Sample Flag
Find %
Sample Flag Description
301(k) Sample
Complaint Sample
Dealer Voluntarily Holding
Exhibit Sample
Factory Food Sample
Fumigated
Inv. Samples of Fifth Exhibits
Pesticide Sample
Reconditioned
Split Sample
Survey Sample
Under State Embargo
Find
OK
Cancel


FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 2358
Sample Class: Normal Everyday Sam
Sampling District: MIN-DO
Status: In Progress
Modif Count #:
Collector: Rogers, Sylvia H
Collection Date: 10/04/2005
Lot Size: 20 cs/10 ctns/24/9 oz. bars
Sample Origin: Domestic
Sample Basis: Compliance
Sample Type: Official
FIS Sample Number: 05 901863
Episode Number:
Related Sample:
Compliance Number:
Sample Description: Sample consists of 1 carton of 24/9 oz. chocolate candy bars.
Collection Reason: FU to EI of 10-8-2004 Re: Check for insect filth & bact. contamination. (CP Food Safety) Pesticide Examination
Collection Remarks: Dealer vonuntarily holding until 10-28-2005
Associated Firms
Resp Firm Type: Manufacturer
Dealer is Consumer
FEI Number B
Firm Type
Firm Name
Add
Delete
Product
Product Code: 34 F F T 01 B
Product Name: Chocolate Candy Bar, without Nuts and Fruit; Paper
Brand Name: Burton Milk Chocolate Bars
Product Description: Chocolate candy bars
Product Label: Bars labled in part with overwrap label "***9 oz. Net Wt. ** Sweet Milk Chocolate***Ingredients - Milk Chocolate, stabilizers," Mar
Documents Obtained
Manufacturing Codes
Sample Flags
FACTS Version 4.9.01 - [Maintain Sample Collection]
Action Edit Options Related Info Navigate Tracing Window Help
Page 1 2
Sample Collection
Sample Number: 2358
Sample Class: Normal Everyday Sam
Sampling District: MIN-DO
Status: In Progress
Modif Count #:
Collection Method: collected two bars from each of 12 previously unopened ctns selected at a rate of 1 ctn from each of 12 previously unopened cases
State:
County:
Country of Origin:
Estimated Value: $480.00
Sample Cost: $5.30
Payment Method: Cash
Receipt Issued: None
Carrier Name:
Date Shipped:
Consumer Complaint Number:
Recall Number:
How Prepared: Each bar wrapper identified as below with sub numbers "1a,1b" to "12a,12b". The 24 bar carton sealed as below.
Collector's ID On Package/Document: "2358 10/4/05 SHR"
Collector's ID On Seal: "2357 10/4/05 Sylvia H. Rogers"
Sample Delivered To: United States Mail, Minneap
Sample Delivered Date: 10/04/2005
CR & Records Sent To FACTS Org: SEA-DO
CR & Records Sent To Non FACTS Org:
Storage Requirement: Ambient
Dairy Permit Number:
Food Canning Establishment:
704 (d) Sample
National Drug Code:
CRx/DEA Schedule:
702 (b) Portion Collected
Collection PACs
PAC Code
Description
03803D FOOD SAFETY / MICROBIOLOGICAL SAMPLE
04004A PEST & INDUS CHEM IN DOM & IMP FOODS - P
Add
Delete
FACTS Org?
Physical Sample Sent To
PRL-NW
Add
Delete


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



1 Insert sample number. When applicable, use prefix, e.g. “INV”, “FS”, “DOC”, “PS”, etc. (See IOM 4.4.10.2)

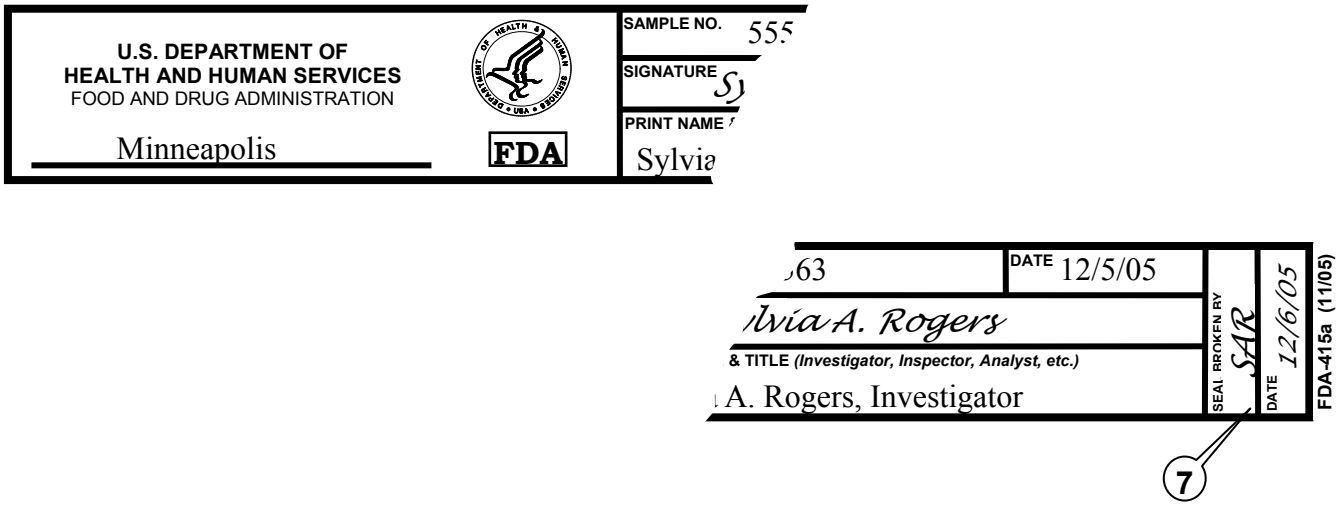
2 Insert date sealed. Use figures, month, day, year. (See # 7 below when seal is broken for any purpose.)

3 Sign your usual 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 district - 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.

Shippers 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						
PROPER SHIPPING NAME OF ARTICLE as listed in the Restricted Articles Tariff Federal Aviation Regulations or IATA Restricted Articles Regulations,	Class Or Div-sion	UN Or ID No.	Subsi-diary Risk	Quantity and Type of packing	Packing Inst.	Authorization
DRY ICE (CARBON DIOXIDE SOLID)	ORM A OR 9	UN 1845	N/A	5 Fiberboard cartons net weight 20 lbs. dry ice each carton	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 condition 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

Shipper's Declaration Not Required

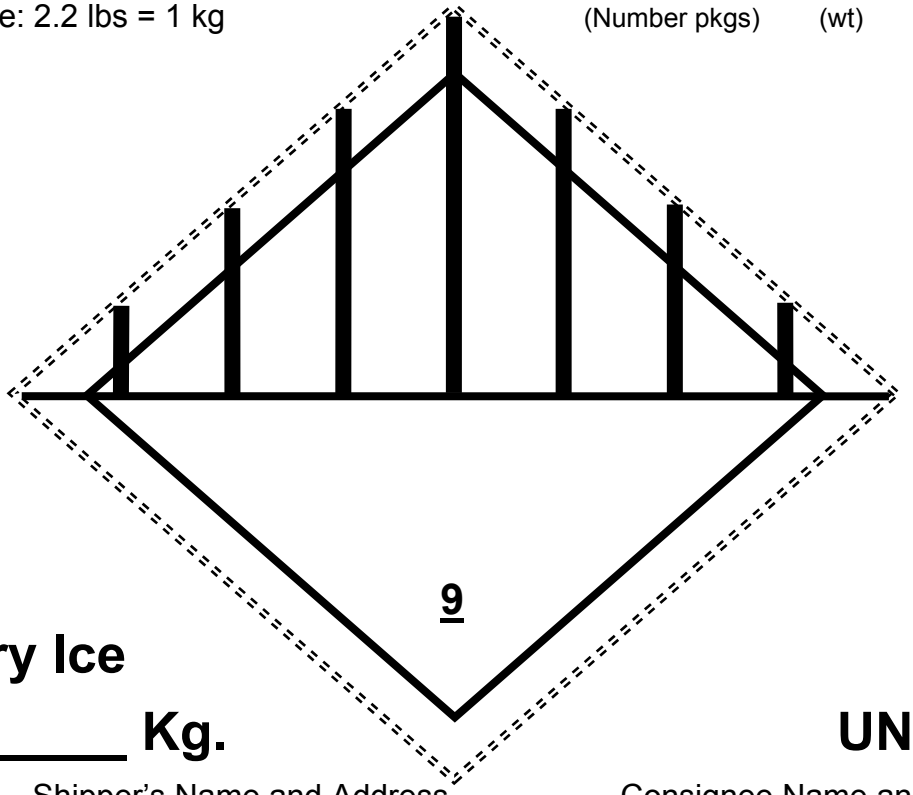
Part B is required

Dry ice amount must be in kilograms

Note: 2.2 lbs = 1 kg

Airwaybills/airbills must have the following:

1. "Dangerous Goods – Shipper's Declaration not required."
2. Dry Ice, 9, UN 1845
3. _____ X _____ Kg 904 III
   (Number pkgs) (wt)



Dry Ice

_____ Kg. **UN 1845**

Shipper's Name and Address

Consignee Name and Address

_____ _____

_____ _____

_____ _____

Bottom portion of label must be completed by shipper.