Chapter 4 – Sampling

4.1 – General

Collecting samples and conducting inspections (both of which are discussed in Chapter 5) and reviewing imported products at entry (which is discussed in Chapter 6) are the primary ways investigators contribute to OII's mission of *conducting rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.*

This chapter will provide further information to support you in those tasks, mainly to assist you in collecting, documenting, and submitting samples for analysis and/or review. While this chapter details the process of collecting samples for many of the situations you are likely to encounter, it is important to note that each sample collection is unique. If you should encounter situations not covered in this chapter and need additional information, consult with your supervisor and, if needed, the relevant servicing laboratory.

4.1.1 – Purpose – Why Do We Collect Samples?

Collecting samples is a critical part of FDA's regulatory activities. We collect samples of FDA-regulated products for a variety of reasons, such as:

- to gather information about potential safety issues (i.e., surveillance).
- to document a violation.
- to support the government's charge that there is a violation of the law.

This chapter contains information on the following topics:

- the types of samples investigators collect,
- roles and responsibilities of investigators when collecting samples,
- procedures for collecting and reporting of samples, and
- examples of special sampling situations.

4.1.1.1 – What is a valid sample?

A valid sample is the starting point--and keystone--for most regulatory actions. Evidence, as you know, is required to support your observations and reports of violative conditions—and samples of FDA-regulated products can be used as evidence. However, to be used as evidence, the sample must support the government's charge that there is a violation of the law. It must also conform to the rules on admissibility of evidence, such as demonstrable chain of custody.

In general, a properly collected and prepared sample (in other words, a *valid* sample) contains or is accompanied by the following:

- A portion of the lot[1] of goods for laboratory analysis and a 702(b)[2] reserve portion of the goods, if appropriate, and/or documentation demonstrating the violation represented by the lot.
- A report of your observations of the lot.
- Labels and labeling, or copies of such, which "accompany" the goods.
- Documentary evidence of federal jurisdiction over the lot, including where the violation was committed; information about individuals responsible for the violation; and similar information.
- Signed statement (affidavit) from individuals who may be called upon as witnesses should there be a subsequent court action.

While inspections and investigations may precede sample collection, under the law, a *valid* sample must ultimately be obtained for judicial cases to proceed.

4.1.1.2 – What are your responsibilities when collecting a valid sample?

Proper sample collection is the keystone of effective enforcement action. Approach every sample you collect with diligence and thoroughness, and the mindset that you may be asked to testify in court regarding all details associated with the sample, including the actions you took while collecting it. Take regulatory notes regarding your sample collection that will provide sufficient detail to refresh your memory at a later date (see IOM 2.1 for additional information on regulatory notes). Be objective, factual, accurate, and thorough. Mistakes or deficiencies, however trivial they may seem, can damage the government's case.

Sample numbers are obtained using the FDA sample reporting systems. For samples that are not in import status, you are responsible for obtaining sample numbers in the Field Accomplishments and Compliance Tracking System (FACTS) in advance of collecting a sample and completing the Collection Report (C/R) in FACTS. For samples collected while products are in import status, sample numbers are obtained when Import C/Rs are completed in FDA Import Systems (OASIS/SERIO).

You are responsible for timely completion of the Collection Report after collecting the sample (See IOM 4.6 for minimum information to be entered into FACTS).

4.1.1.3 – Personal Safety while Collecting Samples

It is important to note that, while sampling, you may encounter situations that could have safety and personal protective equipment (PPE) considerations. Hazards and/or dangers associated with sampling could include, but are not limited to:

- Dusts
- Explosion hazards

[1] A *lot* generally means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

[2] Section 702(b) of the FD&C Act [21 USC 372(b)] requires the FDA to furnish, upon request, a portion of an official sample for examination or analysis to any person named on the label of an article, the owner thereof, or his attorney or agent.

- Confined spaces
- Farms and poultry houses
- Altered atmospheres and environments
- Biological hazards (e.g., Hantavirus, BSE, parasites, fungus)
- Chemical hazards
- Physical and radiation hazards
- Ergonomic hazards

The IOM Safety Chapter (IOM Chapter 10) contains basic information to help you anticipate, recognize, evaluate, and apply control strategies to eliminate or minimize hazardous conditions and unsafe practices you may encounter.

Due to the variability of potential safety situations during sampling, it is not feasible to describe what to do in each instance. The decision of what to do in each individual circumstance rests with you, your Industrial Hygienist liaison, and your program division management.

When you are unsure about the best and safest way to collect a sample, talk to your supervisor.

4.1.2 – Authority to Collect Samples

IOM 3.2.2 outlines FDA's authority to collect samples and provides references to relevant sections of the Food Drug and Cosmetic Act (FD&C Act). Understanding the statutory authority can assist you in your daily work, including when faced with a refusal to permit a sample collection, for example. You can find detailed information about the statutory and regulatory frameworks underpinning our FDA sampling authority in chapter 3 of the IOM.

Section 801 of the FD&C Act [21 U.S.C. 381] gives the FDA the authority to collect samples of FDA-regulated products which are being imported or offered for import into the United States (see IOM 6.1 for more information on FDA's import operations and import authority).

4.1.3 – Responsible Parties

There are many types of individuals that can be responsible for assuring FDA-regulated products are neither adulterated nor misbranded. You should be familiar with the following definitions. It is important to properly identify these parties when you collect a sample so that the appropriate action can be taken if a sample is violative.

4.1.3.1 – Dealer

Dealer means the person[3] who has possession of the FDA-regulated product at the time the sample is collected. Note that the dealer may not necessarily be the owner of the goods, but the one in possession of them at time of sample collection, such as a third-party logistics company. In addition, the dealer may or may not be the party responsible for the violation (i.e., responsible party).

For example, in the case of a "301(k) sample," the responsible party will always be the dealer. Under Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] it is prohibited to alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or the do any other act with respect to FDA-regulated products, if such act is done while held for sale (whether or not the first sale) after

[3] Section 201(e) of the FD&C Act [21 U.S.C. 321(e)] defines the term *person* as an individual, partnership, corporation, or association. Throughout this chapter this definition is used.

shipments in interstate commerce and results in such article being adulterated or misbranded. IOM 4.1.4.2.2 provides additional information on 301(k) samples.

If the person you are collecting samples from may be subject to FDA regulatory action, given a likely or known violative condition of a lot, you should issue them a Form FDA 482[4] before collecting samples. See IOM 4.1.2. If in doubt about the need to issue a Form FDA 482, it's better to err on the side of caution and proceed with issuing the form. If there is no EIR, attach a copy of the FDA 482 to the collection report (C/R). See IOM 4.6.4

4.1.3.2 – Manufacturer

Manufacturer means the person that makes the FDA-regulated product. If you collect a sample from the manufacturer, then the dealer and manufacturer are the same.

Determining if the manufacturer is the party responsible for the violation will depend on several factors and, in most situations, will require further investigation. For example, if you collect a sample of animal food at a farm where a customer experienced death of their animals and that sample is confirmed to be adulterated, then an investigation to determine where, and at what stage, the adulteration occurred should be conducted. If the adulteration is determined to be caused by the animal food manufacturer, then the manufacturer committed a prohibited act as the introduction or delivery for introduction into interstate commerce of any food that is adulterated or misbranded is prohibited under Section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

4.1.3.3 – Shipper

Shipper means a person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food or other commodity in the United States by a carrier or multiple carriers sequentially.

4.1.3.4 – Carrier

Carrier means a person (e.g., owner-operator, partnership, corporation) who physically moves a product in commerce within the United States. The term carrier does not include any person who is transporting product while operating as a parcel delivery service.

4.1.4 – Official Samples

Title 21, Code of Federal Regulations, Part 2.10 (21 CFR 2.10) describes the criteria required for a sample of FDA-regulated product to be considered an *official sample*. A sample is an *official sample* if records (see IOM 4.4.4) or other evidence obtained show that the shipment, or other lot of the article from which the sample was collected, was:

- Introduced or delivered for introduction in interstate commerce, or
- Was in or was received in interstate commerce, or
- Was manufactured in a Territory or the District of Columbia.

Section 201(a)(2) of the FD&C Act [21 U.S.C. 321 (a)(1)] defines the term *Territory* as any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

[4] All FDA forms are available at this address: https://fda.sharepoint.com/sites/insideFDA-Administrative/SitePages/Admin-Forms.aspx

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

Import samples are official samples and require you handle them with the same care and diligence as domestic official samples (see IOM 6.4).

Official samples can be either *physical* or *documentary* (the latter referred to as DOC samples). The only difference between a physical official sample and a DOC official sample is that the physical article is not collected for a DOC sample since DOC samples consist only of records. Both physical and DOC samples are official samples if they meet the description in 21 CFR 2.10. Details about collecting these samples are provided in IOM 4.1.4.2, for physical samples, and 4.1.4.1, for DOC samples.

Every sample collection is unique. Whether you are collecting a physical sample or a DOC sample, one thing that remains consistent is that both types of official samples, both physical and DOC, need to be representative of a lot for which federal jurisdiction can be established. If violative, the official sample will serve as a basis for enforcement action.

The FDA has various enforcement tools that can generally be divided into the following categories: advisory actions and other notices of violations; administrative actions; and judicial actions (see IOM Chapter 3 for more information about FDA's regulatory tools). While a *valid* sample is typically the starting point, and keystone, for most regulatory actions, there are different requirements for collection of an official sample, depending on the FDA's intended enforcement action. Advisory actions (see IOM 3.4) and administrative actions (see IOM 3.5), which do not involve the judicial system, do not require the collection of an official sample (physical or DOC). However, the requirements to collect official samples may vary depending on your assignment, program, and/or division. If you are recommending an advisory action, consult with your supervisor to determine if an official sample is required. DOC samples, which include the collection of records demonstrating interstate commerce, are required for judicial actions, such as seizure and injunction.

For the FDA to initiate a 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. There are products and situations where interstate commerce is not required to act against a violative product (for example, in cases involving counterfeit drugs, medical devices, oleomargarine/colored margarine, or products manufactured in a territory of the United States). If you encounter these situations, discuss the need for collecting interstate commerce records with your supervisor, or follow established procedures within your division or program regarding the collection of interstate commerce records.

The type of interstate records (transportation records, freight bill, waybill, bills of lading. etc.) to be collected are outlined in IOM 4.4.4. Note that the evidence required to demonstrate interstate commerce, and the types of records needed to establish it, depends upon the violation and the type of judicial action proposed.

To meet the criteria of a *valid* sample, the official sample must meet all the following conditions:

- Accompanied by records that establish both the federal jurisdiction and the identity of the individual(s) having knowledge of the lot's movement and custody of its records (see IOM 4.4.4). (Evidence of interstate movement is not required for medical device samples but, according to

policy, is to be obtained when a seizure, injunction, prosecution, or civil penalty is contemplated).

- Representative of the lot from which it was collected.
- If a physical sample, large enough to permit proper laboratory examination and provide a 702(b) reserve portion when necessary. (See IOM 4.3.2.2 for more information on collecting 702(b) portion.)
- Handled, identified, and sealed in such a manner as to maintain its integrity as evidence, with a clear record of its chain of custody.

Every official sample (physical or DOC) will be fully documented at the time of collection (that is, recorded in your regulatory notes) and a collection report prepared, unless instructed otherwise by the program or assignment.

4.1.4.1 – Documentary Samples (DOC Samples)

4.1.4.1.1 – What is a documentary official sample (DOC sample)?

A DOC sample is not a sample of records. It is a sample representing a lot of a regulated article (e.g., food, drug, biologic, or device). Other elements of an official sample described in IOM 4.1.4 are required and apply except DOC samples are not officially sealed. DOC samples consist of the article's labels (photocopies or photos), accompanying labeling (e.g., leaflets, brochures, promotional materials, including internet websites) and documentation of interstate movement (e.g., freight bills, bills of lading, affidavits; see IOM 4.4.4). Refer to Section 201 of the FD&C Act [21 U.S.C. 321] for the definition of labels (201(k)) and labeling (201(m)). Typically, your DOC sample would also include additional documents (that is, supporting evidence), such as photos of the product, drawings, sketches or schematics, production records, diagrams, invoices, or similar items. (See IOM Exhibits 4-1 and 4-2.) These additional records typically demonstrate the violation you are documenting. For example, production records for a specific lot may show a violation of GxPs[5]. A physical sample is not required, because under GxPs FDA does not need to show the product fails to meet a specification. Failure to meet GxPs renders the product adulterated. In the cases of misbranding, the labels or labeling may be all that is required to demonstrate the violation.

Because no product is collected, a Form FDA 484, Receipt for Samples, is not issued for DOC samples.

See IOM 4.7.2.5 and speak to your supervisor about any division or program specific guidance on identifying records associated with a DOC sample. Do not officially seal these records. List all records on the collection report (C/R). Use a continuation sheet (FDA 464a) if necessary. If any photos are taken as part of the DOC sample, the electronic media must be officially sealed per IOM 5.6.7.5. Attach the documents and photos along with any other records associated with the sample to the printed C/R. See IOM 4.6.4.

When the anticipated action is not judicial, records of interstate commerce and documentation of violations may be collected and added to the EIR in lieu of a DOC sample. If you are unsure if

[5] GxP is a term which includes all practices related to manufacturing FDA products, such as, good manufacturing practices, good clinical practices, good laboratory practices, etc.

you should collect a DOC sample or document interstate commerce in your EIR, consult your supervisor.

4.1.4.1.2 - When Should You Collect a DOC Sample instead of an Actual Physical Sample of the Product?

A DOC sample is collected when an actual physical sample is not practical. For example, in instances in which the article is:

- very large or complex,
- fixed, as in the case of a permanently installed device,
- too expensive/cost prohibitive to sample,
- no longer available,
- there is no need for laboratory examination,
- must remain in place due to on-site emergency purposes, like a single piece of life support equipment which must remain in emergency service until a replacement is available.
- going to be recommended for seizure based on misbranding charges. For instance, if during availability check, the lot sampled is found to have been distributed, but a new shipment, identically labeled, is on hand, then the new shipment may be sampled on a DOC basis since another physical sample and examination is not required. In this case, regulatory action may proceed based on the earlier examination, and thus, only labeling, transportation records, the appropriate dealer affidavits, and an inventory of product on hand need to 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 for field stripping than it is to photocopy or photograph all accompanying labels. In these cases, the sample is handled in the same manner as any other DOC sample, once the original labeling has been removed and the remainder of the sample destroyed. You will want to provide a prominent explanation on the collection report to alert reviewers that the original units collected were destroyed after the original labeling was removed. Note, however, that this field-stripping procedure is not appropriate in instances in which complete, intact, and labeled units are desired for exhibit purposes, even though there is no intention of analyzing the units obtained.

A DOC sample collected to document deviations of GxPs should contain records that adequately document the deviations encountered. You should explain what is being documented in the remarks section of the C/R of the documents obtained. Fully describe any record collected as part of the DOC sample, and wherever possible, indicate the page of the document that demonstrates the deviation.

Documentary (DOC) samples are not required to support advisory actions such as untitled or warning letters and regulatory meetings. However, records of interstate commerce should always be collected and incorporated into the establishment inspection report (EIR) to document FDA jurisdiction over any products suspected to be in violation. An affidavit (see IOM 4.4.5) identifying the product(s) of concern, labels/labeling, invoices, statements regarding interstate commerce, and key evidence of violations should be prepared for signature by the

appropriate party and attached to the EIR in support of advisory actions. DOC samples should always be prepared in situations in which further FDA judicial and/or administrative action is anticipated such as seizure, injunction, warrants, administrative detention, suspension of registration, mandatory recall, and prosecutions. Investigators in training may still be required to prepare documentary samples as directed by their supervisor.

4.1.4.2 – Physical Samples

This section describes some examples of situations warranting collection of physical official samples and describes how you should proceed in collecting them.

4.1.4.2.1 – In-transit sample

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

- A bill of lading (BOL) or other order to ship the lot interstate has been issued; or
- The owner/shipper or agent acknowledges, preferably by signed affidavit, that they ordered the lot to be shipped interstate; or
- The owner or operator of the common carrier acknowledges, preferably by signed affidavit, that they have an order from the shipper to move the lot interstate.

Refer to IOM 4.2.4, 4.2.5.1, and 4.3.3 for special considerations when collecting an in-transit sample.

4.1.4.2.2 – 301(k) sample

A 301(k) sample is typically defined as a sample collected from a lot of food, drugs, devices, tobacco products, or cosmetics that has become adulterated or misbranded while being held for sale, regardless of whether or not its first sale, after shipment in interstate commerce. See Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] for complete language surrounding this prohibited act. The term *301(k) sample* is shorthand to describe certain samples collected from lots that become violative after shipment in interstate commerce.

Since some act took place that resulted in the adulteration or misbranding of a previously non-violative product after shipment in interstate commerce, it is necessary in any *301(k)* documentation that you:

1. Identify the act causing or leading to the adulteration or misbranding,
2. Establish when and how this act occurred, and
3. Identify the individual(s) responsible for causing the violation.

This last feature, more than any other, distinguishes a *301(k) sample* from other physical official sample types. When you report the sample collection, the responsible party will always be the dealer. See IOM Exhibits 4-1 and 4-7.

Consider the following example of a 301(k) sample and steps taken to establish it: To document *Listeria monocytogenes* adulteration, for instance, of a ready-to-eat food caused by contamination of a raw material at the finished product manufacturer, you would need to document receipt of an unadulterated, raw material as well as the subsequent adulteration caused by the firm's handling or processing of the raw material during the manufacturing of the ready-to-eat food. As such, you would need to show that there was *L. monocytogenes* at the

manufacturer that either did, or may have, contaminated the ready-to-eat finished product. To establish a violation of 301(k), you would also need to demonstrate that the raw material was not adulterated *prior* to receipt at the manufacturer. Towards this end, you would collect an official sample of the unadulterated raw material. (You would also typically collect an investigational sample consisting of environmental swabs from the processing areas and/or equipment for analysis of *L. monocytogenes* to attempt to determine the location in which the unadulterated, raw material was contaminated.) The interstate commerce is demonstrated for the sample, not through the product manufactured at the location, but the incoming product that was not adulterated.

301(k) samples can also be used to document adulteration (including noncompliance with GxPs) or misbranding of other regulated commodities, including medical devices, drugs, and biologics. Note the following guidance associated with 301(k) samples and various commodities. For example, when collecting a 301(k) sample associated with a drug product, you should attempt to document 'adulteration' or 'misbranding' of the active ingredient by the firm's actions. There may be cases where the active ingredient was not received in interstate commerce. In these instances, you would instead document the container or another ingredient that was received in interstate commerce. In cases involving biologics, for example, a DOC sample may be collected of a container or bag used for collection of whole blood, because the product (whole blood) was collected at the donor site being inspected. Since the whole blood is collected onsite, there is no interstate commerce for it. However, the firm subsequently may have adulterated or misbranded the anti-coagulant (a drug) in the blood bag.

And when collecting a 301(k) sample for medical devices from a finished device manufacturer, you should collect and document all of the following:

- Interstate shipment records for receipt of a component.
- The manufacturing records showing inclusion of the component in the finished device.
- Records showing the finished device was held for sale or distributed, regardless of whether or not in interstate commerce.
- Labels, labeling for the finished device.

Your observations and documentation should demonstrate the firm’s actions adulterating (e.g., GMP issues) or misbranding (e.g., labeling) the finished device that was distributed in relation to the associated component.

4.1.4.2.3 – Post-Seizure (PS) sample

A lot under seizure is in the custody of the U.S. Marshals Service. If either the claimant or the government desires a sample from the seized lot, 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 to collect the sample. If the method of collection is improper, you may make constructive suggestions, but do not but do not challenge or interfere with the method that is chosen. You should, however, report exactly how the sample was drawn. Unless the claimant objects, mark subsamples collected with the notation, “PS", your initials, and the date. PS 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.

4.1.4.2.4 – Import sample

Import samples are physical samples of products that originate from another country, collected while the goods are in import status. Import status ends when U.S. Customs and Border Protection (CBP) releases the article from the import database system. (See IOM Chapter 6.)

4.1.4.2.4.1 – Special Domestic Import Sample (SDI)

SDIs are import samples collected from lines that are released from import status immediately after collection and before sample analysis is complete. This sample type is used primarily for the collection of perishable products and special sampling assignments. This sample type may also be used for other designated sampling situations as directed. (See IOM chapter 6.4.9.)

4.1.4.2.4.2 – Mail Entry sample

A mail entry sample is a sample of an imported product that enters the United States through the U.S. Mail.

4.1.4.2.5 – Domestic import sample (DI)

DI samples are official samples of foreign products that have passed through customs and are now in domestic commerce. The FDA may have previously taken a sample of the product while in import status, or the product may have been permitted entry without being sampled. If sampled while still in import status, the samples collected are import samples, and not DI samples. However, once the product leaves import status and enters domestic commerce, any sample collected from it is then considered an official DI sample.

When collecting DI samples, especially if a violation is suspected, attempt to determine the port of entry and the importer of record (the party in whose name the entry is made, see IOM 6.9.43). Report this information on the C/R, where you should include the name of the country of origin of the product and the country code, if known.

A sample is classified as DI, if any of the following situations apply:

- The label declares the product to be from a foreign country,
- The label bears the word, *imported*,
- Records obtained or reviewed reveal the product originated in a foreign country,
- It is known that the product is not grown or produced in the United States; is packed as a single item with few, or no other ingredients added; and is not manipulated in any major manner that would otherwise change 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.
- 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, for which 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 to achieve this is to establish a paper trail of records going back as far as possible in the distribution chain to the actual entry.

- Preface the sample number with the prefix “DI” in the same manner that other sample type prefixes are used (e.g., "DOC", “INV”, "PS") on:
    - The physical product (sample),
    - Related documents
    - Official Seals

4.1.4.2.6 – Additional Sample

This is a physical sample collected from a previously sampled lot of either a domestic or imported product. Note the following sample numbering approaches:

- In instances of additional import samples, the sample collected must have the same sample number as the original sample collected.
- In instances of additional domestic samples, the sample collected will have a different sample number, but it must be flagged as an Additional sample and the original sample number referenced in the *Related Sample* block on the C/R.

4.1.4.2.7 – Reconditioning sample

Reconditioning samples are taken from lots that have been reconditioned under a consent decree, or other agreement, to bring the lots into compliance with the law. The sample is taken to determine if the reconditioning was satisfactorily performed. These samples should be submitted as official samples.

4.1.4.2.8 – 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 is typically used with import samples. See IOM 4.1.4.2.4.

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

- Evidence of marked containers distributed throughout the lot, indicative of a representative sample.
- Marked cases that are consistent with the submitted lab package.
- Quantity removed for sampling is consistent with the lab package.

Careful attention should also be paid to any indication that the containers selected for sampling by the private sample collector have been staged for sampling. Staging is reflected through markings, deliberate damage to labeling, and placement within the pallets, for example.

If you find evidence that a non-conforming private sample was collected, it is important that you immediately terminate audit activities/sampling and report the adverse findings to appropriate compliance staff for evaluation. The agency will then make decisions on a lot-by-lot, case-by-case basis regarding the entries and/or sampled products submitted for importation.

Note, too, that audit samples should be recorded under the same PAC codes as surveillance samples and can apply towards the completion of applicable work plan and/or performance goals.

4.1.4.2.9 – Induced Samples

An induced sample is an official sampled ordered or obtained in response to some type of advertisement or promotional activity. The sample is procured by mail, telephone, online order, or other means, without disclosing any association of the requester or the transaction to the FDA. See IOM 4.3.4.2 for additional information.

4.1.4.2.10 – Undercover Samples (Commonly Known as Undercover Buys)

An undercover sample (or undercover buy) is an official sample, obtained in much the same manner as an induced sample. Undercover buys may be made at the point of sale, or via a purchase completed online, by email, text, or by phone. Explanations and/or cover stories, developed ahead of time, are necessary to dispel any suspicions about the requester that may surface in face-to-face, phone, or email discussions. Undercover buys are frequently used in investigations of health fraud or complaints of illegal activity, in which the information cannot be substantiated or refuted through more conventional means.

Undercover buys may be used to augment an existing investigation or inspection effort and may be performed to document violations in firms with a history or pattern of noncompliance. See IOM 4.3.4.2 for additional information on how to collect induced samples, a type of undercover buy. Your supervisor or the assignment will provide specific instructions and procedures to be followed when collecting an undercover sample. For example, you may induce the sample by telephone or online. You may need a "cover story" if collecting multiple containers of the product. If collecting an undercover sample as part of a special assignment, you will rely on instructions provided in the assignment. Note, too, that your division or program may also have specific procedures to follow when conducting an undercover buy.

4.1.4.2.11 – Online Samples

An online sample is an official sample purchased online, versus being collected at a physical location. Samples may be collected online as induced or undercover buys, but in both cases, the FDA should *not* be identified as the purchaser of the product. Routine samples may also be purchased online as directed by your supervisor or by assignment.

Interstate commerce is still documented for these samples. Interstate commerce evidence can be obtained by documenting the location from which the sample is shipped and the method of its delivery (e.g., UPS, USPS, or FedEx). These online samples may be collected and paid for using dedicated and unidentifiable equipment (i.e., FDA laptop, FDA cell phone, and FDA credit card). Your supervisor and/or the specific assignment will provide instructions and procedures to be followed when collecting an online sample. See IOM 4.1.4.2.9, 4.1.4.2.10, and 4.3.4.2 for additional information.

4.1.5 – Investigational Samples (INV)

Investigational (INV) samples are *not* official samples. They are collected to document observations, support regulatory actions, and/or provide other information. As such, they do not need to be collected from lots in interstate commerce or under federal jurisdiction. The sample itself does not need to be

from a product regulated by the FDA. Because these samples can be used as evidence in court, they must be sealed, and their integrity and chain of custody protected. Examples of INV samples include:

- Samples flagged as factory food samples or in-line samples. These samples may consist of raw materials, in-process, and unpackaged finished products that demonstrate manufacturing conditions. See IOM 4.3.6.6.3.
- Samples associated with exhibits. These may be filth exhibits and other articles taken for exhibit purposes during inspections to demonstrate manufacturing conditions, storage conditions, employee practices, or other conditions. Typically, filth exhibits submitted as part of an INV sample are not tied to any specific lot of product but are meant to illustrate the conditions at a firm. For example, samples flagged as INV Samples of filth exhibits frequently consist of apparent rodent excreta pellets, apparent nesting material, apparent rodent-gnawed material, and other evidence of rodent activity. Multiple sub-samples collected along the entire perimeter of a room in a manufacturing facility, food storage area, or warehouse may be used to demonstrate a rodent infestation. See IOM 4.6.2.7.7.
- Environmental samples – See IOM 4.3.6.6.1.
- Certain complaint samples: These are injury and illness investigation samples from certain complaints in which there is no federal jurisdiction, or the alleged violation offers no basis for subsequent regulatory action. See IOM 4.1.7. Conversely, complaint samples from lots for which federal jurisdiction *is* clear should be submitted as official samples.

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

Note: Photographs taken to document conditions observed, or subsamples collected, are included as *exhibits* to establishment inspection reports. Photographs taken of labeling and records (e.g., bill of lading (BOL), invoice, and manufacturing records) that are associated with sample collections are included as *attachments* to collection reports. See IOM 4.7.2.4, 5.6.5 and 5.6.7

4.1.6 – Survey Samples

Survey samples are part of the FDA's proactive sampling, conducted on a surveillance basis to gather data or other information on FDA-regulated products. Survey samples are not official samples. Samples collected under the Drug Quality Sampling and Testing (DQST) program are examples of survey samples. Concerning interstate records for DQST refer to CP 7356.008.

4.1.7 – Non-Regulatory Sample

Non-regulatory samples are those collected and analyzed by the FDA for other federal, state, or local agencies of products over which the FDA has no jurisdiction.

4.2 – Dealer Interactions

Maintaining a positive professional interaction with the dealer helps to facilitate the sample collection.

4.2.1 – Dealer Definition and Good Will

For sample collection purposes, the dealer is the person who has possession of a particular lot of goods. The dealer does not have to be a firm or company in the business of buying or selling goods. It may be a private individual, a physician, or a public agency—individuals or parties who obtain products to use, but

not to sell. The dealer may also be a party who does not own the goods, but has possession of them, such as a public storage warehouse or transportation agency.

Establishing good 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 their 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.

Consider the following suggestions to promote positive exchanges with dealers:

- 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 5.1.4.2.1 and 5.5.1.
- Explain the purpose of your visit. Be prepared to answer the dealer's questions and attempt to relieve any apprehensions while at the same time being careful not to reveal any confidential information.
- Do not disparage the product, its manufacturer, or shipper.
- Do not reveal the suspected violation 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.
- In the instance that an FDA 482 is not necessary for collecting a sample, but the dealer requests one anyway, go ahead and issue the requested FDA 482. Attach a copy to the C/R. See IOM 4.6.4.

4.2.2 – Dealer Objection to Sampling Procedure

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

4.2.3 – Refusal to Permit Sampling

Challenges to FDA authority while collecting samples may be encountered by a dealer who, for various reasons, including both personal and professional ones, 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 of the FD&C Act [21 U.S.C. 372]. If you have not already done so, issue an FDA 482, Notice of Inspection, (except in the case of foreign inspections – see IOM 5.1.4.2.3) as soon as it becomes apparent the dealer will continue to object.

Point out and discuss the authorities provided by in the following FD&C Act sections: 702(a), 702(b) [21 U.S.C. 372(a) and (b)] and 704(a), 704(c), 704(d) [21 U.S.C. 374(a), (c), and (d)] and the precedent case

mentioned in IOM 3.2.1. 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 5.1.4.2.3 and Compliance Policy Guide manual section 130.100 for further discussions on resolving the impasse.

If an FDA 482 has been issued prior to a sample refusal situation, the copy of the FDA 482 is to accompany the EIR, or a memorandum outlining the facts of the refusal if no EIR is prepared. If you are on a foreign inspection in which an FDA 482 is not issued, reference relevant Compliance Programs and Chapter 3 of the Guide to International Inspections and Travel Manual for reporting guidance.

4.2.3.1 – Limiting or Preventing Collection of Samples of a Drug

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

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

Also see IOM 3.2.1.4.

4.2.4 – Carrier In-Transit Sampling

Caution: First see IOM 4.3.3 for conditions that must be met before collecting in-transit samples from common carriers.

When collecting samples from in-transit lots in possession of a commercial carrier, issue the carrier or the carrier's agent an FDA 482. Attach a copy to the copy of the C/R. See IOM 4.6.4.

4.2.5 – Receipt for Samples

When 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. The receipt is to be issued to the owner, operator, or agent-in-charge, upon completion of the inspection, but prior to leaving the premises.

Always issue an FDA 484 for samples of prescription drugs, including narcotics and controlled substances. See IOM 4.2.5.3, 4.2.5.4, and 5.1.4.2.3.

Note: There are several situations in which you should not issue an FDA 482 and FDA 484. For example, an FDA 482 or FDA 484 should normally not be issued for induced, undercover, or online samples. In addition, check with your division/program policy on issuing an FDA 482 and FDA 484 while collecting surveillance samples at retail establishments (e.g., grocery store, big-box retail store).

4.2.5.1 – Carriers/In-Transit Lots

See an example FDA 472, Carrier's Receipt for Sample, under IOM Exhibit 4-4. Give the original receipt to the carrier or the carrier's agent. See OII SOP-000530, Sample Obligation and Processing concerning payment for samples for routing of FDA 472.

4.2.5.2 – Dealer Requests Receipt

When collecting physical samples of regulated products not in connection with an establishment inspection (EI) or in instances where no FDA 482 has been issued, do not routinely issue an FDA 484, Receipt for Samples, except for prescription drugs, narcotics, and/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 records associated with the C/R. See IOM 4.6.4.

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 the FDA.

Each dealer in narcotic and controlled drugs is assigned its own unique DEA registration number. Any time you collect a sample of a narcotic or controlled drug, be sure the dealer's DEA registration number is entered in the appropriate block of the FDA 484. Be sure to double check the number for accuracy, as an error on your part may result in possible investigation for drug shortages.

When samples of narcotic or controlled drugs are collected, the complete DEA registration number must be entered under the FIRMS DEA NUMBER block on the FDA 484, and the Receipt for Samples given to the person from whom the samples were collected.

When completing the FDA 484 for samples of narcotic or controlled drugs includes the trade and chemical name; strength of drug; sample size; container size; lot, batch, or control number; manufacturer's name and address; division address and the sample number. See IOM 4.6.4. 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 drugs are collected from dealers, individuals, or during inspections. Attach a copy of the FDA 484 to the C/R. See IOM 4.6.4.

4.2.5.5 – Preparation of FDA 484

Exhibit 4-5 provides instructions for completing the FDA 484, Receipt for Samples, and an example of a completed FDA 484.

4.2.5.6 – Routing of FDA 484

The signed original Receipt for Samples (FDA 484) should be given to the firm, preferably to the individual you gave the FDA 482 and FDA 483 (as applicable). See IOM 4.2.5.3 regarding receipts for narcotics and controlled drug samples.

Copies of the FDA 484 should be attached to the C/R and to the establishment inspection report (EIR) if the sample was collected during an inspection.

An FDA 484 attached to the C/R can be used to avoid repetition of the descriptions of the subsamples when numerous subsamples are collected. If you use an FDA 484 for this purpose, be sure the numbers you assign to the physical subsamples match those on the FDA 484, and that the sub-descriptions are adequately described. See IOM Exhibit 4-5. If errors are noted after issuance, handle the same way as instructed per IOM 5.5.10.9. Also, the Remarks section of the C/R should include notation of this practice if used.

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 their identification of the records covering interstate shipment should be factual and specific. If there is any question about accurate identification of the lot or records, be sure to determine all facts and establish identification as clearly as possible. Be alert to any identifying marks, too, which may later be used on the witness stand for positive identification.

4.2.6.1 – Private Individuals

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

4.2.6.2 – Seriously Ill Individuals

If you collect samples from an individual for contemplated regulatory action, and it is obvious the individual 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 principal witness cannot testify in a legal proceeding.

4.2.7 – Sampling from Other Government Agencies

IOM 9.2 for sampling information specific to other government agencies (OGA).

4.2.8 – Payment for Samples

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

An exception to this is import samples. The FDA does not pay for import samples at the time of collection. The importer should bill the appropriate division office. The FDA will not pay for violative import samples. See 21 CFR 1.91.

4.2.8.1 – Post Seizure (PS) and Reconditioning Samples under Court Order

You should not pay for, or offer payment for, any post seizure (PS) or other similar sample--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 them the court order. If you are still refused 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 the representatives of firms who have federal supply, Veterans Administration, or other contracts with the federal government, the cost of the sample

shall be determined by the scheduled price. Inquire of the firm if it is 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 to charge a lower price that is more equitable. If asked, inform the dealer that the government considers a fair price to be the dealer's invoice cost plus a nominal charge (usually 10-15%) for freight, handling, and storage.

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

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

4.2.8.3 - Method of Payment

There are four ways to pay for samples.

- The sample costs may be billed to the division. Encouraging dealers to bill the division is the preferred method for paying for samples.
- The treasury debit card may be used at point of sale (POS)
- You may use your travel card to make a cash withdrawal to purchase samples *only* when in travel status. You may never use your travel card to purchase a sample at POS.
- Personal funds may be used to pay for the sample. While OII policy currently allows for you to pay for samples with your own personal funds then submit for reimbursement, you should speak to your supervisor about alternatives prior to using personal funds to pay for a sample.

See IOM 4.6.2.45.

4.2.8.3.1 - Costs Billed to Division

Billing sample costs to the division is, in many instances, the most practical method of payment. This is particularly true where substantial costs are involved due to large sample size; expensive samples; the samples collected involve third parties, such as carriers and public storage warehouses; or in instances when delivery followed by subsequent billing is the dealer’s normal business practice.

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

OII SOP-000530, Sample Obligation and Processing, describes the process for paying invoices to the division for samples. There are two related documents that investigators should provide to

the firm when the firm will bill the division. One is Form-000870, a Vendor Process Payment Letter, and provides guidance to the vendor how to send their bill to the FDA. The other is Form-000874, a list of DFA contacts that the dealer should submit information to. These forms can be provided in hard copy at the time of sample collection or e-mailed to the firm after sample collection. If the forms are e-mailed, be sure to download the form to your computer and share the actual document (and not the links provided here). You should keep in mind that the links are dynamic and the information in them may change. Be sure that you give the dealer the current letter and contact.

4.2.8.3.2- Treasury Debit Card

The Treasury Debit Card program is voluntary. Details about joining the program can be found on the OII Treasury Debit Card Program SharePoint Site. If you carry a treasury debit card, it may be used at point of sale (POS) to purchase samples. If the vendor will not accept the debit card, you may use an ATM to get cash to pay for the sample.

The treasury debit card should only be used to purchase samples, not to buy supplies or to pay for shipping costs.

When traveling, you may use your government issued travel card to obtain cash from an ATM and add the expense of the sample and ATM fee to your voucher. The treasury debit card may be used to purchase samples online. When purchasing samples online, the cost of shipping and handling may be included in the cost of the sample.

If you use a treasury debit card, be sure to complete all appropriate paperwork and submit it as directed on the SharePoint site.

4.2.8.3.3 - Payment with Personal Funds

As previously noted, you are expected to encourage the dealer to bill the division for the cost of the sample. Personal funds to purchase samples should be used as a last resort when other methods of payment are not available. You must use personal funds to purchase samples. It is not mandatory to use personal funds. You may obtain a treasury debit card and use it instead. If you choose to use personal funds, speak to your supervisor before doing so. You will not be able to obtain reimbursement via a local voucher. Reimbursement for samples paid for from personal funds will be made via submission of an OF-1164 form as described under the Division of Financial Operations (DFO) Budget Execution procedures.

Sample costs cannot be charged directly to your government credit card. Using your government travel credit card to obtain a cash withdrawal is not ideal. However, you can use your government travel credit card to withdraw an ATM advance to pay for your sample only when you are in travel status. You are required to obtain your supervisor's approval (via email or other written form), prior to using your government travel credit card, to make a cash withdrawal to purchase samples. The amount of the withdrawal should be limited to the cost of the sample. You should submit your itemized claim for samples along with the cash withdrawal fee, as applicable, as part of your voucher using the electronic travel management system. Include the following information and documentation when submitting the voucher for reimbursement: sample number, receipt for the sample purchase, receipt showing the cash withdrawal fee if applicable, and approval from your supervisor to use the government travel credit card.

4.2.8.3.4 - Online Payment

Online samples, if they are undercover buys, should be paid for using a dedicated and unidentifiable FDA credit card. Other special assignment online samples should be paid for using a district or division P-card. The sampling assignment should provide guidance for an online payment. If guidance is not found in the assignment, check with your supervisor for program or division specific procedures to pay for online samples. Do not use your government travel or personal credit card to pay for online samples.

The treasury debit card may be used to purchase online samples including any shipping charges from the vendor. The treasury debit card may not be used to purchase shipping materials, coolants, or to ship samples to the lab. See the Treasury Debit Card Program FAQs.

4.2.8.4 – Sampling – Labor Charges

Additional labor, such as use of forklift, or other assistance may be required to move merchandise, skids, pallets or perform other actions, to properly sample and restore a lot. Usually, assistance with such labor will be available on the premises from the firm's employees. If you determine assistance is needed but unavailable at the firm, contact your supervisor to determine next steps.

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

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

4.2.9 – Dealer Voluntary Hold

This section deals solely with a *voluntary hold* on regulated products. See IOM 3.7.1 for specific statutory authorities for detaining meat, poultry, egg products, and medical devices.

There is no specific authority for requesting a voluntary hold on a lot but, voluntary holds by a dealer shall be encouraged in instances 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 hold on perishable items.

4.2.9.2 – Obtaining a Voluntary Hold

When the lot is clearly adulterated, or when instructed to do so by your supervisor, request that the dealer voluntarily hold the product. Explain the rationale for the request and a potential timeframe for the hold. If the dealer objects, discuss their responsibility under the law and the public health

consequences that may result. If the dealer indicates a reluctance to voluntarily hold the lot, call their attention to Section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

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

Always place a time limit on voluntary holds using your best estimate of how long it will approximately take to complete the analysis and reach a division decision. In estimating this time frame, you'll want to 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 center compliance office can request an extension of the voluntary hold. Also, be sure to document the voluntary hold in your regulatory notes and in the dealer's affidavit.

Also note the following special situations and/or potential responses from a dealer regarding voluntary holds:

- 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 that the FDA does not condone shipping violative goods. Direct their 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 hold you should provide or arrange for supervision/oversight of the denaturing per IOM 3.7 If the dealer proposes to recondition the lot themselves, refer them to your center compliance office for approval of their method. See IOM 3.6 and IOM 3.6.3.
- If the dealer still refuses, discuss the situation with your supervisor. A state embargo (see IOM 3.3.1) or administrative detention (IOM 3.5.11) may be the next action.

4.3 - Collection Technique

In most cases, when collecting a sample, you must ensure that the sample collected is a good representation the dealer's lot. The goal of collecting a sample for laboratory analysis is to provide the laboratory a part of a lot that represents the overall lot. This means that the way you collect the sample, as well as all the activities involved before it arrives at the lab, should leave the product in the sample, and in the same state, as the product that remains at the dealer. So, for example, a refrigerated sample collected for microbiological analysis should remain refrigerated until it is delivered to the laboratory.

4.3.1 - Lot Restoration and Identification

4.3.1.1 - Restoring Lot(s) Sampled

After completion of your sample, restore lots to their original condition. Do not leave partially filled shipping cases, or short-weight or short-volume containers in the lot after sampling. Do not leave the lot in any condition that might encourage pilferage or make it unsalable.

When collecting from either full cases or bulk containers, replace sampled units by back-filling from a container selected for that purpose. Avoid contaminating the back-filled units. If necessary, correct the contents' declaration on the containers that were sampled to reflect the actual contents now 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.

After collecting your sample, carefully re-close all containers and shipping cases. If necessary, request assistance from the dealer's employees to help restore the lot, or arrange, through the dealer, to employ outside help. See IOM 4.2.8.4.

4.3.1.2 - Identifying Lot(s) Sampled

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

Should the dealer object to your identification procedure, attempt to reach a compromise, such as, placing the identification in an obscure location. If the dealer still objects, accede to their 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 a detention, seizure, or other action ensues. It also aids the dealer in differentiating between containers that have been opened by the FDA, as opposed to those opened by pilferage or torn open by rough handling. It may be necessary to mark more containers than sampled to assure proper identification of the lot, for example when a lot may be split for distribution after sampling. This must be done by using permanent identification, for example, through handwritten identification or by using a rubber stamp.

Note that many inks have the potential to penetrate the product and act as a contaminant, interfering with the analysis. As such, do not use markers on sample containers that allow for any penetration into the product.

Many inks will penetrate to the product and act as a contaminant, interfering with the analysis. Do not use markers on sample containers which allow penetration into the product.

Water base markers will run when damp and must be covered with tape.

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

See 4.7.2.3 for identification techniques.

4.3.2 - 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 (found at the end of this chapter after the Exhibits), should be used if the Compliance Program doesn't state the sample size. If none of these sources furnish the sample size, consult with your supervisor or the relevant laboratory. Also, collect sufficient sample when necessary to allow for the 702(b) portion if appropriate. See IOM 4.3.2.2 and 4.3.2.3.

4.3.2.1 - Medical Device Samples

The following table represents the devices for which there are instructions on physical sampling 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.

Also see the following references with regards to collecting medical device samples:

WEAC-MEMO-2012-04-13.01_Medical Device Sampling Guidance Memo and OEIO Field Examination, Label Examination, and Sampling Work Instructions.

Review your assignment and, if needed, discuss it with your supervisor prior to collecting physical samples of medical devices.

4.3.2.2 - 702(b) Requirement

Under section 702(b) of the FD&C Act (21 U.S.C. 372(b)), when the FDA collects a sample of a food, drug, or cosmetic for analysis, FDA must, "upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent."

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

- Devices and tobacco products are not included in the statutory requirement of Section 702(b).
- The amount available for sampling is less than twice the quantity estimated to be sufficient for analysis. If this is the case, collect all that is available.
- The cost of twice the quantity estimated to be sufficient for analysis exceeds $150.00. If the sample is critical, and the cost exceeds $150.00, consult with your supervisor.
- The sample cannot, by diligent use of practicable preservation techniques available to the FDA, be kept in a state in which it could readily and meaningfully be analyzed in the same manner and for the same purposes as the FDA's analysis. Examples of this include fresh produce, water samples, and environmental swabs. If you are at all unclear on this point, consult with your supervisor, or servicing laboratory, to confirm that practicable preservation techniques are indeed not available.
- The sample is collected from a shipment being imported or offered for entry into the United States (import samples).
- The sample is collected from a person named on the label of the article or their 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.
- The sample is collected from the owner of the article or their agent, and the article bears no label--or if it bears a label, no person is named on it.

In the remarks section of the C/R, describe the specific circumstances and justification for not collecting the 702(b) portion. The documentation is not needed if the product is a device or tobacco

product, or the assignment or compliance guide already states why the 702(b) portion is not needed.

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

4.3.2.3 - Collecting the 702(b) Portion

As noted already, whenever possible, collect separate subsamples in order to provide the firm a portion as required by Section 702(b). Each duplicate subsample should be collected from the same bag, box, case, or container. The total sample should be *at least twice* the quantity estimated to be sufficient for analysis, including a reserve portion for the servicing FDA laboratory. If unable to collect separate subsamples, ensure that the total amount collected for each sample subsample, or the total amount collected from an undivided sample, is at least twice the amount estimated to be sufficient for analysis. See IOM 4.6.2.58.

4.3.3 - 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 (to include being photographed, information on the outside copied, etc.), and records of the shipment may be obtained. However, such package may not be opened by an FDA employee, or by an employee of the common carrier at the request of an FDA employee, except as provided below.

4.3.3.1- Examination without a Warrant

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

- The consignor or consignee affirmatively consents to examination and/or sampling of the contents; or the agency has reliable information that 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
- The Agency has reliable information that 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 a reliable source that establishes 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.]

4.3.3.2 - Examination with a Warrant

Confer with your supervisor on any question concerning the need for an inspection warrant to examine the contents and/or sample an in-transit package. Your center compliance office should be consulted if criteria for requesting a warrant are not clear.

If a decision has been made to recommend a warrant, the Office of Field Regulatory Operations , Division of Field Enforcement (OFRO/DFE) should be contacted. Follow the procedures outlined in the Regulatory Procedures Manual 6-3.

If a common carrier reports a violative article that 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, the FDA may still need an inspection warrant to examine the material. Unless all the conditions for independent sampling in IOM 4.3.3.1 exist, you must consult with your supervisor, who can arrange for a headquarters consultation as outlined above.

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

4.3.3.3 - 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 seal applied.

4.3.4 - Special Sampling Situations

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

Do not collect human or animal biological materials (for example, urine, feces, sputum, blood, blood products, organs, tissues) or FDA-regulated products potentially contaminated with biological materials unless arrangements for special handling and special treatment have been made in advance with the Regulatory Operations Safety Staff. Most OII-servicing laboratories are not prepared or certified to handle these materials. In addition to guidance for special sampling situations provided below, sampling guidance may also be found in IOM 1.5 – Safety under IOM 1.5.3 - Sampling.

Some products like essential oils should not be collected in plastic containers or paraffin-coated caps. Use glass, cork, foil covered, or non-plastic, non-paraffin closures. If unsure of the appropriate container/lid type, contact your servicing lab for guidance.

Please contact your servicing lab to determine an appropriate sampling container and sample size for medicinal and other gases.

4.3.4.1 - Samples Collected During Investigations of Complaints, Counterfeiting, Tampering, Foodborne Disease, and/or Injury/Illness

Detailed instructions for investigating and sampling products in connection with consumer complaints, tampering, foodborne outbreaks, injury, and adverse reactions, etc., appear in Chapter 8 of the IOM.

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. For example, there is little need to collect a physical sample of an insect-infested box of cereal from a complainant. Both you and the consumer can readily see it is insect infested. The laboratory would also find it insect infested. No practical

purpose would be served by either collecting or examining such a sample. Photographs can be used to document the infestation.

During consumer complaint investigations/follow-up events--when blood or body fluid contamination is suspected, and when there is no apparent illness or injury--samples should not be collected without first contacting Emergency Operations. This is due to the lack of confidence in the analytical methods and the results associated with certain blood and body fluid samples. As such, the decision to collect a sample will be made on a case-by-case basis, and in consultation with the Office of Regulatory Testing and Surveillance, Emergency Operations, and the Medical Products Inspectorate and Tobacco Operations.

4.3.4.2 - Undercover Buy Samples

If this sample type is desired, your supervisor will provide specific instructions and procedures to be followed. This planning will likely involve the following factors or questions:

- 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 (for example., Sidney H. Rogers should not use Samuel H. Right). In addition, do not use a division office or resident post as a return address when ordering products or literature.
- Whether to use order blanks contained in the promotional package, advertisement, or promotional activity; or whether false ones will be used.
- Whether money orders, your credit card numbers, bank checks, or your personal checks should be used for payment. It depends on the situation, but money orders are preferred since these do not involve personal accounts.
- Where the requested items are to be sent. For example, will you use a rented P.O. Box, home address, General Delivery, etc.
- 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.

Do not telephone your order in from the office or your home phone because the firm may have "Caller ID" and be able to identify your location by the phone number. For samples induced online, use a non-FDA network computer.

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 other payment document. When all documents for ordering the item(s) are prepared--photocopy all the materials, including the addressed envelope, for your C/R--and submit the order.

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

4.3.4.3 - Collecting Surveillance Samples on Farms

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

On farm sample collections should be limited to instances where it is specifically mentioned in an assignment. When you are planning to collect surveillance samples on a farm, you should call the farm at least 24 hours in advance to notify the farm of FDA's intent to collect samples and share the commodity of interest.

During the pre-notification call, the investigator should also determine an estimate of what the sample(s) will cost if the farm decides to charge for the samples. The investigator will take enough cash to cover the cost of the samples collected and not ask the farm to bill FDA as may be done in other sampling situations. If the farm decides to charge for samples and you did not bring cash, use the government travel card to withdraw cash from an ATM and withdraw the exact amount needed to cover the cost of the samples. As a last resort, personal funds may be used, do not ask the farm to bill FDA.

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

When on farm and viewing the inventory of product to be collected, the investigator will determine if the sample size needed will exhaust the farm's supply of the product or may cause the farm to not be able to meet customer needs. If so, consideration should be given to not collecting the sample or if possible, modifying the size of the sample. If the sample collection will exhaust the entire inventory, the investigator should discuss this with responsible farm management and determine how soon inventory will be restored and if the farm management believes the sample collection will impose an economic disadvantage to the farm. If the responsible party states that it will cause an economic disadvantage, the investigator should not collect the sample at that time, but rather plan to return at another time when additional inventory will be available for sampling or consider selection of another site for collection.

Samples collected from farms should be identified as Investigational (INV) and interstate commerce is not necessary. Produce samples collected from farms do not require the collection of a 702(b) portion.

4.3.4.4 – Collecting Samples During Foreign Inspections

An FDA 482, Notice of Inspection (Section 704(a) of the FD&C Act [21 U.S.C. 374(a)]) is not required to be issued to a foreign facility prior to conducting an inspection or collecting a sample, unless the firm is a U.S. Military facility, however; credentials should be presented to the top management official. See IOM 5.1.4.2.1 and 5.1.3.

Please note that an FDA 484, Receipt for Samples (Section 704(c) of the FD&C Act [21 U.S.C. 374(c)]), is issued to the owner, operator, or agent in charge (OOAC), describing any samples obtained during the course of an inspection.

You should follow the specific assignment instructions for sample collection at foreign firms. Consult with your program foreign division point of contact for additional guidance for collecting and shipping foreign samples.

4.3.4.5 – Notification for FDA Samples Collected During a Foreign Establishment Inspection or During FDA Activities in a U.S. Territory Outside of the Customs Territory of the United States

When shipping a sample collected during a foreign establishment Inspection or during FDA activities in a U.S. territory outside of the Customs territory of the United States (e.g., Guam, American Samoa, etc.), follow these notification procedures:

- FOOD SAMPLE: After the sample has been collected, prepared, and ready for shipment, but before it is delivered to the carrier, email the Division of Targeting and Analysis (DTAS) Watch Commanders oiioiodtaswatchcommanders@fda.hhs.gov and copy the Division of Import Operations (DIO) Information Duty Officer (IDO) FDAImportsInquiry@fda.hhs.gov with the following information:
    - Name of carrier (UPS, FedEx, etc.)
    - Date to be shipped
    - Tracking number(s)
    - Number of packages
    - Declared contents (Example "FDA Food Sample for analysis")
    - Product(s): Description of product(s), sample size including individual retail package size (if collected),
    - FDA Lab and address to be shipped to
    - Name and office address for the contact point (Person shipping the sample)
    - Manufacturer: Name and full address of the facility who manufactured the product(s)

The DTAS will address anything related to Prior Notice (PN). The DTAS is available to file and provide PN confirmation numbers 24 hours a day, 7 days a week. Once a PN is filed, the DTAS will provide the PN confirmation number by return e-mail so that it can be provided to the carrier at the time sample is delivered for shipment. If necessary, the shipper can email or call the DTAS at any time and ask for the Watch Commander on duty. If contacting the DTAS by phone, please call direct at 571-468-1488 or, if able to call toll free, use 866-521- 2297. If any non-PN issues arise with the shipment and importation of the sample, email the IDO. The IDO can facilitate communication to the field divisions, through the Division Import Activity Liaisons (DIALS), to help expedite the shipment.

- NON-FOOD SAMPLE: After the sample has been collected, prepared, and ready for shipment, but before it is delivered to the carrier, email the DIO Information Duty Officer (IDO) FDAImportsInquiry@fda.hhs.gov with the following information:
    - Name of carrier (UPS, FedEx, etc.)
    - Date to be shipped

- Tracking number(s) Number of packages
- Declared contents (Example "FDA Sample for analysis")
- Product(s): Description of product(s), sample size including individual retail package size (if collected),
- FDA Lab and address to be shipped to
- Name and office address for the contact point (Person shipping the sample)
- Manufacturer: Name and full address of the facility who manufactured the product(s).

If any issues arise with the shipment and importation of the sample, email the IDO. The IDO can facilitate communication to the field divisions, through the Division Import Activity Liaisons (DIALS) to help expedite it.

4.3.5 - Aseptic Sample

Aseptic sampling is often used in the collection of in-line samples, environmental samples, product samples from bulk containers and collection of unpackaged product that is being collected for microbial analysis.

Aseptic sampling is a technique used to prevent contamination by your sampling technique. Aseptic sampling involves the use of sterile sampling tools and sterile containers. Good aseptic sampling technique is demonstrated when the sample is contacted only by the sterile sampling tools or the sterile container used for sampling. Samples collected using good aseptic technique are important as they will support testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment. Aseptic sampling is critical to not only samples that will undergo microbiological analysis, but also to samples subject to chemical tests that might be altered by microbial activity. For chemotherapeutics, make sure that the shipping conditions ensure that microbial populations remain inactive and do not have the opportunity to degrade the analyte. The most ideal approach, whenever possible, is to collect intact, unopened containers.

Products in 55-gallon drums, or similarly large containers, either aseptically filled or heat processed, should not be sampled while the shipment is enroute, unless the owner accepts responsibility for the portion remaining after sampling. Try, instead, to arrange sampling of these products at the consignee's location so the opened containers can be immediately used or stored under refrigerated conditions.

For more guidance on aseptic techniques, you may consult the course, Food Microbiological Control 10: Aseptic Sampling, available to FDA employees through the OTED Intranet Site.

4.3.5.1 - General Procedures

If it is necessary to open containers, draw the sample and submit it under conditions that will prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling techniques. Take steps to minimize exposure of the product, sampling equipment, and the interior of sampling containers to the environment.

4.3.5.1.1 - Sterilized Equipment

Use only sterilized equipment and containers. These can be purchased sterile, obtained from a servicing laboratory, or in an emergency, at local cooperating health agencies. If pre-sterilized metal tools are unavailable, the metal tools can be sterilized immediately before use with a propane torch. If using this tool, permit it to cool in the air or inside a sterile container before using. Another acceptable method, albeit of last resort, is soaking the tools with 70% alcohol

and flaming off. Ensure collection controls used are within the manufacturer's expiration date prior to use.

If it is necessary to drill, saw, or cut the item being sampled (such as large frozen fish, cheese wheels, frozen fruit, etc.), use stainless steel bits, blades, knives, etc., that can be flame sterilized with 70% alcohol wherever possible. Note that wooden-handled sampling instruments are particularly susceptible to bacterial contamination (because of wood being of porous nature), are difficult to sterilize, and thus should be avoided.

4.3.5.1.2 - Cautions

Be extremely careful when using a propane torch or other flame when sterilizing tools and equipment. Evaluate environmental and other conditions pertaining to explosive vapors, dusty air, flame-restricted areas, firm policy and/or management wishes. Also, the use of supportive devices should be considered when the torch is not being handheld. In addition, 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, then use sterile disposable-type gloves. Surgeon's gloves are a good choice. Use a new glove for each sub and submit an unopened pair of gloves as a control. See IOM 4.3.5.5.

4.3.5.1.3 - Opening Sterile Sampling Containers

Plan your aseptic sampling approach, including organizing your sampling tools prior to sampling. When opening sterile sampling containers, work rapidly and efficiently. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid. (See IOM 4.3.4)

4.3.5.1.4 - 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.

4.3.5.2 - Sampling Dried Powders

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

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

Note the following procedures have been approved by the scientific units at headquarters, and should be used when sampling based upon the way the product has been packaged:

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

1. Remove as much dust as possible from the seam end by brushing it and then wiping it 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 open the walls of the bag and the poly-liner enough to permit sampling--being careful that no extraneous material, such as dust, bits of twine, paper, etc., drops into the product.
3. Carefully scrape off the surface of the product with a sterile device and aseptically draw the sample from the material below.
4. Carefully reclose the bag and re-stitch by hand, or by machine if a firm, or FDA-portable, sewing machine is available.

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

4.3.5.2.3 - Bags With Filling Spouts

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

- Brush and alcohol wipe the area around the spout and carefully pull-out spout 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.
- Carefully spread apart the sides of the spout and aseptically draw the sample. A trier or long-handled device is usually better for this type of opening because of the limited opening.
- Carefully close the spout with a firm twisting motion and be sure the opening is closed prior to pushing it back into the bag.

4.3.5.3 - Collecting Water Samples

When it is necessary to collect water samples for bacteriological examination, use the following procedures:

- Use sterile bottles. If de-chlorination of the sample is necessary, you should place sodium thiosulfate, sufficient to provide a 100 mg/l concentration, 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, that the bacterial load is the same as when collected.
- Carefully inspect the outside of the faucet from which the sample will be drawn. Do not collect the sample from a faucet with leaks around handle.
- Clean and dry the outside of the faucet.
- Let the water run from the fully open faucet for at least 30 seconds or for 2 or 3 minutes if the faucet is on a long service line.
- Partially close the faucet to permit the collection of the sample without splashing. Carefully open sample bottle to prevent contamination, as in any other aseptic sampling operation.

- Fill bottle carefully without splashing and be sure no water from your hands or other objects enters the bottle. Do not over fill the container. Leave a small air bubble at top.
- Unless otherwise instructed, the minimum sample size for bacteriological examination is 100 ml.
- Pack the sample into a clean insulated shipping container with clean ice packs to keep the sample cool while in transit. Do not use wet ice to ship the sample to the lab.
- Deliver the sample to lab promptly. If the 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.

4.3.5.4 - Sample Handling

Please see the following other sample types and techniques recommended to assure their integrity:

- For frozen samples, pre-chill sterile containers before use and keep samples frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration. See IOM 4.7.3.5 and 4.7.3.6.
- Under normal circumstances, dried products may be shipped unrefrigerated except in cases where they would be exposed to high temperatures, that is, above 37.8oC (100oF).
- Submit samples subject to rapid spoilage (for example, specimens of foods involved in poisoning cases, etc.) by immediate personal delivery to the analyst where feasible.
- For light-sensitive drug samples, ensure the use of appropriate light-restricting containers.
- For flammable material samples (for example, alcohol-based hand sanitizers), use appropriate and approved containers, cushioning materials, and safe sample-handling instructions per the FDA Safety Office.

4.3.5.5 – Closed Controls

When collecting any samples using aseptic techniques, submission of unopened, closed controls are required. See SOP-001052 (ORA Field Bulletin #30 – Food Program Area – Instruction for Environmental Sampling) for more information on environmental samples. Field Guidance documents can be found on the FDA SharePoint site.

For each lot of sterile sampling equipment used to take the sample, submit closed controls identified as one or more subsamples (also known as control subs).

For each lot of sterile sampling equipment used to take the sample, submit closed controls identified as one or more subsamples (also known as control subs).

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

Examples of various control subs and techniques to be employed are:

- Sterile Containers: Where sterile containers are used to collect aseptic samples, submit one unopened container that was sterilized in the same manner as containers used for sampling.
- Sterile Disposable Gloves: If sterile disposable gloves are used to handle the product, submit one unopened pair of gloves as a control.

- Sterile Swabs/Sponges: When collecting environmental samples with swabs or sponges, submit an unopened swab or sponge as a control.
- Sterile Sampling Equipment: Where pre-sterilized sampling tools are used (for example, scoops, containers, swabs, whirl-pak bags, spoons, spatulas, triers, etc.), the closed controls will consist of one unopened sampling tool from each lot used.

4.3.6 – Documenting Filth and Other Contamination

Documenting the presence of filth or other deleterious material, involves the collection of samples using strategies and techniques that represent the product or condition. These samples are selective and generally contain more subs (larger) than samples collected for economic or misbranding purposes.

When widespread evidence of filth or other adulteration is present, 402(a)(4) conditions (see Section 402(a)(4) of the FD&C Act [21 U.S.C. 342(a)(4)]) are documented through the combination of selective sampling (IOM 4.3.6.3) and field examination (IOM 4.3.6.1).

Documenting filth--such as rodent, insect, or bird contamination--requires thorough examination of numerous lots of products to determine the extent of adulteration, along with collecting investigational (INV) samples (IOM 4.1.5) inclusive of filth exhibits and photographs supporting the nature and extent of the evidence. Separate filth sub samples should be collected from various areas within the firm to illustrate the extent of questionable conditions that led to adulteration.

Numerous lots of regulated products should be examined, as you collect official samples of those products demonstrating violative conditions. Filth, such as rodent, insect, or bird contamination, observed on the exterior of food containers, on pallets containing the product, or on the floor adjacent to the products should be selectively sampled and treated as sub samples of the official sample. Documenting potential adulteration of several lots helps establish the widespread nature of the adulteration. Compliance Policy Guide (CPG) 580.100 Food Storage and Warehousing - Adulteration - Filth (Domestic and Import) can help you determine what to collect for the sample, as well as determine minimum criteria for direct reference seizure. (Consult your supervisor when you find evidence that meets the criteria set forth in CPG 580.100.)

When observations indicate that a ready to eat food may be suspectable to microbiological contamination, samples may be selectively collected. The samples collected should document manufacturing conditions conducive to adulteration. Refer to IOM 4.3.6.5 for instruction on selectively collecting microbiological samples.

When regulatory action appears to be warranted, document recent sales of product from the lot in question. If unsure of the significance of your observations, speak with your supervisor for guidance.

4.3.6.1 - Field Examination to Document Contamination

A field examination is a physical inspection performed on a product to determine the product's condition, its integrity, or practices used during its storage. The examination includes physically examining several containers (cases, cans, bags, units, etc.) of a product. When conducting such exams, take care to describe your observations for each container of product examined and all sub samples collected, ensuring to record the violative nature of the lot along with any exhibits supporting your observations in your regulatory notes and subsequent C/R Collection Remarks, C/R Continuation Sheet FDA Form 464a, or Analyst Worksheet FDA Form 431. Observations should be recorded to accurately and specifically describe the following: general storage conditions, violative condition(s) of the lot, physical relationship of the violative lot to other lots in the area, how you

conducted the examination, and the number of units you examined. Use quantitative observations, (for example, “insect cast skins and 12 live and dead insects were observed on the exterior product bags of a pallet containing 6/50 lb. bags of Triticale Meal. The pallet was located approx. 20 feet east of the elevator shaft, adjacent to pillar identified as #8 on the floor plan diagram.”).

As in the example notation above, report, if present, the number and location of live and dead insects, rodent pellets, or other potential sources of adulteration discovered inside the containers, as well as on their exterior surfaces. Provide diagrams and measurements of areas of urine or other bio-chemical stains on each container and the extent of penetration. Correlate findings of the examination with photographs and the physical sub samples you’ve collected. Providing a floor plan diagram identifying the locations where subsamples were collected helps visualize the overall violative condition(s).

The subsamples collected from obviously violative lots may be reduced to decisively selected exhibits in instances in which the field examination is carefully described and documented. The field examination and the report of findings will serve as the analysis.

4.3.6.2 - Random Sampling

When sampling to determine the characteristics of a lot, or the condition of a lot is not known without further analysis, samples should be chosen at random. Samples collected at random yield information about the average composition of the product lot. Random sampling methodology is used when you have no information or method of determining which units are violative. If a violation exists, it will be found by laboratory methodology at a specific confidence level, pending the sample size chosen.

The sample size to be collected is usually described in your assignment. If the assignment doesn’t specify one, follow the guidance found in the applicable Compliance Program, or the IOM Sample Schedule Charts after the Exhibits in this chapter. If no sample size guidance is furnished, discuss an appropriate sample size and 702(b) portion with your supervisor (see IOM 4.3.2.2 and 4.3.2.3). The general rule is to collect samples from the square root of the number of cases or shipping containers in the lot (or available for sampling if lot size is unknown) but not less than 12 or more than 36 subs. Subs are collected in duplicate when including a 702(b) portion. If there are less than 12 containers, all should be sampled.

4.3.6.3 - Selective Sampling

When there is widespread evidence of filth or other adulteration present, random sampling methodology is undesirable and unnecessary. Under these conditions, examine the lot and select portions of product to sample that demonstrate the violative nature of the lot.

When selectively collecting samples, ensure you include exhibits such as diagrams and photographs that demonstrate the violative condition, along with identifying the containers of product that were sampled from that lot. Exhibit 4-22 contains selective sampling criteria and guidance for sampling for filth, chemical contamination, and mold contamination.

4.3.6.4 - Abnormal Containers

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

4.3.6.5 - Microbiological Samples

During inspections of firms producing products susceptible to microbial contamination (for example, peanut butter; dried milk; dairy products; frozen, ready-to-eat seafood; crème-filled goods; breaded items; prepared salads; etc.), sampling may be warranted, based on observations or as directed in the Work Plan, Compliance Program, or assignment. Follow instructions under IOM 4.3.6.6 when collecting microbiological samples to document manufacturing conditions conducive to adulteration.

4.3.6.5.1 – Collection Of Samples For Molds

Mold Samples: During inspections of manufacturers such as canneries, bottling plants, milling operations, etc., it may be necessary to collect scrapings or swabs of slime or other material to verify the presence of mold. The sample should represent the conditions observed at the time of collection and consist of sufficient material to confirm and identify mold growth on the equipment. If possible, take photographs and obtain scrapings, or bits of suspect material. Describe the area scraped or swabbed (for example, “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 filled with a small amount of a 3-4% formalin solution. Large amounts of slime may be placed in a wide-mouth glass jar with either a 1% formaldehyde solution, or a 3-4% formalin. Note: Formalin is normally sold as a standard stock solution of 37%. To obtain the required 3-4% formalin solution, you’ll need to mix 10 ml of the 37% stock solution with 90 ml of distilled water. This will yield the appropriate strength solution necessary to “fix” the mold.

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

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

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 formaldehyde, may be frozen. Check with your laboratory for its recommendation regarding preserving mold samples.

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

Sampling for products susceptible to microbial contamination and the environment in which they are produced may help identify the presence of pathogenic microorganisms before they can cause illness. With the recent increase in foodborne outbreaks and inspections identifying links between outbreaks and environmental contamination (including that associated with non-food contact surfaces), there will be an increased focus on routine environmental sampling during inspections. Conduct environmental surface sampling as directed by the work plan, compliance program or

assignment, or based on inspectional observations. If you are unsure of the circumstances under which to perform environmental sampling, consult with your supervisor. Also see IOM 5.8.7.3 for inspectional guidance for firms producing products susceptible to contamination with pathogenic microorganisms.

Collection of environmental and product samples for microbiological testing requires a thorough understanding of critical factors associated with the production of the specific product being inspected. In other words, to prove the establishment is being operated in an insanitary manner, it is necessary to show the manufacturing operation or conditions at the facility that are likely to, or have contributed to, the bacterial load of the product. When feasible, inspections should include equipment conditions before a day's production begins as well as the clean-up at the end of the day's production. Note that for environmental Salmonella sampling, it is preferable to sample before the plant conducts a wet cleaning operation.

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

In-line sampling should be conducted based on observations or as directed. When visible microbial contamination is observed, collect finished product as directed in the compliance program or assignment.

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

4.3.6.6.1 - Environmental Sampling

HFP has developed guidance on the specific locations within a firm to collect environmental samples to increase the likelihood of detecting Listeria monocytogenes and Salmonella that may be present. See IOM Exhibit 4-20 and 4-21 and SOP-001052 (Field Bulletin #30 – Food Program Area – Instructions for Environmental Sampling for guidance on environmental sampling/locations for these microorganisms. In addition, please view the training video Environmental Sampling in Food Manufacturing mentioned in SOP-001052 (Field Bulletin #30 – Food Program Area – Instructions for Environmental Sampling), which provides technical and procedural information on environmental sampling.

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

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

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

Zone 1: Refers to all direct food contact surfaces, such as slicers, mixers, conveyors, utensils, racks, worktables, etc. For inspections focusing on the presence of Salmonellae, such as firms producing peanut products and other dry product environments, food contact surfaces are normally not sampled unless specifically requested in the assignment or CP. In contrast, for inspections focusing on detection of Listeria monocytogenes, such as firms producing seafood or cheese products in a wet environment, sampling of food contact surfaces is essential.

Zone 2: Encompasses the areas directly adjacent to food contact surfaces (Zone 1). For investigations focusing on Salmonellae, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, Zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation, and air- handling equipment, and floors. In a much larger room for example, one that measures20,000 square feet), Zone 2 is the area in the immediate vicinity of food contact surfaces, such as around the exposed product where you could envision a pathway to product contamination either through the actions of people or machines.

Zone 3: The area immediately surrounding Zone 2. Zone 3 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of people or the movement of machinery. Examples of Zone 3 areas include: corridors and doorways leading into food production areas or areas in a large production room that are further away from food-handling equipment than typical zone 2 areas. Walls, phones, forklifts, and "mules", even if physically located in Zone 2, should be considered part of Zone 3 due to a decreased likelihood of cross-contamination.

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

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

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

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

Swab subsample numbers for each organism are as follows:

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

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

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

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

Medical Devices:

Environmental sampling for medical device manufacturers should follow the same strategies outlined above, as well as any other instructions provided by your supervisor.

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

These instructions should be followed to ensure standardization of FDA environmental sample technique across divisions:

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

Dey-Engley (D/E) neutralizing broth or buffer[6] has been shown to be effective as a neutralizing agent against the widest range of sanitizing agents that may be in use by a firm and, per ORS, is the one to be used for general purpose environmental sampling.

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

Sampling Equipment:

If sources cannot be located for sponges or swabs pre-hydrated with D/E Neutralizing buffer or broth, use un-hydrated sponges and swabs along with single use tubes of D/E neutralizing broth. Do not add additional D/E buffer or broth to other types of hydrated sponges and swabs that

[6] The terms broth or buffer are used interchangeably for this product.

contain either a neutralizing broth or an enrichment broth, as this may dilute the concentrations of both components to the extent that they will not be effective.

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

Other general sampling supplies you will need for environmental sampling:

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

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

Sampling Method:

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

Gloves:

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

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

Sampling of Dry Surfaces:

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

- Wash and sanitize your hands to the mid-forearm. Use clean disposable paper towels for drying your hands.
- From the outside of the sponge bag, manipulate the handle toward one side. Pull off the top of the whirl-pak bag holding the Sponge-stick along the perforation. Using the tabs on both sides of the wired band, pull gently to open the bag. Do not remove the Sponge-stick.
- Pour into the Sponge-stick bag 9-10 ml or sufficient volume of DE neutralizing broth on the side *away* from the handle to hydrate the sponge (do not get broth on the handle). Be careful not to touch the opening of the broth container to any non-sterile surface before or during this transfer.
- Massage the sponge through the outside of the bag to facilitate absorption. From the outside of the bag, push the Sponge-stick to the upper portion of the bag. While pushing the sponge-stick up from the bottom of the bag, squeeze excess D/E broth from the sponge back into the bag. The sponge should be moist but not dripping wet.
- Using aseptic technique, unwrap and place a sterile glove upon the hand you will use for swabbing. Do not touch any non-sterile surface (i.e., clothes, skin, counter tops, etc.) with the outside surface of the sterile glove. The other hand can be left ungloved for manipulation of non-sterile surfaces and materials if preferred.
- Remove the Sponge-stick from the bag using your gloved hand. Using even and firm pressure, push the sponge in one direction across the desired area of the environmental surface 10 times vertically, then 10 times horizontally. If visible soil or residue is present, sample the surface by vigorously rubbing the sponge over the designated area until the soil or residue is removed. Sampling of large flat surfaces (i.e., floor, table tops, and conveyor belts) should cover areas as referenced above, and dependent on if the area is unclean, or has been cleaned and sanitized. It may be necessary to wet the sponge with additional neutralizing broth when sampling large and/or porous areas. Try to use only enough buffer to keep the sponge gliding smoothly over the surface. If there is excess buffer, squeeze it back into the whirl pack bag and continue until you have sampled the entire sampling site.
- After sampling, return the sponge to the original Whirl-Pak bag with any excess buffer, snap off the handle in accordance with the product instructions that accompany the Sponge-stick, and submit as a subsample.
- Remove the used sterile glove and discard.
- Squeeze as much air out of the bag as possible. Roll the top of the bag over several times until it is folded all the way down to the sponge. Fold in the tabs to lock the fold in place. Place the sponge bag inside another empty Whirl-Pak or equivalent bag and seal as before. Both bags must be tight enough to provide both a leak proof seal and minimal airspace during shipment of the moistened sponge.
- As soon as possible, place the double-bagged sponge inside an insulated cooler, with pre-frozen gel packs to keep the samples cold, but not frozen, and transport/ship the sample to the servicing lab for analysis so it is received by the lab within 24 hours of collection.

Sampling of Wet Surfaces:

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

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

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

Sampling of Dry Surfaces:

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

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

Sampling of Wet Surfaces:

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

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

Closed Controls:

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

Open Controls:

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

Sample Numbering:

Often, multiple days are required to collect an appropriate number of environmental swabs. If an environmental surface sample is collected on multiple days during an inspection, use a new sample number for each day, (for example., sample no. 100000 on the first day and sample no.

100001 on the second day). The subs should be numbered sequentially (for example, subs 1-100 on the first day and subs 101-175 on the second day). Link the sample numbers to the assignment for tracking purposes. Environmental swab subs should be numerical—that is, 1, 2, 3, etc., while control subs should be alphabetic—that is, a, b, c, etc.

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

All environmental samples, including swabs, soil, water, and animal scat, are to be identified as Investigational (INV). Use the following environmental sampling product codes:

- 52Y[][]07 for Farm Environmental Swabs/Samples
- 52Y[][]08 for Process/Manufacturing Environmental Swabs/Samples
- 52Y[][]** for Animal Carcass Rinse/Swabs, where **= 01 (Beef), 02 (Chicken), 03 (Lamb), 04 (Pork), 05 Turkey), 06 (Other Animal Swabs)
- 52Y[][]09 for Postharvest Water (for Agriculture use)
- 52Y[][]10 for Preharvest Water (for Agriculture use)
- 52Y[][]11 for Spent Sprout Irrigation Water (use for testing)
- For Drug Environmental Swabs/Samples use product code 66Y[][]07.

Do NOT use the product code of the covered product for environmental samples.

4.3.6.6.3 – In-Line Sampling/Factory Food Sample

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

Each in-line subsample will consist of approximately 114 g (4 oz), in duplicate (702(b) portion), if that amount is available (Also see IOM 4.3.2.2 - 702(b) Requirement). All in-line samples must be collected aseptically. In addition, each inline sample should include open and closed controls. The open control should be "opened" prior to sample collection, and "closed" when sampling is concluded. The open control should be placed near the location where the sample is being collected. The inside of the open control should be exposed only to the air in the environment. Do not set open controls, such as gloves, directly onto the floor, or in contact with equipment, etc. If different lots of sampling equipment are used (for example, two different lots of gloves are used during sampling) then each lot should be represented by both an open and a closed control.

The following are areas vulnerable to microbial growth in which in which you'll commonly collect in-line samples (Note that this is not a comprehensive list since each firm will be different, and sampling will be dependent processing/packaging techniques, as well as the type of finished product produced):

"Raw" ingredients used in the manufacturing of finished foods (including those conveyed by bulk tankers) should be considered for sampling to determine the effect of subsequent processing on bacterial content. Of particular concern are raw materials that can support microbial growth, are not normally cooked or prepared in a manner that is 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 (for example, 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.

4.3.6.6.4 - Finished Product Sampling

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

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

For medical devices labeled as sterile, but with suspected or apparent defective packaging, refer to CPG 300.400 for additional information and consult with your supervisor for additional instructions.

4.3.6.6.5 - Reporting Environmental Sampling Results on the FDA 483

Environmental sampling in OII's foods program has received heightened focus as of late, as evidenced by increasing assignments in the field. To better support consistent policy in this area, criteria for reporting positive environmental sample results on the FDA 483 has been outlined by the Office of Chief Counsel (OCC) and the ACRA. Note the following guidance in support of this policy. This applies to the foods program only.

Significant positive environmental sample results, from swabs collected at food firms, are to be reported on the FDA 483 if the results are known prior to the conclusion/closeout of the inspection. However, this does not mean you should unnecessarily extend inspections to include

the results. The reasoning behind the implementation of this policy is that it addresses the following important activities and objectives:

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

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

1. The sampling is related to a current or future foods program inspection/investigation.
2. The inspection has not been closed (Note: it is not requested that the period of inspection be extended for the purpose of receiving analysis results).
3. The positive sample finding(s) you uncover represent a significant observation, for instance, you are able to clearly demonstrate a route of contamination from the environment to the product by establishing positive sample result(s) in Zones 1 and/or 2 for *Listeria,* or positive sample result(s) in Zone 2 and/or 3 for *Salmonella.*

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

Note regarding medical devices:

Positive environmental sampling results for medical devices may be reported on the FDA 483 with concurrence from CDRH.

4.3.6.7 - Samples for Viral Analysis

Sample instructions will be issued by the appropriate center, on a case-by-case basis.

4.3.7 - Economic Violations

4.3.7.1 – Net Weight and Volume Determinations

In cases where you are directed to collect samples for short weight or volume, consult with ORTS regarding the number and size of subsamples and the servicing laboratory to be used, unless already outlined in an assignment. Consult with your management about whether or not a field examination is required during the sample collection.

Exhibit 4-6 is FDA form 485, Field Weight Sheet, and may be used if conducting a field examination.

Instructions for use of the form are on the second page of the exhibit.

To use the form, 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.

4.3.7.2 Economic Labeling

See FDA's Industry Resources on the Changes to the Nutrition Facts Label for guidance. See HFP's Office of Dietary Supplement Programs and Office of Nutrition and Food Labeling websites as well as FDA.gov for the most up-to-date information regarding claims in labeling. (Note: access to ONFL SharePoint site must be requested.)

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

4.3.8 - 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.

Review your Compliance Program Guidance Manual and IOM 4.3.6.1 and 6.3 for field examination techniques that may be applicable to specific products or a specific industry. Compliance Program Guidance Manuals also contain decomposition sample schedules.

4.3.8.1 - Whole-Bag Screening

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

Conduct the examination in a well-lit 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.

4.4 – Documents Collected with Sample

An official sample is not complete without records documenting its existence in interstate commerce. Additional documents may be collected, such as processing records and laboratory procedures used by the dealer.

Follow your division or program procedures for maintaining hardcopy and/or electronic records covered in this section. See 4.6.4 – Routing.

4.4.1 – General Considerations/Procedures regarding Documents

Ensure the copies of records obtained pertain specifically to the sample collected. If copies of certain records are unavailable (for example, shipping records are no longer available at the site or have been destroyed due to age), you should add statements documenting the circumstances on the affidavit and, if possible, document where these records could still be obtained and from whom.

Do not remove the dealer's only copy of records. Whenever possible, scan, photograph, or photocopy it. Reproductions must be reviewed to ensure all relevant information is readable and to verify the copy you receive is an accurate representation of the original record.

Digital tools may also be used to enhance the contrast of documents scanned or photocopied to make them more readable. Whenever enhancement is applied to a document using any method, document the steps taken in your notes and the corresponding collection report.

In cases where the finished product being sampled is not shipped to interstate customers, but is formulated from raw materials with interstate origin, jurisdiction may be established by documenting the interstate shipment of one or more major raw materials. (This would be a 301(k) sample. See IOM 4.1.4.2.2.) An affidavit from a knowledgeable and responsible firm official may be used to link copies of records showing interstate movement of the raw material with copies of records showing subsequent use in the lot being sampled; if documentation of the use in production is not available or clear, statements on an affidavit may be collected to support the linkage.

4.4.2 – Identifying Sample Records

Identify copies of all records obtained (except copies of FDA forms) and attach to the collection report labeled with the sample number (including the prefix if appropriate), collection date, and collector’s name or initials (the investigator who completes the collection report is the collector, See IOM 4.6.2.10). If more than one document (other than FDA forms) is to be attached to the collection report, include a sequential document number as part of the document label which will be used to refer to the document in the list of documents as part of the collection report in FACTS; copies of FDA forms may be assigned a sequential document number for identification in the collection report, but should not be labeled or altered from their original form. If a document (other than FDA forms) is more than one page in length, it should be numbered to allow reviewers to determine if any pages are missing. See IOM 5.6.7.5 and 5.6.11.2.

Here is an example of this labeling, where it is applied to the second page of the third document attached to a collection report:

“DOC117883
7/12/2022
ENH
Document 3, Page 2 of 12”

If the firm maintains their records electronically, see IOM 5.6.7.5 and 5.6.11.2.

4.4.3 - Evidence Required

When documenting known violative situations with a sample and its related records, you need to consider whether you have established FDA's jurisdiction, documented the interstate commerce, shown a violation, and determined responsibility for the violation (JIVR). See IOM 2.3.1.

When the violative nature of a sample is not known at the time of collection--for example, when laboratory analysis is necessary to determine the adulteration of a product regulated by the FDA--collection of available documentation to support a potentially violative situation should be considered. Consult with your supervisor for guidance.

4.4.3.1 – General Considerations for Evidence

When you are collecting evidence, including samples, to demonstrate a violation(s), it is important to understand the specific charges that may be made and the anticipated action the agency may take. Most charges would be made against the product or a person and are prohibited acts that can be found in Section 301 of the FD&C Act [21 U.S.C. 331]. Additional information and guidance on the evidence required to support certain judicial actions is available in the Regulatory Procedures Manual, Chapter 6.

Note that throughout this section, the term dealer is used with the same meaning as outlined in IOM 4.1.3.1 of this chapter; essentially, the dealer means the person who has possession of the FDA-regulated product at the time it is been collected, regardless of the firm's operations. A dealer may be a manufacturer, warehouse, or other operator.

Below are the most common prohibited acts encountered by investigators and the kinds of evidence you may collect to demonstrate such violations. Since each case is different, you must consider carefully if you have collected the appropriate evidence to show the violations that may be charged. You should also keep in mind that more than one prohibited act may be applicable to a product, or person, and so you should be prepared to document multiple violations related to the same product, or document multiple instances of the same prohibited act that occurred related to multiple products.

You should also consider the appropriate action the division will be taking. If the division would be considering an injunction, for instance, it is important to demonstrate that the violative action is ongoing and that collecting recent evidence to demonstrate that multiple lots of product/s were violative will support such an action. For a seizure action, you will need to consider if the division will pursue a single lot seizure or a mass seizure of products. Evidence required for a mass seizure needs to show an ongoing, widespread, uncorrected condition that causes all products the dealer holds at a location to be violative. Be sure to discuss the appropriate action with your supervisor who will likely want to confer with the center compliance office . However, do not let delays conferring with others delay your collection of evidence. (See 4.4.3.2)

4.4.3.1.1 - Introduction into Interstate Commerce (FD&C Act 301(a) and 301(d) charges)

If the dealer is shipping adulterated or misbranded product, collect evidence showing the dealer distributed the product in interstate commerce. You should obtain evidence showing the date of shipment and the specific shipping information of the product. Your evidence must show shipment to another state or territory of the product in question.

This prohibited act also includes "delivery for introduction into interstate commerce." If you cannot obtain evidence showing shipment in interstate commerce, then you need to show that the dealer had knowledge that the person they were distributing it to 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)].

4.4.3.1.2 - Adulteration or Misbranding in Interstate Commerce (FD&C Act 301(b) charges)

Collect evidence showing that the specific product in question was in interstate commerce at the time that it was rendered violative. See Section 301(b) of the FD&C Act [21 U.S.C. 331(b)]. If you are documenting a shipper violation at a dealer, it is your responsibility to show the storage conditions at the dealer did not contribute to the violation. Obtain an affidavit describing handling of the goods after receipt, and any other information that supports the violation. An example of this could be a refrigerated or frozen product that was shipped without proper refrigeration and "spoiled" before receipt at the dealer. Keep in mind when documenting this violation at a dealer who received the product, that there is also the violation found in IOM 4.4.3.1.3. Either or both charges may be made, and both should likely be documented.

4.4.3.1.3 - Receipt in Interstate Commerce (FD&C Act 301(c) charges)

If the dealer knowingly receives adulterated or misbranded product, collect evidence showing receipt of violative product in interstate commerce. The documentation collected may be the same as that collected in IOM 4.4.3.1.2. In general, when making this charge, you should demonstrate that the dealer was aware of the violative condition of the product before the delivery or accepted the delivery knowing the product was violative. Whether it was sold or given away is immaterial. See Section 301(c) of the FD&C Act [21 U.S.C. 331 (c)].

If the dealer causes the adulteration or misbranding of an FDA-regulated product, it is a 301(k) violation. See 4.4.3.1.6 below.

4.4.3.1.4 - Manufacture Within a Territory (FD&C Act 301(g) charges)

Under this prohibited act, the product does not need to be shipped in interstate commerce. The mere act of manufacturing a violative product in a territory (as defined in Section 201(a) of the FD&C Act [21 U.S.C. 321(a)(2)) is prohibited. Collect evidence revealing that the product was manufactured within any territory. Note that the term territory does not include the Commonwealth of Puerto Rico. See Section 301(g) of the FD&C Act [21 U.S.C. 331(g)].

4.4.3.1.5 - False Guaranty (FD&C Act 301(h) charges)

A guaranty typically involves a statement that the product being sold to the dealer in in compliance with the FD&C Act or FDA regulations. In addition to evidence showing the guaranty is false (for example, the product was adulterated when received) obtain copies of the specific guaranty. Also collect any shipping records associated with the violative product. Each guaranty usually covers a specific sale (and delivery) on or about a definite date to the holder of the guaranty. Although interstate commerce is not required, you should obtain evidence demonstrating that the consignee normally engages in some kind of 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.

4.4.3.1.6 - Dealer Violation (FD&C Act 301(k) charges)

For this prohibited act, you must collect records showing the dealer received the product in interstate commerce and that the product was made violative by the dealer. One example of this is adulteration of product in a filthy warehouse where there is rodent activity and there is evidence that the product is being adulterated with filth by the rodents (for example, a rodent infestation). Another example is where a drug manufacturer receives an unadulterated active pharmaceutical ingredient and by failing to follow GMPs manufactures a violative product. In both cases, collect evidence of interstate origin of the article (in our examples, the product found adulterated by rodents or the active pharmaceutical ingredient) and proof of a specific action which adulterates or misbrands the article (for example, evidence of rodent activity or failure to follow GMPs). See Section 301(k) of the FD&C Act [21 U.S.C. 331(k)] and IOM 4.1.4.2.2.

4.4.3.2 – Evidence for Seizure, Injunction or Criminal Prosecution

For a seizure action (see IOM 3.8.3), the FDA must fulfill the following: establish jurisdiction over the product, show its interstate movement, and document a violation. However, it is not necessary to establish responsibility for the violation.

You should obtain copies of all available records that show the article was introduced into or in interstate commerce or held for sale after shipment in interstate commerce. Additional information on the requirements for seizure actions can be found in the RPM, Chapter 6-1. See also 21 U.S.C. 334 (FD&C Act 304) - Seizure.

For an injunction (see IOM 3.8.4) or criminal prosecution (see IOM 3.8.5), the proof required depends on the violations of the law. Information on the specific requirements for these actions can be found in the RPM, Chapter 6-2 and 6-5. See also 21 U.S.C. 331 (FD&C Act 301) - Prohibited Acts.

4.4.3.3 - Complaint or Injury Samples

Generally, samples collected from complainants during investigation of injuries or foodborne outbreaks are investigational in nature and significant documentation of interstate commerce is not collected. 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 well documented. Affidavits from the consumer, retailer, and wholesaler should be obtained as applicable.

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 by obtaining necessary affidavits and interstate records. See IOM 8.1.5 for additional instructions on tampering, counterfeit, and other complaint samples.

4.4.4 - Documenting Interstate Shipments

The minimum set of records ordinarily submitted with an official sample will consist of a copy of the invoice covering the sale of the lot, batch, or unit to the dealer; the transportation record showing interstate commerce; and an affidavit signed by the dealer that identifies both the lot, batch, or unit sampled and the applicable records. See IOM 4.4.2.

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

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

4.4.4.1 - Sales Records

An invoice does not establish interstate commerce and thus federal jurisdiction. It does not prove actual movement of an FDA-regulated product. However, it may provide information as to the value of the goods, the 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, be clear on which lines correspond to the sampled products and identify those in the collection report. Other records which may be collected in addition to an invoice to show product sales are: copies of purchase orders, receiving records, canceled checks, correspondence, etc. If no invoice is available for a sample, one or more of these should be collected and included in the collection report.

In addition, invoices often show details about the contents of a shipment and its value, and a Bill of Lading (BOL) may not. For example, a BOL may indicate one pallet of canned food, but the invoice will declare that the purchaser paid for “50 cases of 6 containers each of #10 cans of green beans” and include the cost per container. Tying the Invoice and BOL together shows exactly what product was shipped in interstate commerce under the BOL. The BOL often refers to an invoice # and vice versa as well. The affidavit is critical to tie the two together.

Invoices covering in-transit shipments usually are not available. For these samples, 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 specific transportation record covering the shipment. The transportation record will generally be available after the shipment is delivered.

4.4.4.2 - Transportation Records for Common Carrier Shipments

Section 703 of the FD&C Act [21 U.S.C. 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 U.S.C. 374(a)] provides mandatory access, upon presenting your credentials and issuing a written notice of inspection, to documents covering the interstate movement of non-prescription drugs for human use, prescription drugs, and restricted devices. The authority applies to inspection of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs for human use, or restricted devices are manufactured, processed, packed, or held.

Note: At times, you may have only the name of the carrier (trucking company), with no address or phone number. If you are unable to locate the trucking company, contact the local office of the U.S. Department of Transportation (DOT) Federal Motor Carrier Safety Administration (FMCSA). Local contact information can be found at the FMCSA field office contact information website.

4.4.4.2.1 - 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 that it is required only after a written request is issued. If refused, after providing a written request as outlined below, politely explain that 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.

4.4.4.2.2 - Written Request For Records

If a carrier, consignee, or any other person refuses to supply I.S. records, and it is apparent they 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 it was obtained.

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

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

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

4.4.4.2.3 - Bill of Lading

The shipper who delivers the goods to the carrier for shipment, prepares the bill of lading (BOL), which is an order for the carrier to move the goods. When the carrier's agent signs the BOL, they acknowledge receipt for the shipment. The carrier's office in city of origin of shipment maintains a copy of the BOL. Information normally included on the BOL 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.

4.4.4.2.4 - 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 BOL, plus additional data about the carrier's handling of the shipment and costs involved. Railroads prepare freight bills at their destination offices, where copies can be made. Waterborne vessels and aircrafts may combine the BOL 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 they received the goods directly in interstate commerce.

4.4.4.2.5 – Waybill

The transportation company uses the waybill in its own operations, and it accompanies the shipment during transit. Copies are not generally 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/parcel services, such as Federal Express and United Parcel Service, may establish their own codes for air freight waybills. Air freight waybills may be referred to as air bills, airway bill or air waybills, depending on the company/service.

4.4.4.3 - Mail or Parcel Service Shipments

Record the facts obtained from the dealer on the FDA 463a, Affidavit, or FDA 463, Affidavit (Parcel Post/Service). See IOM Exhibit 4-9.

Collect shipping documents, including the shipping label, shipping details, and proof of delivery of the shipment. To obtain documentation for USPS shipments, ask the dealer where the sample is being collected, and ask the dealer to use the shipment label reference number to print the shipping documents from https://www.usps.com. If the article was shipped with Express Mail®, point-by-point tracking details are available. To obtain documentation for parcel service (for example, UPS and Fed Ex shipments, ask the dealer to use the “tracking number” to print the shipping documents from the parcel service’s website. Always attempt to collect copies of the original wrappings showing cancellation of origin office and address sticker if the dealer is the recipient of the shipment, since the recipient will usually not be able to print the shipping label. Wherever possible, collect an affidavit to link the carrier’s (for example, UPS, FedEx, etc.) tracking number document to the actual shipment and delivery documentation and attach to the collection report.

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

4.4.4.4 - 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. If possible, 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.

4.4.4.5 - Form FDA 1662, Copy of Invoice/Shipping Record

A Form FDA 1662 can be used to record invoice and/or shipping record information (see Exhibit 4-8). Invoice information can be entered in Section I, Copy of Invoice. For invoice information, record entries covering items sampled and indicate omissions by asterisks. If the invoice bears a Food and Drug guarantee, copy the guarantee on the back of the FDA 1662. Bill of Lading or Freight Bill information can be entered in Section II, Copy of Shipping Record. Enter the type of shipping record in Block 21. If only one section is used, leave the other section blank and submit the entire form.

4.4.5 – Affidavits

Statements on various affidavit forms may be obtained from individuals who have in some way dealt 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 individual who can testify in court to those facts, can be used either to establish federal jurisdiction or the responsibility for a violation. The statement may cover the following items: identify documents proving I.S. movement of goods sampled, name the individual who can testify to the identity of the goods sampled, and certify that the sample collected is from the lot of goods covered by the records. While these statements may be obtained from firm management, when possible, it may be necessary to obtain affidavits from other knowledgeable individuals if management is not personally aware of, and cannot testify to, such matters. See IOM 4.5.1 for additional requirements for Bioresearch Monitoring affidavits.

4.4.5.1 - 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 that they have read and understood the statement. A handwritten statement on the affidavit by the affiant, declaring that they have read and understood the statement, is a valuable tool to counter the possibility the affiant might later claim ignorance of what was signed.

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. See IOM 8.1.5.9.9

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

You should only sign the affidavit in the presence of and immediately after the affiant has signed it. As the wording on an affidavit above your signature reads, "Subscribed and sworn to before me at ***," with “subscribed,” in this context, meaning to attest by signing--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 that they have signed is true. You and the affiant should sign all pages of a multi-page affidavit. If you provide a copy of the affidavit to the affiant, it must be a copy and not the original, which now serves as an official FDA document.

If the affiant requests to have legal counsel review the document before they are willing to sign, and such review would not significantly delay the course of the sample collection or other activity, the affiant may make a copy of the unsigned document and provide it to their counsel. If the review will significantly delay the course of the sample collection or other activity, attempt to reach a mutually agreeable resolution with the affiant. If none can be reached, document the matter as a refusal to sign the affidavit. See IOM 4.4.5.3.

If the affidavit is signed, offer to provide a copy of the signed document to the affiant. Retain the original signed document for submission with the collection report. If a refusal is encountered to sign the affidavit, see instructions just below in IOM 4.4.5.3.

4.4.5.2 – Affidavits for Non-English or Limited English Proficiency Speakers

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

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

If the affiant requests to have legal counsel review the document before they are willing to sign, and such review would not significantly delay the course of the sample collection or other activity, the affiant may make a copy of the unsigned document and provide it to their counsel. If the review will significantly delay the course of the sample collection or other activity, attempt to reach a mutually agreeable resolution with the affiant. If none can be reached, document the matter as a refusal to sign the affidavit. See IOM 4.4.5.3.

If the affidavit is signed, offer to provide a copy of the signed document to the affiant. Retain the original signed document for submission with the collection report.

4.4.5.3 - 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 their own handwriting. Ask the affiant if the statement is true and correct. Ask them 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 their 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; it is only necessary to include this statement on the last page of the document. Detail the actions taken by both parties, such as: "I recorded the above facts as the affiant revealed them. The affiant then read the statement and avowed it to be true." Or, in contrast: "The affiant refused to read and sign the statement and stated their reason for refusing to sign was 'upon advice of corporate counsel.'" (An affiant might also refuse, claiming "corporate policy," or something similar, among other reasons). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit. Once the refusal is documented on the affidavit, it is not necessary to include any additional narrative under the "Refusals" heading of the EIR.

After the refusal has been documented, and if the affiant requests a copy of the unsigned affidavit, inform them that copies of refused affidavits are not routinely provided to firms, but may be requested under FOIA.

4.4.5.4 - Confidential Source

You should take special precautions when obtaining an affidavit from a confidential source or whistleblower. The affiant may be reluctant to sign a statement that reveals their identity. See IOM 5.4 for guidance on interviewing a confidential source or whistleblower.

4.4.5.5 - Affidavit (Dealer/Warehouseman FDA 1664)

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. You should also strike out the words or letters in parentheses that are not applicable.

Be certain that the dealer knows what they are signing. Before the individual signs the statement, they should be asked to affirm the affidavit is true and accurate.

4.4.5.6 - 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 they are qualified to make the statement. The facts can be arranged in an order roughly paralleling that of the FDA 1664. In general, a narrative that describes the events and circumstances chronologically is most manageable. Whatever format is used, the recorded facts must be intelligible to the reader unfamiliar with the transaction. See IOM Exhibit 4-7, 4-10, 4-11, 4-13 and 4-14.

Ascertain all the facts and record those that 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 by the affiant are an indication that they have read and understood the statement. A handwritten statement by the affiant declaring that they have 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, they 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.

4.4.5.7 - Affidavit (Jobber FDA 1664a)

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 that are not applicable.

Be sure the jobber knows what they are signing. Before the individual signs, they should be asked to affirm that 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.

4.4.5.8 – Affidavit (Parcel Post/Service FDA 463)

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

4.4.5.9 – Affidavit (In-Transit Sampling FDA 1664b)

See IOM 4.1.4.2.1 and 4.3.3.3 for definition and sampling procedures. When obtaining samples from in-transit lots, if it is a straightforward uncomplicated sample requiring no unusual explanations, the FDA 1664b, Affidavit (In-Transit Sampling) may be used. See IOM Exhibit 4-3. Otherwise, use the regular Affidavit, FDA 463a.

4.4.6 – Documenting Sample Manufacturing

During collection of a sample at a manufacturer or similar entity, collection of available manufacturing records may be warranted to help establish interstate commerce, document manufacturing issues, or for other reasons depending on the reason for sampling.

The records you collect should generally show the receipt of a component, part, or ingredient after shipment in interstate commerce; the use of that component, part or ingredient in the finished product that is being sampled, the acceptance and release of the finished product for shipment/delivery; and, where applicable, documentation of potentially significant deficiencies in those activities which may render the product adulterated or misbranded (301(k)). If documentation is not present in one or more of these areas, an affidavit from a knowledgeable individual may be collected in conjunction with other documentation to establish the manufacturing of the products being sampled.

When collection of manufacturing records is indicated, consider collecting the following types of records to support your sample:

- Receiving Records - Some firms may maintain a receiving log, receiving record, or an entry in an electronic system to indicate receipt of the components, parts, or ingredients used in production of an FDA-regulated product. Obtain documentation showing the receipt of at least one component, part, or ingredient used in the production of the finished lot, batch, or unit being sampled--such as a component that has moved previously in interstate commerce.
- Manufacturing records – Depending on the firm and the commodity, records showing the manufacture of finished products may vary, including documents referred to as batch records, device history records, etc. Obtain documentation showing the incorporation of the component, part, or ingredient above, into the finished product lot, batch, or unit being sampled.
- Acceptance records – Depending on the firm and the commodity, records showing the responsible individual(s) who accepted and released the products for distribution may be

present on a form, in an electronic system, in an email, or documented in some other manner. Obtain the documentation showing the authorization for release of the lot, batch, or unit being sampled.

- Manufacturing deficiencies – When samples are collected, particularly as part of an inspection, one or more potential deficiencies may be observed in the manufacturing process that could result in the products being adulterated or misbranded. Where this is known at time of sampling, obtain documentation supporting these potential deficiencies.

4.4.7 - Labels And Labeling

All samples collected must include copies of the product label and any other labeling associated with the product collected, unless the sample collected is unlabeled (for example, as with inline samples and INV samples).

Refer to Section 201 of the FD&C Act [21 U.S.C. 321] for the definition of *label* (201(k)) and *labeling* (201(m)).

Labels and labeling are critical to establishing FDA's jurisdiction over a food, drug, device, tobacco product, or cosmetic. In addition, labels/labeling are important for other reasons, such as determining which regulatory provisions and/or prohibited acts may apply to the product.

No special effort is needed to obtain copies of a label when it is affixed to the individual units collected. However, you should note that goods may be accompanied by labeling that is not affixed to the product, and in these instances, will need to obtain clear and complete copies of that additional/accessory labeling. You can obtain a copy of the original labeling by requesting an exact duplicate copy of the original from the dealer, or through photographing, scanning, or photocopying the original labeling. Even though your sample assignment may not specifically request the collection of accompanying labeling, you should still determine if such labeling exists--and if it is present--collect it.

Unless directed otherwise by your compliance program (CP) or assignment, collecting one clear and complete copy of original labels and labeling is sufficient. Scan or photograph the labels and labeling digitally so that they can be readily reviewed by various individuals located in separate offices. Do not collect the actual label or labeling if *only* one copy is available as this may inadvertently correct any misbranding that may be present or introduce misbranding via the removal of legally mandated information. Instead, if this is the case, take photographs or other copies of the single, actual label as described above. Furthermore, do not collect a *print proof* or any type of prototype as your copy of the original product label or labeling.

When documenting labeling violations, refer to the relevant Compliance Program or discuss with your supervisor if more than one original copy is required. Another means to achieve this is that a sample of product may be collected and its label stripped in order to obtain original labels.

4.4.7.1 – Definition: Labels and Accompanying Labeling

A label is a display of written, printed, or graphic matter appearing upon the immediate container of an article.

Labeling includes all labels and other written, printed, or graphic matter appearing upon any article, or any of its containers or wrappers, or accompanying (not necessarily affixed to) such article. Labeling includes such materials as--circulars, booklets, placards, displays, window streamers, books, article reprints, websites, instructions/directions for use, manuals, technical bulletins, etc.--that

supplement or explain a product and/or are part of an integrated distribution system for the product.

4.4.7.2 – Collection: Labels and Accompanying Labeling

When collecting physical copies of labels/labeling, request that the dealer identify collected copies of accompanying labeling with their initials and the date (Note: a manufacturer may be considered a dealer if the product being sampled is located at the manufacturer). This initialing and dating is important as it will identify these copies of labeling if they are introduced into court later. If the labels/labeling are obtained electronically, verify with the dealer that the provided files accurately represent the labels/labeling requested. In many cases, labels/labeling may change over time, so ensure that the copies provided are in fact relevant to the lot, batch, or unit sampled--particularly for documentary samples where the product and its labeling may no longer be present at the dealer.

Prepare a dealer's affidavit on the FDA 463a, being sure to include the relationship of the labeling to the goods. This affidavit should include the following information, where relevant:

- Description of Labeling – Describe, at least briefly, each piece of labeling by name or by using an identifiable quote. If labeling contains a revision number or other identifier, include that information (for example, a leaflet entitled, "Do You Have Tired Blood", a window streamer entitled, "Amazing New Tranquilizer", or an operator's manual entitled, "ABC Treatment Unit, Model 5600, Revision 1.2"). Also note the quantity of such labeling on hand, when relevant.
- Location of Labeling - Report the location of each different piece of literature and how much or many is at that location. If the labeling and the product are in functional proximity at a point of sale, provide diagrams or photographs of their relationship.
- Method of Distribution - Determine how the labeling is made available to consumers and/or the public. Describe how it is displayed, such as: for voluntary pick-up; mailed to prospective customers; distributed without being displayed; placed in the shipping container with each product shipment; etc. 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 (for example, e.g., to whom will it be sent and when).
- Source of Labeling - Describe who created/provided the labeling, such as whether the labeling was sent to the dealer by the shipper of the goods, or if the dealer prepared the labeling themself, or if it originated from another source. It is important to document this information to establish and "fix" responsibility in the event the agency pursues action against that individual/firm. It is not necessary to determine or fix responsibility in order to seize the goods. If the labeling may cause misbranding of the products being sampled, also document the shipment of the labeling, if a source other than the dealer supplied the labeling.
- Instructions to Dealer - The manufacturer or shipper may provide sales promotion instructions to the dealer. Obtain copies of such instructions if available.

4.4.7.2 - Bulk Shipments

Do not remove the label from bulk containers such as drums, barrels, and large bags, if this will result in misbranding the article. Instead, photograph or trace the label if none other is available.

Note: Besides using tracing paper, it is also 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 help highlight the tracing.

4.4.7.3 - Unlabeled or Partially Labeled Lot

The regulations provide for controlled shipment in interstate commerce of unlabeled goods, but only if:

- The shipper operates the establishment where the article is to be processed, labeled, or repacked.

OR

- The shipper, when not the operator of the establishment, has obtained from the owner a detailed written agreement signed by the operator. This 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 ensure that the article will not be adulterated or misbranded within the meaning of the FD&C Act, and upon completion of the processing, labeling, or repacking.

Determine if there is a labeling agreement and obtain copies of pertinent correspondence related to the agreement.

4.4.7.3.1 - 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 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.

4.5 - Bioresearch Monitoring (BIMO) Samples

Samples collected under the BIMO program primarily include bioequivalence samples. Collect and ship these samples per Compliance Program 7348.003, In Vivo Bioavailability/Bioequivalence Studies (Clinical), Section 8, Reserve Samples, and any specific instructions found in the assignment memo. In addition to CP 7348.003, special instructions for BIMO affidavits, collection reports, and sample shipment are included in the sections below.

4.5.1 - BIMO Affidavits

In the BIMO program, affidavits (FDA 463a) will generally be obtained to document violative conditions or unusual circumstances observed during an inspection. Additionally, an affidavit will accompany all sample collection reports, regardless of whether or not the firm provides a statement on company letterhead attesting that the test and reference product reserve samples are representative of those used in inspected BA/BE studies, and that they were stored under conditions specified in accompanying records (for example, protocol or labeling). The reason for this is because all bioequivalence samples are considered official samples, and as such must be accompanied by an affidavit.

4.5.2 - BIMO Collection Reports (C/Rs)

All subs collected for a bioequivalence sample, including investigational product, reference, and placebo, will be included on one collection report. A scanned copy of the collection report and all associated documents will be uploaded into eNSpect as an attachment to the EIR. Additional instructions specific to certain fields on BIMO C/Rs are as follows:

4.5.3 - Sample Type

The sample type for all bioequivalence samples will be "Official." Select "Domestic-Import," if applicable. Note that Domestic-Import samples are considered Official; this is just the way the drop-down menu is set up.

4.5.4 - Sample Description

Ensure that this field includes a description of the investigational product collected, as well as the reference and placebo if applicable.

4.5.5 - Reason for Collection

Reference the relevant compliance program (for example, CP 7348.003, "In Vivo Bioavailability-Bioequivalence Studies- Clinical"), the assignment memo, and the inspection dates if applicable. Note that there will not be a suspected violation for surveillance samples.

Then add the following statement and edit as appropriate: "Sample of bioequivalence investigational product, reference control, and placebo. Sample is representative of test product used in study supporting Protocol (insert Study #)." You will specify the analysis desired as follows: "Collected for drug assay analysis." Include the application number (for example, ANDA 12345).

4.5.6 - Associated Firms

List all firms related to the investigational product. Associated firms for the reference and placebo can be listed in the Collection Remarks field or on a continuation sheet.

4.5.7 - Product Code and Product Name

The product code and product name listed should be that of the test article.

4.5.8 - Brand Name

List the brand names for the test article, reference, and placebo, if applicable.

4.5.9 - Product Label

Quote the label and labeling from the test article, reference, and placebo (if applicable). Be sure to use Collection Remarks or a continuation if necessary and specify which labeling goes to which product.

4.5.10 - Sample Flags

There should be no sample flags for bioequivalence samples, unless the sample is a complaint sample. This is rare.

4.5.11 - Estimated Value

It may be difficult to estimate the value of a bioequivalence sample. If the firm is not able to provide you with the value of the lot remaining after sampling, use the estimated cost of the innovator if possible. If you cannot provide an estimate, leave the field blank and note in the Collection Remarks, "Estimated Value is unknown."

4.5.12 – C/R & Records Sent to FACTS Org

For domestic C/Rs, select your division from the list of values and send the hard copy C/R and all associated documents to Division of the collecting CSO when complete. For samples collected on foreign inspections, select the appropriate center/division (for example, CDER-CP for bioequivalence samples) from the dropdown menu and send the hard copy C/R and all associated documents to the center/division office contact specified in the assignment memorandum.

4.5.13 - BA/BE Sample Shipment

See assignment memo for current name/ address of laboratory performing sample analysis.

4.6 – Reporting Sample Collections (Completing your C/R)

For each sample collected, prepare a FACTS Sample Collection Report (C/R). Remember that the C/R is the basis for most administrative and regulatory actions.

The data you enter into specific fields of the report will provide the critical information needed by compliance officers to capably prepare documents for legal proceedings and to the analyst so that the correct analysis is performed. While there may be more than one right way to describe the information you are documenting, the readers of your collection report rely on your clear and complete descriptions to understand the specific situations you have documented. See IOM Exhibits 4-1, 4-2, 4-15, and 4-16 for examples.

Also note that if changes are needed to the firm data listed in FACTS, you should update the information in the Firm Management System (FMS) or contact your division's OEI coordinator for assistance.

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

Ideally, the C/R should be saved before the sample is shipped to the laboratory. Occasionally, you may have to ship a sample to the laboratory before saving the C/R. In these cases, at a minimum, the C/R must be saved before the sample is received by the laboratory. There are times when you will not be able to enter all information in a C/R before you need to save it. The following fields must be completed so that you can save the C/R in FACTS:

- Sample Class
- Sampling Organization
- 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
- C/R and Records Sent To

Before the lab will accept the sample, you must complete the following in FACTS:

1. Collector's Identification on Package and/or Label
2. Collector's Identification on Seal (if applicable)
3. Size of Lot
4. 704(d) (if applicable, see 4.6.2.9)
5. 702(b) (if applicable, see 4.6.2.9)

Only the collector has editing privileges for the signed, original sample collection record. As collector, you may modify the original record, but revisions should be minimized, and you must electronically sign each revision. All modifications of the original record are permanently retained as part of the original record. A permanent electronic record trail is created, capturing, and retaining every change to original and subsequent records. If retrieval of the sample collection data is needed, the original record and all changes to the original record can be retrieved. See IOM 4.5 for additional information for Bioresearch Monitoring sample collections.

4.6.1 – Sample Type

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 necessary, followed by the FACTS sample number.

4.6.1.1 – Additional Sample (ADD)

To identify an official physical sample collected from a previously sampled lot. However, do not report or document as an "ADD Sample" those instances when only additional records or documentation are obtained for the sample. See IOM 4.1.4.2.10.

4.6.1.2 - Audit/Certification

To identify an official 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 FD&C Act. See IOM 4.1.4.2.8.

4.6.1.3 - Documentary (DOC)

To identify an official sample comprised of documents and photographs, collected without a physical product. See IOM 4.1.4.1 and Exhibits 4-1 and 4-2.

4.6.1.4 - Domestic Import (DI)

To identify an official sample collected from foreign products, which have passed through Customs and entered domestic commerce. Note that the country of origin must be reported on the C/R. See IOM 4.1.4.2.5.

4.6.1.5 - Food Standards (FS)

To identify a sample collected to provide information on which to base Food Standards.

Note: Samples of standardized foods are not FS Samples.

4.6.1.6 - Investigational (INV)

To identify a sample collected to document observations, and/or where interstate commerce does not exist or is not necessary (for example, environmental swabs, filth samples). See IOM 4.1.5.

4.6.1.7 - Mail Entry

This sample type is only for import operations and should not be selected in FACTS. (See IOM 4.1.4.2.4.2)

4.6.1.8 - Non-Regulatory

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

4.6.1.9 – Official

To identify a sample that is representative of a lot of any product covered by the FD&C Act for which interstate commerce can be documented. See IOM 4.1.4.

4.6.1.10 - Post Award

To identify an official physical sample collected under the Government-Wide Quality Audit Program (GWQAP).

4.6.1.11 – Post-Seizure (PS)

To identify samples collected pursuant to a court order from a lot under seizure. See IOM 4.1.4.2.3.

4.6.1.12 - Regulatory

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

4.6.2 – Preparation

The 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.

The fields described below are listed in alphabetical order for your ease of reference. (See Exhibit 4-25 for the fields listed in FACTS entry order to facilitate completing a C/R. Please note that when a PDF C/R is generated, the field names may change on the report.)

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

4.6.2.1 - 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 individual is involved in the collection, add their time by clicking on the "Add" button. See IOM exhibit 4-16 page 2.

4.6.2.2 - Analytical Assignment

Select the “beaker” icon on page 2 and enter the sample Collection PACs, Analysis PACs, PAF (Program Area Flag) and Lab Organization for your sample. Select the PAC and PAF based on the sample assignment, compliance program, or other guidance as appropriate. Select the Lab Organization based on the LST Dashboard, the sample assignment, compliance program, or other guidance as appropriate. Note that the analytical PAC and PAF may be different from the collection PAC and PAF. Enter any 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.

4.6.2.3 - Brand Name

Enter the brand name of the product. This is typically found on the labeling of the product (for example, “Blue Bunny” carrots). For medical devices, additional research may be required to determine a brand name. It is important to identify the product completely so that the compliance officer can communicate accurate information to the relevant court and U.S. Marshal in the event of a seizure.

4.6.2.4 - Carrier Name

Enter the name of the transportation company that transported the goods in interstate commerce (if known at the time of preparation of the C/R). 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 that moved the component you are documenting across state lines. For a 301(a) sample, used to document 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. Note that a transportation company is not to be confused with a shipper which is an establishment type and the entity responsible for causing the interstate movement of the product. See IOM 4.1.3.4.

4.6.2.5 - Collection Date (Date Collected)

Enter the sample collection date using the format, mm/dd/yyyy. Note that the default date is today's date—and to be careful not to use the default date if the sample was not collected on the date the C/R is created.

Only one date can be entered if the sample collection was accomplished over several days, use the last day of the sample collection. This date should be used to identify the physical sample and any records attached to the C/R. However, you can use the Collection Remarks section to note the additional dates and any other relevant information associated with an extended, multi-day sample collection.

4.6.2.6 - Collection Method (Method of Collection)

Describe how you collected the sample and which subs are the 702(b) portion, if applicable (See IOM 4.3.2.2 and 4.3.2.3.). Relate the number and size of the sampled units and subsamples to show how each was taken; note any special sampling techniques used; and completely describe the collection method of each sub of selective samples with multiple subsamples, including your observations of the conditions. 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 4.7.2.1 regarding sub identification.

Example descriptions:

- "Two cans of product randomly collected from each of 12 previously unopened cases selected at random."
- "Subs collected using aseptic technique and placed in sterile glass jars or whirl-packs"
- "Subs 1-10 consist of approx. 1# of product. Subsamples 1-10 collected from bulk storage Bin #1 composited in unused, brown, paper bag."
- “Two live insects collected from seam of bag #2. Live insects were observed exiting bag, and two were collected upon exit.”

4.6.2.7 - Collection PACs

Select the appropriate Program Assignment Code (PAC) from the list of values. Select the PAC based on the sample assignment, compliance program, or other guidance as appropriate.

4.6.2.8 - Collection Reason (Reason for Collection)

Enter the reason for sample collection to include the compliance program and/or assignment directing the sample collection; the analysis desired; the suspected violation, if any; and if collected during an inspection to document violations state such and indicates the date(s) of inspection. Identify any inter-division, regional, headquarters initiated, assignment document(s) in sufficient detail so the document can be located, if necessary. See IOM Exhibits 4-1 and 4-16.

4.6.2.9 - Collection Remarks

Enter any remarks you feel are necessary and describe any special circumstances related to the sample. You may also use a "C/R Continuation Sheet", FDA 464a if you need more space.

The following information is required if applicable (this list is not meant to be all inclusive):

- If a 704(d) [21 U.S.C. 374(d)] letter is indicated, include the name, title, email address (if available), and the telephone number of the most responsible individual at the firm to which the analysis results letter should be addressed. (IOM 4.6.2.59)
- If a 702(b) [21 U.S.C. 372(b)] portion is required per the compliance program, assignment, or policy--but is not collected--describe the specific circumstance and justification for not collecting the 702(b) portion. (IOM 4.6.2.58)
- If the sample is an in-transit sample, state as such, and include the name of the individual (for example, the driver) and the firm carrying the good, their telephone number, email, as well as the location where you collected the sample.
- If the dealer firm is a consumer, report the name, address, phone number and email of the consumer. Include a remark to indicate if the consumer has requested information about the analytical results (see IOM 8.1.3).
- If the sample is an environmental sample of a firm, where human and/or animal food is manufactured, processed, or packed, include the name, title, email address, and the telephone number of the most responsible person at the firm to which the analysis results letter should be addressed. Note: Do not check the 704(d) box in FACTS (see 4.6.2.59). Environmental samples do not meet the criteria of 704(d) but FDA provides the sample results to firms. Sharing these sample results is done by HFP for human foods and it is not a responsibility of OII.

- If the dealer is voluntarily holding the sampled product, include the name, title, email address, and the telephone number of the most responsible person at the firm to which the analysis results letter should be addressed. Note: Select the appropriate flag in FACTS as described under 4.6.2.27.3.
- If the sample is not sealed on the same day it was collected, describe the reason for the delay and the storage conditions you've employed to ensure the chain of custody of the sample will be maintained.
- If the sample is submitted to a non-FACTS affiliation entity (for example, a state) for regulatory action, provide the reason you submitted it that entity. (See IOM 4.6.2.16)
- If the sample is flammable, identify the flash point in °F or °C.

4.6.2.10 – Collector

As collector, your name will auto populate here.

4.6.2.11 - Collector's ID on Package/Document

As the sample collector, quote your identification placed on the packages, labels, etc. (for example, "55563 12/5/05 SHR"). Samples are to be quoted with the information in the order shown in the example without additional symbols, words, or characters. See IOM 4.7.2.3. 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. You may include the sub numbers used in this block outside of the quotes (for example, "55563 12/5/05 SHR" subs 1-30).

4.6.2.12 - Collector's Id On Seal

Directly quote the identification you used on the Official Seal applied to the sample (for example, "55563 12/5/05, Sylvia H. Rogers, Investigator" Be sure, as in the example, to include your title too. See IOM 4.7.4 and Exhibit 4-17. If you use the FDA metal seal, enter the words "Metal Seal" followed by the seal identification and number (for example, "U.S. Food and Drug 233"), entering the actual number of the seal used.

The Collection Remarks field should be used to describe any discrepancy between the date the sample was sealed and the date it was collected, as normally, the sample should be sealed on the same day as it's collected.

4.6.2.13 - Consumer Complaint Number

If the sample relates to a consumer complaint, select the Sample Flag for Complaint sample and enter the complaint number in the Sample Flag Remarks. That way it is easy to identify what Complaint the CR is related to and more accessible on reporting.

4.6.2.14 - Country Of Origin

Select the country of origin, if known. This field is particularly important when the sample is a Domestic Import Sample.

4.6.2.15 – County

Select the county where the sample was collected (or grown, if a pesticide sample of an agricultural product, for instance). This field is particularly useful with regards to pesticide samples as it can aid later communications with state officials, in the event of a violative result. Generally, though, this field is usually not applicable for most samples.

4.6.2.16 – C/R & Records Sent to FACTS Org (Orig C/R & Records To)

Enter the District Office of the collecting CSO associated with the sample. This field requires some thought on your part, as collector, in consultation with your supervisor. For a 301(k) sample in which the dealer is responsible, this is the division where the sample was collected. Additional notes for consideration: Do not assume the address on the label is the location where follow-up to a violative sample will be initiated, and do not send the records to another division unless you know it is the division of the actual responsible firm. Field survey samples will be filed by the collecting division. When a non-FACTS affiliation (for example, a state) is selected, provide the reason for doing so in the remarks section.

For foreign human and animal food sample collections, select FOR-HFP as the division from the dropdown menu and send the hard copy C/R and all documents to the Division of Foreign Human and Animal Food Operations.

4.6.2.17 – Controlled Prescriptions and Drug Scheduling

Controlled Prescriptions (CRx) follow a schedule set by the Drug Enforcement Agency (DEA). Details can be found at DEA Drug Scheduling. Choose the appropriate schedule from the list of values, if applicable.

4.6.2.18 - Dairy Permit Number (Permit Number)

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

4.6.2.19 - Date Shipped

Enter the date of interstate shipment in the format, mm/dd/yyyy, if known. 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.

4.6.2.20 - 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 individuals signing any affidavits in the Remarks field. Be sure to describe the reason each document attached to the collection record was obtained. (For example, when referring to a bill of lading, indicate that it was collected to document the interstate movement of the product.) Also, indicate which documents were collected to document specific violations encountered during inspections. State the number of pages for each document if it contains more than one page and refer the reader to the appropriate section/page of the document that 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 (for example, an 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 (as guided by your supervisor or center compliance office). This section may also be used to list C/R attachments, including FDA-generated forms. See IOM Exhibit 4-1.

4.6.2.21 - Episode Number

Enter an episode number if applicable. This is a number related to pesticide samples, see IOM 4.6.2.27.8.

4.6.2.22 - Estimated Value

Enter the estimated wholesale value of the lot remaining after sampling. Obtain this information from invoices or other records. (Note: this is not the value to be used for seizure bond purposes; however, it may be used by the division to evaluate whether seizure is an appropriate action.) Provide a best guess 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 that is representative of what was shipped.

4.6.2.23 - FEI Number

The FEI number is a unique identifier used to identify firms associated with FDA-regulated products. Enter the FEI, if known, or use the "B" button to query FMS and find the FEI for the firms associated with your sample. If an FEI does not exist, you may need to add the firm to the FMS. Take care in entering search criteria to avoid creating unnecessary FEI numbers--consult your division OEI coordinator for assistance. Note that you must enter an FEI for a dealer on every C/R, unless you check the box indicating the dealer is a consumer.

4.6.2.24 - Firm Name

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

4.6.2.25 - Firm Type

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

4.6.2.25.1 – Dealer

This is always the firm from which the sample was collected. There must be a dealer entered on every C/R, 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. However, there are circumstances in which 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 4.1.4.2.1), enter the consignee of the lot as the dealer and be sure to state in the Collection Remarks field that the sample was collected in-transit, and from whom sample originated (for example, name of driver and their carrier firm), and where sampled.

4.6.2.25.2 – Grower

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

4.6.2.25.3 – Harvester

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

4.6.2.25.4 - Ingredient Supplier

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

4.6.2.25.5 – 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 this case, you can enter the FEI *twice* and identify it as both the manufacturer and the dealer.

4.6.2.25.6 – Repacker

A repacker is a firm that repacks FDA-regulated products without manipulating the product or relabeling it.

4.6.2.25.7 – Shipper

The shipper is the firm responsible for causing the interstate movement of the product. Note this is not to be confused with the Carrier, the entity physically moving the product interstate.

4.6.2.26 - 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.

4.6.2.27 – Flag

Flags are used to alert readers of your C/R to what the sample is documenting and any special circumstances related to that sample. The Sample Flag will be printed at the top of your hard copy C/R. For example, when you collect a 301(k) sample, the flag will indicate that this is a 301(k) sample and alert the reader to the fact that you are documenting adulteration after shipment in interstate commerce. The following situations require an entry in the Sample Flags screen in FACTS (See IOM 4.6.2.49 and Exhibit 4-15):

4.6.2.27.1 - 301(K) Sample

Use this flag when the sample meets the definition of a 301(k) sample (IOM 4.1.4.2). Use the Flag Remarks field to state the product or ingredient that you documented as moving in interstate commerce.

4.6.2.27.2 - Complaint Sample

Use this flag for any sample collected from a complainant during follow-up investigation. Record the complaint number in the Sample Flag Remarks.

4.6.2.27.3 - Dealer Voluntarily Holding

Use this flag when the dealer is voluntarily holding product until sample results are received. This information will be important for the compliance officer to know when preparing a seizure or other regulatory action. This information needs to be entered as soon as the C/R is created, so the laboratory can adequately prioritize sample analysis and provide a timely notification to the firm.

4.6.2.27.4 - Exhibit Sample

Use this flag when the sample is to be used exclusively for court exhibit, without analysis.

4.6.2.27.5 - Factory Food Sample

Use this flag when sample(s) of any item, used in the production of any food product, are taken during the establishment inspection. However, do not use this flag for finished product samples or for environmental samples. See IOM 4.3.6.6.3.

4.6.2.27.6 – Fumigated

Use this flag when the product has been fumigated by the FDA prior to shipping, see IOM 4.7.3.1. Enter the name of fumigant in the Flag Remarks field. However, do not use this flag for products that may have been fumigated by someone else prior to sampling.

4.6.2.27.7 - Inv. Samples Of Filth Exhibits

Use this flag when the sample consists of filth (for example, gnawings, excreta pellets, wood splinters, etc.) collected from a product or its environment. These samples are Investigational Samples and the prefix INV is added to the sample number when identifying.

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

In a food firm = 52YY-99	**In a drug firm = 66Y--99**
52 = Misc. food related items	66 = Misc. drug related
Y = Exhibits	Y = Exhibits
Y = Sub class - None	- = Dash
- = Dash	- = Dash
99 = Evidence exhibits n.e.c.	99 = Evidence exhibits n.e.c.

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

4.6.2.27.8 - 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 sample was grown, must be entered in the appropriate fields in the Collection Record.

Pesticide Episode – Such an "episode" is defined as a violative finding associated with a pesticide, or other chemical contaminant, 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 (for instance, growing season).

Here are a few examples of pesticide episodes and points of clarification:

- Samples of cantaloupes from Mexico reveal violative residues. Note: Any destination point samples or subsequent compliance samples from the same shipper or grower, along with the original sample, would be considered an episode.
- Grower Jones has violative residues of chlorothalonil on collards for which there is no tolerance. Note: Field samples, I.S. samples, and packing shed (or warehouse) samples of these collards would all be part of the same episode.
- Grower Jones also has violative residues of omethoate on kohlrabi that are discovered about two months later. Note: This is a separate episode.
- Along with the omethoate on kohlrabi, Grower Jones has violative residues of omethoate on beets. Note: Normally this would be considered a separate episode from the previous episode; however, if information is or becomes available showing that both residues resulted from the same application of the pesticide, or that the residues are/were closely related in some other way, the beets might be considered as part of the kohlrabi episode.
- Grower Smith has violative residues of disulfoton and permethrin on kale. Note: This would be considered one episode because only one commodity is involved.

Also note that the Episode Number will be the sample number of the first violative sample collected in a series of samples and is used to identify the other related samples within an episode. The division must ensure that the same and correct Episode Number is used within the division, and any other divisions, involved in any follow-up to the original violative sample. This number must appear in the Episode Number field of the FACTS C/R.

Note for Imports: The *detention without physical examination* procedures provide for recommending detention based on a single violative pesticide finding. (See RPM Chapter 9-6.) Given these procedures, we can anticipate that the number of compliance samples collected in follow-up to a violative finding should likely diminish appreciably and, in most cases, will be limited to occasional audit samples. These follow-up 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.

4.6.2.27.9 – Produce Related Result Requested

Use this flag when samples are collected of Raw Agricultural Commodities.

4.6.2.27.10 – Public Land Sample

Used primarily by the produce program. Samples collected on public land (not owned by any firm or farm). Use this flag for public water samples.

4.6.2.27.11 – Reconditioned

Use this flag when a sample is collected in connection with a reconditioning operation in accordance with a court order.

4.6.2.27.12 - Split Sample

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

4.6.2.27.13 - Survey Sample

Use this flag for any sample collected under a compliance program or assignment that identifies the samples are collected as part of a survey. Also, use this flag for any sample collected under the Drug Surveillance Program (CPGM 7356.008); in which case you should enter the survey number in the flag remarks section. Note that SCOPE and Total Diet Study samples are not generally considered Survey Samples.

4.6.2.27.14 - Under State Embargo

Use this flag when the lot is being held under state embargo. Enter the point of contact, their contact information, and how long the embargo is in effect, in the Flag Remarks field.

4.6.2.28 - Food Canning Establishment

Enter Food Canning Establishment Number if applicable. Information on Food Canning Establishment registration can be found at: Food Canning Establishment Registration Information.

4.6.2.29 - Hours

This is automatically populated on the hardcopy C/R based on your Accomplishment Hours (See IOM 4.6.2.1).

4.6.2.30 - How Prepared

Explain how the sample was prepared prior to submission to the laboratory, including how you identified some or all of the units, and how you wrapped and sealed the sample. Also, note any

special preparation methods, such as fumigation, freezing, refrigeration, etc., and the state in which the sample was delivered to the laboratory (for example, in paper bags, original container, etc. If coolants or dry ice were used, also indicate that here. It is important to be specific about how you protected the integrity of the sample and the chain of custody (for example, “Subs identified as noted, placed in unused, brown paper bag; bag taped shut and FDA seal completed (as noted) and applied, bag identified as noted in pen/ink. FDA 525 attached to sealed bag, placed in brown, cardboard box and prepared for shipment, then delivered to division security guard desk for UPS pick-up”). If a 702(b) portion is collected, describe how that portion was handled and prepared as well. See IOM 4.3.2.2 and 4.3.2.3. If the sample was collected by multiple participants, clearly explain which steps were performed by each participant.

4.6.2.31 - Lot Size

Enter the amount of goods that were on hand before sampling as determined by your inventory of the lot. Include the number of shipping cases and the size of the components with units (for example, 75 (48/12 oz.) cases, 250/100 lb. burlap bags, 4/100,000 tab drums, 24 cases containing 48/12/3 oz. Tins). Note that some programs require specific units here to evaluate appropriate sampling size (e.g., mycotoxins lot size in lbs. or fluid ounces).

For DOC samples (see Exhibit 4-1 and 4-2) indicate the size of the lot manufactured as described in the records collected, e.g., “one x-ray machine” or “5000 syringes.” In the remarks section, describe the amount of any product remaining on hand at the time the DOC sample was collected.

If accompanying literature is involved, for either a DOC or physical sample, describe and state the amount on hand (for example, “5000 syringes and 1000 promotional brochures”).

4.6.2.32 - Manufacturing Codes

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

Enter any expiration dates in the Exp. Date field.

4.6.2.33 - National Drug Code (NDC)

Enter if applicable.

4.6.2.34 - Payment Method

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

4.6.2.35 - Product Code

Enter the 7-character product code, consulting the Product Code Builder for guidance. Note, too, that when 301(k) samples are collected, the full product code of the finished product must be entered. See IOM Exhibit 4-1. See IOM 4.6.2.27.7 for product codes for filth or evidence exhibits. Other special product code considerations include environmental samples. See environmental sample identification instructions under IOM 4.3.6.6.2.

4.6.2.36 - 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.

4.6.2.37 - 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 an Rx or non-Rx. Quote sufficiently from accompanying literature to fully identify. In the case of a DOC, sufficiently describe the article to adequately identify what has been sampled.

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

When quoting from a label, or labeling, use exact spelling, capitalization, punctuation, arrangement, etc., as found on the original label/labeling. Do not insert [sic] within the quote to highlight when a word is misspelled. Use asterisks in a series of three (***) to indicate any omissions.

4.6.2.38 - Product Name

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

4.6.2.39 - Recall Number

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

4.6.2.40 - Receipt Issued (Receipt Type)

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

4.6.2.41 - 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.

4.6.2.42 - 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.

4.6.2.43 - Sample Basis

Select from the two choices, as described below, on the list of values.

"Compliance" means the sample was collected on a selective basis as the result of an inspection, complaint, or other evidence of a problem with the product. "Surveillance" means the sample was

collected on an objective basis where there was no inspectional or other evidence of a problem with the product.

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

4.6.2.44 - Sample Class

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

4.6.2.45 - 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 that they will bill you later, enter the estimated cost in this field and state that it is an estimate in the Collection Remarks field.

4.6.2.46 - 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.

4.6.2.47 - Sample Delivered To

Enter the person 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 in-person to an analyst, report "In person to Analyst Richard R. Doe." If you shipped the sample, enter the name of the carrier to whom the sampled was delivered. Also, enter the carrier shipment tracking number. If the sample is shipped by air, enter the air waybill number. If shipment is by parcel post, give the location of the post office (for example, "P.P., Austin, TX") For a DOC sample, this field may be left blank. If the sample is being sent to a non-FACTS laboratory, enter the laboratory here.

4.6.2.48 - Sample Description

Briefly describe what the sample consists of (for example, three unopened, 200-tablet bottles; 20 lb. case of iceberg lettuce; or DOC sample consisting of records, literature, and photographs, etc.).

4.6.2.49 - Sample Flags

Click on the "Sample Flags" button to choose an appropriate flag using the list of values. See IOM 4.6.2.27 and Exhibit 4-15.

4.6.2.50 - Sample Number

Select the pre-assigned sample number using the list of values. Be certain the Sample Number matches the one you used to identify the sample. If no value is selected the system will generate a sample number when the record is saved.

4.6.2.51 - Sample Origin

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

4.6.2.52 - Sample Sent To

Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORS Sample Distribution site. See IOM 4.6.4. 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.

4.6.2.53 - 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 4.6.1.

4.6.2.54 – Sampling Organization

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

4.6.2.55 – State

Select the state from where the sample was collected. If the dealer firm is a consumer, select the consumer's state.

4.6.2.56 – 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.

4.6.2.57 - Storage Requirements

Select from the following list of values:

- Ambient – Used to indicate product is stored under conditions in which the temperature is not controlled.
- Frozen (self-explanatory).
- Refrigerated (self-explanatory).
- Flashpoint – Used to designate the flashpoint of a flammable substance (Identify the flash point in °F or °C in the 'Remarks' section).

Note: This field is not required for DOC samples.

4.6.2.58 - 702(b) Portion Collected

Check this box if the sample you collected contains a 702(b) portion of any food, drug, or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. This includes samples in which 1) the sample schedule already accounts for the 702(b), 2) you collected in duplicate and separated the duplicate out, or 3) you collected in duplicate and did not separate the duplicate out. If you did not separate the 702(b) portion, note this in the remarks so the

laboratory can separate the 702(b) portion. If no 702(b) portion was collected, do not check this box and provide reason for non-collection in the Collection Remarks section (See IOM 4.3.2.2 and 4.3.2.3).

4.6.2.59 - 704(d) Sample

Check the 704(d) box if all answers to the following questions are "yes,":

1. Was the sample collected a food?
2. Was the sample collected during an inspection?
3. Was the sample collected from an establishment where food is manufactured, processed, or packed?
4. Was the sample collected to ascertain whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food?

Note: Guidance on 704(d) is provided in FMD-147 including examples of what constitutes "unfit for food".

Include in the Collection Remarks the name, title, email address (if available) and telephone/fax number of the most responsible person at the firm. See also IOM 4.6.2.9.

4.6.3 –Lab Servicing Table (LST) Dashboard

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

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

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

4.6.3.1 – Other Information

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

Additional information on sample collections and laboratories, including assignments, SCOPE and contacts, can be found at the link to Field Guidance.

Also reference 4.7.5.4 - Routing of Samples.

4.6.4 – 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

email, 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.

Follow division or program procedures for submitting C/Rs. If there is no established procedure, forward C/R from FACTS and original hardcopy or electronic records through your supervisor to the division office compliance branch most likely to take regulatory action.

4.7 - Sampling: Preparation, Handling, Shipping

4.7.1 – Objective

The preparation, handling, and shipping of samples is your responsibility, and must be carried out in a manner that assures the sample's integrity and supports testimony that the sample examined was the same sample you collected from the documented shipment. Samples need to be kept under lock, or in your possession, until sealed.

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

4.7.2 - Identifying Marks

4.7.2.1 – Subsamples

Identify a representative number of subsamples (subs) with the sample or entry number (including prefix, if appropriate), collection date, and your initials. If individual sub identity must be maintained, assign and mark each sub with a separate number. 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 or entry number, fully identify each sub and describe them on the C/R. Subsamples from an INV sample 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, 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, your initials and collection date--on peel-off labels, tape, etc., in advance of sampling to save valuable time.

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

4.7.2.2 - 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 (for example, a sample bearing a sticker label that can be peeled off).

4.7.2.3 - Identification Techniques

Mark a representative number of subsamples with the sample or entry number, collection date, and your 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 is the one to initial the subs. After identifying them, reinsert circulars removed from packages. See IOM 4.3.1.2 for procedures on identifying lots from which sample was taken.

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 then covering the identification with transparent tape for protection.

Fine point Sharpie (permanent ink markers) may be used on paper labels. Note, too, that permanent ink markers freeze at a lower temperature than ball point pens and other markers when you find yourself sampling in freezers, or outside when it is below freezing (32°F/0 C). Do not use permanent-type markers when identifying subs in absorbent containers as the ink may penetrate into the product and contaminate the sample (for example, flour in a bag with no outer plastic layer).

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

4.7.2.4 – Photographs

Unless they are part of a DOC Sample or are used to show labels or labeling, 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, including those of labeling, records, or the product, are identified with the sample or entry number, collection date, and initials. If photos are printed direct from film, identification of the original photo should occur on the border or backside. See IOM 4.4.2. Attach any photos to the FACTS Collection Record.

In describing photographs, do not mark the face of the print. Narrative descriptions may be placed on the mounting paper *next to* the print or, if explanatory graphics are required, you may use a plastic overlay. See IOM 5.6.7.5 for negative identification and submission procedures, and IOM 5.6.7.5 for digital photos.

For imports photographs: See IOM 6.1.8– Photographs: Identification and Storage.

4.7.2.5 - Records - Accompanying Literature and Exhibits

Identify all copies of sample records, accompanying literature, and attached documents with the sample or entry number (including prefix, if applicable), collection date, and your initials, as described in IOM 4.4.2. If an attached document is more than one page in length, it must be

numbered or attached in a manner that will always allow future reviewers to determine if any pages are missing. For example, numbering pages as in “1 of 10,” or “2 of 10,” etc., will let the reviewer know that a total of 10 pages should exist in the attachment.

4.7.3 - 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 (for example, analyzing milk for drug residues). If you are not sure about any handling procedures, please check with the relevant laboratory. Products requiring refrigeration (for instance, fresh crabmeat undergoing bacteriological analysis) should be shipped in ice. Some products may be collected at room temperature but will need to be refrigerated or shipped under refrigeration. For example, this includes raw agricultural products collected in the field for microbiological analysis. Use your experience and knowledge to determine the most appropriate packing and shipping method and consult with the analyzing lab about any questions you have regarding sample handling.

4.7.3.1 – Fumigation

See IOM Safety Chapter regarding fumigation and preparing samples using fumigation (IOM 10.12.6.2).

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), are an alternative fumigant. However, do not use mothballs or moth flakes containing naphtha or naphthalene. Also, 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 by applying to a cotton ball that is placed inside an appropriate container; or by cutting small portions of commercial pesticide strips that are also placed in an appropriate container.

4.7.3.1.1 - Fumigation Safety Precautions

Follow safety precautions when fumigating samples. Contact your local servicing laboratory or l Safety Data Sheet (SDS) for the appropriate protective gear and handling of fumigants. Additional guidance:

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. Ensure that DOT regulations and guidance and International Air Transport Association (IATA) guidelines are followed when mailing or shipping samples containing a fumigant or preservative. Exceptions applying to small quantities are listed in 49 CFR 173.4.

4. The sample identification data on your packaging, the FDA-525 and C/R, must always identify the fumigant and method of fumigation, and/or preservative used.
5. Safety Data Sheets (SDS) 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 SDS.

4.7.3.1.2 - 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 reopen 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.

4.7.3.1.3 - Exceptions To Fumigation

When submitting samples or exhibits to show *live* infestation, do not fumigate. Be sure to 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. Also, do not fumigate samples submitted for pesticide residue analysis.

4.7.3.1.4 - 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 as glycerol). These chemicals can be obtained from your servicing laboratory. Do not collect rodents or animal tissues unless specifically instructed. Ensure 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 the preservative used on FDA 525, C/R, and on sample container. Enclose a copy of the SDS with the shipped sample. Follow DOT and IATA guidelines when shipping or mailing samples with preservatives as stated under Fumigants.

4.7.3.2 – Samples for Label and Labeling Review

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

Samples may alternatively be collected of the product and the label field-stripped from the container. The product can be destroyed either onsite where it was collected, or in the office. The stripped label could also be submitted as part of a DOC sample. (See IOM 4.1.4.1). Be sure to document in your C/R all actions related to stripping the label and destroying the product.

4.7.3.3 - 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.

4.7.3.4 - 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.

4.7.3.5 - Frozen Samples

You should pre-chill sterile containers before collecting frozen samples. Also, transfer liquids in glass to expandable containers before freezing. If the liquid must be frozen in glass, leave sufficient headspace to allow for expansion. If freezer facilities are not available or if the sample is to be shipped, pack with dry ice in insulated containers. Note: Dry ice may be obtained from ice cream or dry ice dealers.

Your district office or resident post should have insulated shipping containers on hand, but if there are none, economical polystyrene (Styrofoam) containers are available at most variety stores. However, most polystyrene containers are not designed for shipping so will need to be packaged carefully inside shipping cartons to protect them during shipment. Note: If your division desires the return of Styrofoam freezer chests or ice packs used in shipping samples, note this fact on the C/R and FDA 525.

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

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.

4.7.3.5.1 - Shipping Frozen Samples

If using a U.S. Government BOL, 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 sample separately.

Dry Ice Guidance

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. However, 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 as the extreme cold generated by the dry ice may cause the plastic to become brittle and rupture.

All shipments involving dry ice should be next day or sooner delivery. Tests have shown the following amounts of dry ice will be adequate when this method is used:

For samples already in frozen state: 5 to10 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 following practices for shipping dry ice with respect to CFR 49, the International Air Transport Association (IATA) regulations, and the UPS Dangerous Goods Agreement:

For non-medical, non-hazardous U.S. domestic air packages with 2.5 kg (5.5 pounds) or less of dry ice, mark the outer carton in the following way using in prominent one-inch block letters:

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

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

1. **Indicate in Campus Ship that you will be shipping dry ice or attach "**Hazardous Materials" shipping papers available from the carrier (note that a $8 per package of dry ice fee applies).
2. The package must be prominently marked in one inch block letters as containing "Dry Ice" or "Carbon Dioxide, Solid", UN1845 (See: IOM Exhibit 4-19).
3. A label identifying dry ice contents is available from the carrier (for an example, see IOM Exhibit 4-19).
4. The net weight of dry ice at the time of packaging must be indicated on the shipping papers and can also be marked on the outer package prominently in one-inch block letters.
5. UPS Dangerous Goods Agreement is required here. A UPS "Dangerous Goods Agreement," available from the shipper, is required to be filled out and provided to the shipper at time of shipment.

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

See IOM 4.7.5.6 when shipping sample packages containing hazardous or toxic items by air.

4.7.3.5.2 – Control

If it is necessary to ensure the shipment does 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. Be sure to note this approach on the C/R and ask the sample custodian to ensure that the ice remains frozen.

4.7.3.6 - 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 product to maintain the required temperature range.

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

4.7.3.6.1 – Control

If it is necessary to show the sample temperature did not go above the desired or specified temperature, you can use one of several methods, such as including a pre-chilled, shaken-down, maximum reading thermometer or a commercially available indicator. 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.

4.7.4 - Official Seals

Domestic samples (excluding DOC samples) should be sealed with form FDA 415a, Official Seal, or, in some situations with the FDA Metal Seal. See IOM 4.7.4.6 for use of metal seals.

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 other 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 or ship your samples on the date collected so that the C/R, sub identification, and the final official seal bear the same date, and thus enhance sample integrity. However, if you cannot finish sample preparation on the same day it was collected, you must explain in the C/R Collection Remarks field what steps you took to protect the integrity of the sample (for example, I sample was officially sealed and locked in supply cabinet, or locked in safe, etc.). If you cannot ship the same date as collected, you should at least complete identifying the subs and sealing the container on that day. In cases where subs need to be identified on the next day before shipping, use an Official Seal to seal the subs. On the next day, you can break and sign the seal. Explain in your regulatory notes and attach the broken seal to your C/R.

Never place more than one sample in the same officially sealed package. Large samples with numerous subs may be split into two or more containers with more than one official seal. When a 702(b) portion is collected, it is advisable to use at least two containers with one container containing only the 702(b) portion. Clearly identify the container holding the 702(b) portion so that the lab analyst does not unintentionally break the seal and open that container. Separate official seals should be applied to each container.

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

official seals that are more than 5 years beyond the expiration date indicated by the manufacturer of the seal.

4.7.4.1 – Preparation of Official Seal

Inscribe the FDA 415a, official seal, with the division office name, sample number (with the appropriate prefix), the date applied, and 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.

4.7.4.2 – 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 (for instance, container is a waxed container, frosted over, or sweating, etc.), then wrap or place the sample in a container to which the official seal will hold. See IOM 4.7.4.6.

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

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

After applying the seal, you can take a photograph of it, in case it is damaged in shipping or if there the analyst notes an error in the transcription onto the C/R. The photograph may be, but does not need to be, attached to the C/R.

4.7.4.3 - Sealing Method

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

4.7.4.4 - 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:

- Covering the official seal with a sheet of heavy wrapping paper or heavy clear plastic (for example, like that from a document protector) of sufficient size to cover the surface of the official seal.
- 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.

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 that the official seal is underneath, and to take care when removing the protective paper. Conversely, 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.

4.7.4.5 - Broken Official Seals

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

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

4.7.4.6 - 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 C/R. See IOM 4.3.3.3 for instructions on the use of the metal seal to reseal railroad cars or conveyances. When a supply of these seals is needed by your division, contact the Office of Global and Specialty Human Food Inspectorate at (301) 796-0360.

4.7.4.7 - 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. For instance, the FDA metal seal is often used to seal rail cars or vehicles, as indicated in IOM 4.3.3.3.

You may use an official seat to seal questionable or suspicious records encountered during an inspection or investigation to prevent their tampering until such records can be reviewed. These seals do not need to be retained unless found tampered with however the use of the seal should be documented in EIR. .

4.7.5 - Sample Shipment

OII SOP-000178 covers all shipments made by OII.

The FDA collects a wide variety of samples, some of which may contain unstable, toxic, or hazardous materials (this includes etiological agents, radiation products, chemicals, hard swells, etc.). Therefore, use safety precautions in handling and shipping commensurate with the hazard. ORTS provides guidance on shipping hazardous goods here: Shipping of Dangerous Goods (sharepoint.com). See also IOM 4.7.5.6.

4.7.5.1 Preparing the box for shipping

Place the words "SAMPLE NO" or "ENTRY NO" (in all caps) followed by the FDA sample number(s) (with appropriate prefix) in the blank space at the bottom of the shipping label. Avoid writing directly on reuseable shipping containers. The package(s) should be properly identified with the FDA office that is shipping the sample and the laboratory or other office receiving the sample. This

alerts the receiving mail room that the package contains a sample and must go to the sample custodian.

Note that certain Department of Transportation (DOT) regulations exist pertaining to carrier inspection of packages. As such, be prepared to instruct the carrier to contact the shipper (FDA) prior to any package inspection that may require breaking the official seal. Carriers have been known to break official FDA seals during package inspection during transit and have compromised sample integrity in the process. 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.

4.7.5.2 - Method of 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.

4.7.5.2.1 - USPS Shipments

Before using the contract carrier, you should determine if using United States Parcel Post (USPS) is a more cost-efficient mode of shipping the sample. USPS should be used *only* for non-emergency, non-perishable samples and when the package meets USPS limits. Details on shipping by USPS can be found at How to Send a Package: Domestic. The same webpage can be used for scheduling a pick-up too.

4.7.5.2.2 – Contract Carrier Shipments

The FDA contracts with a carrier for almost all shipments. You should use the contract carrier whenever possible. (SOP-000178 provides guidance for using the contract carrier to ship samples.)

4.7.5.2.3 – Use of other Shippers for Samples

When the contract carrier cannot deliver the sample in time for the laboratory to conduct the analysis, then discuss with your supervisor other appropriate methods for shipping the sample. For example, if the contract carrier cannot guarantee overnight delivery in the morning for a sample collected during an outbreak, then use of another carrier may be permitted.

4.7.5.3 - FDA 525 - Sample Package Identification

Form FDA 525 - Place the FDA 525, sample package identification, near the official seal. Do not affix the FDA 525 on the outside of the shipping container or under the official seal. Provide the following information on the FDA 525:

1. Division or Headquarters' laboratory to which the sample is directed, City, State, and unit symbol (e.g., SRL, HFD-400, HFS-300, etc.).
2. Date.
3. Your division and symbol.
4. Sample or Entry 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 regarding the analysis to be made.
10. The Assignment Number and Name if sample was collected as part of an Assignment.
11. When entering information for "Package___of___Packages," the number of packages should be the number of sample packages. Also enter any pertinent remarks. Also note if your division desires the return of any freezer chests, ice packs, or maximum/minimum thermometers used.
12. Provide any relevant special storage instructions. Mark the appropriate block and enter the suggested refrigeration temperature, if necessary. Elaborate in Remarks, if necessary, too.
13. Print your name.
14. See IOM 4.7.3.4 when using the FDA 525 as a sample package.

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

4.7.5.4 - Routing of Samples

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

4.7.5.4.1 - Samples to Administration Laboratories

When shipping samples to headquarters or other special laboratories, follow the procedures for each laboratory found in Exhibit 4-24.

4.7.5.4.1.1 - Split Samples

In instances where the sample examination duty is split between a Headquarters Division of the National Center for Drug Analysis, and an OLOAS laboratory then you should follow the directions noted in Exhibit 4-24. Also, submit the Original C/R and records to the servicing laboratory, whether or not it is affiliated with the home division.

4.7.5.4.2 - Sample Shipment to Outside Agencies

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

4.7.5.5- Notifying Receiving Laboratories

When frozen, perishable, or high priority items are shipped, notify the receiving division or lab by telephone, or email, that you have shipped the sample. Be sure to provide all of the following information:

1. Sample Number.
2. Name of Product.
3. PAC/PAF and/or requested analysis.
4. Number of Parcels in Shipment.
5. Carrier's Name.
6. Carrier's Waybill or Tracking Number.
7. Carrier's Train, Truck, Bus, or Flight Number.
8. Estimated Time and Date of Arrival.

9. Relevant Remarks (for instance, "Sufficient Dry Ice provided to maintain frozen until approx. 8:00 a.m., (date)").
10. Place the name and telephone number of the person that is to receive the sample on the outer shipping container near the address, with instructions to the carrier to contact the above-named individual upon arrival of the package.

4.7.5.6 - 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 that the FDA ships 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.

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

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

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

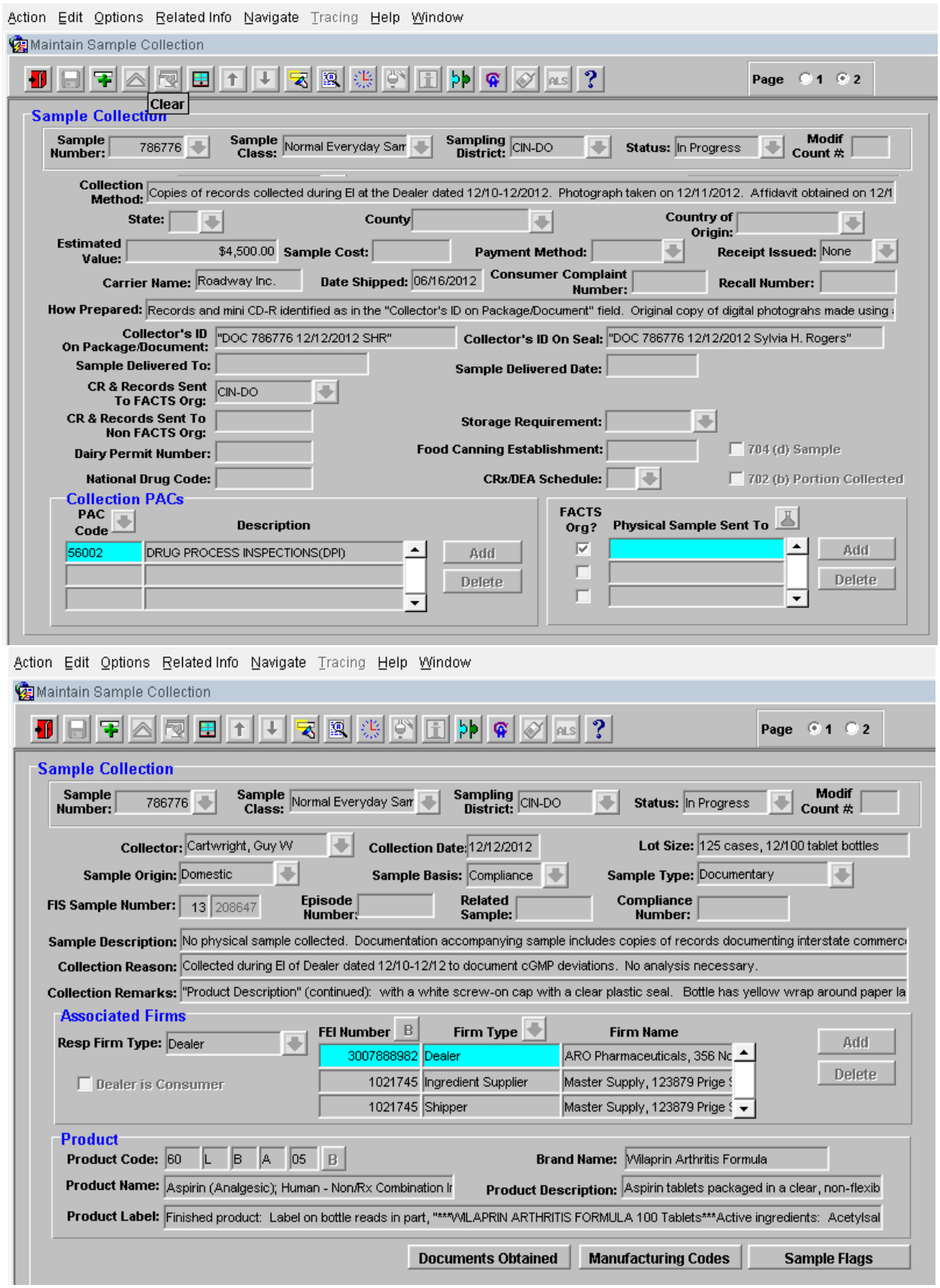
4.7.5.7 – Additional Precautions When Shipping Samples

The following precautions should be observed when shipping samples:

- Always pack liquid products in sufficient cushioning and absorbent material to absorb any breakage that might occur. Check with USPS or other carriers regarding shipment of liquids.
- Hard swells may explode. Wrap them heavily in paper and cushioning material for shipment and submit promptly.
- Observe special precautions when shipping products in pressurized containers to avoid exposure to excessive heat. Air shippers that ship in non-pressurized planes may also have special requirements for this type of container. Check USPS or other carrier for regulations, precautions, or restrictions before shipping products in this type of container.
- Special precautions for both packaging and shipping radioactive substances must be observed. If necessary, consult your supervisor, the FDA 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 with Exp. Date 11/30/2026. This license number should be used for any shipments of radioactive products to WEAC.

4-1- FACTS SAMPLE COLLECTION SCREEN



Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 786776

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

Flag	Flag Remarks
301(k) Sample	

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

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

Compliance Num	Country of Origin

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

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

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

Product Label
See continuation.

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

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

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

Description of Sample
See continuation.

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

How Prepared
See continuation.

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

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

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

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

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

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

Remarks
See continuation.

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

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

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

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

Continuation:

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

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

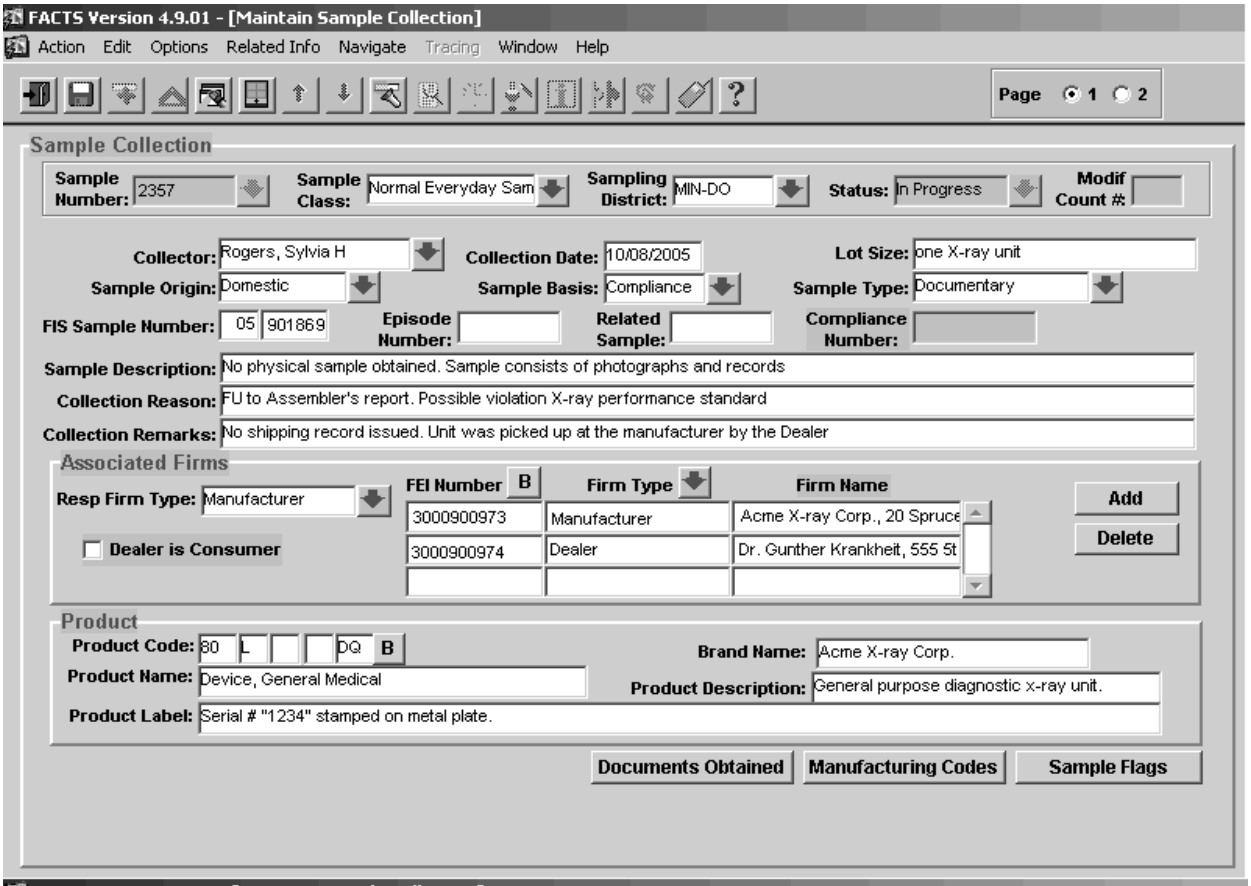
Description of Sample
No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce and cGMP deviations, one photograph and an affidavit.

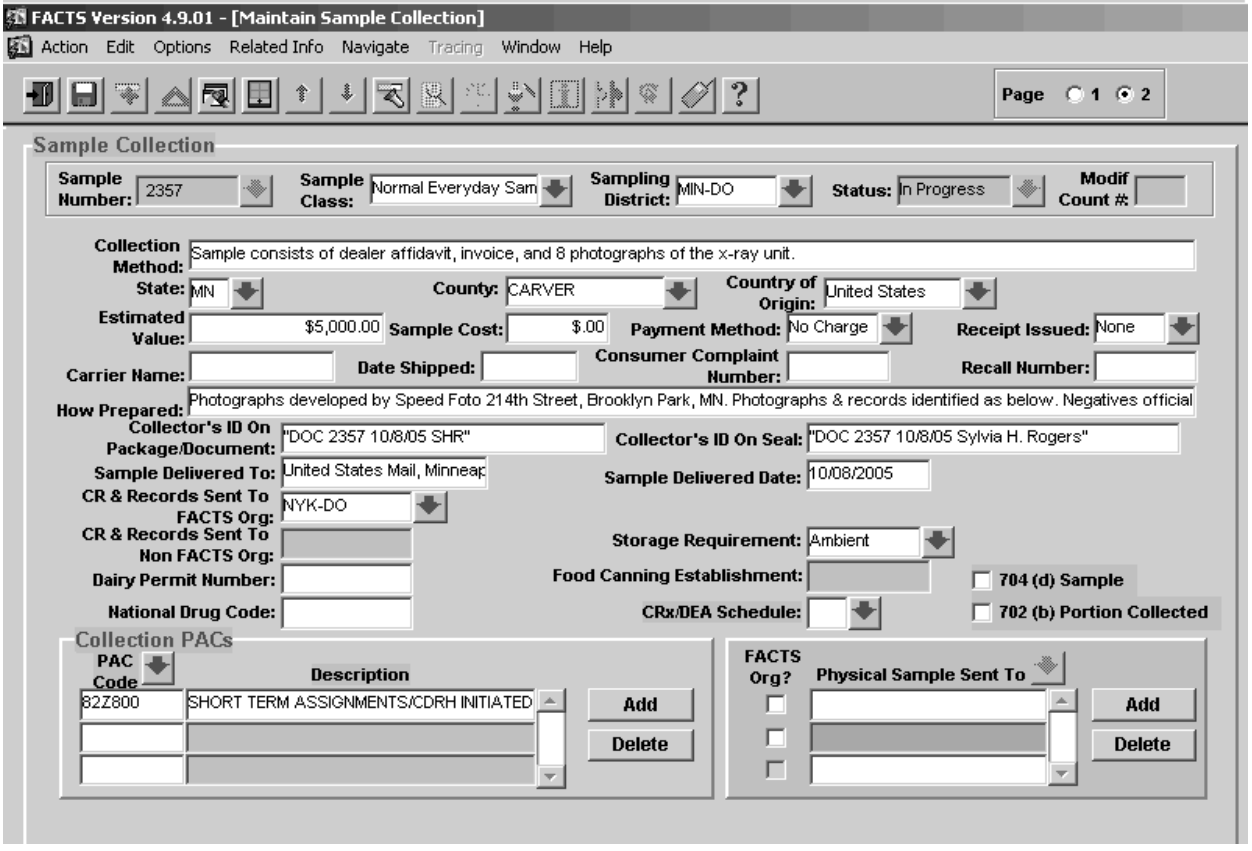
How Prepared
Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photograhs made using a mini CD-R, which was officially sealed In a FDA 525 envelope as in the "Collector's ID on Seal" field.

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

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

4-2 FACTS SAMPLE COLLECTION SCREEN





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

AFFIDAVIT *(In-transit Sampling)*

SAMPLE NO.

STATE OF

COUNTY OF

Before me, _____ , 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 _____

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

_____
(Carrier or firm name, city & state)

_____ as _____
(Title of position)

On _____, at _____.
(Date) *(City & state where sampled)*

The above named FDA employee collected a sample consisting of _____
(Description & number of units sampled)

_____

_____

from _____
(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)*

_____
(Consignee name & address)

_____.

The aforesaid sampled shipment(s) was (were) identified to the FDA collector by _____
(Name of individual

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

(Copy of) Shipping Record(s) _____, number _____,
(Type record - B/L, Waybill, etc.)

dated _____, issued by _____

_____, which were identified by _____
(Name & title of individual

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

AFFIANT'S SIGNATURE

Subscribed and sworn to before me at _____
(City and State)

this _____ day of _____, _____.

_____
(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, 1952; and P.L. 96-88, effective May 4, 1980.

FORM FDA 1664b (8/01) PREVIOUS EDITION MAY BE USED. PSC Publishing Services (301) 443-6740 EF

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NO. 550 West Jackson Blvd., Suite 1500, South Chicago, IL 60661 312-353-5863

TO	NAME AND TITLE OF INDIVIDUAL	DATE
	John B. Carr, Driver	11/06/2004
	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)	CONSIGNOR AND ADDRESS (Street, City, State and ZIP Code)
XYZ Wholesale 111 S. Water Market Chicago, IL 60601	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	
Two cases (48 count)	Lettuce - Best Yet Brand	A-23764

SAMPLE COLLECTOR'S NAME	TITLE	SIGNATURE
Sylvia H. Rogers	Investigator	Sylvia H. Rogers

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

PSC Publishing Services (301) 443-6740 EF

4-5 – INSTRUCTIONS FOR COMPLETEING THE FDA 484, RECEIPT FOR SAMPLES

Block 1 - Enter the address of the home district of the firm and telephone number including area code.

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

Block 3 – Enter the date the form was issued. If this differs from the sample collection date (for example in the case of environmental sampling), enter the collection date(s) in Block 9.

Block 4 – Enter the complete sample number here. Be sure to include any prefixes such as "DI" or "INV".

Block 5 – Enter the firm's legal name. This should be the firms legal name and not the DBA (doing business as), trade name, or alias.

Block 6 – If the firm is a dealer in narcotics or controlled drugs, enter their Drug Enforcement Administration (DEA) number here.

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

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

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

Block 11 – Enter the amount paid for the sample (even if borrowed, the owner may ask rent for it) and check the appropriate box. If there is no charge, 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 individual, enter amount and check the "Credit Card" box.

Block 12 – A signature is required in block 12 from the person providing the sample regardless of whether the sample was purchased, borrowed, or provided at no charge..

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
158-15 Liberty Avenue
Jamaica, NY 11433
718-340-7000

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Richard A. Frost, General Manager	12/13/2007	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. 360ll(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, Dilaudid HCl (hydromorphine) 2mg/cc, lot # 01032313 manufactured by Knoll Pharmaceutical Co. Orange, NJ.

Add Continuation Page

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 $15.00 ☐ VOUCHER ☐ CREDIT CARD	Richard A. Frost

13. COLLECTOR'S NAME *(Print or Type)*	14. COLLECTOR'S TITLE *(Print or Type)*	15. COLLECTOR'S SIGNATURE
Sylvia H. Rogers	Investigator	Sylvia H. Rogers

FORM FDA 484 (3/06) PREVIOUS EDITION MAY BE USED

RECEIPT FOR SAMPLES

Page 1 of 1 Pages
PSC Graphics: (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 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."

FORM FDA 484 (3/06) BACK

4-6 – FIELD WEIGHT SHEET – FDA 485

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DATE: 9-16-05
2. SAMPLE NUMBER: 55532
3. PRODUCT: Spaghetti in plastic bags: "Genoa Semolina Vermicelli***Delmonico Foods, Inc. San Francisco, Calif.***Net Weight 12 ozs."
4. TYPE OF BALANCE: Gurley

5. RESPONSIBLE FIRM AND ADDRESS (Zip Code): Delmonico Foods, Inc.
4701 Canal Street
San Francisco, California

6. ADDRESS WHERE WEIGHED: Medicine Bow Wholesalers
23 Railroad Ave.
Cheyenne, Wyoming

7. WAREHOUSE — a. TYPE: Wholesale Grocery Warehouse; b. TEMPERATURE: 80° F; d. HUMIDITY: est. 20%

8. NO. OF — a. CASES IN LOT: 325 48/12 oz.; b. CASES SAMPLED: 12; c. SUBS WEIGHED FROM EACH CASE: 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: DEN-DO
15. EMPLOYEE SIGNATURE: Sidney H. Rogers
16. EMPLOYEE TITLE: Investigator

FD FORM 485 (5/85) PREVIOUS EDITION MAY NOT BE USED FIELD WEIGHT SHEET

4-7 – AFFIDAVIT – "301(k) Sample" – FDA 463a

AFFIDAVIT	SAMPLE NO. 55533
STATE OF Kansas	COUNTY OF Sedgwick

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Joseph H. Roe in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Vice President in charge of production of the Doe Bottling Co., Inc., 123 Main, Thistown, Kansas 67201; and as such I have knowledge of the raw material receiving and use, and carbonated beverage production at this firm.

The sample consisting of two cases, 48- 10 ounce bottles, of Kola Cola, coded ABCD, collected by Investigator Rogers on November 15, 1999 was from a lot of 2668 cases produced by this firm on October 7, 1999. The copies of our production records for October 7, 1999 consist of a Syrup Room Report dated 10-6-99, a two-page Production Report dated 10-7-99, an undated in-line Control record, and a Finished Drink Control Record dated 10-7-99. Copies of these records were provided to the investigator and cover our production of this lot.

The above described lot was made in part from a portion of a lot of bulk liquid sugar received October 3, 1999 from the Sweet Sugar Co., Boise, Idaho, in railroad tank car ATSF 98765, unloaded October 6, 1999. The copies of the Sweet Sugar Co. invoice number 468 dated Sept. 26, 1999; freight waybill number UP-3579 dated Sept. 27, 1999 issued by the Union Pacific Railroad Co.; and our receiving report number 01-23 dated October 3, 1999 were provided to the investigator and cover this shipment.

The above described lot was also made in part from a portion of a lot of Kola Cola syrup base received September 23, 1999 from the Kola Cola Co., Thattown, Texas. The copies of Kola Cola Co. invoice number KCO1928 dated Sept. 20, 1999; freight bill number X-98125 dated Sept. 21, 1999 issued by Speedy Truck Line Co.; and our receiving report number 01-01 dated Sept. 23, 1999 were provide to the investigator and cover this shipment.

The above described lot of Kola Cola was identified to the investigator by William S. Doe, Production Supervisor. I identified and provided copies of the records to the investigator.

AFFIANT'S SIGNATURE AND TITLE

Joseph H. Roe, Production Vice President

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

Doe Bottling Co., Inc. 123 Main, Thistown, Kansas, 67201

Subscribed and sworn to before me at Thistown, Kansas this 15th day of November, 1999.

Sidney H. Rogers
(Employee Signature)

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

4-8 – COPY OF INVOICE/SHIPPING RECORD – FD 1662

1. LOCATION	2. NAME OF SAMPLE COLLECTOR	3. DATE COLLECTED	4. SAMPLE NUMBER
Pine Bluff, Arkansas	Sylvia H. Rogers	10-8-05	55566

SECTION I - COPY OF INVOICE

5. CONSIGNOR *(Name, Street, City, and State)*	6. CONSIGNEE *(Name, Street, City, and State)*
Captain Sam Seafood, Inc. 719 Butler Ave. New Orleans, LA	Razor Back Super Market 1207 Little Rock Dr. Pine Bluff, AR

7. GUARANTEE	8. INVOICE NUMBER	9. INVOICE DATE
-----see reverse-----	477	9-20-05

10 QUANTITY	11 UNIT SIZE	12 DESCRIPTION OF ARTICLE(S)	13 UNIT PRICE		14 TOTAL	
10 cs.	24/4.5 oz.	Horseshoe Brand Canned Medium Shrimp	2	84	56	80
5 cs.	10/5 lb.	Frozen Green Hills 21-25 Shrimp	1	10	275	00
		**********				
5cs.	24/8 oz.	Horseshoe Brand Canned Cove Oysters	5	25	52	50
		**********				
2 cs.	6/4 lb.	Frozen C&P Small Shrimp	1	50	72	00
			15. **TOTAL**		642	80

SECTION II - COPY OF SHIPPING RECORD

16. SHIPPER *(Name, Street, City, and State)*	17. CONSIGNEE *(Name, Street, City, and State)*
Captain Sam Seafood, Inc. NOLA	Razor Back Super Market 1207 Little Rock Dr. Pine bluff, AR

18. CARRIER *(Name, City, and State)*

Sea Breeze Trucking, Inc. NOLA

19. CAR OR EQUIPMENT NUMBER	20. WAYBILL DATE & NUMBER	21. TYPE OF RECORD *(Specify)*	22. RECORD NO.	23. RECORD DATE
Van 109	N/A	F/B	06641	9-20-05

24. SHIPPED FROM *(City and State)*	25. ROUTE	26. DATE SHIPPED
NOLA	N/A	9-20-05

27 DESCRIPTION OF ARTICLE(S)	28 NO. PKGS.	29 WEIGHT	30 RATE	31 CHANGES
Canned Food	20	300	172	5.16
Frozen Seafood	8	350	224	7.84

32. RECEIVED BY	33. DATE REC'D	34.				
P. Monteux s/s	9-26-05	**TOTAL**	28	650		13.00

4-9 AFFIDAVIT (PARCEL POST) – FDA 463a

AFFIDAVIT *(Parcel Post/Parcel Service)*

SAMPLE NO. 2358

STATE OF: Colorado

COUNTY OF: Pueblo

Before me, Sidney H. Rogers an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20U.S.C.3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Joseph D. Bullard in the county and state aforesaid, who, being duly sworn, deposes and says: (I) (My firm) received on or about the day of July 10th, 2005, in response to an order previously given by me, two (packages, containers, etc.) consisting in whole or in part of a product designated "4 ounces NET***Johnson's Eye Ease***Reservation Special" via: (parcel post, United States mail) (United Parcel Service) from Old Indian Herb Co. 294 N. Blackfoot St., Boise, Idaho 30854 and covered by attached copy of invoice number C-20 dated 7-2-05; after unpacking the goods the (parcel post) (parcel service) wrapper was destroyed; and on the 12th day of July, 2005, Inspector/Investigator Rogers obtained from me a sample consisting of 10-4 oz. bottles of Johnson's Eye Ease coded "J-638" on the bottle label, shipped and described as aforesaid and for which he paid me the sum of $25.00 in (cash) (voucher) (billed).

Remarks: I first learned of this product while reading the January 2005 issue of "The Retired Engineer." I use it to relieve the burning and itching in my eyes after working in the heat and dryness.

AFFIANT'S SIGNATURE AND TITLE

Joseph D. Bullard

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

Subscribed and sworn to before me at Crow, Colorado *(City & State)* this 13th day of July, 2005.

Sidney H. Rogers /

(Employee's Signature)

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

FORM FDA 463(4/83) PREVIOUS EDITIONS ARE OBSOLETE

4-10 - AFFIDAVIT – FDA 463a

AFFIDAVIT	SAMPLE NO. 55555
STATE OF Oregon	COUNTY OF Klamath

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared George W. Hughes in the county and State aforesaid, who, being duly sworn, deposes and says:

I live at 482 Abricia Ave., Klamath Falls, Oregon. On October 18, 1999, my neighbor, Dr. Samuel Thompson, asked me to pick up some medical instruments from a firm in Santa Rosa, California for him. Later that same day I drove to Santa Rosa in my 1997 Dodge Ram pick-up truck which has Oregon license plates, number FAS 682. My Oregon driver's license number is OR0123-45-6789.

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

I drove back to Klamath Falls, Oregon after picking up a load of wine for my wine cellar, and arrived home on or about 11:00 PM.

The next morning, October 20, 1999, I delivered the 4 containers to Dr. Samuel Thompson at his office, 2209 Timberline Ave., Klamath Falls, Oregon.

I did not charge Dr. Thompson for the pick-up and delivery because I make regular trips to pick up wine in Santa Rosa for my wine cellar.

AFFIANT'S SIGNATURE AND TITLE

George W. Hughes, Owner

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Hughes Wine Cellar, 483 Abrecia Ave., Klamath Falls, 97210

Subscribed and sworn to before me at Klamath Falls, Oregon this 4th day of November, 1999.

Sidney H. Rogers
(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-11 – AFFADAVIT – FDA 463a

AFFIDAVIT

SAMPLE NO. 166455

STATE OF: Florida

COUNTY OF: Orange

Before me, Paul A. Revere, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Nicholas I. Herkimer in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Warehouse Manager at ABC Distribution Company, 200 Harding Street, Orlando, FL 32806 and have held this position for 3 months. Previously, I held the position of Traffic Manager here for 10 years. As such, I am familiar with and can identify records associated with the receipt, storage and shipment of goods at my firm.

On or about 3/1/01, my firm received a shipment of 500 cases, 24-½ fl. oz. bottles/case of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops from Sawyer Corporation, 51 Summer Street, Andover, MA 01810. This shipment was delivered to my firm by Yellow Freight Company, 1553 Fairlawn Street, St. Louis, MO 63126 and is covered by Sawyer Corporation invoice number 1500 dated 3/1/01 and bill of lading number 2000 dated 3/1/01.

On 4/1/01, I identified and provided Investigator Revere copies of the documents described in this statement. On 4/1/01, Investigator Revere collected a sample consisting of 96 - ½ fl. oz. bottles of Opti-One brand 0.12% Phenylephrine HCl Ophthalmic Drops, lot number 020101, from the shipment described above. This sample was provided to the FDA at a cost of $192.00, which will be billed.

I read this statement and agree it is true.

AFFIANT'S SIGNATURE AND TITLE: Nicholas I. Herkimer, Warehouse Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)

ABC Distribution Company, 200 Harding Street, Orlando, FL 32806

Subscribed and sworn to before me at Orlando, FL this 1st day of April, 2001.

Paul A. Revere

(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-12 – AFFIDAVIT – (Dealer/Warehouseman) – FDA 1664

AFFIDAVIT *(Dealer/Warehouseman)*

SAMPLE NO. 55563

STATE OF: Arkansas

COUNTY OF: Jefferson

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared Henry O'Rourke, in the county and State aforesaid, who, being duly sworn, deposes and says: The sample consisting of Two Cases (24/8 oz. Each) Horseshoe Brand Canned Cove Oysters collected by the above FDA employee on 3-10-99 was from shipment(s) received by us from Captain Sam Seafood, Inc. New Orleans, LA on 3-7-99 and so identified to the collector:

That the copy of invoice(s):

	NUMBER	DATE	NUMBER	DATE	NUMBER	DATE
1)	06641	3/6/99	2) 06643	3/7/99	3)	

and (copy of) shipping record(s):

	TYPE: *(B/L, F/B)*	NUMBER	DATE	ISSUING FIRM OR CARRIER
1)	F/B	4778	3/6/99	Acme Freight Lines, Inc. NOLA
2)	F/B	A-9321	3/7/99	Thru-Fast Lines, Little Rock, AR
3)				

which were identified and furnished the collector, cover this (these) shipment(s):

That said shipment(s) was (were) entered for the account of N/A

under Lot no. _____.

The collector paid me the sum of $ 21.32 (in cash) ~~(by voucher)(to be billed)~~ for the sample.

REMARKS

AFFIANT'S SIGNATURE & TITLE

Henry O. O'Rourke, Warehouse Manager Plant #12

FIRM *(Name and address, include ZIP Code)*

Southeastern Seafood Distributors, Inc.
#4 Canal Street Dock Red River Basin Area, Little Rock, AR 72901

Subscribed and sworn to before me at Little Rock, AR

(City and State)

this 10th day of March, 1999

Sidney H. Rogers

(Employee's Signature)

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

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

4-13 – AFFIDAVIT – FDA 463a

AFFIDAVIT	SAMPLE NO. 55545
STATE OF Tennessee	COUNTY OF Shelby

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared George R. Applegate in the county and State aforesaid, who, being duly sworn, deposes and says:

I am manager of John's Curb Market, 342 East Johnson St., Memphis, Tennessee. As such, I have knowledge of purchasing and receipt of products at the market.

On September 2, 1999, FDA Investigator Sidney H. Rogers collected from my firm a sample consisting of six - 4 pound cans of Red River Brand Pure Sorghum. This sorghum was collected from a lot of six cases, each containing 4 - 4 pound buckets (cans) purchased by me from Ted Buymore who regularly sells sorghum in this area. Ted delivered this lot of six cases to my market on August 28, 1999 in a red panel GM truck with Alabama license plates. I do not know the license number.

AFFIANT'S SIGNATURE AND TITLE

George R. Applegate, Manager

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

John's Curb Market, 342 East Johnson St., Memphis, TN 38110

Subscribed and sworn to before me at Memphis, Tennessee this 2nd day of September 1999.

Sidney H. Rogers
(Employee Signature)

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

FORM FDA 463a (5/07) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 OF 1 PAGES

4-14 – AFFIDAVIT – (Jobber) – FDA 1664a

AFFIDAVIT *(Jobber)*

SAMPLE NO. 55563

STATE OF: Arkansas

COUNTY OF: Jefferson

Before me, Sylvia H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared Patrick T. Palmer, in the county and State aforesaid, who, being duly sworn, deposes and says: The lot of The lot of 325 cases, (24/ 4 ½ oz. cans) of Jolly Miller Canned Mushrooms.

which we invoiced and sold to Patriot Markets, Inc. Frankford, Pennsylvania, on 4-12-99.

was a portion/all of a parcel shipped to us by Northern Light Foods, Inc. Duluth, Minnesota.

and is covered by submitted (copy of) invoice(s):

	NUMBER	DATE	NUMBER	DATE	NUMBER	DATE
1)	3914	4/4/99	2)		3)	

and (copy of) shipping record(s):

	TYPE: *(B/L, F/B)*	NUMBER	DATE	ISSUING FIRM OR CARRIER
1)	B/L	20018	4/5/99	Northern Freight Carriers
2)				
3)				

REMARKS

AFFIANT'S SIGNATURE & TITLE

Patrick T. Palmer, Warehouse Manager Plant #12

FIRM *(Name and address, include ZIP Code)*

Liberty Wholesale Grocers
3210 11th Ave. Frankford, PA 19105

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

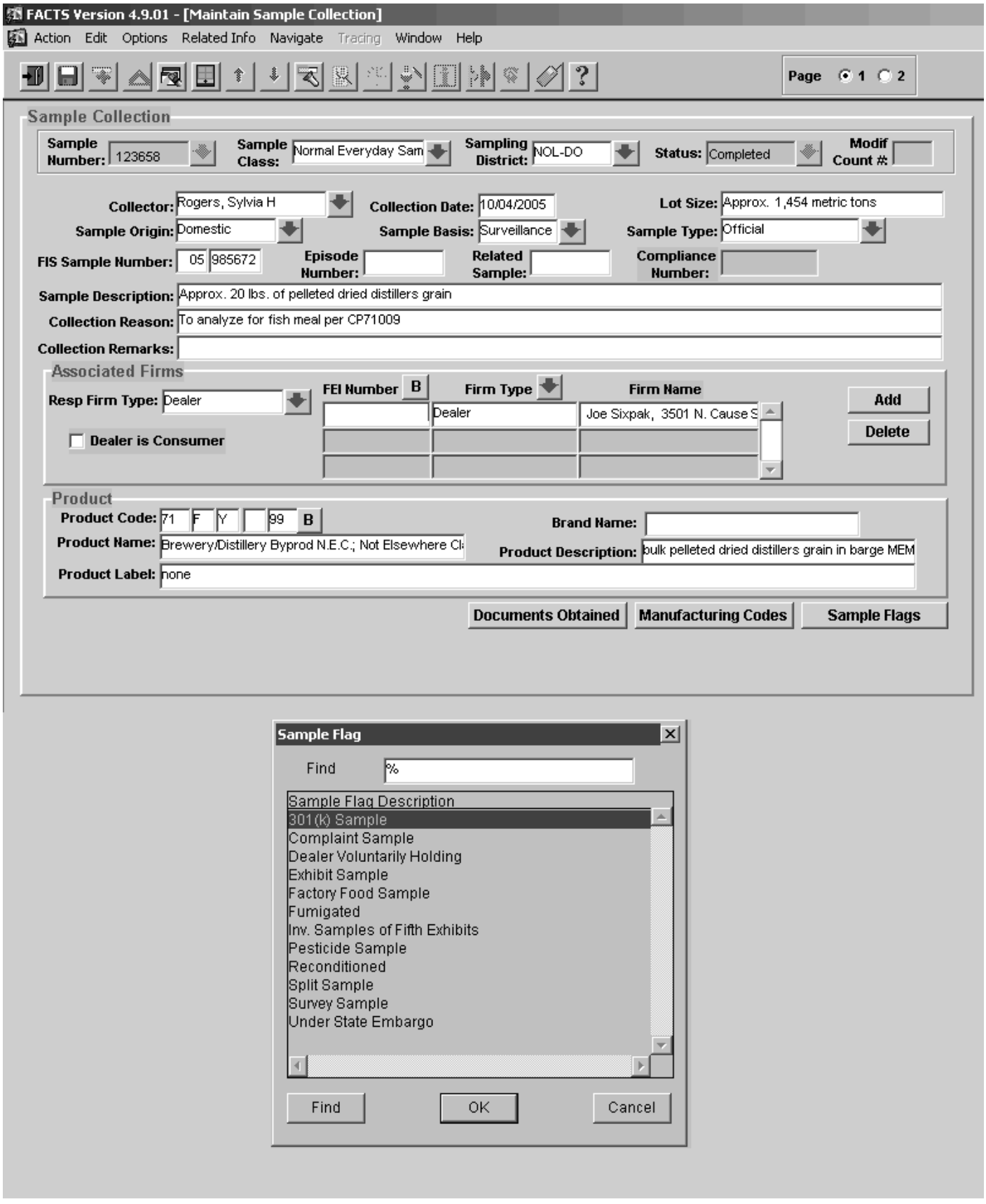
this 28th day of April, 1999

Sylvia H. Rogers
(Employee's Signature)

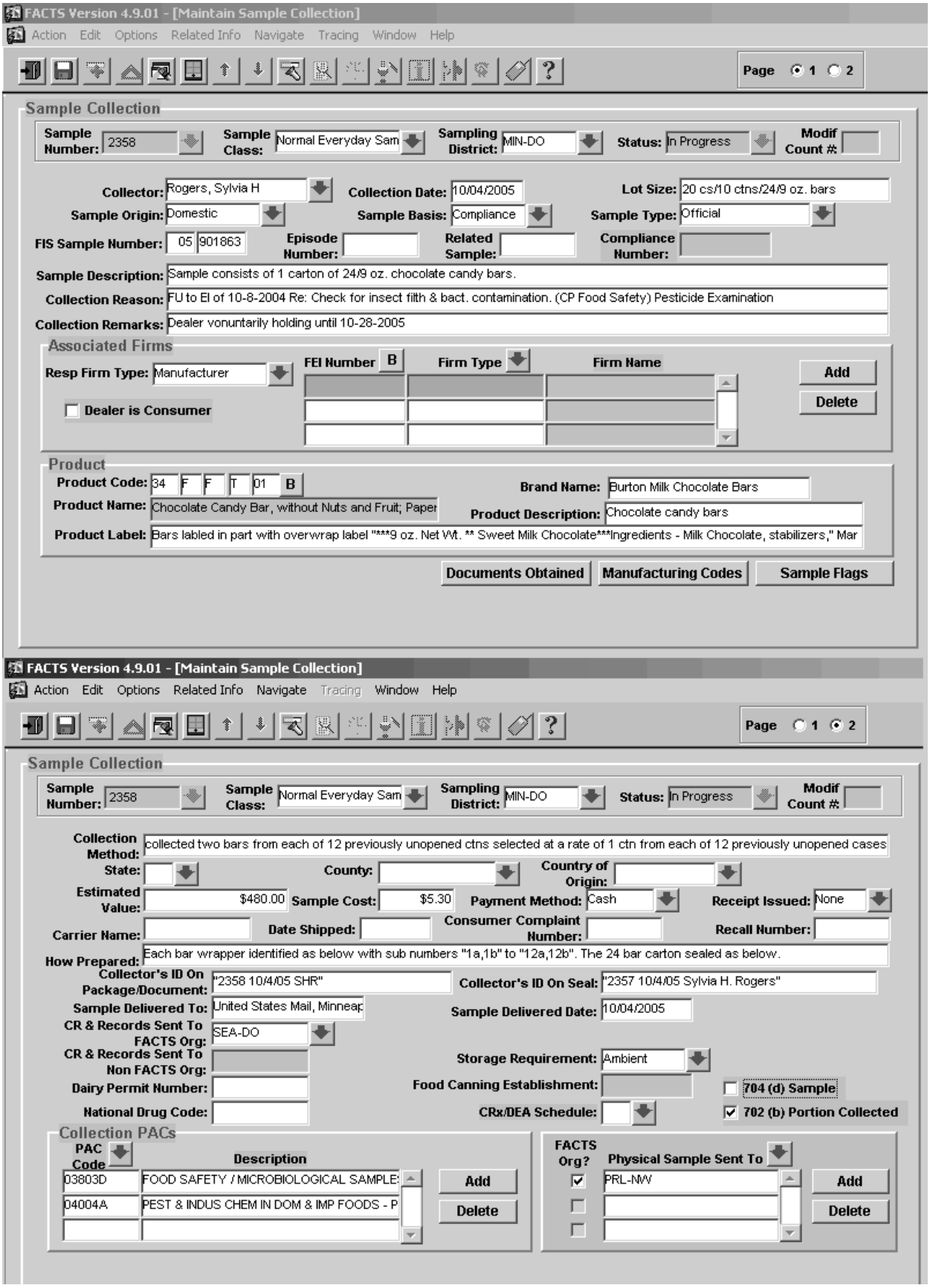
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953;and P.L. 96-88, effective May 4, 1980.

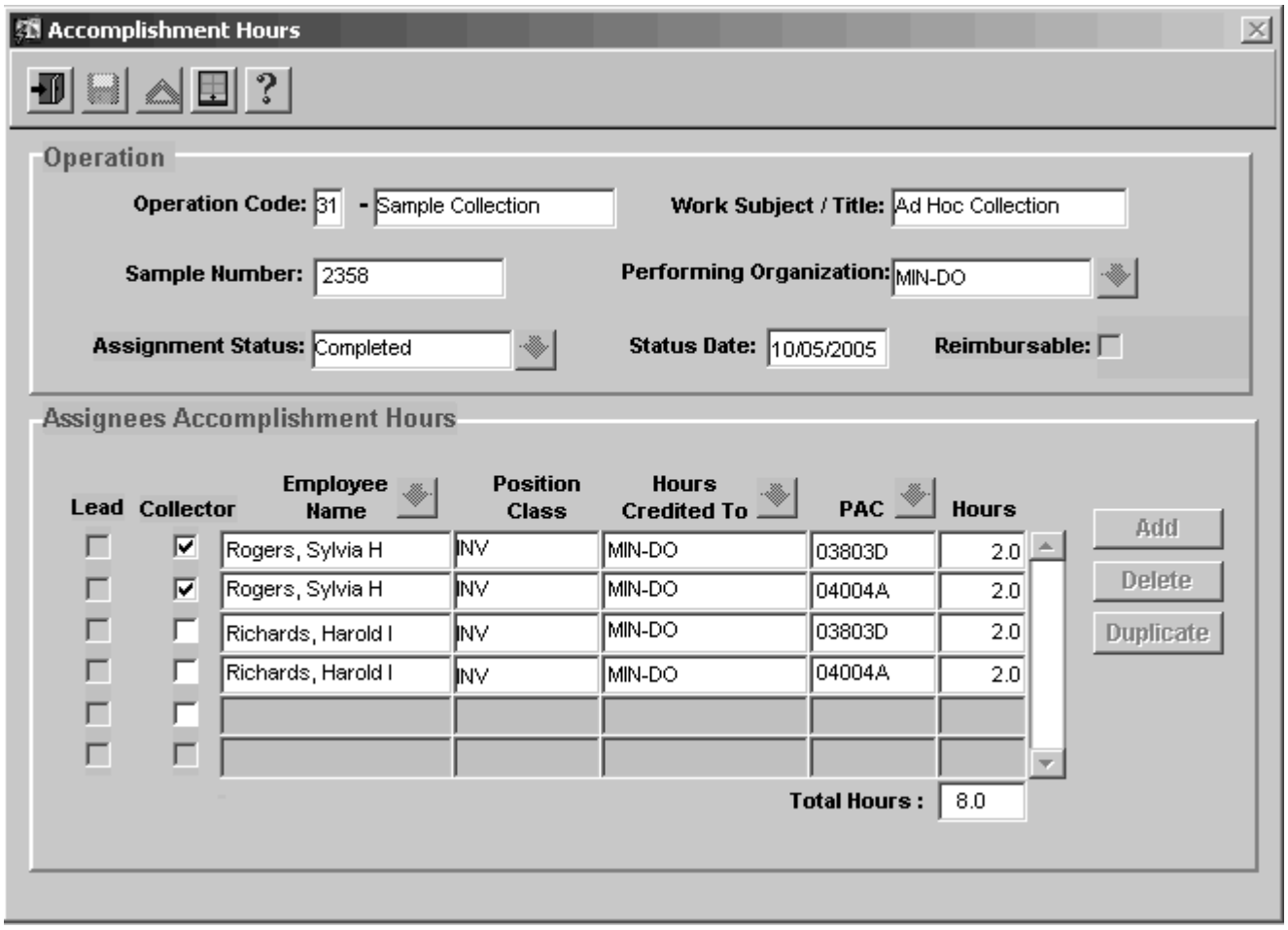
FORM FDA 1664a (7/01) PREVIOUS EDITIONS ARE OBSOLETE

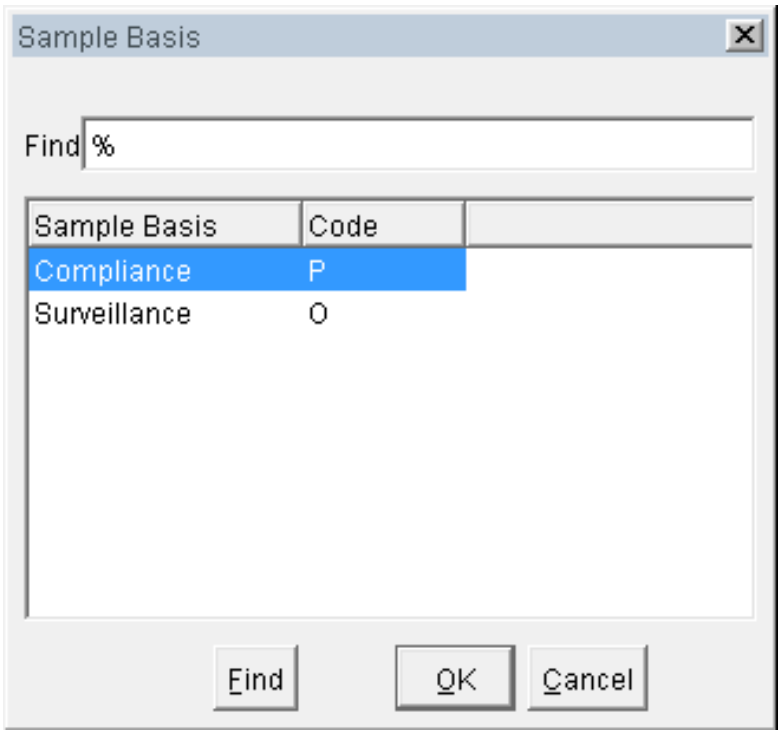
4-15 FACTS SAMPLE COLLECTION SCREEN



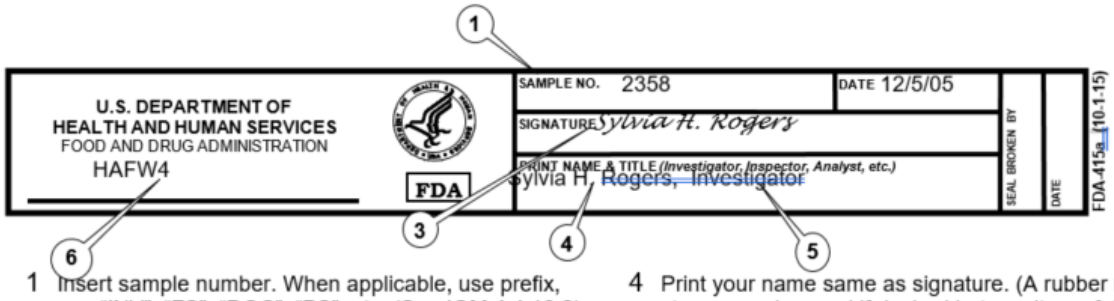
4-16 FACTS SAMPLE COLLECTION SCREEN




Accomplishment Hours
Operation
Operation Code: 31 - Sample Collection
Work Subject / Title: Ad Hoc Collection
Sample Number: 2358
Performing Organization: MIN-DO
Assignment Status: Completed
Status Date: 10/05/2005
Reimbursable:
Assignees Accomplishment Hours
Lead
Collector
Employee Name
Position Class
Hours Credited To
PAC
Hours
Rogers, Sylvia H INV MIN-DO 03803D 2.0
Rogers, Sylvia H INV MIN-DO 04004A 2.0
Richards, Harold I INV MIN-DO 03803D 2.0
Richards, Harold I INV MIN-DO 04004A 2.0
Total Hours : 8.0
Add
Delete
Duplicate


Sample Basis
Find %
Sample Basis
Code
Compliance P
Surveillance O
Find
OK
Cancel

4-17 OFFICAL SEAL – FDA 415a



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

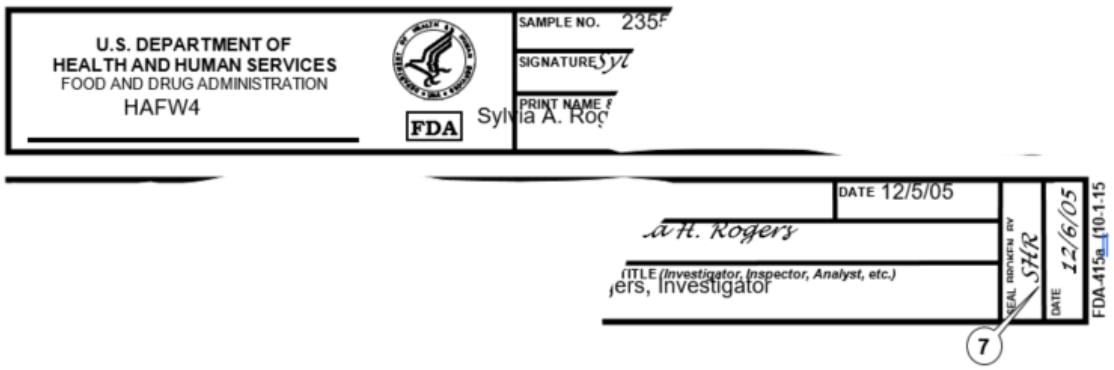
2 Insert date sealed. Use figures, month, day, year. (See # 7 below when seal is broken for any purpose.)

3 Sign your signature.

4 Print your name same as signature. (A rubber name stamp may be used if desired but use it carefully and do not smear.)

5 Print your title.

6 Print your divisional affiliation acronym (ie. HAFW4, DPQOII).



5. When seal is broken for any purpose, initial here and enter the date broken. Submit broken seal with sample records.

4-18 DECLARATION FOR DANGEROUS GOODS

Shipper

U. S. FOOD & DRUG ADMINISTRATION
6601 N.W. 25th St. Room 236
Miami, FL 33122

Air Waybill No.
Delta 7012-6140

Page 1 of 1 Pages

Collection Report Number
2555

Consignee

Food and Drug Administration
60 Eighth Street
Atlanta, GA 30309

U.S. GOVERNMENT SHIPMENT

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORTATION DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*

~~PASSENGER AND CARGO AIRCRAFT~~ | ~~CARGO AIRCRAFT ONLY~~

Airport of Departure
Miami, FL

Airport of Destination
Atlanta, GA

Shipment type *(Delete non-applicable)*

NON-RADIOACTIVE | ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification						
PROPER SHIPPING NAME OF ARTICLE as listed in the Restricted Articles Tariff Federal Aviation Regulations or IATA Restricted Articles Regulations.	Class Or Division	UN Or ID No.	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization
DRY ICE (CARBON DIOXIDE SOLID)	ORM A OR 9	UN 1845	N/A	5 Fiberboard containers net weight 20 lbs. dry ice each container	173.615 or 615	
	Note: Include these notations on all Dry Ice shipments.					

Additional handling Information

DO NOT OPEN THIS PACKAGE, IF PROBLEMS ARISE, CONTACT SHIPPER AT (305)555-3344

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked and labeled, and are in all respects in the proper condition for transport by air according to the applicable International and National Government Regulations

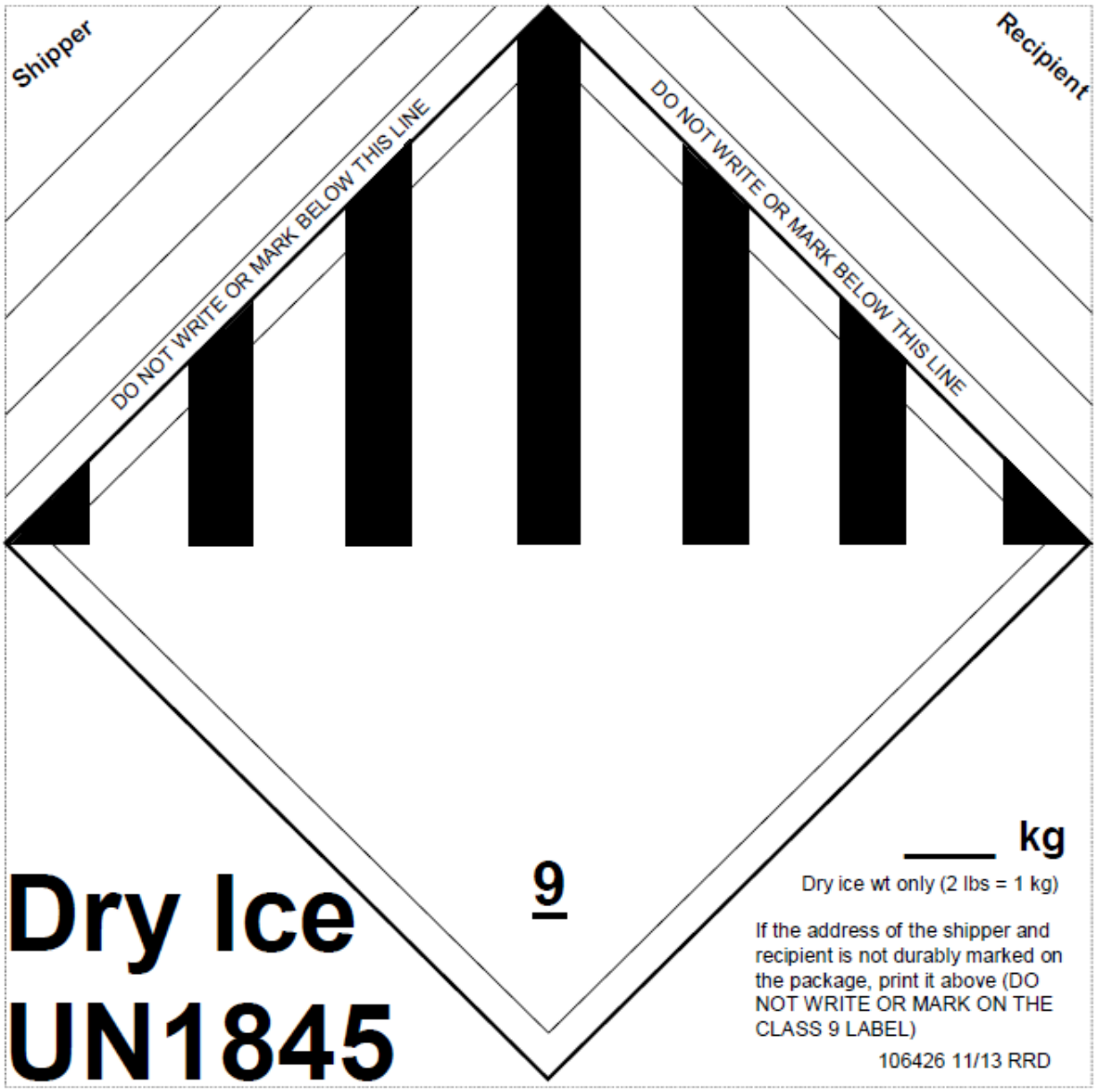
Name/Title of Person Signing
Sidney H. Rogers
Investigator

Place and Date
Miami, FL (9-8-99)

Signature *(See warning above)*
Sidney H. Rogers

FORM FDA 3082 (3/83) PREVIOUS EDITION IS OBSOLETE

4-19 DRY ICE LABEL



4-20 Environmental Sampling for Detection of Listeria monocytogenes, HFP Guidance

BACKGROUND

Listeria monocytogenes has been associated with such foods as raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 0°C permits multiplication in refrigerated foods.[4] Listeriosis is a foodborne illness of major public health concern because of the severity of the disease (meningitis, septicemia, and pregnancy complications such as miscarriage or stillbirth), a high case-fatality rate, and a long incubation period. *Listeria monocytogenes* differs from most other food-borne pathogens because it is widely distributed, resistant to diverse environmental conditions, including low pH and high NaCl concentrations, and is microaerobic. The multitude of ways it can easily enter food processing plants and its ability to grow and survive for long periods of time (in the environment, in/on foods, and in food processing plants) under adverse conditions have made it a major concern for many manufacturing industries in recent decades.[2]

SAMPLE COLLECTION

DO Collect Samples From:	**DON'T Collect Samples From**:
Moist/wet areas with standing water	Dry, clean areas
Direct food contact surfaces	Employees – work shoes, hands etc.
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Hand wash or eyewash stations
Sanitizing foot mats – if disinfectant is not maintained this can be a good harboring source and point of transfer to other areas of the facility	Packaging materials – jars, lids, etc.
Cleaning Equipment – automated floor cleaning equipment, brooms, mops, waste containers especially underside, etc.	Raw agricultural products – raw peanuts etc. or any food contact surface used exclusively for raw foods.
Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators and evaporator condensate pans	Outside the plant – roof, parking lot, walkways, etc.
Product conveyors – cables, belts, joints, where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product	Zone 4
Motor and Electrical Housings – that are not cleaned and/ or sanitized.	
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks, etc.	
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks, and crannies.	
Doorways - floor area leading directly into production areas	
Drains – Not during production	
Ice Makers – inside, scoops, underside of top of ice chamber	
Ceilings and Walls – in production areas coolers and freezers	
Door gaskets to coolers and freezers; damp insulation around pipes	

References:

- FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling
- Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs. 383-403.
- Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs. 55 – 67
- Bad Bug Book. *Listeria monocytogenes*, Page 100
- Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready to Eat Foods Draft Guidance.

4-21 Environmental Sampling for Detection of Salmonellae, HFP Guidance

BACKGROUND

Salmonellosis has been known to be a food-borne disease since the late 1800s. It still remains a major food safety concern throughout the world, is the major cause of bacterial foodborne illness in the U.S and is a pathogen of significant interest to FDA. The major reservoirs for Salmonellae are raw meats, poultry, and eggs; the organism is also isolated from aquaculture products and fruits, vegetable, and nut meats. Salmonellosis outbreaks have been associated with a variety of foods, including raw seafood, fresh produce, egg products, cake mixes, unpasteurized milk, peanut butter, chocolate, and salad dressings. Salmonellae are known to survive and grow in the natural environment, including water sources. It is ubiquitous and has been recovered from some insects and nearly all vertebrates and invertebrates. This makes the recovery and identification of Salmonellae critical as an environmental contaminant.

SAMPLE COLLECTION

DO Collect Samples From:	DON'T Collect Samples From:
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Employees – work shoes, hands etc.
Sanitizing foot mats – if dry	Hand wash or eyewash stations
Cleaning Equipment – central vacuum systems, automated floor cleaning equipment (e.g., Tenent type walk-behind or riding sweepers, brooms, mops, etc.) Pay particular attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks.	Packaging materials – jars, lids, etc.
Air conveying equipment – air filters; air ducts and intake and exhaust vents; food residue on equipment and floors if old and dry	Direct food contact surfaces –cleaned often, would be unlikely to have residual organism growth.
Product conveyors – cables, belts, joints, where product residue accumulates, if the residue is old and dry	Raw ingredients– raw peanuts refined sugar, etc.
Unsealed control and drive chambers; electrical/ mechanical service boxes that are not cleaned and/ or sanitized. Look for dry dust and residue in these boxes.	Outside the plant – roof, parking lot, etc.
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	Areas with running water and very wet areas
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks etc.	Zone 4
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks, and crannies if dry.	

Doorways - floor area in doorways leading into or out of the production facility or onto the roof
Pallets – Floor under wooden or plastic pallets and pallets themselves
Floor drains - use a sponge to scrub dry residue from floor drain grids and walls

References:

1.FDA. Investigations Operations Manual 2008. 4.3.7.7 – Environmental Sampling

2. Doyle, Michael et al. Food Microbiology Fundamentals and Frontiers 2nd Ed. Pgs. 141-178.

Cliver, Dean and Riemann, Hanns. Foodborne Diseases 2nd Ed. Pgs. 55 – 67

1- SALMONELLA SAMPLING PLAN

PURPOSE:

To determine the presence of *Salmonella* in processed foods and soils/water used for the growth of foods intended for human consumption.

APPLICABILITY:

This sampling plan is applicable to the inspection of either a continuing series of production lots or to isolated lots consisting of an identifiable collection of process units (cans, bags, packages, or similar units). Additionally, the soil plan is for use during on-farm investigations requiring the sampling of soil for the presence of *Salmonella*. This plan is for use by FDA for regulatory purposes.

FOOD CATEGORIES:

Foods are listed in three categories based on the number of *Salmonella* hazards and whether a food is to be consumed by infants, the aged, or infirm.

The three defined *Salmonella* Hazards of foods are:

- The food or an ingredient of the food is a significant potential source of *Salmonella*;
- The manufacturing process does not include a controlled step that destroys *Salmonella*; and
- The food has significant potential for microbiological growth if "abused" in distribution or by consumers.

Classification of Foods:

Foods have been classified into three food Categories for regulatory sampling purposes. The foods are listed in the Categories by Product Code sequence.

NOTE: For imported seafood products, see CPGM 7303.844

NOTE: For products not listed, check with your supervisor. The Division will request categorization from the Office of Field Programs/Center for Food Safety and Applied Nutrition (HFS-600), or, when time is of essence, the Division will make the categorization and obtain later concurrence from HFP.

Category I

This includes all foods that would normally be in Category II except that they are intended for consumption by the aged, the infirm, and infants.

Category II

This includes the foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
03	Bread, rolls, buns, sugared breads, crackers, custard, and cream filled sweet goods
05	Breakfast cereals, ready to eat
07	Pretzels, chips, and specialty items
09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and Cheese products

13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption.
14	Pasteurized and unpasteurized imitation dairy products for consumption
15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish, and crustacean products; smoked fish, shellfish, and crustaceans for consumption
17	Unflavored gelatin
20-22	Fresh, frozen, and canned fruits and juices, concentrates and nectars; dried fruit for consumption; jams, jellies, preserves and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing and oleomargarine
27	Dressings and condiments (including mayonnaise) salad dressing and vinegar
28	Spices including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Chewing gum and candy
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products
36	Syrups, sugars, and honey
38	Soups
39	Prepared salads

Category III

This includes the following foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
02	Whole grain, processed grain, and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products normally cooked before consumption
26	Vegetable oils, oil stock and vegetable shortening

35	Dry dessert and pudding mixes that are cooked prior to consumption
37	Frozen dinners, multiple food dinners
45-46	Food chemicals (direct additives)

SAMPLE COLLECTION

Each sub will consist of a minimum of 100 g (approx. 3.53 oz). The usual subsample is a consumer size container of a product. Subsamples should be obtained at random to ensure that the total sample is representative of the lot. When a lot consists of identifiable subsamples (e.g., different codes), sub samples should be obtained from subsamples in the proportion that the subsamples are to the whole lot.

More than one subsample may be collected from large institutional or bulk containers when the number of sub samples required exceeds the number of containers in the lot. A subsample will consist of more than one container when the lot consists of containers smaller than 100 g (e.g., 4 - 25 g containers is a subsample).

When a sample is collected by transferring it to sample containers, a sample control must be submitted which consists of an empty sample container that is exposed to the same conditions under which the sample is collected. See IOM 4.3.6.2 and 4.3.6.5 on controls. Use aseptic technique when sampling from bulk containers.

SAMPLE SIZE

The following sample sizes also apply to the finished product portion of in-line samples when analyzed for Salmonella. Each subsample will consist of at least 100 gm (approx. 3.5 oz).

The 702(b) [21 U.S.C. 372(b)] portion is included in these subsamples; however, all subs must be collected for proper analysis. Do not reduce the number of subsamples when collecting import samples.

FOOD CATEGORY	**NUMBER OF SAMPLE UNITS (SUBS)**
I	60
II	30
III	15

SAMPLE SUBMISSION

Submit all samples collected to your division's microbiological servicing laboratory unless directed otherwise by your supervisor or assignment. See IOM 4.5.5.2.

FARM INVESTIGATIONS – SOIL AND WATER SAMPLES

Soil Samples

When conducting an investigation at a farm that was implicated as the source of produce contaminated with Salmonella, and the crop is exposed to soil or water splash from the soil, such as leafy greens, cantaloupes, or cucumbers, soil samples may yield important information as to how the produce was contaminated, especially if a soil amendment such as animal manure or compost was used, or if the crops on that field were rotated and animals grazed on the land previously.

Unless specific instructions were provided by the office issuing the assignment, generally 5 sub samples are collected per field, one from the growing area on each corner, and one near the center. Additional samples may be collected based on observations, such as animal incursion, areas where water may drain, portions of the field susceptible to road dust or runoff, etc. Each field should be issued a separate sample number for ease of identification and review of data. A 1000 ml whirlpack should be filled with soil from a depth of 1 to 3 inches using a sterile scoop and double

bagged. Take a photograph of each area where samples are collected and indicate the location and subsample number on a diagram of the field.

Soil samples should be submitted to the lab at 4°C (39°F) or below.

Water Samples

If specialized equipment such as a peristaltic pump are not available, collect water in a sterile, 1000 ml Nalgene sample bottle from wells and surface water. When collecting a surface water sample, a sterile pipette with a re-usable suction bulb is recommended. Using the end of the pipette, stir the surface of the sediment until the water becomes cloudy and then collect this water. Salmonella may form a biofilm or colonize sediments and be recovered well past the outbreak period.

Water samples should be submitted to the lab at 4 °C (39 °F) or below.

Environmental samples will be submitted as Investigational Samples (INV).

2- SAMPLING SCHEDULE FOR LOW-ACID CANNED AND ACIDIFIED FOODS

Low Acid Canned Foods

Field Examination

1. At the beginning of the inspection, conduct visual exams of warehouse stock/product offered for import for evidence of abnormal cans including swollen and leaking cans, wet cases, swarms of fruit flies around isolated pallets, etc.
2. If the visual exam or inspectional evidence indicates possible problems, such as under processed lots, lots with questionable seam integrity, or abnormal cans, exam the affected lots. Preferably field examine lots that have been warehoused at least 14 days.
3. A lot to be examined will be one production code.
4. Follow the chart below for the field examination**.** If abnormal containers are found, always collect an official sample of the lot, if possible. For lots with abnormal cans collect an investigational sample ONLY when there is not enough product available to collect an official sample. In all cases, include on the collection report: the lot size, the number of containers examined, and the number of abnormal containers found by type (e.g., hard swells).
5. The chart provides instructions on the number of cans/cases to examine depending on the size of the lot. **When the maximum number of containers / cases have been examined for the specified lot size, collect a sample if one or more abnormal containers are found.** The exam can be discontinued early based on the number of abnormal containers found. For example, if examining a lot consisting of 3409 or more cans, if 11 abnormal cans are found after examining 1000 cans, discontinue the exam and collect a sample.
   a. Flippers. Only one end is slack or slightly bulged and the end remains flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.
   b. Springers. One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge, but only one will remain flat when pressed, the can is a springer. Springers result from moderate positive pressure in the can. Buckling or extensive denting of the side wall may produce a springer.
   c. Swells. Both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can
   be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

NOTE: Other abnormalities or defects, such as visibly leaking cans, severe dents around seams, gross seam defects, severely rusted containers should be reported on C/R, (with numbers of cans defective cans observed) but not counted as "abnormal containers" for the purposes of the sequential field examination. Do not collect leakers, but report the number observed. It may be necessary to collect samples of other defects (e.g., seam defects) to support observations and document the severity of the defects. In some cases, photographs may be a suitable substitute for collection of physical samples.

If a sample is collected, identify on the C/R, by sub-sample number, the condition of each container in the sample (e.g., sub-sample 1 - flipper; sub-sample 2 - hard swell; - sub-sample x - normal). Report the results of the warehouse stock examination in the EIR and in FACTS. See IOM 5.5.7.3

Special Sample Handling: If you are shipping swollen cans, double bag, and ground ship the sample. If the cans are moderately swollen or worse, you should ship the sample with ice packs.

When the 'Reason for Collection' on the Collection Report includes can seam analysis, the CSO shall collect the can seam specifications for the cans in the sample. This is specific to the can manufacturer and can size collected in the

sample. Can seam specifications will be submitted in the FD-525 along with the Collection Report for the servicing laboratory.

		PACKED 48/CASE		PACKED 24/CASE		PACKED 12/CASE		PACKED 6/CASE		*Number Abnormal Containers to Discontinue Examination Early
Lot Size Contain	Number to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	
192 or less	All	1 - 4	all	1 - 8	All	1 - 16	All	1 - 32	all	3
193 - 288	192	4 - 6	4	8 - 12	8	16 - 24	16	32 - 48	32	5
289 - 384	all for≤ 298 298 if greater	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all ≤ 50 50 if greater	6
385 - 576	363	8 - 12	8	16 -24	15	32 - 48	30	64 - 96	61	7
577 - 912	433	12 - 19	9	24 - 38	18	48 - 76	36	96 - 152	72	8
913 - 1488	480	19 - 31	10	38 - 62	20	76 - 124	40	152 - 248	80	9
1489 - 3408	529	31 - 71	11	62 - 142	22	124 - 284	44	248 - 568	88	10
3409 or more	576	71 or more	12	142 or more	24	284 or more	48	568 or more	96	11

1. Sample Size for Samples Collected as a Result of a Field Exam:
   a. Official Sample
      The sample will consist of all abnormal containers and the number of normal cans specified under "2. Official Samples" below (e.g., if 8 abnormal containers are observed during the examination of a lot containing 696/ 2 lb. cans the sample will consist of the 8 abnormal cans and 48 normal cans, collected 2 cans from each of 24 cases). Open additional cases, if necessary to meet this requirement. This will provide enough product for complete analysis, including: can seam, incubation, aerobic and anaerobic growth, pH and water. Note that the sample size given for normal cans includes the 702(b) portion.
   b. Investigational Sample and Import Sample.
      Samples for laboratory examination will consist of all abnormal and 12 normal containers.
2. Other Sampling
   Official Samples
   a. Filth, Micro, etc. (Includes 702(b) [21U.S.C.372 (b)] portion)

Collect each subsample to duplicate from a separate case, if possible. Mark subs 1a, 1b, 2a, 2b, etc. Collect as follows:

NET WEIGHT	SIZE OF LOT	MIN TOTAL CANS	CANS/CASE
795 gr (28 oz) and smaller	Up to 50 cases	48	2 from 24
	More than 50 cases	96	2 from 48
Over 795 gr (28 oz)	Up to 600 cases	48	2 from 24
	More than 600 cases	72	2 from 36

   b. Standards Assay (Includes 702(b) portion)
      NOTE: Sample sizes listed below are based upon the requirements of the Standards (21 CFR 145.3). When sampling products which are likely to be non-uniform throughout the lot because of variations from standards of quality, identity, fill-of-container, grade, etc., collect each subsample in triplicate from a separate case. Mark subs 1a, 1b, 1c, 2a, 2b, 2c, etc. Collect as follows:

NET WEIGHT	NUMBER OF CANS OR PACKAGES	MIN TOTAL CANS	CANS/CASE
1 kg (2.2 lbs.) or less	4800 or less	48	3 from 16
	4801 to 24,000	72	3 from 24
	24,001 to 48,000	96	3 from 32
	48,001 to 84,000	144	3 from 48
	84,001 to 144,000	264	3 from 88
	144,001 to 240,000	384	3 from 128
	Over 240,000	600	3 from 200
Greater than 1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2400 or less	48	3 from 16
	2401 to 15000	72	3 from 24
	15001 to 24000	96	3 from 32
	24001 to 42000	144	3 from 48
	42001 to 72000	252	3 from 88
	72001 to 120,000	384	3 from 128
	Over 120,000	600	3 from 200
Greater than 4.5 kg (10 lbs.)	600 or less	48	3 from 16
	601 to 2000	72	3 from 24
	2001 to 7200	96	3 from 32
	7201 to 15000	144	3 from 48
	15001 to 24000	252	3 from 88
	24001 to 42000	384	3 from 128
	Over 42000	600	3 from 200

Acidified Foods

A lot is defined as one production code.

Field Examination

Conduct a reconciliation examination and check for damaged or destructive container closures. For example, during a visual examination the following may be observed: 1) glass containers with obvious closure defects such as excessive torque on the lid and/or insufficient security, 2) plastic and semi-rigid containers with obvious defects such as leakers and poorly sealed lids, or 3) metal containers with damage or obvious container defects to the double seam.

Conduct a field examination if abnormal containers are observed during the reconciliation examination. Follow the applicable instructions provided above (see Low-Acid Canned Food “Field Examination” section, including chart) when performing a field examination.

Sample Collection

For acidified products, the equilibrium pH determines whether the product will support organisms of public health significance. Spoilage in such products is usually due to inadequate heat treatment to kill spoilage organisms. Spoilage may be significant because high numbers of microorganisms may affect the adequacy of the thermal process. Molds and some bacteria can grow in an acid environment and actually utilize acid as one of their nutrients; and thus, raise the pH to a level above 4.6 where *Clostridium botulinum* or other toxin-producing microorganisms can grow.

Microbial spoilage can be detected by observing swollen lids on jars or swollen can ends. The liquid may be turbid, and a whitish deposit may be visible on the product or in the bottom of the jar. Collect samples for pH testing. Samples must be collected randomly from the entire lot. **Sample size does not include 702(b) portion**.

1. # 10 cans – Use the following sample size for containers larger than 795 gr (28 oz): Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot. Sample size is 12 containers.
2. # 2 half (1/2) cans – Use the following sample size for containers equal to 795 gr (28 oz) or smaller: Randomly select 2 normal containers from each of 12 randomly selected cases (if available) in the lot. Sample size is 24 containers.

If abnormal containers are encountered, collect all abnormal containers (up to a maximum of 24) in addition to the normal containers collected for pH testing (referenced above). Indicate on the C/R the total number of containers examined, and the number of each type of abnormality and defect observed. Also indicate the estimated percentage of abnormal containers in the lot.

3- PESTICIDE SAMPLES

(Includes 702(b) portion)

DO NOT FUMIGATE PESTICIDE SAMPLES

INTRODUCTION

The objectives of FDA's pesticide monitoring program are to gather information on levels and incidences of pesticide residues in the nation's food supply and to initiate enforcement actions against shipments of foods and feeds found to contain illegal pesticide residues. To meet both objectives, it is necessary to collect samples of foods and feeds for pesticide residue analysis. This section describes procedures for the collection of raw agricultural and processed commodity samples. These procedures apply to both domestic and import arenas. Additionally, a separate set of procedures for collecting samples in conjunction with special investigations, such as samples collected to determine levels of pesticide residues in soil, water, and growing crops, is included.

For pesticide samples, the laboratory will maintain a portion of the composited sample as the 702(b) [21 U.S.C.372(b)] portion.

Pesticide sample sizes no longer differentiate between Surveillance and Compliance Samples. All pesticide samples will be collected as directed below. Remember to include the state and county or country of origin in the Flag. See IOM 4.6.2.27.

For appraisal purposes, you must Flag each Domestic as to the basis for sampling in accordance with the definitions below.

Pesticide Compliance Sample. Collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a "Pesticide Surveillance Sample" that was found to contain actionable levels of pesticide residues. Flag "Pesticide Compliance".

Pesticide Surveillance Sample. Collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. Flag "Pesticide Surveillance".

Divisions have the option to collect 1 intact shipping case of fresh produce from packing sheds or large produce warehouses. The one case must meet the minimum sample size specified below. This "one case" option may be used on any import sample or on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the samples according to the instructions below. This "one case" sampling does not apply to large items such as melons.

NOTE: If "one case" option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

Plant products: description of primary samples and minimum size of laboratory samples (total weight of all subs or units collected).

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
1. PRIMARY FOOD COMMODITIES OF PLANT ORIGIN			
All fresh fruits, All fresh vegetables, Frozen bulk produce (not retail) except dry pulses			
Small sized products units generally < 25 g	Berries, peas, olives	whole units, or packages, or units taken with sampling device	1 kg (2.2 lbs.)
Medium sized products units generally 25 - 250 g	Apples, oranges, corn on the cob, potatoes	whole units, or units taken with sampling device	1 kg (2.2 lbs.) (at least 10 units)
Large sized products units generally > 250 g	Cabbages, lettuce, cucumbers, grapes (bunches, except for sulfites), sweet potatoes	whole units, units taken with sampling device	2 kg (4.4 lbs.) (at least 5 units)
Pulses, Cereal grains	soybeans, peas, lentils, rice, wheat (except from rail carloads)		1 kg (2.2 lbs.) 1 kg (2.2 lbs.)
Tree nuts	(except coconuts)		1 kg (2.2 lbs.)
	coconuts		5 units
Oilseeds	peanuts		0.5 kg (1.1 lb.)
Seeds for beverages and sweets	See CP 7304.004		0.5 kg (1.1 lb.)
Herbs (*For dried herbs see section 3 of this Table*)	fresh parsley others, fresh	whole units or units taken with sampling device	0.5 kg (1.1 lb.) 0.2 kg (0.5 lb.)
Spices	See CP 7304.004	whole units or units taken with sampling device	0.1 kg (0.25 lb.)
2. PRIMARY ANIMAL FEED COMMODITIES			
Primary feed commodities of plant origin			
Legume animal feeds, and other forages and fodders		whole units, or units taken with sampling device	1 kg (2.2 lbs.) (from at least 10 units)
Straw, hay and other dried products		whole units, or units taken with sampling device	1 kg (2.2 lbs.) (from at least 10 units)
Note. See IOM Sample Schedule Chart 4, Wheat Carload Sampling for guidance in the collection of samples by trier from railcars and trucks.			
3. PROCESSED FOODS OF PLANT ORIGIN **Secondary food commodities of plant origin**, dried fruits, vegetables, herbs, milled cereal products **Derived products of plant origin**, teas, vegetable oils, juices, by-products for animal feed and miscellaneous products **Manufactured foods (single ingredient) of plant origin**, **Manufactured foods (multi-ingredient) of plant origin**, including products with ingredients of animal origin where the ingredient(s) of plant origin predominate(s), and breads			
Products of high unit value		packages or units taken with a sampling device	0.1 kg* (0.25 lb.)
Solid products of low bulk density	Hops, Tea	packaged units, or units taken with a sampling device	0.2 kg (0.5 lbs.)
Other solid products	bread, flour, apple pomace, dried fruit	packages or other whole units, or units taken with a sampling device	0.5 kg (1.1 lbs.)
Liquid products	vegetable oils, juices	packaged units, or units taken with a sampling device	0.5 L or 0.5 kg
** A smaller laboratory sample may be taken from a product of exceptionally high value but the reason for doing so should be noted in the collection report.*			
4. EGGS AND DAIRY PRODUCTS			
Poultry eggs			
Eggs, except quail and similar		whole eggs	12 whole chicken eggs, 6 whole goose or duck eggs

Commodity classification	Examples	Nature of primary samples to be taken	Minimum sample size and number of units of each laboratory sample
Eggs, quail and similar		whole eggs	24 whole eggs
Milks		whole unit(s), or unit(s) taken with a sampling device	0.5 L
5. PROCESSED FOODS OF ANIMAL ORIGIN **Secondary food commodities of animal origin**, skimmed milks, evaporated milks, and milk powders **Derived edible products of animal origin**, milk fats, butters, butter oils, creams, cream powders, caseins, etc. **Manufactured food (single ingredient) of animal origin**, **Manufactured food (multi-ingredient) of animal origin**, (including products with ingredients of plant origin where the ingredient(s) of animal origin predominates(s))			
Liquid milk, milk powders, evaporated milk and cream, cream, dairy ice cream, yogurt		packaged unit(s), or unit(s) taken with a sampling device	0.5 L (liquid) or 0.5 kg(solid)
Notes. (i) Evaporated milks and evaporated cream in bulk must be mixed thoroughly before sampling aseptically. *(ii) Milk powder in bulk should be sampled aseptically, passing a dry borer tube through the powder at an even rate.* *(iii) Creams in bulk should be mixed thoroughly with a plunger before sampling but foaming, whipping, and churning must be avoided.*			
Butter and butter oils (butter, whey butter, low fat spreads containing butter fat, anhydrous butter oil, anhydrous milk fat)		whole or parts of packaged unit(s), **or** unit(s) taken with a sampling device	0.2 kg or 0.2 L
Cheeses, including processed cheeses	units 0.3 kg or greater	whole unit(s) or units taken aseptically with a sampling device	0.5 kg
	units < 0.3 kg	whole unit(s)	0.3 kg
Note. Cheeses with a circular base should be sampled by making two cuts radiating from the center. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides.			
Liquid, frozen, or dried egg products		unit(s) taken aseptically with a sampling device	0.5 kg

9. GRAPES FOR SULFITES

Collect approximately 900 - 1800 g (2 - 4 lbs.) of grapes [10/100 - 200 g (1/4 to 1/2 lb.) subs]. Each subsample will consist of individual grapes, not bunches, and will be collected from different lugs (cases) on as many different pallets in the lot as possible. No grapes that are damaged during the sampling procedure should be included in the sample. However, grapes with damage prior to sampling may be included in the sample.

If sulfiting pads are present, grapes sampled should be selected from areas closest to and directly under the pad.

Monitoring activities should be focused upon lots of grapes with the highest potential for violative sulfite residues.

Direct efforts to lots of grapes sulfited through fumigation or to lots with multiple fumigations especially towards the end of the harvesting season and also to lots with significant numbers of damaged grapes (split, crushed, or unusually wet, if such damage is apparent).

Sample lots of grapes sulfited through the use of sulfiting pads, with or without additional fumigation. If at all possible, sample lots subjected to the following conditions, which could cause high sulfite residues:

- Lots subjected to un-refrigerated storage of 2 or more hours during warm weather.
- Unusual shipping conditions (ships at sea during heavy storms).
- Lots with significant numbers of damaged grapes.
- Lots containing evidence of sulfite pad damage sufficient to cause spilling of sulfiting agent onto grapes.

Special Sample Handling

Place sample in tightly closed airtight glass mason jar(s) or sealed plastic bag(s). Although no effort should be made to commingle subsamples, more than one subsample may be placed in the same container for shipping convenience.

Appropriate cooling procedures are:

Place samples in shipping container or cooler with sufficient ice or other refrigerant to keep sample refrigerated until arrival at the laboratory. Sample should be placed immediately in a refrigerator at or below 7 degrees C. If sample is not to be analyzed within a few hours, the sample should be placed in a freezer, which is maintained at or below -20 degrees C.

Or, if the sample is frozen, place the sample in a container with sufficient dry ice to keep the sample frozen until arrival at the lab. The sample should then be placed in freezer upon arrival at the laboratory.

1. **FISH AND SHELLFISH PRODUCTS**

NOTE: THIS SAMPLE SIZE FURNISHES SUFFICIENT FISH FOR HEAVY METAL ANALYSIS.

Packaged Fish, fresh, frozen, smoked, cured, or shellfish (except oysters)

Collect 12 subs - minimum sub size is 453 g (1 lb.)

Bulk Fish - .453 - 1.35 kg (1 - 3 lb.)/fish

Collect 12 subs, each sub to consist of 453 g (1 lb.) of edible fish

Bulk Shellfish (except oysters)

Collect 12 - 453 g (1 lb.) subs

Canned Fish and Shellfish Products (except oysters)

Collect 12 subs - 5 cans per sub

Other Fish and Shellfish Products

Oysters - Collect 12 1-pint subs

Fish Flour and Meal

Follow the guidance in section 5 above.

SWORDFISH FOR HEAVY METALS

These sample sizes must be used whenever sampling swordfish, either for audit, surveillance, or compliance purposes.

Whole Fish (dressed, head removed)

Characterize lot in terms of fish sizes, i.e., small, medium, and large. The following dressed weight ranges are used for classification:

Small Fish - Weighs less than 36.4 kg (80 lbs.)

Medium Fish - Weighs 36.4 - 54.5 kg (80 - 120 lbs.)

Large Fish - Weighs more than 54.5 kg (120 lbs.)

For lots consisting of 12 or more fish, the representative sample to be collected will be determined by the following formula:

ns = (n) (Ns)/N

ns = the number of fish in a given weight range from which subsamples must be taken

n = total number of subsamples to be collected from the lot. (In using this formula n will always equal 12)

Ns = the number of fish in a given weight range in the lot

N = the total number of fish in the lot

Example: If a lot consists of 25 fish and is characterized as: 5 small fish [less than 36.4 kg (80 lbs.)], 15 medium fish [36.4 - 54.5 kg (80 - 120 lbs.)], and 5 large fish [greater than 54.5 kg (129 lbs.)], the sample should be collected as follows:

small fish $\frac{(12)(5)}{25} = 2.4 = 2$

medium fish $\frac{(12)(15)}{25} = 7.2 = 7$

large fish $\frac{(12)(5)}{25} = 2.4 = 2$

TOTAL SAMPLE: 11 sub samples

Usually, the total sample will consist of 12 subsamples. However, due to rounding numbers of subsamples determined by the formula may be 11 or 13 in some instances. The total sample should consist of the specific number of sub samples determined by the formula in all cases.

Each sub sample should consist of approximately a 0.5 kg (1 lb.) steak cut from just below the nape of the fish. Care should be taken to avoid mutilation of fish. The sub must consist of edible flesh. If a private laboratory is conducting the analysis, individual fish from which the sub sample is taken should be identified with a tag or other suitable method. This will permit FDA to take audit samples from the same fish sampled by the private laboratories.

For lots consisting of 12 or less fish, collect 1 sub from each fish.

Swordfish Loins (slabs or sides cut from dressed whole fish which has been boned or trimmed).

Use the same formula stipulated for whole fish, with the exception that the following weight ranges should be used to characterize the lot:

Small fish loins = weighs 9.1 - 18.2 kg (20 - 40 lbs.)
Medium fish loins) = weighs 18.2 - 36.4 kg (40 - 80 lbs.)
Large fish loins = weighs over 36.4 kg (80 lbs.)

Swordfish Steaks

Collect 12 sub samples, i.e., 12 steaks, at random from different containers in the lot (as many as possible)

Canned Swordfish

Collect 12/453 g (1 lb.) sub samples at random

11. RETAIL CONTAINERS CANNED, FROZEN AND DRIED FOODS

Collect retail containers equal to the number of primary units specified above.

12. SPECIAL INVESTIGATIONS

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

For leafy vegetables, such as lettuce, cabbage, etc.: INV Samples collected in the growing field should be representative of local commercial harvesting practices If the local practice is to strip outer leaves at the time of harvest, this practice should be followed when collecting field samples. In head lettuce, for example, the lettuce may be packed directly into shipping cartons in the field, in which case 6 or 8 outer leaves are left on the head to be removed at the retail outlet. In other instances, each head is stripped of 2 or 3 outer leaves and individually wrapped in plastic, placed in shipping cartons, and the consumer receives the produce in this condition. Describe sampling method on C/R and describe how packing shed handles produce prior to shipping (e.g., washing, waxing, stripping, etc.).

Soil Samples

Collect soil samples from fields according to the following 3x3 grid diagram:

	a	b	c
1	o	o	o

2	o	o	o
3	o	o	o

Sample at the 9 locations indicated by the "o". If the field being sampled is very large, you may have to sample it using a 4x4, 5x5, or even larger grid pattern.

Subs are to be placed in clean quart glass jars, which have been washed in water, rinsed in methanol, and air dried. If methanol is not available, use washed, air dried jars and submit an empty jar as a control. Note on CR that jars were or were not rinsed with methanol.

Obtain two "6 in" deep plugs (1-2 in. in diameter from each sampling location. Place two plugs from each location in cleaned glass jars, place clean aluminum foil over top of jar and seal with screw cap.

Soil samples should be submitted to the lab at 4° C (39° F) or below.

Water Samples - Collect 3 quarts of water from the same sampling source (e.g., faucet, stream, lake, etc.) and place in cleaned, washed and methanol rinsed jars as described under "Soil Samples".

Submit water samples to lab at 4° C (39 ° F) or below.

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

GENERAL

Official Samples shall be collected whenever feasible unless they are not required to accomplish the objective of the assignment. Investigational Samples shall be collected only when Official Samples are not readily available.

Consult with your supervisor in cases of doubt as to sample cost, size, or collection technique.

When collecting samples in glass jars, line the lids with aluminum foil which has been certified by the laboratory as contaminant free or use Teflon lined lids.

If shipment of shell eggs is required and breakage may result during transit, subs may b e broken, shells discarded, and liquid magma collected in clean glass jars. Each sub jar should be properly identified.

Samples collected at Packing Sheds should be representative of the produce as shipped in commerce. DO NOT strip outer leaves from subs collected at packing sheds from bulk lots, shipping cartons ready for shipment, in-transit lots or at final destination. If the packing shed practice is to strip outer leaves prior to shipment, follow this practice when collecting the samples. Describe the sampling method on the C/R.

DO NOT USE magic markers, etc. to identify sub bags, because the ink may affect assay results. Use stick on labels to identify sub bags.

Collect samples in the container in which the dealer is packaging the product. If the dealer is packaging the product in plastic bags, collect sample in these bags. If the firm is not packing the product, collect the samples in paper bags, cardboard cartons, etc. Do not use plastic bags as this may interfere with the analysis, unless the bags are certified as contaminant free by your division laboratory.

Samples must be delivered as promptly as possible to the laboratory if regulatory action is to be taken against actionable lots.

Hold samples in cold storage until ready to be shipped or delivered to the laboratory. If the sample is of a hard fruit or vegetable (such as apples, pears, butternut squash), and is shipped overnight delivery, it can be shipped to the laboratory unrefrigerated, but the FDA 525 should direct refrigeration upon receipt.

Use aseptic technique, where applicable, when collecting samples of finished products from bulk containers.

4- WHEAT CARLOAD SAMPLING

I. SAMPLING NORMALCARS

CAUTION: WHEN USING A GRAIN PROBE, BE CAREFUL NOT TO CLOSE THE TRIER COMPARTMENT DOORS ON YOUR FINGERS.

Collect samples only of specific assignment.

A. Equipment

1. Double tube compartmented trier, 60 in. long
2. Sampling cloth at least 60 in. long
3. 1000 ml plastic graduate
4. Paper bags or other suitable containers capable of holding more than one quart of sample and do not use canvas bags.
5. FDA Metal Car Seals for resealing railroad cars
6. Aluminum ladder
7. Block and tackle to open railcar door

B. Drawing Sample

Principal sources of grain samples are railcars, barges, and trucks. Draw 5 probes (in duplicate) for each sample taken as described below. However, if the sample is to be Field Examined, an initial sample of 5 probes drawn as indicated below will be sufficient.

Probe samples from railcars and trucks as follows:

Probe #1 - From Center of car

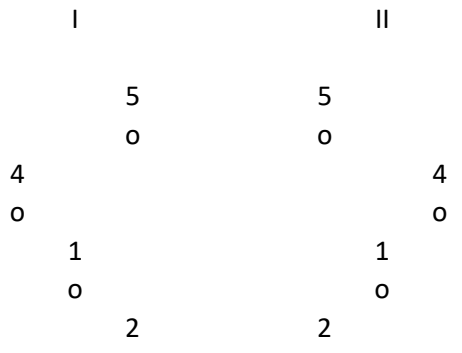
Probe #2 - From 3-5 feet back from door post toward end of the car and approximately 2 feet from the side of the car.

Probe #3 - From 3-5 feet from the same end of the car, but approximately 2 feet from the opposite side of car as Probe #2.

Probe #4 - Same as Probe #2, but opposite end of car.

Probe #5 - Same as Probe #3, but opposite end of car.

Sketches I and II below are alternatives showing the approximate sampling locations.



Insert trier in the grain at an angle of about 10° from the vertical, with the slot up and closed. Open slots. Give trier 2 or 3 short up and down motions, so that the openings will fill. Close slots (SEE CAUTION AT BEGINNING OF SCHEDULE), withdraw trier and carefully empty over sampling cloth. The cloth should be long enough to catch product from each compartment separately when you open the trier compartment doors; e.g., about 6 feet long.

C. Field Examination

Examine each pocket of the probe separately, looking for evidence of pink wheat, rodent pellets, insect damage and uneven loading or plugging. Note any insect infestation and record types of insects and whether live or dead. Count and report for each probe the number of rodent pellets, or rodent pellet fragments. Follow procedure in I.C.2 below. Count as pellets any that are sufficiently large to be readily identified by size, shape, surface coating, and/or presence of rodent hairs. Report the number of rodent pellets per sub. Measure the volume of each sub (probe) in quarts and calculate the average number of pellets per quart per I.C.2.a below. Place pellets from each sub in separate vials and submit with each wheat sub. Place each of the wheat subs in clean, paper bags.

Do not use canvas bags or take glass jars into railcars.

Substantially larger loads will require additional probing or larger samples taken from falling grain during loading or unloading operations.

Submit all suspect samples to laboratory for confirmatory analysis.

1. **Non-Violative Samples**. When field examination shows sample as non-violative, return grain to the car, unless collected for pesticide analysis. Report results in the Remarks Section of the C/R.
2. **Violative Samples**
   a. **Rodent Pellet Contamination**. The guideline for determining whether wheat is violative due to rodent contamination is: "9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per kg of wheat."

NOTE: Since it is impractical to weigh rodent pellets and wheat in the field, the following estimations can be used. Mouse pellets average approximately 8.7 mg each and a kilogram of wheat about 2.35 pints. This translates roughly as 1 pellet per quart of wheat or 1/2 pellet per pint.

Where your field examination reveals one or more rodent pellets (or you can estimate that sufficient fragments of rodent pellets exist to equal one pellet) in a quart of wheat, take duplicate probes to furnish the claimants portion. Take the duplicate probes from the same locations as the original probes. Place the duplicates in separate containers and identify these to correspond with the original probes.

b. **Pink Wheat**. Where evidence of pink wheat or other fungicide treated wheat is found, collect 15 probe samples. Take 5 probes from each end of the car and 5 probes from the center of the car. Submit the three 5-probe portions separately, using new clean containers.

c. **Insect Damaged Kernels**. The violative status of these samples should be established by laboratory analysis. When any evidence of insect damage is revealed by cursory examination, collect duplicate samples and submit for laboratory analysis.

3. **Resealing Cars** See IOM 4.3.4.
4. **Procedures for Actionable Cars.** If field examination reveals an average of one or more rodent pellets per quart or gross evidence of insect-damaged kernels, evidence of plugging, or "pink wheat" contamination, determine any movement of the car or other disposition of the grain and notify your supervisor immediately.
5. **Preparation of Sample for Laboratory Analysis**. If a sample can be delivered to the laboratory promptly and confirmatory analysis handled expeditiously, freezing of the FDA subsamples is not necessary. The claimant's (702(b)) portion of the sample, however, must be frozen. It is preferable to freeze the subsamples in paper bags. If a freezer is not available, the subsamples (in paper bags) can be placed in a cooler box with dry ice. Do not use glass jars with dry ice. Officially seal all subsamples. If dry ice is used, you must label the shipping container as described in IOM 4.5.5.8.6. See Exhibit 4-19. Indicate frozen storage on the FDA 525.

D. Special Reporting

Submit an Analyst Worksheet (FDA-431) for each sample analyzed and found in compliance. See IOM 4.3.7.1. If field examination shows the sample is possibly actionable, report analytical results in Remarks Section of the C/R.

II. SAMPLING PLUGGED CAR

If uneven loading, layering, or "plugging" is suspected, contact your supervisor as to whether to sample or not. A 'plugged" car is a railcar, truck, or barge load of grain where the contamination is suspected of being in only one portion or layer of grain. Plugging is usually the deliberate mixing of violative grain below the surface or in isolated pockets of grain.

A. Equipment

Equipment needed is the same as in 1.A. above except:

1. Double tube grain probe must have individual compartments permanently separated.
2. Small containers of sufficient size to hold the contents of each compartment of each grain probe.

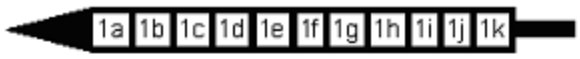
B. Procedure

1. In the Remarks Section of the C/R, draw a diagram showing actual "plugging" pattern suspected.
2. Each sample consists of thirty probes of grain with each probe compartment maintained as a separate sub. Each sample thus consists of 300-330 subs depending on whether a 10 or 11 compartment probe is used and if grain depth is sufficient to insert the probe to fully cover all compartments of the probe.
3. Probe each load and number the probes as follows:

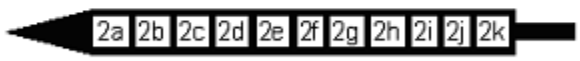
1 4 7 10 13 16 19 22 25 28
2 5 8 11 14 17 20 23 26 29
3 6 9 12 15 18 21 24 27 30

4. Identify the subs by probe number plus compartment letter starting with small "a" as the compartment nearest the tip of the probe.

Example:



Probe #1



Probe #2

5. Submit sample to your division's servicing laboratory. See IOM 4.5.5.2.

5- IMPORTED WHITEFISH SAMPLING SCHEDULE

GENERAL

This Sample Schedule objective is to maintain import lot integrity from time of importation thru FDA inspection or examination and final action.

Shipments will be special manifested from non-lab ports to DO cities and other cities designated by the DD as FDA inspection points. These shipments will arrive in Customs bonded trucks under seal applied by Customs at the port of entry. Customs Entry documents and commercial invoice will accompany each shipment. The commercial invoice contains a description of the lots in the shipment and will serve as a guide in the selection of the lots to be sampled.

1. Special Manifested Shipments:
   a. Determine if seals are intact and record seal number.
   b. FDA metal seals may be broken and lots checked against invoice.
   c. Customs seals may be broken only if authorized by Customs.
   d. Lots which are not to be examined will be released by completing the "MAY PROCEED" block of the FDA-701.
   e. Sample lots to be examined by using either the Single or Sequential Sampling Plan depending on whether examination is made at the DO Lab or at the dock. The Sequential Plan can only be used where additional fish are immediately available for cutting.
2. Definition of a Lot & Selection for Examination.
   a. A lot is defined as "Each group of fish of a distinct size, listed in the invoice as from a distinct lake, will be considered as a separate lot. Where an invoice does not list lakes of origin of boxes of fish in a shipment, fish of the same size and kind will be considered to comprise a single lot. When the size of the fish or lakes of origin in a shipment are not specified, the shipment will be treated as a single lot."
   b. Limit sampling to lots containing 5 or more boxes unless deliberate splitting up of lots is suspected.
   c. Basis for Sampling. Select lots for sampling on either a "selective" or "objective" (random) basis. The criteria in selective sampling may be prior knowledge or suspicion that fish listed as from a given lake are likely to have excess cysts; that the shipper has been known to manipulate shipments; etc. Regardless of the reason for selective sampling, record the basis for sampling each lot in your examination report. Simply list the basis as "selective" or "objective" next to the results of each lot sampled.
   d. Normally, select boxes in a lot for sampling at random. However, where there's evidence of layering, selectively sample the suspect boxes.
3. Sampling Schedule.
   a. Imported samples of whitefish & related fish for parasites. The sampling schedules estimate lot quality more precisely, thereby reducing the likelihood of passing a lot which should be detained, or vice versa, due to an inadequate sample.
      SCHEDULE A below is a single sample plan for use in collecting samples for examination in the division lab or other location where it is impossible or undesirable to return and obtain additional fish.
      SCHEDULE B below contains sequential sampling plans for use when the exam is made at a customs office or a carrier's dock where you have immediate access to the lot and can obtain additional fish, if necessary.
      The sequential plan for lots of 20 to 100 boxes is presented in tabular form. The sequential sample plan for lots of 100 or more boxes is presented in a sampling chart. For small lots of 5-20 boxes, a sequential sample plan is not feasible. All import sampling plans are based on lot size and the sizes of the fish in the lot. When lots are very good or very poor quality, in terms of cyst infestation, double sample plans require a smaller sample size on the average than single sampling plans, to reach a decision.
   b. Domestic Samples for Parasites.
      i. For Laboratory Examination. Lots of 11 or more boxes; Collect at least 25 fish from a representative number of boxes. For small lots, under 11 boxes; Collect 12 fish from a representative number of boxes.
      ii. For Examination in Other Than Laboratory. Cut a preliminary sample in accordance with the appropriate double sampling plan, Schedule B. Cut the additional sample where indicated or

bring the additional sample to the laboratory for examination.

SCHEDULE A - SINGLE SAMPLE PLAN

Number of Boxes in Lots	NUMBER OF KG'S (POUNDS) IN A SAMPLE 1/		
	Jumbo or Large 2/	Medium 2/	Small 2/
5 - 19 boxes	12.7 kg (28lbs)	10.5 kg (23lbs)	7.3 kg (16lbs)
20 - 100 boxes	24 kg (73lbs)	20.5 kg (45lbs)	15 kg (33lbs)
100 or over	32 kg (70lbs)	25.5 kg (56lbs)	17.8 kg (39lbs)

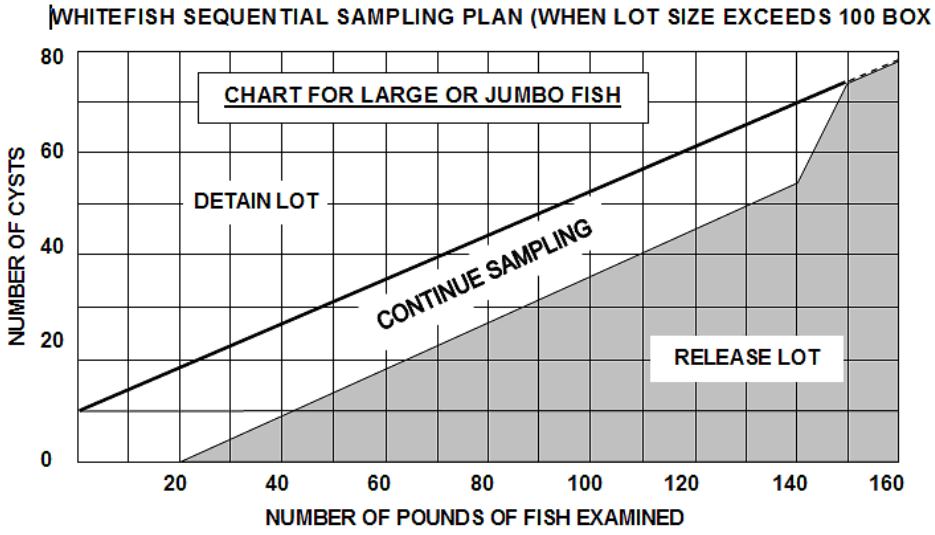
1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.

2/ RANGE OF WEIGHT OF FISH IN EACH SIZE CLASS:
SMALL Under 675 g (1 1/2lbs)
MEDIUM 675 g (1 1/2lbs) & under 1.4 kg (3lbs)
LARGE 1.4 kg (3lbs) & under 1.8 kg (4lbs)
JUMBO Over 1.8 kg (4lbs)

SCHEDULE B - SEQUENTIAL SAMPLE PLAN
1. Limited to lots of 20 - 100 boxes. 454 kg (1000lbs) to 2272 kg (5000lbs)

Size of Fish 1/	Size of preliminary Sample	Cysts/45.5 Kg (100lbs) in Preliminary Sample			Size of ADD'L SMPL	Cysts/45.5 Kg (100lbs) in sample	
		PASS	DETAIN	TAKE ADD'L SMPL		PASS	DETAIN
Large & Jumbo	16 kg (35lbs)	30 or less	70 or more	31-69	28.6kg (63lbs)	49 or less	50 or more
Medium	12.3 kg (27lbs)	26 or less	67 or more	27-66	19.5 kg (43lbs)	49 or less	50 or more
Small	8.2 kg (18lbs)	38 or less	61 or more	39-61	11.8kg (26lbs)	49 or less	50 or more

1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.
2/ For lots of 100 boxes or over, use the Sequential Sampling Chart for the particular size fish in the lot.



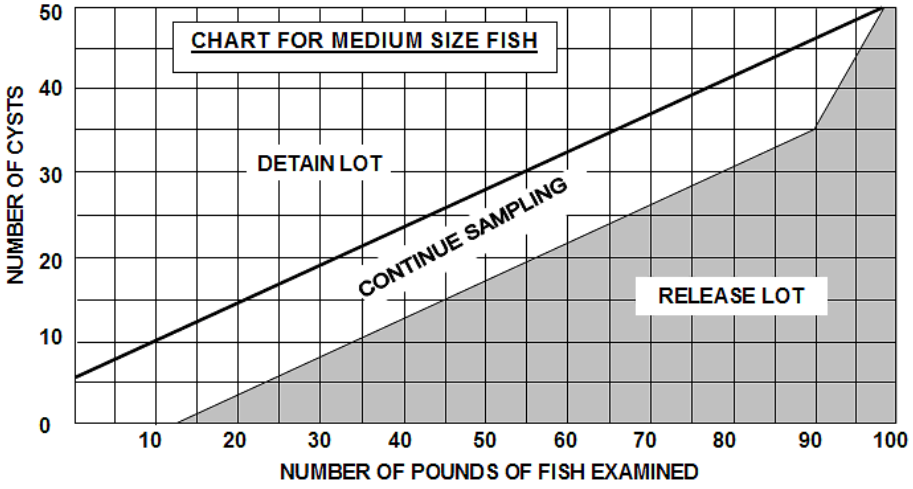


CHART FOR MEDIUM SIZE FISH
DETAIN LOT
CONTINUE SAMPLING
RELEASE LOT
NUMBER OF CYSTS
0
10
20
30
40
50
10
20
30
40
50
60
70
80
90
100
NUMBER OF POUNDS OF FISH EXAMINED

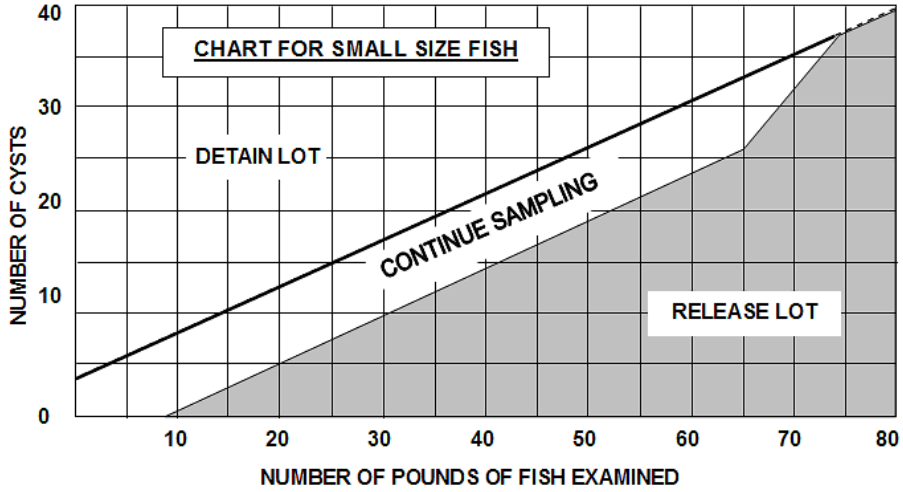


CHART FOR SMALL SIZE FISH
DETAIN LOT
CONTINUE SAMPLING
RELEASE LOT
NUMBER OF CYSTS
0
10
20
30
40
10
20
30
40
50
60
70
80
NUMBER OF POUNDS OF FISH EXAMINED

6- MYCOTOXIN SAMPLE SIZES

MYCOTOXIN SAMPLE SIZES				
Please consult 21U.S.C. 372(b) regarding duplicate portion for 702(b)				
HUMAN FOOD PRODUCTS				
Product	PACKAGE TYPE/ LOT SIZE: lbs. [1]	NUMBER OF INCREMENTS (SAMPLE UNITS) TO COLLECT [2]	MINIMUM SAMPLE UNIT SIZE: g (lb.)	MINIMUM TOTAL SAMPLE SIZE: kg (lbs.)
Fluid: e.g., milk and apple juice	≤ 22,000	6	500 mL (16 fluid oz.)	3 L (96 fluid oz.)
	> 22,000 ≤ 150,000[3]	20	250 mL (8 fluid oz.)	5 L (160 fluid oz.)
Processed snack food: e.g., corn chips, candy bars with/without nuts **Milk Products:** *(refer to CP 7307.001) e.g., cheese, yogurt	Consumer [3] or Bulk	10	454 (1.00)	4.5 (10)
Ground Products and Finished Food				
Grain products e.g., meal, flour grits, pasta, and breakfast cereals **Edible seeds, oil seeds and nut products** e.g., smooth butter, flour, paste **Spices**; **dried ground** e.g., ginger, pepper	≤ 2,200	10	454 (1.00)	4.5 (10)
	> 2,200 ≤ 4,400	12	454 (1.00)	5.5 (12)
	> 4,400 ≤ 22,000	15	454 (1.00)	6.8 (15)
	> 22,000 ≤ 150,000 [4]	20	454 (1.00)	9.1 (20)
Whole and non-Ground Products				
Whole Grains e.g., shelled corn, wheat, sorghum, barley, rice **Edible and oil seeds:** e.g., melon, pumpkin, sesame, soybean, sunflower **Spices; dried whole**: e.g., ginger, nutmeg **Beans:** e.g., coffee beans, pinto beans	≤ 220	10	454 (1.00)	4.5 (10)
	> 220 ≤ 2,200	15	303 (0.67)	4.5 (10)
	> 2,200 ≤ 4,400	20	227 (0.50)	4.5 (10)
	> 4,400 ≤ 22,000	30	227 (0.50)	6.8 (15)
	> 22,000 ≤ 150,000[4]	50	182 (0.40)	9.1 (20)
Peanuts and tree nuts (shelled or in-shell), except in-shell Brazil nuts e.g., peanuts, almonds, pecan, pistachios **Crunchy nut butter** **Dried fruits** e.g., figs, raisins	≤ 220	10	454 (1.00)	4.5 (10)
	> 220 ≤ 2,200	20	454 (1.00)	9.1 (20)
	> 2,200 ≤ 4,400	30	454 (1.00)	13.6 (30)
	> 4,400 ≤ 22,000	60	378 (0.83)	22.7 (50)
	> 22,000 ≤ 150,000[3]	100	227 (0.50)	22.7 (50)
	Number of bags	NUMBER OF SAMPLE UNITS TO COLLECT[2]	MINIMUM SAMPLE UNIT SIZE: g (lb.)	MINIMUM TOTAL SAMPLE SIZE: kg (lbs.)
Brazil nuts in-shell	< 200	20	454 (1.00)	9.1 (20)
	> 200 ≤ 800	40	454 (1.00)	18.2 (40)
	> 800 ≤ 2,000 [5]	60	454 (1.00)	27.3 (60)
ANIMAL FOOD PRODUCTS[6]				
Product	PACKAGETYPE/ LOT SIZE: lbs.[1]	NUMBER OF SAMPLE UNITS TO COLLECT	MINIMUM SAMPLE UNIT SIZE: g (lb.)	MINIMUM TOTAL SAMPLE SIZE: kg (lbs.)
Whole Grains: e.g., shelled corn, wheat, sorghum, barley, rice **Oilseeds:** e.g., soybean, cottonseed **Grain products:** e.g., cracked corn, corn screenings, wheat middling	≤ 4,400	20	227 (0.50)	4.5 (10)
	> 4,400 ≤ 22,000	30	227 (0.50)	6.8 (15)
	> 22,000 ≤ 150,000[3]	50	182 (0.40)	9.1 (20)
Oilseed and nut meals e.g., peanut meal, cottonseed meal, soybean meal **Milled corn products** e.g., corn gluten meal, cornmeal, hominy	Consumer[3] or Bulk	40	227 (0.50)	9.1 (20)
Complete mixed animal food e.g., poultry feed, cattle feed, swine feed, pet food	Consumer or Bulk	20	227 (0.50)	4.5 (10)

[1] If you have any questions, please consult the appropriate FDA Center for further assistance.
[2] Sample unit integrity must be maintained.
[3] For sampling of consumer packages, please consult the IOM or the appropriate FDA Center for further assistance.
[4] If a lot is more than 150,000 lbs., please consult the appropriate FDA Center for further assistance.

[5] If a lot is more than 2,000 bags, please consult the appropriate FDA Center for further assistance.
[6] When foods are not designated as animal food, the food should be sampled according to the schedule for human food.

7- SAMPLING SCHEDULE FOR CANNED FRUIT - FILL OF CONTAINER - AUTHENTIC PACK

Collect samples only on a specific assignment or during inspections when it appears that the firm is not filling the containers to capacity.

1. **INVESTIGATIONAL SAMPLES:** Authentic Pack Preparation. Procedure for preparing authentic factory packs.
   a. Remove 72 cans, 3 at a time, from packing line after fruit has been added and before syruping.
   b. Mark 24 cans with the sub numbers A-1, A-2, A-3, etc.; 24 cans with sub numbers B-1, B-2, B-3; and 24 cans with sub numbers C-1, C-2, C-3, etc. See IOM 4.5.2.3.
   c. Drain water from the "B" subs by inverting each can for 10 seconds, holding the fruit so it doesn't fall out.
   d. Obtain gross weight of each can and record data for each series of sub on 3 separate FDA-485 - Field Weight Sheets.
   e. Add additional fruit of the same kind and style to the "C" subs until the cans are filled to capacity. Do not tamp the contents or crush the fruit.
   f. Record the number of fruit pieces added where the size of the fruit makes the procedure reasonable. Do not make time consuming counts of small pieces of fruit or berries.
   g. Obtain the gross weight of the "C" subs after additional fruit is added and record on "C" series Field Weight Sheet.
   h. Return all 72 cans to the filling line for syruping, exhausting, sealing, etc. in normal cannery operation.
   i. Remove cans after cooking and cooling.
   j. Identify cans with a single INV Sample number.
   k. Attach FDA-485 - Field Weight Sheets to C/R.

2. **OFFICIAL SAMPLES**
   See Sample Schedule Chart 2 for sample size.

3. **SPECIAL REPORTING AND PRECAUTIONS**
   a. Report coding of cans and shipping cases.
   b. Obtain label specimen(s) for the slack filled products.
   c. Report shipments made before the inspection or since previous inspection in the same canning season.
   d. Do not prepare Authentic Factory Samples when the cannery is packing for USDA fill-of-container certification unless:
      i. USDA inspection is not continuous.
      ii. USDA Certification is for quality only.
      iii. USDA recommendations for weights are not being followed.

4. **SAMPLE SUBMISSION**
   Submit samples to your division's designated workplan servicing laboratory.

8- SAMPLING SCHEDULE FOR IMPORTS - COFFEE, DATES AND DATE MATERIAL

1. Coffee - Import Field Examination - Note: Examine a minimum of six bags of coffee beans regardless of lot size. If a significant number of defective beans or significant contamination is found during the examination of these six bags, continue the examination using the following schedule, which applies for both Import Field Examination and samples for laboratory analysis:

LOT SIZE	NO. BAGS TO BE SAMPLED
100 or less	6 bags
101 - 200	10 bags
201 - 1000	15 bags
over 1000	20 bags

   a. Sample each bag with a trier, collecting 1/2 pt. of beans from the top and 1/2 pt. from the bottom of the bag. The total quantity of beans taken from each bag must be the same, since both wharf and laboratory examinations are to be performed on a composite sample of all beans collected. Shake each sub on a #8 sieve nested in a pan. Dump the sifted beans from each sub into a bag of sufficient size to hold and permit mixing all of the subs collected from the lot. Composite the subs. Do not maintain individually.
   b. Macroscopic Filth Examine the siftings for macroscopic filth (live and dead whole insects, excreta pellets, extraneous material, and sweepings), reporting findings for each sub separately. See IOM 4.3.7.4. Transfer macroscopic filth, including all sifted material to a second bag and submit to the laboratory for confirmation. If live insect infestation is encountered, freeze the filth portion containing the insects and the composite coffee bean sample. The lot will be detained if a live insect infestation is encountered, however, proceed with the defect bean examination since the reconditioning process will depend on the results.
   c. Defect Bean Examination Thoroughly mix the composite sample of coffee beans and remove three-hundred beans at random. Examine each individual bean visually (or at a 5X magnification) for insect tunneling and mold damage. Count as moldy only those beans with 1/4 or more of the surface being moldy. Note: Each division office has examples of the various types of reject beans.
      Accept the lot if twenty or less rejects are found and discard the sample. Report your wharf examination into FACTS or OASIS, depending on your assignment; no Sample Collection Report is necessary.
   d. If twenty-one or more rejects are detected, return beans examined to the composite and submit to the laboratory. You may discontinue the examination when twenty-one rejects are detected. When a sample is submitted to the laboratory, all import field examination time is reported as a field exam in FACTS and the sample collection time is reported as an import sample collection. All necessary documents for an import sample collection must be completed.

2. Dates & Date Material - Filth

   In the laboratory, dates, like in-shell nuts are sampled in accordance with a sequential sampling program, i.e., all subsamples are composited, and 100 dates are sampled at a time, repetitively, until such time they either exceed or fall under certain reject numbers. It is not uncommon to have to examine 3 to 6 (100 date) repetitions. It is therefore important for each subsample to contain at least 300-400 dates or a 3-pound chunk of date material. Bag subs separately and identify. Sample according to the following schedule:

NUMBER OF SUBSAMPLES REQUIRED

NO. CONTAINERS IN LOT*	WHOLE DATES	DATE MATERIAL
100 or less	3	4
101 - 600	8	6
601 - 1200	14	8
1201 - 2000	26	10
2001 - 2800	36	12
2801 - 6000	44	14
6001 - 9600	56	16
9601 - 15000	68	18
Over 15000	82	22

   * Schedule is based upon unit containers weighing between twenty and one-hundred pounds. For containers exceeding one-hundred pounds each, consider as two or more containers. For example, a one-hundred and fifty-pound container is considered as two containers; a three-hundred pound container as three containers, etc.

   a. Identify each subsample separately.
   b. Each lot will be a separate sample. Reconditioning, if possible, will be based on lot numbers.
   c. Jujube sampling – collect according to the above schedule for dates and date material. Do not identify jujube samples as dates, *Phoenix dactyllifera*. Jujubes, *Zizphus jujube*, are usually labeled as Chinese Red Dates, Dried Red Dates, or Honey Dates and are not misbranded when labeled as such due to long standing use of these names.
   d. If live insects are noted, include these as part of the sample collected and report on the C.R. which subs

contained the insects and how many insects, adult, or larvae, were noted. If live infestation is noted, place all subs from the lot sampled in large plastic whirl-pak bags and freeze or place in a cooler on dry ice.

9- SAMPLING SCHEDULE FOR COLOR CONTAINING PRODUCTS & COLOR ADDITIVES

The following schedule provides general guidance for collecting samples of foods and cosmetics to determine whether non-permitted colors are present, rather than to determine the actual level of a particular color. This schedule was developed with the assumption that color distribution in the lot will be homogeneous. In the case of heterogeneous products, your supervisor should contact the Human Foods Program, Office of Field Programs, Division of Enforcement (HFS-605) to determine sample size.

INDUSTRY CODE		SAMPLE SIZE (DO NOT COMMINGLE CODES) (Min. 225 g (8 oz)/pkg Unless otherwise specified)
GRAIN AND BAKING		
02	Whole grains, Milled Grain Products and Starch	2 retail packages
03	Bakery Products, Doughs, Bakery Mixes, and Icings	2 retail packages
04	Macaroni and Noodle Products	2 retail packages
05	Cereal Preparations Breakfast Foods	2 retail packages
07	Snack Food Items (Flour, Meal, or Vegetable Base)	2 retail packages
DAIRY		
09	Milk, Butter, and Dried Milk Pdts	Liquid Pdts: 2 pts where possible Solid: 2 packages
12	Cheese and Cheese Products	2 retail packages
13	Ice Cream and Related Products	6 items per sample (If item is single serving; i.e., cup, popsicle, bar, etc.) 2 pt. containers where possible, or 1 quart or 1/2 gal
14	Filled Milk and Imitation Milk Products	2 pints
EGGS		
15	Egg and Egg Pdts	2 dozen whole eggs (e.g. colored hard-boiled Easter eggs) 2 retail pkg of egg pdts
FISH		
16	Fishery/Seafood Pdts	2 retail packages. Any collection of smoked salmon should be selective, based on inspectional evidence
MEAT & SIMULATED MEAT PRODUCTS		
17	Meat, Meat Products and Poultry	2 retail packages
18	Vegetable Protein Pdts	2 retail packages
FRUIT, NUT AND VEGETABLE PRODUCTS		
20-22	Fruit & Fruit Pdts	2 retail packages canned or glazed. 12 fresh fruit (e.g., oranges, etc.).
23	Nuts & Edible Seeds	2 retail packages
24-25	Vegetable & Vegetable Products	2 retail packages
26	Vegetable Oils & Olive Oil	Liquids - 2 pints Solids - 2 retail packages
DRESSINGS AND SPICES		
27	Dressings & Condiments	2 retail packages
28	Spices, Flavors, & Salts	Extracts - 2 pints Solids - 2 retail packages
BEVERAGES		
29	Soft Drinks & Waters	6 Retail Units (Cans, Bottles, Packets)
30	Beverage Bases, Concentrates, and Nectars	Liquids - 1 pint Solids (Powder mix, packets) - 6 Consumer Pkg Solids - 2/225 g (8 oz) or larger containers
31	Coffee and Tea	2 retail packages
32	Alcoholic Beverages	2 pints or 1 quart
CONFECTIONS AND DESSERTS		

33	Candy w/o chocolate, Candy Specialties, and Chewing Gum	2 retail packages
34	Chocolate & Cocoa Pdts	2 retail packages
35	Gelatin, Rennet, Pudding Mixes, & Pie Fillings	6 pkgs - smallest consumer size
36	Food Sweeteners (Nutritive)	2 pints

MULTIPLE FOODS, SOUPS, SALADS, BABY FOOD AND DIETARY

37	Multiple Food Dinners Gravies, Sauces and Specialties	Single Serving Dinners, etc. - 4 pkgs Two Consumer Pkgs when 1 pkg serves more than 2
38	Soups	Same as 37 Above
39	Prepared Salad Products	Same as 37 Above
40	Baby (Infant and Junior) Food Pdts	Sufficient retail pkgs to total at least 454 g (1 lb.) of food
41	Dietary Conventional Foods and Meal Replacements	Same as 37 Above

COLORS AND COSMETICS

50	Color Additives for Foods Drugs, and Cosmetics	1. Straight Color 28 g (1 oz) powder. 2. Color Mixtures 110 g (4 oz) Liquid, paste or powder. If mixture contains over 50% pure dye, 55 g (2 oz) is sufficient
53	Cosmetics	Four retail packages of the same lot code for each shade (color) in the product line, if the product is strongly colored. (e.g., Lipsticks, hair coloring products, eye mascara, eye liners, make up pencils of all types) Sufficient number of retail packages to equal 1 lb. or 1 pt. of sample if the product is lightly colored. (e.g., creams, lotions, shampoos, bath products, shaving preparations, and perfumes.) Note: Always collect a minimum of two retail units of each product.

MISCELLANEOUS

	Bulk Items (Any bulk food or cosmetic)	Dry - 454 g (1 lb) Liquid - Min 36 fl oz

10- DRUG SAMPLING SCHEDULES

(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size[1]	
	INV Sample[2]	Official [702(b) & Check][3]
DRUGS	36	86
DEVICES	46	106

LEGEND:

[1]Double sample size requirements when individual containers are 2 ml (2 g) or smaller.

[2]INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.

[3]Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) [21 U.S.C. 372(b)] and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting division lab, plus a separate 100 tab portion to be split for dissolution testing.

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	MINIMUM SAMPLE SIZE (Includes 702(b) portion)	
	Sub Size	Nos. of Subsamples
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 g or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your division for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 4.3.6 through 4.3.6.5.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your division unless directed otherwise.

11- VETERINARY PRODUCTS, FEEDS, & BY- PRODUCTS FOR ANIMAL FEEDS

1. GENERAL

This sampling schedule may be used as a guide in the collection of surveillance or compliance samples resulting from division assignments or as a follow-up to violative inspections and/or investigations. Before collecting follow-up samples to violative inspections or investigations, contact your supervisor since it may be necessary for your division to consult with the Atlanta Center for Nutrient Analysis (HFR-SE680) when unscheduled compliance sampling is contemplated.

2. SAMPLE PRODUCT, SIZE, & SPECIAL INSTRUCTIONS

Vitamin-mineral testing, sampling instructions and information. Sample size includes 702(b) portion.

Unless excessive cost is a factor, collect at least 3 intact containers from each lot or control number. When sampling from bulk lots, collect appropriate subs from a minimum of 3 different bulk containers in the lot.

DOSAGE FORM VITAMIN-MINERAL PREPARATIONS (Single/Multiple Ingredients)

PRODUCT	NO. SUBSAMPLES	MINIMUM TOTAL SAMPLE SIZE	REMARKS
Injectables	3 vials/amps	30 ml	Split samples for sterility testing (60 vials/amps)
Tabs/Caps	3 retail units	300 Tabs/Caps	Split sample for micro tests (10/50 tab/cap subs)
Liquids	3 retail units	4 fl. oz.	Split sample for micro tests (10/2 fl. oz. subs)
Powders	3 retail units	112 g (4 oz)	Same as above

FEEDS & BY-PRODUCTS FOR ANIMAL FEEDS (Vitamin-Mineral Claims)

Vitamin A & D Concentrates, Supplements & (A&D feeding	3 retail units (1/2 gal or less)	3 lbs. (1.4 kg) 3 pints	Limit samples to those products containing at least 800 units/g Vit A and/or 80 Feeds units/g Vit D
Vitamin B2 (Riboflavin) Concentrates, Supplements, & feeds	Same	Same	Limit samples to those products containing at least 20 mg/lb.
Vitamin B12 (Cyanocobalamin) Concentrates, Supplements & feeds	Same	Same	Limit samples to those products containing at least 1 mg/lb
Multiple Vitamins Concentrates, Supplements, & feeds.	Same	Same	Limit samples to those products meeting vitamin levels listed above.

3. SAMPLE SUBMISSION

Submit all samples for Vitamin Potency analysis to the Atlanta Center for Nutrient Analysis (HFR-SE680). Submit samples for filth analysis, microbiological examination, sterility, etc. to your division servicing laboratory.

12- MEDICATED ANIMAL FEEDS SAMPLING

Medicated Premixes

1. Investigational Samples (INV Samples)
   To demonstrate suspected drug carryover or other chemical contamination during manufacturing, collect 1-900 g (2 lbs.) of static residual material in the equipment, and the finished product premixes.
2. Official Physical Samples 702(b) [21U.S.C.372(b)] Portion Included
   For expensive premixes or components, collect a total of 3/170 gm (6 oz) subs; One sub from each of 3 containers. In the case of premixes packaged in plastic; e.g., mini-packs, follow instructions under bagged premixes.
   a. Bagged Premixes
      Collect 10 - 454 g (1 lb.) subs from each lot. Sample all bags in lots under 10 bags, for a total of 10 subs from the lot.

      Collect 454 g (1 lb.) subs from at least 10 different bags selected at random in lots of more than 10 bags.
   b. Bulk Premixes
      Collect at least 10 - 454 g (l lb.) subs, from different locations in the lot providing a minimum total sample of 4.5 Kg (10 lbs.).
3. Documentary Samples (DOC Sample) - Refer to IOM 4.1.4.2 for guidance on the collection of DOC Samples.

Medicated Feeds

1. Investigational Samples (INV Sample)
   Collect 1 - 900 g (2 lb.) of static residual material in the equipment and correlate with finished feed samples to show that residues are being carried over into the finished product.
2. Official Samples (Includes 702(b) portion)
   a. Bagged Complete Feed
      Collect a total sample of not less than 2.3 kg (5 lbs.) from each lot. Collect 454 g (1 lb.) subs sampling all available bags from lots of 10 bags or less. If lot size is greater than 10 bags, collect 454 g (1 lb.) from each of 10 bags selected at random.
   b. Bulk Complete Feed
      Collect at least 10 - 454 g (1 lb.) subs from different points in the bulk lot to obtain a minimum total sample of 4.5 kg (10 lbs.).
   c. Concentrates/Supplements
      If the concentrate or supplement is relatively inexpensive, follow the sampling procedures for complete feeds. Limit sampling of more expensive drug materials, concentrates, or supplements to no more than 3 containers taking a 170 g (6 oz) or 6 fl. oz. sub from each of the 3 containers.
3. Documentary Samples (DOC Sample)
   a. Feed Subject to MFA Approval - Collect DOC Samples of products processed without required MFA approval. Where the plant does not ship in IS commerce, but ingredients are received from IS sources, document the IS nature of drug ingredients and the "Held For Sale" status of the finished feed. Labeling of drug ingredients must be submitted.
   b. Misbranded Products - Collect a DOC Sample for misbranding or labeling deficiencies. The failure to provide warning and/or withdrawal statements which could present danger to animals or man, or gross evidence of false and misleading therapeutic claims, are factors for consideration.

Sampling Precautions (See IOM Sample Schedule Chart 4)

1. Insert the trier the full length of the bag when sampling bagged premixes, or complete feeds.
2. Clean trier between sampling the different lots of premixes or complete feeds.
3. Place subs in a clean, airtight container, preferably clean glass jars.
4. Do not fumigate samples intended for potency analysis, drug carryover or cross-contamination.

Sample Submission

Submit samples to your division's servicing laboratory or as directed by your assignment or supervisor. See IOM 4.5.5.2.

13- SAMPLE SIZES WITH APPLICATION TO FOOD PRODUCTS FOR ALLERGENS

Note: Follow 4.3.2.2 concerning collection of the 702(b) portion of the sample. Guidance below does not include 702(b) portion.

All subs should be at least 100 grams of product (approximately 3.5 ounces), except in case of consumer complaint samples (see 1a).

1) **"For Cause"** samples should consist of 2 subs. "For cause" sampling should be limited to instances where there is a reasonable probability that a product may contain an allergen and the labeling of the suspect product does not indicate the presence of the allergen; for example, from a consumer complaint, a downstream consignee laboratory analysis. Only collect "For Cause" samples after consulting with your Emergency Response Coordinator and HFP (see IOM 8.2.3.4.3).
    a. For consumer complaint samples, collect the remainder of the consumed product in its original container and a control sub of at least 100 grams of the same product, preferably from the same lot. The consumed portion should always be all remaining product and does not need to be at least 100 grams. Do not collect samples of foods prepared by the consumer or foods in refuse containers.
2) Collect 10 subs when heterogeneous contamination is suspected. Samples may be collected randomly from multiple production lots or from random production times in one production lot.
3) During inspections or investigations of manufacturing facilities:
    a. Collect 2 subs each for samples *where cross-contamination* or undeclared allergen is suspected to be inherent in the sample may include: source ingredients, in-line samples, product scrapings from equipment, finished product (at manufacturer) and/or finished product released into commerce.
    b. Only collect equipment swabs at the direction from HFP.

14- SAMPLE SIZES FOR FILTH ANALYSIS

Table 1. Sample Size for Filth Analysis: Dried Fruit, Dried Peas, Dried Beans

This table provides specific instructions outlining sample sizes for dried peas, beans, and fruit products to be analyzed for filth. Guidance in CP 7303.050, Foodborne Biological Hazards, indicates that in the absence of specific instructions outlining the expected sample size for a given product, ten (10) subsamples, each with 2 lb., should be collected at random.

Note that these two CPGs provide direct reference seizure criteria, but do not provide sampling guidance (quantity to collect for lab analysis):

- CPG Sec 585.225, Black-Eyed Peas (Cow Peas, Field Peas) Dried - Adulteration with Lygus Bug Damage
- CPG Sec. 585.575 Peas and Beans Dried - Adulteration Involving Storage, Insect Damage, Rocks

For food storage and warehousing, the following may be of interest: CPG Sec. 580.100 Food Storage and Warehousing-Adulteration-Filth (Domestic and Import).

SAMPLE SIZES FOR FILTH ANALYSIS			
Please collect a duplicate portion for 702(b) [21U.S.C. 372(b)] when directed or required per IOM 4.3.2.2 and 4.3.2.3			
HUMAN FOOD PRODUCTS - Dried Fruit, Dried Peas, Dried Beans			
Product	**NUMBER OF SUBSAMPLES to COLLECT**	**MINIMUM SUBSAMPLE SIZE**	NOTES
Dried Peas and Beans	12	1 lb.	
Dates and Date Material	See Notes column	--	See specific sampling guidance in CPG Sec. 550.300. Note: There is important sampling information in MOU 225-72-2001, which is related to imported dates and which outlines responsibilities for USDA/Agricultural Marketing Service (AMS) and the FDA.
Jujubes **(also called Chinese date or red date)**	See Notes column	--	See specific sampling guidance in IOM, Chapter 4: Sample Schedule Chart 8 - Sampling Schedule for Imports - Coffee, Dates and Date Material
Prunes	10	2 lb.	See also CPG 550.700
Raisins	10	2 lb.	Imported raisins: Sample collection of import raisins should only occur when deemed appropriate by the Memorandum of Understanding (MOU) between the AMS and FDA. See MOU 225-73-2007. Only when indicated for collection, collect 10 subsamples of 2 lb. each. See also CPG Sec. 550.750.
Dried Fruit Products	6	100 units of fruit[1]	Collect six (6) subsamples, each with a minimum of 100 units of fruit.[7] Note: It's recommended to verify by count that each subsample contains at least 100 units. When that is not practical, the below weight approximations may be helpful. • Small fruits (e.g., cherries, blueberries): 2 lb. usually contains 100 units • Medium fruits (e.g., persimmons, apricots, figs): 4 lb. usually contains 100 units • Large fruits (e.g., all tamarind pods): 6 lb. usually contains 100 units

Produce: Sample Collection and Shipment of Produce for Filth Analysis - Container and Temperature Considerations

These instructions apply to sample collections of produce to be analyzed for filth. This information is intended to supplement the information provided in the CP 7303.050, Foodborne Biological Hazards. When collecting samples of produce for filth analysis, please consider the type of container and temperature requirements on the product labeling, if there is labeling. If there is no label, or if the label does not specify a storage temperature:

[7] There should be 100 whole fruits. When fruit has been cut into 'pieces', do not count each piece as one whole fruit.

- Dried produce – Collect in doubled paper bag (not plastic bags, unless in retail bags); ship at ambient temperature.
- Fresh produce – Ship at refrigerated temperature (for example, cooler with some type of "Ice Pak", "Liquid Ice", "Sno-Gel", "Kool-It", or similar materials to maintain the required temperature range). Ship overnight, if possible. Do not use bagged (or “wet”) ice.
    - For bulk product, collect each subsample in a doubled paper bag, placed inside a plastic bag or mesh bag.
    - Another option is to use the original container, if economically feasible. If the original container is used, or if the product is in bulk, consider adding packing material to the container so that the product will stay in place and not move around during shipment.

4-22 Sample Criteria for Selective Sampling for Filth

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

How FDA products are manufactured, stored, or shipped can lead to these products being adulterated directly. These products can also be deemed to be adulterated indirectly if they were manufactured, stored, or shipped under insanitary conditions. The evidence of these adverse conditions is obtained through sampling and documenting through an inspection (Chapter 5). The criteria for documenting food adulteration in this section should serve as guidance for documenting adulteration with other FDA regulated products. It is ultimately the investigator's responsibility to develop the evidence of adulteration and defining the scope of the adulteration (lot specific, product specific, location specific). Photographs taken during sampling (Chapter 5) can be very useful in court proceedings and litigation. Considerations of how product is packaged or contained should be factored when determining how to sample for adulteration. For example, it is harder to show environmental adulteration of products contained in a metal container or closed system verses a cardboard container where there may be no linings to protect the product.

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:

- Current or old
- Isolated or widespread

If it is isolated to one lot (possible FD&C 402(a)(3) charges - contain in whole or in part filth or is otherwise unfit for food or 501(a)(1) if a drug or device product).

Widespread adulteration 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. These would be possible FD&C 402(a)(4) charges for food or 502(a)(2)(A) charges if a drug or device.

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

Your sample collection should be sufficient to document the extent of the violative conditions and not be limited to this minimum. Even where these minimum prerequisites are not met, you should collect samples as exhibits and evidence, particularly where adulteration under section 402(a)(4) of the FD&C Act [21 U.S.C. 342 (a)(4)] or 501(a)(2)(A) of the FD&C Act [21 U.S.C. 351(a)(2)(A)] 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 center compliance office so evaluation of evidence for a possible mass seizure can commence.

General Guidance for Selective Sampling

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

Note: A 702(b) portion is not required for import samples or medical devices. However, if a dispute arises, or a potential for regulatory action exists, a 702(b) portion may be collected. Contact your supervisor for additional guidance, if necessary.

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:

- Use a coherent numbering/identification system for subsamples to avoid unnecessary confusion for the lab.
- Provide a detailed listing of individual sub descriptions on the C/R.
- If possible, provide a copy of any maps, photos, or other additional documentation to the laboratory.
- 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.

Note: Whenever a portion of food is collected as part of a selective sample FD &C Act Section 704(d) applies and the C/R should be marked as such.

Documenting Rodent Contamination

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

The storage facility is rodent infested and:

- Three or more of the bags in the lot are rodent gnawed;

Or

- 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

- 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:

- 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

- 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

- 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.

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 ultraviolet (UV) 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 ultraviolet 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 ultraviolet 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 UV 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).

Collecting Exhibits or Subsamples fo Rodent Contamination

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

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

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

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

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

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

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

different containers or bags of different manufacturers, collect controls to represent each type or manufacturer of the containers.

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

Summary of Sample for Rodent Evidence

The complete official sample will consist of:

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

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

Documenting 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.

The product contains:

- 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
- 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.

Or:

- The product contains one or more live insects in each of three or more immediate containers.

Or:

- 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.

Or:

- 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.

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.

Collecting Exhibits or Subsamples of Insect Contamination

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

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

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

Summary of Sample for Insect Evidence

The complete official sample will consist of:

- Subsamples of insects, larvae, webbing, etc.
- Subsamples of portions of the containers with entrance or exit holes.
- Subsamples of small portions of the product from directly beneath holes.
- Subsamples of small portions of product serve as 702(b) portions See IOM 4.3.7.4.1.
- Product labeling.

- Interstate documentation.

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

Documenting Bird/Avian Contamination

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

- 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

Or

- Bird excreta is present on the exteriors of at least five of the containers, and the product contains bird excreta in one.

Or

- 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.

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.

Collecting Exhibits and Subsamples

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

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

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

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

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

Summary of Sample for Bird Evidence

The complete official sample will consist of:

- Subsamples of stained bagging, or portions of the containers.
- Subsamples of unstained bagging, or portions of the containers for controls (minimum three required).
- 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.
- Subsamples of small portions of product to serve as 702(b) portions.
- 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.
- Product labeling.
- Interstate documentation.

Documenting 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.

Documenting Mold Contamination

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

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

from living corn. Corn that has been in storage for a lengthy period of time (3 months or more) may give false positive BGYF. Therefore, determine how long the corn being sampled has been in storage. If it has been in storage over three months, do not use the following field screening procedure.

Essential steps for this black light procedure are:

- A 10 lb. sample representative of the corn lot must be obtained by probing, or by continuously sampling a grain stream.
- Examine using a 366 nm UV light (portable black-lights meet this criteria).
- 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.
- Use a 2 lb. portion, and carefully observe the entire corn surface one kernel at a time. Examine the entire sample using this procedure.
- Count all BGYF glowers (kernels or particles that "glow" bright greenish-yellow). Compare the BGYF color with a fluorescent standard, if one is available. Normal corn, if it fluoresces, will fluoresce a bluish white.

If four (4) or more BGYF particles are detected in the 10 lb. screening sample, collect a sample for laboratory analysis.

4-23 – AFFIDAVIT – FDA 463a

AFFIDAVIT

SAMPLE NO. DOC1069683

STATE OF: Texas

COUNTY OF: Harris

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 Mary K. Johnson in the county and state aforesaid, who, being duly sworn, deposes and says:

I am Mary K. Johnson, Quality Systems Manager, for Texas MedTech, Inc., located at 720 MedTech Drive, Houston, TX 77001. I have held this position for approximately five years but have also previously been involved with manufacturing processes as a production operator at Texas MedTech for approximately four years. Texas MedTech is a manufacturer of automated external defibrillators (AEDs). As the Quality Systems Manager, I have oversight of quality functions including receiving inspection, complaint handling, medical device reporting, nonconformances, management reviews, and corrective and preventive actions. I am knowledgeable and familiar with all documents and records that are maintained pertaining to the design and development, manufacturing, labeling, distribution, and return policies of Texas MedTech products.

During an inspection at our facility conducted between the dates of 12/03/2019 and 12/11/2019, I provided copies of documents and records to FDA Investigator Sidney H. Rogers. These included device history records, design history file records, labels, labeling, sales records, and shipping records which pertain to the receipt of incoming components, manufacturing, acceptance testing, labeling, sale, and interstate shipment of the Texas MedTech Lifesaver AED (part number 10005-001 Rev. C). The AEDs are identified with a five digit lot number and six digit serial number as well as a part number, revision iteration, and unique device identifier for the purposes of identification and traceability.

On 10/20/2016, my firm received a supplied shipment of 100 battery packs, part number 10007-006 Rev. B and lot number 20161014, from Battery Solutions, LLC, located at 526 Portside Road, Portland, ME 04102, via FedEx. The sale of the 100 battery packs is covered by Texas MedTech Purchase Order #16207, dated 10/11/2016, and Battery Solutions Invoice #36910, dated 10/18/2016. FedEx tracking number 5812643725491 provides evidence of the shipment of battery packs on 10/18/2016 from Portland, ME to our facility in Houston, TX. These battery packs were labeled in part "***Battery Solutions, LLC***Portland, ME***AED Pro Battery Pack***DC 12V 4.2Ah***Lot Number 20161014". Upon receipt of this shipment, my firm performed an incoming inspection of the battery packs (including the review of the certificate of conformance from Battery Solutions) and placed an acceptance label containing the aforementioned information on the inspection form. The incoming inspection form for vendor lot number 20161014 shows that it was assigned internal Texas MedTech lot number 1610 (part number 20005-001 Rev. B). Battery pack serial number 2016327 was included as

AFFIANT'S SIGNATURE AND TITLE

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

Texas MedTech, Inc.
720 MedTech Drive, Houston, TX 77001

Subscribed and sworn to before me at _____, *(City and State)*

this _____ **day of** _____, **20**____.

_____ *(Employee's Signature)*

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

FORM FDA 463a (5/07) PSC Graphics (301) 443-1090 EF Page 1 of 3

AFFIDAVIT

SAMPLE NO. DOC1069683

STATE OF: Texas

COUNTY OF: Harris

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 Mary K. Johnson in the county and state aforesaid, who, being duly sworn, deposes and says:

part of MedTech lot number 1610.

This lot of serialized battery packs, identified internally as lot number 1610, was used in the manufacture of an AED (part number 10005-001 Rev. C, lot number 05126, and serial number 160524) which included battery pack serial number 2016327 with a final release of 12/09/2016. The manufacturing operations of this AED are documented on a traveler as part of the device history record and identified that final acceptance activities were completed.

A copy of the label for the finished AED and the battery pack were included in the device history record. The AED was labeled in part "Texas MedTech, Inc.***Houston, TX 77001***Lifesaver Automated External Defibrillator***P/N 10005-001 Rev. C***Lot Number 05126***Serial Number: 160524***Mfg Date: 12/09/2016***" while the battery pack was labeled in part "Texas MedTech, Inc. ***Houston, TX 77001***AED Pro Battery Pack***DC 12V 4.2Ah***P/N 20005-001 Rev. B***Lot Number 1610***S/N 2016327". Associated labeling, including the Instructions for Use, were provided to Investigator Rogers. These labels and labeling represent what is currently in stock at my firm. I also provided a copy of the case carton label that is applied to the shipping container at the time of shipment to the consignee. There are currently 187 finished Lifesaver AEDs in inventory with various lot numbers, all of which include the original battery pack, as documented in Texas MedTech Inventory List, dated 12/11/2019. Investigator Rogers took photographs of our inventory on 12/11/2019 as well. A distribution list was provided to Investigator Rogers which documents allocation of finished Lifesaver AEDs to consignees as of 12/09/2019.

The finished AED, serial number 160524, was allocated to Texas MedTech Sales Order #170215, dated 02/15/2017, documenting the intended sale to Prairie View High School, located at 712 West Prairie Drive, Appleton, WI 54911. The AED was sent to Prairie View High School from our facility in Houston, TX as indicated by Texas MedTech Packing Slip #1732, dated 02/17/2017, with a sales order reference of 170215. The shipment of the finished AED from our facility in Houston, TX to Appleton, WI is documented by FedEx tracking number 5823982513841 with a ship date of 02/17/2017 and delivery date of 02/19/2017.

AFFIANT'S SIGNATURE AND TITLE

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

Texas MedTech, Inc.
720 MedTech Drive, Houston, TX 77001

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

this _____ **day of** _____, **20**____.

_____
(Employee's Signature)

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

FORM FDA 463a (5/07) PSC Graphics (301) 443-1090 EF Page 2 of 3

AFFIDAVIT

SAMPLE NO. DOC1069683

STATE OF: Texas

COUNTY OF: Harris

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 Mary K. Johnson in the county and state aforesaid, who, being duly sworn, deposes and says:

My firm initiated CAPA-188 on 08/02/2017 as a result of increasing customer complaints reporting premature battery pack failures when using an AED to deliver potentially life-saving shock therapy to patients. We have received seven complaints in which a death occurred where the premature battery pack failure of the AED was confirmed to have contributed to the death based on complaint investigations. Medical device reports have not been filed for these deaths.

We made design changes to the battery pack through CAPA-188 and associated design change requests in December 2017. These changes were subject to PMA supplement S015 of P130124 which was approved on 06/25/2018. However, the updated battery pack has yet to be distributed to the field and, as of this inspection, we continue to receive complaints for premature battery failures. We have not recalled any AEDs despite this known malfunction.

Complaint #00411 was received on 08/14/2018 with a report that the AED with serial number 160524 malfunctioned due to battery depletion which may have contributed to the patient's death. A replacement battery pack (serial number 2016348) was sent to the customer via FedEx (tracking number 5823982517863) on 08/16/2018 as shown on Packing Slip #1874. This replacement battery pack is the same design as the original battery pack that has known premature battery depletion failures that resulted in CAPA-188 and associated design changes.

Approximately 500 battery packs with the incorporated design changes to address the premature battery depletion failures have been manufactured by our new supplier, Performance Battery Technologies, Inc., located at 234 Washington Street, Chicago, IL 60614, and are currently being held in inventory at our facility in Houston, TX. However, final acceptance activities have not been performed on the updated battery packs to allow for distribution to the field to mitigate the reported battery pack failures.

Ms. Johnson refused to read, listen to, or sign this Affidavit, per Texas MedTech policy defined in procedure number 120-0001-01, Rev B "FDA Site Inspections."

Sidney H. Rogers
12/11/2019

AFFIANT'S SIGNATURE AND TITLE

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

Texas MedTech, Inc.
720 MedTech Drive, Houston, TX 77001

Subscribed and sworn to before me at _____, *(City and State)*

this _____ **day of** _____, **20**____.

_____ *(Employee's Signature)*

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

FORM FDA 463a (5/07) PSC Graphics (301) 443-1090 EF Page 3 of 3

4-24 – HQ LABS

Laboratory/Center	Commodity/Sample Types	Special Directions	Address
Center for Drug Evaluation and Research (CDER)	Drugs	• Do not forward original C/R and records. • Enclose a copy of the assignment memorandum in the FDA 525 envelope. • Affix the FDA 525 to the officially sealed sample package. • Submit the Original C/R and records to the home division, or forward to the home division if other than the collecting division.	Office of Testing and Research, Office of Pharmaceutical Quality, Food and Drug Administration, 645 S. Newstead Ave., St. Louis, MO, 63110, USA
Human Foods Program (HFP) • Office of Regulatory Testing and Surveillance ○ Division of Bioanalytical Chemistry (HFS-715)	Food • Elemental Analysis • Natural Toxins • Nutrients Dietary Supplements • Ingredients • Elemental Analysis • Natural Toxins Cosmetics • Ingredients • Elemental Analysis • Natural Toxins	Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins, nutrients in food, ingredients in dietary supplements, and ingredients of cosmetics.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740
HFP • Office of Regulatory Testing and Surveillance ○ Division of Analytical Chemistry (HFS-705)	• Food Additives • Allergens, • Pesticides • Dietary Supplements • Seafood Toxins • Food Defense Threat Agents • Industrial Chemical	Conducts laboratory investigations in the broad areas of food additives, allergens, pesticides, dietary supplements, seafood toxins, food defense threat agents, and industrial chemicals that may contaminate HFP regulated products	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740

HFP • Office of Regulatory Testing and Surveillance ○ Division of Microbiology (HFS-710)	Pathogens and Toxins in: • Food • Cosmetics Also: Pathogens and Toxins from the processing environment of food and cosmetic facilities.	Develops, optimizes, and validates methods for recovery, detection, identification, and quantitation of pathogens and toxins from foods and cosmetics, and the processing environment. Maintains FDA's food-related gateway to the PulseNet System. Develops and applies subtyping methods to further enhance data generated for Pulsenet, strain identification, and molecular epidemiological investigations.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740
HFP • Office of Applied Research and Safety Assessment ○ Division of Molecular Biology (HFS-025)	Food, • For Chemical or specialized equipment or skills needed for analysis Food Packaging Materials Microbiological – Food Pathogens by rapid methods	Analyzes foods when the chemical methodology is under development or unusual equipment or skills are required, such as radioactivity analysis and migration of food additives from food packaging materials. Microbiologically examines samples for potential food pathogens by rapid molecular biological testing using DNA probes, PCR, and DNA fingerprint analysis.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740

HFP • Office of Cosmetics and Colors ○ Division of Color Certification and Technology (HFS-105)	Color Additive Samples for Food, Cosmetics	Conducts analyses of color additive samples submitted to FDA for certification, assigns certification lot numbers to compliant lots, and denies certification to non-compliant lots. Develops, optimizes, and validates methods for the determination of components and impurities in certifiable color additives. Develops, optimizes, and validates methods for the determination of color additives in foods and cosmetics. Conducts analyses of foods and cosmetics for color additive content when special skills and expertise are not available in the field.	Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740

HFP • Office of Food Safety ○ Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory (HFS-400)	Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals other than birds or mammals, and all mollusks, where such animal life is intended for human consumption. • microbiological and chemical • bacterial and viral pathogen, • natural marine toxins, • aquaculture drugs • products of decomposition	Conducts microbiological and chemical investigation of seafood, including bacterial and viral pathogen, natural marine toxins, aquaculture drugs, products of decomposition, and other contaminants when special skills or equipment required for analysis are not available in the field.	FDA Gulf Coast Seafood Laboratory Iberville Drive Dauphin Island, AL 36528
Center For Drug Evaluation and Research • Division Of Pharmaceutical Analysis (DPA)	Surveillance drug samples • All heparin and insulin samples.	Examines surveillance drug samples collected and shipped under current program directives. Analyzes all heparin and insulin samples.	CDER-OPS-OTR Division of Pharmaceutical Analysis (DPA) 645 S. Newstead, Ave. St. Louis, MO 63110

Center For Biologics Evaluation and Research (CBER)	Biological products	Examines and reviews biological products not covered by a Compliance Program. Prior to shipping a sample, the division should notify either the Sample Custodian, 301-594-6517, or the Regulations and Policy Branch, 301-827-6210, who in turn will notify the Sample Custodian.	Sample Custodian Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Avenue WO75-G707 Silver Spring, MD 20993-0002
Center For Devices and Radiological Health (CDRH)	• Bioburden analysis • Bioindicator analysis • Device and GWQAP device samples for physical and engineering analysis • in-vitro diagnostic device • Antibiotic susceptibility testing (including discs) requiring performance testing	WEAC is the primary laboratory for devices and radiation-emitting products. The CDRH Office of Science and Engineering Laboratories accepts medical devices and radiation-emitting products for testing, but only after assignment or approval from CDRH, Office Health Technology	WEAC 109 Holton Street (HFR-NE400) Winchester, MA 01890-1197 Patrick Regan, Director, Analytical Telephone: 781-756-9707 FAX: 781-756-9757

CDRH	Condom and Glove Samples	Send Southwest and Pacific Region condom and glove samples to the Pacific Regional Laboratory (PRS) Send all other condom and glove samples to WEAC.	Pacific Regional Laboratory (PRS) /Pacific Southwest Laboratory 19701 Fairchild Irvine, CA 92612 WEAC 109 Holton Street (HFR-NE400) Winchester, MA 01890-1197 Patrick Regan, Director, Analytical Telephone: 781-756-9707 FAX: 781-756-9757
CDRH	Radiological health samples	Send radiological health samples to: CDRH/OSEL Sample Custodian HFZ-105 WO62, 10903 New Hampshire Ave, Room 4126 Silver Spring, MD 20993 Telephone: 301-796-2558 FAX: 301-796-9795 **Note:** Contact Office of Science and Engineering Laboratories, 301-796-2558 prior to collection and shipment of any radiological product sample.	CDRH/OSEL Sample Custodian HFZ-105 WO62, 10903 New Hampshire Ave, Room 4126 Silver Spring, MD 20993 Telephone: 301-796-2558 FAX: 301-796-9795

Center for Veterinary Medicine (CVM)	Samples of veterinary products, including documentary samples, and labels/ labeling and advertising materials	Samples of veterinary products, not specifically covered by one or more of the CVM Compliance Programs. 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.	Center for Veterinary Medicine Division of Compliance (HFV-230) 7500 Standish Place (MPN II) Rockville, MD 20855
Center for Tobacco Products (CTP)	Tobacco products • Both compliance and surveillance samples	Do not collect samples of tobacco products unless directed by an assignment, approved by the Center for Tobacco Products, Office of Compliance and Enforcement, or by Division Management	Southeast Regional Laboratory (SRL), Atlanta Center for Tobacco Analysis.

4-25 C/R DATA ELEMENTS IN ORDER OF ENTRY INTO FACTS

This exhibit, which was derived from OBIMO work instructions, attempts to clarify entry of data into FACTS for a sample collection report. This exhibit, which presents C/R data elements in order of entry into FACTS from left to right and top to bottom, can assist the collector if used while completing the C/R. This exhibit includes information from IOM chapter 4 (Sampling) and clarifying remarks added in italicized font where needed. See IOM 4.6.2 for an alphabetized list of data elements.

FACTS Page 1

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.

Select the number you identified your sample with. This number comes from the group of sample numbers you previously generated in FACTS.

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."

Normal Everyday Sample is the typical choice here. If you have something other than a Normal Everyday Sample, your assignment will indicate that and you should select the appropriate choice.

Sampling Organization: Make a selection from the list of values. This is the division which actually collects the sample.

Typically, this is your home division e.g., BIMOW.

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 C/R.**

Be sure to verify the date appearing in this field as above. Assure the date is the actual date collected. ***Slow down!*** *This is a critical field.*

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."

State the size of the lot going from the largest unit to smallest, i.e., from shipping case to immediate container.

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

If the product was imported into the United States and has been released for distribution in Interstate Commerce, it is a Domestic/Import. Domestic samples come from products produced in the United States. For bioequivalence samples collected during foreign inspections at foreign Dealers, select Domestic/Import. Although these samples are not being collected from a lot of product which has passed through US Customs and entered domestic commerce, there is currently no Operation Code for a foreign sample.

Sample Basis: Choose the appropriate value from the list. Values have been changed to differentiate between environmental samples and other samples. Compliance = collected on a selective basis, complaint, evidence that there may be a problem, "for cause"; Surveillance = objective basis. For environmental samples, select Environ–Compl for compliance samples or Environ–Survl for surveillance samples. The Other–Compl and Other-Survl basis values are used for all other samples. Official and INV samples can both be either Surveillance or Compliance.

Select from the two choices on the list of values. "Compliance" means the sample was collected on a selective basis as the result of an inspection, complaint, or other evidence of a problem with the product. "Surveillance" means the sample was collected on an objective basis where there is no inspectional or other evidence of a problem with the product. Please note official samples can be either compliance or surveillance, and INV samples can also be either. See IOM Exhibit 4-16 for more information.

Note: When you have observed a violation and this sample is collected as evidence, it is a Compliance Sample. When you have not observed a violation, but are simply collecting a sample at random, such as a bioequivalence sample for drug assay, that is a Surveillance Sample.

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.

The sample type for all bioequivalence samples will be "Official". Select "Domestic-Import" if applicable. Note: Domestic-Import samples are also Official, however, this is the way the drop-down menu is set up. See IOM 4.5.3.

Consult IOM 4.6.1 and your supervisor to choose the correct Sample Type. This field is actually a part of your sample number. For example, if you collect a Domestic Import Sample, you add the prefix "DI" to your number so that you identify the sample as "DI 123321." Another example is investigational samples, which are collected to document observations such as rodent infestation and/or where interstate commerce does not exist or is not necessary. Filth Exhibits are always investigational samples and would be identified as "INV 123321."

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.

For FY 2009 enter 09. FIS is the Field Information System. That system predates FACTS and is still in use for some laboratory operations.

Episode Number: Enter an episode number if applicable.

***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 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 divison must assure that the Episode Number is used within the division and any other divisions which follow-up to the original violative sample. This number must appear in the **Episode Number** field of the FACTS CR. See IOM 4.6.2.27.8 for examples.*

Related Sample: 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.

The lead sample number is typically the first sample collected. For example, in a violative sanitation inspection you will most likely collect multiple samples. These samples could include samples of product defiled by rodents (including gnawed cardboard cases, urine stained bag cuttings, product located directly beneath urine stains, product randomly sampled throughout the lot, photographs, diagrams of lot, etc.) and filth exhibits (which can include rodent droppings, insect casings, nesting materials, etc.). Designate your first sample as the lead and list this number in the Related Samples field for all other samples collected during the inspection. Note that for the lead sample, this field will be blank. For all other samples where there are not related samples, e.g., a single sample collected, this field will be blank.

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.

Ensure that the field includes a description of the investigational product collected as well as the reference and placebo if applicable.

A statement such as, "Sample consists of retention sample for protocol GDC-695-001 consisting of one block containing three total 100g tubes: GDC 695 Gel (kit 1217), Diclofenac Sodium Gel (kit 1219), and Vehicle Gel (kit 1218)." Labeling, documents (including those other than I/S records) or photos, are also described here. For DOC samples you will state that the sample

consists of photos, records and observed GMP deficiencies. Include anything here collected to document the violation.

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.

Reference the compliance program (e.g., CP 7348.003, "In vivo Bioavailability- Bioequivalence Studies-Clinical", the assignment memo, and the inspection dates (if applicable). There will not be a suspected violation for surveillance samples. Add the following statement and edit as appropriate, "Sample of bioequivalence investigational product, reference control and placebo. Sample is representative of test product used in study supporting Protocol (insert Study #)." You will specify the analysis desired as follows: "Collected for drug assay analysis." Include the application number, e.g., ANDA 12345.

Note there are four pieces of information to report for the Collection Reason. 1) Whether sample was collected during and inspection of the Dealer. 2) The Compliance Program and assignment is applicable. 3) The suspected violation. 4) What analysis is desired. For example, the Collection Reason could be completed as, "Sample of bioequivalence investigational product, reference control and placebo collected during EI of Dealer 10/01/2022. Sample is representative of test product used in study supporting Protocol VBD-1212 under ANDA 12345. Collected pursuant to FACTS Assignment #188118 and in accordance with CP 7348.004. Collected for drug assay analysis."

Collection Remarks: Enter any remarks you feel are necessary. Describe any special circumstances. If a 704(d) [21 U.S.C. 374(d)] letter is indicated, include the name, title, E-mail address (if available) and the telephone/fax number of the most responsible person at the firm to which the letter should be addressed. If a 702(b) sample is not collected, describe the specific circumstance and justification for not collecting the 702(b) portion unless it is a device or tobacco product, or the assignment or guide already states why a 702(b) portion is not needed. If the sample is an in-transit sample, state the sample was collected in-transit, from whom sampled (e.g. driver and carrier firm), and where sampled. If the dealer firm is a consumer, the name and address of the consumer should be entered in the Collection Remarks field, and the consumer's state in the State field. You may use a "CR Continuation Sheet", FDA 464a if you need more space.

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

Include any additional information required to fully explain the collection. This field is also used to describe chain of custody when necessary e.g., describing what conditions the sample was held under until submitted to the laboratory. The CR Continuation Sheet is used when you have

a lot of information to share, such as describing GMP deficiencies, observations, or sub-samples. In the case of a food firm where you have collected multiple subs to document filth conditions or environmental swab samples, you'll want to describe each sub, where it was collected, what it consists of, etc. This will be extremely important information when Compliance is reviewing the sample results and your report for any regulatory follow-up.

Associated Firms Section

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.

This designation requires some thought on the collector's part. Think about the violation you are documenting. Who caused the product to become adulterated? The example of a 301(k) sample listed above says to select the Dealer as the Responsible firm. This is because of the definition of a 301(k) violation. 301(k) prohibits the adulteration of a product <u>after</u> shipment in interstate commerce. Therefore, the Dealer caused the adulteration sometime after receipt in interstate commerce. When you are documenting a 301(a) violation, shipment of an adulterated product in interstate commerce, your responsible firm will be the firm shipping the adulterated product or causing the shipment of the adulterated product. It can be the Manufacturer, or it can be the Dealer. A little thought on what you are documenting will make this designation clear.

Dealer is Consumer? 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 4.1.4.2.1), 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.

Commonly used for Consumer Complaint samples when you collect a sample from the complainant. Be sure to consult with your supervisor prior to collecting samples from a complainant.

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.**

When selecting the FEI, be very careful to select the correct firm. Some tips: compare the street addresses of firms retrieved by the search, look for firms that are Workload Obligation = Y and Operational Status = OPR, if your firm is not returned by your first search don't give up, try different criteria. More often than not, we will be collecting samples from firms that we have been to before. However, if it's a new firm you will need to add that firm and notify the OEI

Coordinator or your supervisor. We want to assure we do not add duplicate firms into the FACTS OEI, thus maintaining the accuracy of the OEI.

Product Section

Product Code: Enter the 7-digit product code. Use the Product Code Builder for guidance. When 301(k) samples are collected, the full product code of the finished product must be entered. See IOM exhibit 4-1. See IOM 4.6.2.27.7 for product codes for filth or evidence exhibits. Special product code considerations include environmental samples. See environmental sample identification instructions under IOM 4.3.6.6.2.

A tip for building a product code within FACTS or Product Code Builder: Enter the name of the product in the Product Name field and click on ExeQry (Execute Query). This will return a list of products containing that text for you to select from and continue to build the code.

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

Typically found on the labeling of the product such as, "Blue Bunny" carrots. Sometimes in the case of DOC samples for medical devices you may need to dig a little to find out if there is a brand name.

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.

Completely describe the product and how it is packaged and packed in shipping containers as appropriate. Note that you go from the product to the outer most layer of packaging.

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

NOTE: When the product sampled is packaged in a 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.

The label quote shall be an exact quote of the label. Use the same upper and lower case letters, misspellings would be quoted as appearing on the label. Start with the principal display panel

*and work your way top to bottom then left to right around the label. For ingredient listings, include any suspect ingredient and major ingredients. Use *** to show omissions of text and graphics. As an example, the sampled product bears an adhesive label which reads in part, "Walgreens *** Deluxe Mixed Nuts No Peanuts Net Wt. 10 OZ (283g) *** INGREDIENTS: Cashews, Almonds, Brazil Nuts, Filberts, Pecans, *** Distributed by: Walgreen Co. Deerfield, IL 60015-4616 ***". Do not use asterisks to indicate a new line of label or panel of the label. Only use asterisks to indicate you have left something out.*

Documents Obtained: Click on the "Documents Obtained" button to enter Document Type, Document Number, Document Date and Remarks for any records collected to support a violation or show interstate movement of the product sampled. Enter an identifying number and date for invoices, freight bills, bills of lading, etc. Include the name and title of person signing any affidavits in the Remarks field. Be sure to describe the reason each document attached to the collection record was obtained. For example, when referring to a bill of lading, indicate that it was collected to document the interstate movement of the product. Also indicate which documents were collected to document specific violations encountered during inspections. State the number of pages for each document if it contains more than one page and refer the reader to the appropriate section/page of the document which shows the deviation you are documenting. Indicate the number of photographs attached. Depending on the sample and what you are trying to document, you may use the document number to record the actual number of the document (i.e., invoice number or bill of lading number) or to order the documents attached. You should order your documents in a manner that allows easy review (be guided by your supervisor or center compliance office). This section may also be used to list C/R attachments including FDA generated forms. See IOM exhibit 4-1.

Remember that documents attached to the C/R are to be identified with the sample number, date of collection and collector's initials.

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.

Be sure to define what the code is e.g., lot number, batch number, serial number, production date, etc. If a two line code is employed by the manufacturer (such as with many canned products), it may be expressed like "12345AGB / GAV45833," where the slash indicates a separate line code.

Sample Flags: Click on the "Sample Flags" button to choose an appropriate flag using the list of values. See 4.6.2.27 and exhibit 4-15.

IOM 4.6.2.27 contains a listing and description of Sample Flags. These are used to alert the reader of your C/R what the sample is documenting if further clarification is necessary. The Sample Flag will be printed at the top of your hard copy C/R. For example, when you collect a 301(k) sample, the flag will indicate this is a 301(k) sample and alert the reader to the fact that you are documenting adulteration after shipment in interstate commerce. Use the Flag Remarks field to state the product or ingredient which has moved in interstate commerce and you have documented.

FACTS Page 2

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 4.7.2.1 regarding sub identification.

Describe exactly how you collected the sample. Describe selective sampling technique if used. For example, “Two Live insects collected from seam of bag #2 and two live insects collected from seam of bag #12 (see diagram of lot sampled). Insects were seen entering and exiting bags. Insects were collected upon exit.” In a rodent or insect infested warehouse, you will most likely need to use the C/R Continuation to fully describe the subs you collect and their relationship to the depth of the adulteration of product and infestation of the warehouse.

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

Optional field, use for Pesticide Samples. Use the LOV (List of Values) button to select the state.

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.

This field should be used to identify where the agricultural commodity was grown. In order to identify the county where the product was grown, you will either need to be collecting the sample from the grower or have documentation demonstrating shipment from the grower to the dealer. If the product is in a container bearing a label, do not simply assume any identified location is the actual location where the product was grown. It is common practice to reuse shipping crates in the produce industry.

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

Products sampled that had been imported into the United States and released to commerce by US Customs and Border Protection are Domestic Import samples. Obtain documentation of their entry (invoices, bills of lading, Customs Form 3461, etc.) where necessary to support a case involving the Importer of Record. Remember that these samples will be identified with a prefix to the sample number of DI.

Estimated Value: Enter the estimated wholesale value of the lot remaining after sampling. Obtain this information from invoice or other records. (This is not the value to be used for seizure bond purposes; however, it may be used by the division to evaluate whether seizure is an appropriate action.) Estimate value if you have no documentary reference. For DOC samples (see IOM 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.

Estimated Value: It may be difficult to estimate the value of a bioequivalence sample. If the firm is not able to provide you with the value of the lot remaining after sampling, use the estimated cost of the innovator if possible. If you cannot estimate, leave blank and note in the Collection Remarks, “Estimated Value is unknown.”

For pesticide samples, try to obtain the size of the field from which the produce was harvested. Have the dealer/grower provide you with the estimated yield per acre and determine the estimated value based on the wholesale value of the expected yield minus your sample. Note: For DOC 301(k) samples where no product is remaining the value will be $0. For bioequivalence samples, review the documentation of the shipment to the site to determine if values are included.

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.

Note that the “Credit Card” option is for your personal credit card, not the Government credit card. You are to obtain a cash advance from an ATM or bank and use cash to pay for samples. If the firm will bill the agency for samples, obtain the invoice to submit with your C/R if at all possible.

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.

Use the LOV button to access the drop down menu. Again, note that credit card is for your personal credit card, not the Government-issued credit card.

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

Use the LOV button to select which type of receipt you issued. You will only use an FDA 472 if you collect a sample from a carrier, such as an in-transit sample from a truck.

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.

Note that this is a transportation company, not to be confused with a Shipper. A Shipper is an Establishment Type and is the entity responsible for causing the interstate movement of the product.

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.

Enter the date that the product was shipped in interstate commerce. This date should be obtained from a shipping record such as a bill of lading, waybill, freight bill, etc.

Consumer Complaint Number: If the sample relates to a consumer complaint, select the Sample Flag for Complaint Sample and enter the complaint number in the Sample Flag Remarks. This way it is easy to identify what Complaint the CR is related to and more accessible in reporting.

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

If you conduct an inspection/investigation and collect a sample as follow-up to a recall, enter that recall number here. Although any routine sample collection may lead to a recall, at the time of sampling you would not know the recall number.

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 4.7.2.1), 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 UPS pickup".

Include here the identification of sub samples (referencing the block 'Collector's ID on Package) and exactly how you packed the sample. Did you wrap in bubble wrap? Did you tape lids down? Did you use Styrofoam peanuts or cooling materials? Include everything you did to the sample from the point you collected it and prepared it for sample submission/shipment. Also, be sure to include that the sample was officially sealed and reference the block 'Collector's ID on Seal.' If the sample was not prepared, sealed, and shipped the same day as collected, use 'Collection Remarks' to describe your efforts to maintain the integrity of the sample and chain of custody.

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 4.6.2.11. 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.

Quote exactly as you identified the sample. What does the "at least a portion" reference mean? When collecting samples with a large number of identical subs, such as 30 packages of shrimp that are packaged exactly the same from the same lot, it may be permissible to identify the first six subsamples with the full sample identification and the remaining subs to be identified with the sub number only. Check with your supervisor for the division policy. Note that every subsample collected will bear the sub number as this correlates to the shipping container you collected it from. As you are collecting your samples, you identify the carton, case, shipping container with FDA, sample number, sub number, date, and your initials. This allows identification that the container was opened and sampled by FDA as well as which carton which sub was collected from. Sometimes it is necessary to return and collect an additional sample from the same lot and sometimes from the same carton as a particular sub was collected from.

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 4.6.2.11 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 & 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.

If you are unable to seal the sample on the same day of collection, describe what steps you took to maintain the sample integrity and chain of custody. For example, "Sample held under lock and key in sample preparation room until sealed on 12/5/05."

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.

If delivered to the office secure lobby for pick up by carrier state so such as, "Delivered to BLT-DO secure lobby for FedEx pick up AWB #_____."

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.

CR & Records Sent to FACTS Org: Enter the District Office of the collecting CSO. For foreign human and animal food sample collections, select FOR-HFP as the division from the dropdown menu and send the hard copy C/R and all documents to the Division of Foreign Human and Animal Food Operations.

Storage Requirements: Select from the following list of values: Ambient; Frozen; Refrigerated.

Storage requirements are those that the sample was stored at when collected or required based on situation. State how the sample should be stored once received by the sample custodian. Remember to complete the FDA 525 with the same information and to include any special preparations in the 'How Prepared' block.

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

704(d) Sample:

Check the 704(d) box if all answers to the following questions are "yes,":

1. Was the sample collected a food?

2. Was the sample collected during an inspection?

3. Was the sample collected from an establishment where food is manufactured, processed, or packed?

4. Was the sample collected to ascertain whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food?

Note: Guidance on 704(d) is provided in FMD-147 including examples of what constitutes "unfit for food".

Include in the Collection Remarks the name, title, email address (if available) and telephone/fax number of the most responsible person at the firm. See also IOM 4.6.2.9.

National Drug Code: Enter if applicable

For samples of drug products.

CRx/DEA Schedule: Choose the appropriate schedule from the list of values, if applicable.

For samples of controlled substances.

702(b) Portion Collected: Check this box if the sample you collected contains a 702(b) Portion of any food, drug or cosmetic to be held by FDA for release to the owner or person named on the label for their own analysis. This includes samples where 1) the sample schedule already accounts for the 702(b), 2) you collected in duplicate and separated the duplicate out and 3) you collected in duplicate and did not separate the duplicate out. If you did not separate the 702(b) portion, note this in the remarks so the laboratory can separate the 702(b) portion. If no 702(b) portion was collected, do not check this box, and provide reason for non-collection in the Collection Remarks section (4.6.2.9).

When the sample size includes the 702(b) portion, you will check this box although you did not collect a separate portion to be reserved, it is intended that the laboratory will portion out the reserve and maintain, if possible.

Collection PACs Section

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

Enter all PACs you collected subs for analysis. When collecting samples, you should try to be as creative as possible. If collecting grain for pesticide analysis and that grain can go either to human food or animal food production, select PACs for both human pesticides and animal feed contaminants. Also, try to think of sampling for multiple PACs when possible. Grains is a good example here also. If collecting grains for pesticides, consider collecting a portion for Mycotoxin analysis as well. You will need to verify the labs conducting the analyses to ensure you ship your samples correctly.

FACTS Org Section

Sample Sent To: Collecting divisions are instructed to submit samples utilizing the Lab Servicing Table (LST) Dashboard located on the intranet on the ORTS Sample Distribution site. See IOM 4.6.3. 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.