

Guide to U.S. Food and Drug Administration Facility Inspections: Food Establishments


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INTRODUCTION - Food Manufacturing Facility Inspection Guidance

The U.S. Food and Drug Administration (FDA) is steadily increasing the number of inspections of foreign food processing facilities that export to the United States. The Food Safety Modernization Act (FSMA) establishes a mandated inspection frequency for food facilities based on risk and requires FDA to increase the annual number of facility inspections. Under FSMA, FDA is mandated to increase foreign inspections from 600 inspections in 2011 to 19,200 per year by 2016. Foreign facility inspections are designed to identify potential food safety problems before products arrive in the United States; to determine the compliance status of firms to FDA's requirements and food safety standards; to help the agency make admissibility decisions when food products are offered for importation into the United States; and, to help ensure that food products under FDA's jurisdiction meet U.S. requirements under the Federal Food, Drug, and Cosmetic Act (the Act).

FSMA Section 103 on preventive controls gives FDA an expressed statutory mandate to require hazard analysis and risk-based preventive controls at registered facilities that manufacture, process, pack, and hold regulated food. FSMA does not change the requirements for facilities already required to operate under preventive control programs such as HACCP (e.g. seafood and juice) or foods subject to the low-acid canned food (LACF) regulation. FSMA will, however, require all other registered foreign and domestic facilities to implement preventive controls and maintain a written preventive control plan.

The following document is intended as a general guidance for food manufacturers to prepare for a facility inspection by the U.S. Food and Drug Administration. It is up-to-date as of June 2013. This document is not intended as an all-encompassing explanation of the regulatory framework for facility inspections, but rather as an overview of the general requirements for food manufacturers. The regulations and guidelines outlined below are subject to variations depending upon the purpose of the inspection, the type of product being manufactured, the size of the facility, etc. The compiled material is offered as guidance for your reference and consideration only and is not intended to represent necessarily the only approach to the safe production of foods. Registrar Corp recommends that, in addition to this document, the links provided in Appendix A be carefully reviewed prior to the date of inspection. Furthermore, if you are unfamiliar with any terms used throughout this document it is recommended that you consult with your facility's expert for clarification.

For your convenience, Registrar Corp has included a checklist in Appendix C, which is intended as a tool to assist you in the preparation for an inspection. The checklist provides an outline of the major requirements detailed in this guidance document. This is only a general list and is not intended to address all possible issues that could arise during an inspection. You may choose to use this checklist, however, as a guide to prepare your facility for a FDA inspection.

REGISTRAR CORP'S FOOD SAFETY SERVICES

Registrar Corp's Food Safety Department assists clients in navigating the numerous FDA regulations regarding food safety, food defense, food manufacturing, and preparation for and responding to an FDA inspection. The Food Safety Department has successfully assisted clients throughout the world prepare for an FDA inspection. In addition, Registrar Corp's Food Safety Department is available to help review your Hazard Analysis and Food Safety Plan, assist in developing or reviewing a Food Defense Plan, and aid in reviewing your corrective action response to an FDA inspection.

Mock FDA Inspections:

If you receive a notice from FDA with a specific date for an inspection, as part of our U.S. Agent service, Registrar Corp can dispatch a food safety expert from the USA to your facility to help you prepare in advance of the FDA inspection. This "Mock FDA Inspection Service" is provided without additional charge (other than travel and lodging costs) as part of our U.S. Agent service. Please notify us immediately if you receive such notice.

Registrar Corp's Food Safety Specialist will help identify potential food safety problems in the structure, processes, procedures, and documentation used in your daily production. During the visit, typically two days (per facility), the Food Safety Specialist will help your staff better understand FDA's expectations.

Registrar Corp also provides Mock FDA Inspections for food facilities that have not designated Registrar Corp as their U.S. Agent. For such food facilities, Registrar Corp provides the Mock FDA Inspection for a fee.

Hazard Analysis and Food Safety Plan Review (FSMA's Risk-Based Preventive Controls or HACCP):

Registrar Corp's Food Safety Department can review your Hazard Analysis and Food Safety Plan. Registrar Corp will review your Hazard Analysis and Food Safety Plan for completeness, effectiveness, and regulatory compliance. After reviewing the plan, we will compile a report of areas where improvements can be made.

Food Defense Plan Development and Review:

Registrar Corp's Food Safety Department provides assistance to develop or review a Food Defense Plan for your operation. A Food Defense Plan identifies measures to minimize the risk of tampering or intentional contamination of food products in your establishment. Our skilled Food Safety Specialists will help guide you through a food defense vulnerability assessment, risk mitigation strategies, and development of the Food Defense Plan.

Assistance Reviewing your Corrective Actions Response to an FDA Inspection:

Registrar Corp's Food Safety Department provides aid in reviewing a client's corrective action response to an FDA inspection. Our Food Safety Experts will format your response to effectively and efficiently present your response to FDA and will advise you if additional supporting evidence is needed to justify your corrective actions. Because of time constraints (response to FDA is normally required within 15 working days), contact us immediately after receiving a Form FDA 483 ("Inspectional Observations") or a warning letter.

If you require assistance, please contact Registrar Corp by phone, email, or by using the "Live Help" on our web site: www.registrarcorp.com. Our nineteen offices worldwide are also available to assist you.

Contents

INTRODUCTION - Food Manufacturing Facility Inspection Guidance.....	2
REGISTRAR CORP'S FOOD SAFETY SERVICES.....	3
PREPARING FOR AN INSPECTION - An Attorney's Perspective.....	6
PREPARING FOR AN INSPECTION - A Food Safety Expert's Perspective.....	7
PREPARING FOR AN INSPECTION - An Inspector's Perspective.....	8
RECEIVING A NOTICE OF INSPECTION.....	9
Flowchart of Registrar Corp Assistance with U.S. FDA Inspections	11
ESTABLISHMENT REGISTRATION REQUIREMENTS	12
PERSONNEL.....	14
Requirements of Employees	14
INSPECTION OF GROUNDS AND SANITARY OPERATIONS.....	16
Grounds.....	16
Plant Construction and Design.....	16
Sanitation Operations	17
Sanitary Facilities and Controls.....	19
EQUIPMENT AND UTENSILS.....	22
PRODUCTION AND PROCESS CONTROLS	23
Hazard Analysis and Risk-Based Preventive Controls	24
Ingredient Handling.....	25
Product Formulation	27
Food and Color Additives	27
Manufacturing Operations.....	28
Facility and Product Inspections	31
Laboratory Tests.....	31
Packaging and Labeling.....	31
Sanitation	32
Pest Control.....	32
Chemical Control.....	32
Defect Action Levels.....	33
Storage and Food Transport Vehicles	34
Distribution	34
Product Complaints and Recalls.....	34
REVIEW OF RECORDS.....	36
Record Review.....	36
Bioterrorism Act.....	36
Preventive Controls and Sanitation Records.....	37

Label Review 38

Requesting Information 39

EMERGENCY PERMIT CONTROL..... 40

END OF INSPECTION 42

Appendix A: Resources 44

Appendix B: Forms 45

Appendix C: Checklist..... 52

PREPARING FOR AN INSPECTION - An Attorney's Perspective

by Russell K. Statman, Esq.

Russell K. Statman is the Executive Director of Registrar Corp. As a practicing attorney, Mr. Statman has advised numerous firms before, during and after FDA inspections, including firms subject to FDA enforcement activities.

You've received notice that your facility will be inspected by the U.S. Food and Drug Administration. What can you do to ensure that it goes well?

First, if necessary, adjust your attitude. Nobody likes to be inspected, scrutinized or criticized. By its nature, the experience may be uncomfortable. If you react emotionally, negatively, or in an adversary manner, you may do or say something that an inspector could perceive as attempting to hide problems. Further, an aggressive posture may be reciprocated. Be courteous at all times. See the human in the inspector, not the faceless bureaucracy that is imposing the rules.

Recognize that the FDA inspector is following a predetermined, required procedure. Cooperate. Do not ask the inspector to change the procedure or argue about the merits of the method. The inspectors do not have discretion to change what they are required to do. Asking them to do so can be counterproductive, irritating or even offensive.

Answer any questions truthfully and completely, but do not volunteer information unless asked. The inspectors will ask for whatever they need. If you volunteer unsolicited information, it may be subject to misinterpretation. Or, it may be seen as being argumentative. If you are well prepared, there will be no need to convince the inspectors with words. Your facility will speak for itself.

The following guide is intended to help you prepare your facility for an FDA inspection, and is based on a manual that the FDA inspectors may follow. A comprehensive checklist of items to prepare for inspection is included. Prepare for the inspection by completing the checklist as if you were the FDA inspector. Scrutinize your own facility, following the checklist.

If you are prepared, cooperative and courteous, and if your facility and processes are satisfactory, all is likely to go well.

PREPARING FOR AN INSPECTION - A Food Safety Expert's Perspective

by Edwin Velez Rivera, M.S., CQA.

Edwin Velez Rivera is the Director of Food Safety at Registrar Corp. As a retired Department of Defense Food Safety Officer, Mr. Velez Rivera offers more than 20 years of food safety, food defense, program management, food facility auditing, problem-solving, and has traveled extensively around the globe and throughout the United States auditing food facilities and helping companies prepare for regulatory inspections.

For many food manufacturing companies, audit preparation is a matter of routine business considering the number of third-party audits they receive throughout the year.

Nevertheless, please understand that FDA inspections are different than your typical third-party audits or audits done under a Global Food Safety Initiative (GFSI) scheme. While these audits do play an important role in developing food safety standards and promoting best practices, they do not automatically translate into a successful FDA inspection. The best way to have a successful FDA inspection is to become familiar with the FDA's rules and regulations that govern the food products you manufacture.

Therefore, preparation for an FDA inspection must begin immediately following the receipt of an inspection notice. Preparation involves taking time to review the documents, procedures, records, and practices that affect your facility's capacity to manufacture, process, pack, and hold safe food products. You should ensure these documents reflect current operations, are up-to-date, and are signed by a person of authority. Also, ensure your employees are properly trained and able to implement your operating procedures. Furthermore, conduct internal audits at planned intervals to determine whether the food safety system conforms to planned arrangements, is effectively implemented and updated, and meets regulatory requirements.

I highly recommend that you have a designated person of authority that is knowledgeable of the operation escort the FDA inspector during the entire inspection process. If the manufacturing process is complex, you may need an entire team to escort the FDA inspector. The escort should, if feasible, arrange to immediately correct any findings (observations) noted by the inspector as soon as they are discovered.

Our goal is for you to have a very successful FDA inspection. Please let us know how we can assist you in this endeavor.

PREPARING FOR AN INSPECTION - An Inspector's Perspective

by Cornelia Rooks, M.A.

Cornelia Rooks, Senior Regulatory Specialist at Registrar Corp. As a retired Division Director within the U.S. Food and Drug Administration, Ms. Rooks has experience as an FDA inspector of domestic and foreign firms during her 25-year career with FDA.

As an establishment that has registered with U.S. Food and Drug Administration (FDA), your establishment is subject to be inspected by FDA. Inspection requests are planned for various reasons. These inspection requests may be routine or come from the Center for Food Safety and Applied Nutrition (CFSAN) within FDA as the result of:

- a. High risk food establishment increased vigilance under Food Safety Modernization Act (FSMA)
- b. The firm has previous volatile inspectional history and or problems
- c. Surveillance inspections of firms, which have been identified using a tiered approach, based on factors as risk, volume of products, complexity of processes, etc.
- d. Firms that have problems related to adverse reactions or were involved in recalls.

An establishment inspection is a careful, critical, official inspection of a facility to determine compliance with laws administered by FDA. Food plant inspections are conducted to evaluate the methods, facilities and controls used in the manufacturing, storage and distribution of foods. The inspector will have complete understanding of the nature of the assignment to inspect your facility. Prior to the inspection, the inspector will review the facility's factory folder, and registration and product information. The purpose is to have an understanding of the facility's operations, products, and compliance history. Therefore, the inspector will be familiar with your type of operation and various aspects of your processes and products.

The inspector should conduct the inspection at reasonable times, within reasonable limits, and in a reasonable manner. They should use diplomacy and tact. They will also, however, use persuasiveness to obtain the necessary information to determine if the facility is in compliance.

It is prudent to cooperate fully with the inspector during the inspection and be prepared for an inspection by ensuring an efficient and safe food facility at all times.

RECEIVING A NOTICE OF INSPECTION

FDA focuses its domestic and foreign food inspections on high-risk food establishments. High-risk food establishments are growers/harvesters, manufacturers/processors, packers, repackers, and holders of “high risk foods,” i.e., those foods that may present hazards or those that FDA believes, based on scientific evidence, may present a high potential to cause harm from their consumption. High risk food commodities include, but are not limited to, modified atmosphere packaged products; acidified and low acid canned foods; seafood; custard filled bakery products; dairy products, including soft, semi-soft, soft ripened cheese and cheese products; unpasteurized juices; sprouts ready-to-eat; fresh fruits and vegetables and processed fruits and vegetables; spices; shell eggs; sandwiches; prepared salads; infant formula; and medical foods.

The selection of foreign high-risk food establishments is based on a risk evaluation of foods imported into the United States. Once high risk foods are identified for a fiscal year, FDA analyzes global- and country-specific data, which includes the number of import line entries (importation volume) and other considerations, such as refusal rates on denied import entries pertaining to these high-risk food products. Countries and firms are then selected based on analyses of this global- and country-specific data. FDA is increasing the number of inspections globally. No one country, region, or company is being targeted for inspection.

FDA's authority to inspect food is obtained from section 704 of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, refusal to permit inspection may result in regulatory actions against your firm’s products including, where appropriate, increased sampling, refusal of admission, or other regulatory action. This

section of the Act requires that the credentials of the FDA Inspector and a written Notice of Inspection (FDA Form 482) be presented to the owner, operator, or agent in charge of the firm before the inspection begins. Typically, FDA will send an email to the address listed in the establishment registration notifying the firm of the inspection. This email will usually contain 2 attachments, one in English and one in the firm’s local language, stating that this is an official notification that the United States Food and Drug Administration (U.S.FDA) is planning to conduct an inspection at your food firm in the near future. See appendix B for an example of this email attachment. Foreign facilities will also have a copy of the email sent to their U.S. agent. Upon receipt of this form, it will be necessary for the firm to respond to FDA and provide the following information:

How to Answer FDA Questions:

<p>1. Be concise; answer only the question that is asked.</p> <p>2. Take corrective actions if possible, commit only to what you can deliver.</p> <p>3. DO NOT volunteer information.</p>	<p>4. Be positive and confident.</p> <p>5. DO NOT guess or speculate.</p> <p>6. DO NOT argue or lie.</p> <p>7. DO NOT panic.</p>
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- The firm’s point of contact, telephone, fax numbers, and email address, if available.
- The firm’s complete physical and mailing address for farm/packing house, manufacturing site and/or food processing facility.

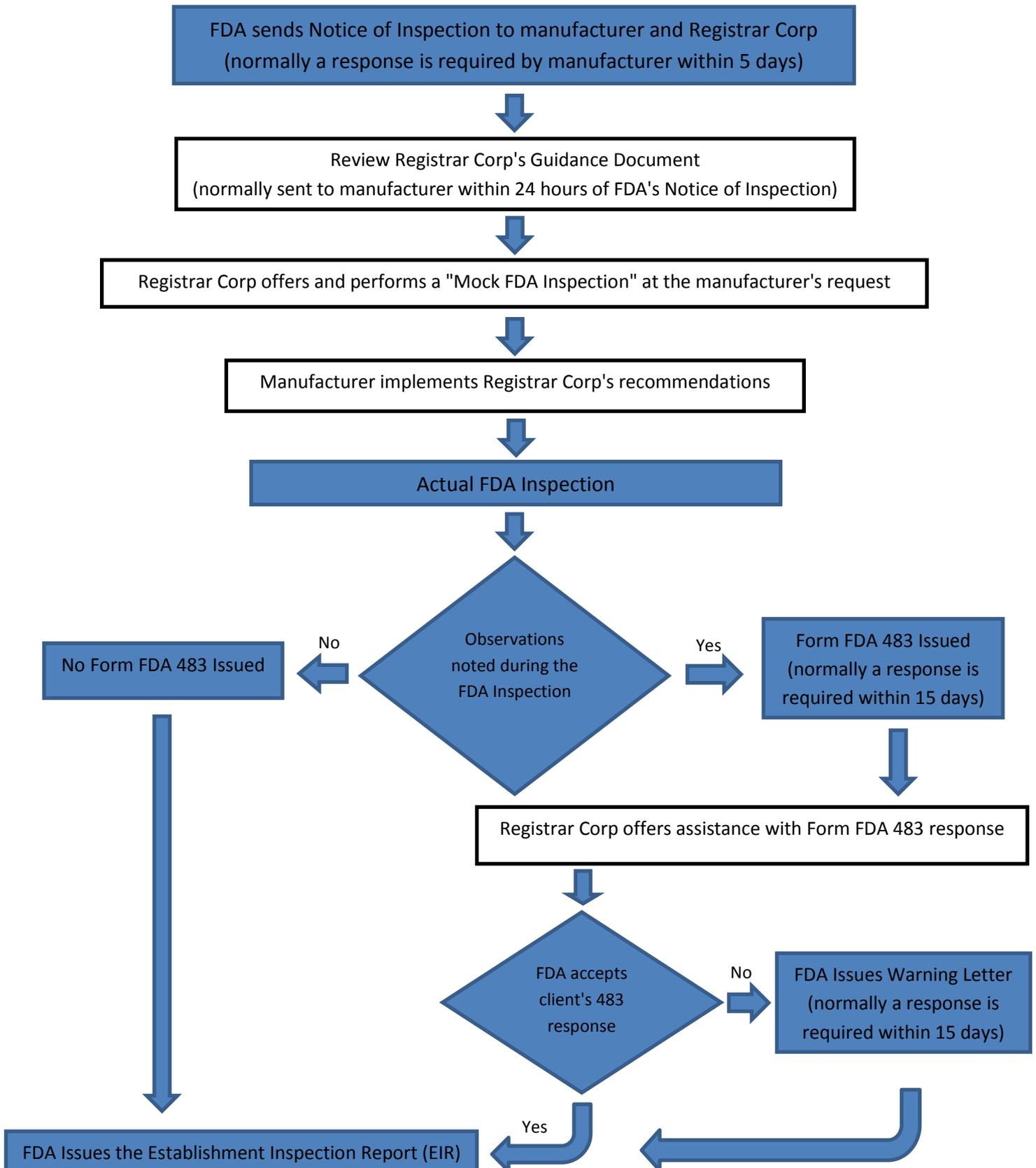
- The firm's operation hours, seasonal operations, and/or any issue that may impact the scheduling of this inspection, if applicable.

You should respond to the notice within five (5) days of receipt. After the firm has responded with the requested information, FDA will contact the firm for guidance regarding travel to the facility as well as provide more information about the inspection date.

Credentials of the FDA Inspector should be shown to the firm's top management officials, be it the owner, operator, or agent in charge. Management may examine the FDA Inspector's credentials and record their number and name. You may not, however, photocopy their information. A new Notice of Inspection (FDA Form 482) must be issued and the purpose of the FDA Inspector's visit will be explained. Plan on having a representative (an escort) from your firm accompany the FDA Inspector during the inspection. A preliminary interview and tour of the premises will usually be conducted early in an inspection so that the FDA Inspector can become familiar with the plant operation and to plan their inspection strategy. During the tour, the FDA Inspector will most likely develop a flow diagram to cover all processing steps from receipt of raw materials through finished product storage and shipment. The inspector will also use this occasion to evaluate the firm's sanitation program.

The flowchart that follows describes the FDA inspection process and highlights Registrar Corp's services in this process. Please refer to it as you read this guide. Note that there are a few minor steps in the process flow between the time your firm receives the notice of inspection and the actual FDA inspection that are not depicted in the flowchart. These steps involve ongoing communication between you and the FDA Foreign Food Inspection Coordinator and the FDA Inspector on the logistics of the inspection (e.g. lodging and airport recommendations, preliminary company and manufacturing information request, confirmation of actual inspection dates, etc.).

Flowchart of Registrar Corp Assistance with U.S. FDA Inspections



ESTABLISHMENT REGISTRATION REQUIREMENTS

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Secretary of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To carry out the provisions of the Bioterrorism Act, FDA published, on October 10, 2003, an interim final regulation, *Registration of Food Facilities*, that requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Under this interim final regulation, all affected facilities must register as of December 12, 2003. If a previously registered processing plant has moved to a new location, the plant must be registered at the new location. The previous registration will become invalid after the move/relocation. Wholesalers, distributors, brokers, etc., are not required to register and file processes. However, they must ensure that processing firms they represent comply with all registration requirements.

FDA Inspectors will likely confirm a firm's registration by asking to see the establishment's registration documents and verifying that the information is correct. Each registration must include the name, address, and phone number for the facility and its parent company (if applicable); the name, address, and phone number of the owner, operator, or agent in charge; all trade names the facility uses; applicable food product categories as identified in FDA's regulation, 21 CFR 170.3; and a statement certifying that the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration. Any changes in this information must be updated with FDA within 60 days of the change. A foreign facility must provide the name, address, and phone number of its U.S. agent. The U.S. agent must either reside in the U.S. or maintain a place of business in the U.S. The U.S. agent cannot use a post office box as an address. The U.S. agent cannot use just an answering service. They must be available to answer the phone or have an employee available to answer the phone during normal business hours.

The responsibilities of the U.S. agent are limited and include:

- assisting FDA in communications with the foreign establishment,
- responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States,
- assisting FDA in scheduling inspections of the foreign establishment, and
- if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, and such an action shall be considered equivalent to providing the same information or documents to the foreign establishment.

The foreign facility must also provide the emergency contact phone number for its U.S. agent unless the facility designates another person to serve as the emergency contact. A domestic

facility must provide an emergency contact phone number. All registration documentation should be made available to the FDA Inspector upon request.

Failure of a domestic or foreign facility to register, update required elements, or cancel its registration in accordance with this regulation, in lieu of providing for the issuance of an emergency permit, is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil action to ask a Federal court to enjoin persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act. If a foreign facility is required to register but fails to do so, food from that foreign facility that is offered for import into the U.S. is subject to being held within the port of entry for the article unless otherwise directed by FDA or the Bureau of Customs and Border Protection (CBP). The FDA inspector will likely document the registration status of the firm, and registration.

PERSONNEL

When an FDA Inspector enters the facility, they will also document information about individuals' responsibilities, including obtaining the full name and titles of the following individuals:

1. Owners, management, partners, or officers.
2. Other management officials or individuals supplying information.
3. The individuals to whom the FDA inspector's credentials were shown and other inspectional forms issued.
4. Individuals refusing to supply information or permit inspection.
5. Individuals with whom inspectional findings were discussed or recommendations made.

Ensure key personnel are readily available during the inspection to help you answer, if necessary, technical questions. Ensure a competent individual or team accompanies the FDA Inspector. Make sure your team and you follow the company's Good Manufacturing Practices (GMPs) when entering food processing and other critical areas and require the FDA Inspector to do the same.

Requirements of Employees

Regulations require plant management take all reasonable measures and precautions to assure control of communicable disease, employee cleanliness, appropriate training of key personnel, and compliance by all personnel with all requirements including the following:

- *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.
- *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
 - Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
 - Maintaining adequate personal cleanliness.
 - Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing

facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated.

- Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
 - Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
 - Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.
 - Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
 - Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
 - Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
- *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.
 - *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part must be clearly assigned to competent supervisory personnel.

FDA will verify these requirements by reviewing written records, company policies, and through direct observation of employees at various stages of the operation to determine if adequate supervision is provided to prevent the contamination of food products, food-contact surfaces, and/or food-packaging materials by employee practices. In addition, it is likely FDA will interview some of the employees. Therefore, it would be prudent to prepare your employees for such interviews to ensure they do not speak of areas outside of their general duties or knowledge.

INSPECTION OF GROUNDS AND SANITARY OPERATIONS

Grounds

The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
- Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant surroundings are bordered by grounds not under the operator's control and not maintained in the manner described above, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

Plant Construction and Design

During inspection, FDA will visually examine the facilities construction and design. FDA requires that plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. Observations will be made and recorded if any deviations are present. In general, the following requirements should be reviewed and evaluated at your own facility:

- Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
- Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, airflow, enclosed systems, or other effective means.
- Permit the taking of proper precautions to protect food in outdoor bulk storage containers by any effective means, including:
 - Using protective coverings.

- Controlling areas over and around the containers to eliminate harborage for pests.
- Checking on a regular basis for pests and pest infestation.
- Examining the storage vessels, as necessary.
- Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
- Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
- Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
- Provide, where necessary, adequate screening or other protection against pests.

If any deficiencies in any of these areas are noted, corrective measures should be taken to ensure the closest adherence to these requirements as possible.

Sanitation Operations

FDA requires that buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. These conditions will be monitored and recorded at the time of inspection and any deficiencies will be addressed in the FDA Inspector’s final report. More specifically, FDA requires that the following sanitation procedures be maintained:

FDA’s Eight (8) Key Areas of Sanitation:	
1. Safety of Water	5. Protection From Adulterants
2. Condition and Cleanliness of Food Contact Surfaces	6. Labeling, Storage, and Use of Toxic Compounds
3. Prevention of Cross Contamination	7. Employee Health Conditions
4. Maintenance of Hand-Washing, Hand-Sanitizing, and Toilet Facilities	8. Exclusion of Pests

- *Substances used in cleaning and sanitizing; storage of toxic materials:* Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
 - Those required to maintain clean and sanitary conditions;
 - Those necessary for use in laboratory testing procedures;
 - Those necessary for plant and equipment maintenance and operation; and
 - Those necessary for use in the plant's operations.

Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be properly identified through labeling, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

- *Pest control:* No pests may be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination. Effective measures must be taken to exclude pests from the processing areas and to protect against the contamination by pests. The use of insecticides or rodenticides is permitted but only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.
- *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of food.
 - Food-contact surfaces used for manufacturing or holding low-moisture food must be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.
 - In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.
 - Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

- Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
- Sanitizing agents must be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
- *Storage and handling of cleaned portable equipment and utensils:* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

If any deficiencies in any of these areas are noted, corrective measures should be taken immediately upon discovery to ensure the closest adherence to these requirements as possible.

Sanitary Facilities and Controls

In addition to the required sanitary practices required as indicated above, each plant must be equipped with adequate sanitary facilities and accommodations including, but not limited to:

- *Water supply.* The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food or food-contact surfaces must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
- *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:
 - Carry sufficient quantities of water to required locations throughout the plant.
 - Properly convey sewage and liquid disposable waste from the plant.
 - Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
 - Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
 - Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

- *Sewage disposal.* Sewage disposal must be made into an adequate sewerage system or disposed of through other adequate means.
- *Toilet facilities.* Each plant must provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
 - Maintaining the facilities in a sanitary condition.
 - Keeping the facilities in good repair at all times.
 - Providing self-closing doors.
 - Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).
- *Hand-washing facilities.* Hand-washing facilities must be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
 - Hand washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
 - Effective hand cleaning and sanitizing preparations.
 - Sanitary towel service or suitable drying devices.
 - Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
 - Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
 - Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.
- *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

These conditions will be monitored and recorded at the time of inspection and any deficiencies will be addressed in the FDA Inspector's final report. If any deficiencies in any of these areas are noted, corrective measures should be taken immediately upon discovery to ensure the closest adherence to these requirements as possible.

EQUIPMENT AND UTENSILS

An FDA Inspector will usually arrive before processing begins in order to evaluate conditions and practices not otherwise observable after plant start-up. This includes adequacy of clean-up, where and how equipment is stored while not in use, how hand sanitizing solutions and food batches are prepared and if personnel sanitize their hands and equipment before beginning work.

FDA Inspectors will examine all equipment for suitability and accessibility for cleaning. They will look to determine if equipment is constructed or covered to protect contents from dust and environmental contamination. The equipment and utensils will be evaluated as follows:

- All plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained. The design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces must be corrosion-resistant when in contact with food. They must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces must be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
- Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- Equipment that is in the manufacturing or food-handling area and that does not come into contact with food must be so constructed that it can be kept in a clean condition.
- Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.
- Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and adequately maintained, and adequate in number for their designated uses.

- Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

Dirty or improperly cleaned equipment and utensils may be a focal point for filth or bacterial contamination of the finished product. Accordingly, all equipment will be examined for suitability and accessibility for cleaning. The FDA Inspector will determine whether the equipment is properly constructed or covered to protect contents from dust and environmental contamination. The FDA Inspector will open inspection ports to check inside only when this can be done safely and evaluate if inspection ports have been painted over or permanently sealed. The FDA Inspector will check the sanitation of machinery, filtration systems, conveyor belts, and utensils such as brushes, scrapers, brooms, and other items used during processing. Handling of mercury and glass as well as UV lamps and chlorine solution pipes will be evaluated for sanitation where applicable. In general, regulations require that equipment and utensils comply with good manufacturing practices. In addition, the FDA will evaluate sanitizing practices throughout the plant to assess their effectiveness, degree of supervision exercised, sanitizer strength, contact time, and methods of use.

Please be aware that regulations pertaining to equipment and utensils in food facilities vary depending on the type of product being manufactured. Please refer to Appendix A (commodity specific guidance). These specific requirements should be reviewed prior to the date of inspection, as it is likely an FDA Inspector will review all records and data pertaining to the particular food product being manufactured.

FDA Commodity Specific Requirements (not all inclusive):	
1. Grain	9. Peanuts and Peanut Products
2. Dairy	10. Vegetable Oils
3. Eggs and Egg Products	11. Dressings
4. Candy without Chocolate	12. Vinegar
5. Candy Specialties	13. Cider
6. Chewing Gum	14. Apple Juice
7. Chocolate and Cocoa Products	15. Frozen Strawberries
8. Tree Nuts	16. Certain Juices

PRODUCTION AND PROCESS CONTROLS

The FDA inspector will look to evaluate all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food. FDA requires that these processes be conducted in accordance with adequate sanitation principles. The inspector will likely walk through the plant to review each of these stages in the manufacturing process and evaluate the overall sanitation of the plant and whether it is under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions must be taken to ensure that production procedures do not contribute contamination from any source.

Appropriate preventive control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. The facility should conduct a hazard analysis of ingredients, processes, and packaging materials and develop preventive controls to reduce to acceptable levels or eliminate the hazards identified in the hazard analysis. It is imperative, in developing preventive controls, to be aware of the potential food safety hazards that are associated with the products and processes of your plant. The rationale for implementing preventive controls is to prevent the potential food safety hazards that are reasonably likely to occur and could cause disease or injury if not adequately controlled. Awareness of potential hazards must also include some knowledge about the most appropriate and effective controls.

Please be aware that any facility that handles major allergens, including, peanuts, soybeans, milk, eggs, fish, crustacean, tree nuts, and wheat, will be subject to additional inspection requirements. Please review the allergen inspection guidance document found in the appendix of this document prior to the inspection.

Prior to the walk through, you should be prepared to provide to the inspector a complete description of any coding systems that are in place and any necessary keys for interpretation.

Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the FD&C Act must be rejected, or if permissible, treated or processed to eliminate the contamination.

Hazard Analysis and Risk-Based Preventive Controls

The owner, operator, or agent in charge should evaluate the hazards that could affect food manufactured, processed, packed, or held in their facility; identify and implement risk-based preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurance that the food is not adulterated or misbranded; and monitor the performance of these controls and maintain records of this monitoring as a matter of routine practice. The plant must have a comprehensive written plan that documents and describes these procedures.

The owner, operator, or agent in charge should conduct a reanalysis whenever significant change is made in the activities conducted at the facility, if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard. The owner, operator, or

agent in charge must revise the written plan if such significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

Preventive controls are those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, and holding of food, would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted, and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, and holding at the time of the analysis.

Ingredient Handling

The control of raw materials used in the production of food products is essential not only because of quality considerations but also due to the effect that variations in raw materials may have on the safety of the finished food product. In some cases, this could lead to a health hazard.

The FDA inspector will evaluate how raw materials are handled from the point of receiving through the manufacturing of the finished product. They will look to determine if growing conditions relative to disease, insects, or weather are affecting the raw material. They will check the measures taken for protection against insect or rodent damage.

FDA requires that raw materials and other ingredients be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against contamination and minimize deterioration. The FDA inspector will look to evaluate the initial inspection of the raw materials and look to see if the raw materials are washed or cleaned as necessary to remove soil or other contamination. The water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. The FDA inspector will also evaluate the containers and carriers of raw materials and see if they are inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

Raw materials and other ingredients must either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they must be heat treated or otherwise preserved during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients from company-approved suppliers under a guarantee or certification. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current FDA regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins. The FDA inspector will review the measures taken to prevent contamination and the verification methods used in the facility.

Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must also comply with applicable FDA

regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination. The FDA inspector will evaluate these measures as well.

The FDA inspector will also observe the method of adding ingredients to the process. They will evaluate whether filth is added into the process stream from dust, rodent excreta pellets, debris, etc., adhering to the surface of ingredient containers. They will also review the effectiveness of cleaning and inspectional operations performed on the materials prior to or while adding to the process and whether specific trimming or sorting operations on questionable material is being carried out. The FDA inspector will report any significant lags during the process or between completion of final process and final shipping in their final report.

Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the Act. Material scheduled for rework must be identified as such. Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated. Likewise, liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against contamination. The FDA inspector will also review these elements during the facility inspection.

The firm will also be evaluated on their acceptance examination and inspection practices including washing and disposition of rejected lots. The FDA inspector may also examine rejected lots, collect appropriate samples, and report consignees. They will also look to determine the general acceptability of raw materials for their intended use and their effect on the finished product. Raw stocks of fruits or vegetables may contribute decomposed or filthy material to the finished product and proper precautions should be in place to prevent this from occurring. The inspector will also be alert for use of low quality or salvage raw materials. Bags, bales, cases and other types of raw material containers will also be evaluated for any signs of abnormal conditions or indications of filthy, putrid, or decomposed items. Any indication of gnawed or otherwise damaged containers will be considered violative material and noted in the final evaluation. Any instances where insanitary storage or handling conditions exists will likely be documented by the inspector through photographs, exhibits or sketches and noted in the final inspection report.

The FDA Inspector will look to determine the controls that the manufacturer exercises over raw materials, including control of the growing practices to prevent undesirable quality and microbiological concerns, time/temperature of blanching, post blanching product temperature, time held prior to processing, and the firms procedures for cleaning the blanching equipment. Any deficiencies in the handling and verifying of raw materials will be noted in the FDA Inspector's final report. All records regarding the examination of raw materials must be in place and current as well as ensuring that handling practices adhere to the requirements above.

Product Formulation

Product formulation will be evaluated during inspection to determine if formulation changes have been made and whether the formulation of a product is compliant with FDA regulations. The FD&C Act does not specifically require management to furnish formula information except for human drugs, restricted devices and infant formulas. Nonetheless, the FDA inspector will likely request the formula for the product especially when necessary to document violations of standards, labeling, or color and food additives. Management may provide the qualitative formula but refuse the quantitative formula. Any refusal to furnish the requested qualitative formula will likely be reported in the FDA inspector's final report.

Food and Color Additives

The FDA inspector will look to evaluate any food additives used in the processing of your food product. Routine inspectional coverage will be directed primarily to the following two types of additives:

1. Unauthorized and illegal as listed in the Food Additive Status List (FASL)¹
2. Restricted as to amount in finished food.

The FDA inspector will look to verify the status of any food additives used and whether they are used and stored under sanitary conditions. The inspector may document and calculate levels of restricted-use additives in finished food if gross misuse or program violations are suspected as follows:

1. List ingredients, which may be restricted substances or food additives, and determine their status by referring to the current FASL. Report complete labeling on containers of these substances.
2. Obtain the quantitative formula for the finished product in question.
3. Determine the total batch weight by converting all ingredients to common units.
4. Calculate the theoretical levels in the final product of all restricted or unauthorized ingredients from the formula by using the Food Additives Nomographs.
5. Determine probable level of restricted ingredients by observing the weight of each ingredient actually put into the batch.

The FDA inspector will likely evaluate the status of color additives observed during each establishment inspection by using the Color Additive Status List.² This list provides the current status and use limitations of color additives likely to be found in food, drug, device, or cosmetic establishments. The inspector may request that any stocks of delisted or uncertified colors be destroyed. If you decline to destroy the colors, the FDA inspector will want to determine what

¹ <http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm091048.htm>

² <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm106626.htm>

disposition is planned, i.e., use in nonfood, non-drug, non-cosmetic or non-medical device products.

Manufacturing Operations

During the inspection, the FDA inspector will also evaluate the day-to-day manufacturing process. This includes evaluating if the equipment, utensils and finished food containers are being maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary, and that equipment is being taken apart for thorough cleaning.

All food manufacturing, including packaging and storage, must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, water activity (a_w), pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, will be reviewed to ensure that they are being held in a manner that prevents the food from becoming adulterated within the meaning of the Act. Compliance with this requirement may be accomplished by any effective means, including:

- Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.
- Maintaining frozen foods in a frozen state.
- Maintaining hot foods at 140 °F (60 °C) or above.
- Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated and will likely be evaluated by the FDA inspector.

Work-in-process must be handled in a manner that protects against contamination. Effective measures must be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. In addition, food transported by conveyor must be protected against contamination as necessary.

Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food must be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination. In addition, effective measures must be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means. The FDA inspector will likely not only review the food products and raw materials themselves to ensure no metal is present in the food but also the measures taken to ensure such contamination does not occur.

Food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven to be effective, or it shall be reexamined and found not to be adulterated within the meaning of the Act before being incorporated into other food.

Mechanical manufacturing steps, such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, or forming, must be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces and by using time and temperature controls at and between each manufacturing step. Heat blanching, when required in the preparation of food, should be affected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, the water used must be safe and of adequate sanitary quality. The FDA inspector will look to evaluate the measures in place to fulfill these requirements.

Batters, breadings, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

- Using ingredients free of contamination.
- Employing adequate heat processes where applicable.
- Using adequate time and temperature controls.
- Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
- Cooling to an adequate temperature during manufacturing.
- Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

- Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
- Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
- Using materials for food containers and food- packaging materials that are safe and suitable, as defined in 21 CFR 130.3(d).
- Providing physical protection from contamination, particularly airborne contamination.
- Using sanitary handling procedures.

Foods such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that rely on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- Monitoring the a_w of food.
- Controlling the soluble solids-water ratio in finished food.
- Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

Foods such as, but not limited to, acid and acidified foods, that rely principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- Monitoring the pH of raw materials, food in process, and finished food.
- Controlling the amount of acid or acidified food added to low-acid food.

FDA also requires that when ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice.

Finally, food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food. Additionally, storage and transportation of finished food must be done under conditions that will protect food against

physical, chemical, and microbial contamination as well as against deterioration of the food and the container. The FDA inspector will note such contamination in their final report.

Facility and Product Inspections

The FDA inspector will evaluate the maintenance of proper controls, by periodic random inspection of the product and process. The inspector will look to determine if the firm's preventive controls, sanitation controls, and good manufacturing practices, accomplish their intended purposes. They will evaluate whether there is established responsibility for specific operations and will systematically evaluate the controls that are critical for the safety of the finished product. The FDA inspector will evaluate the effectiveness of the personnel assigned to inspection operations, whether stations are adequately staffed and supervised, and the maintenance and calibration, as applicable, of critical equipment, measuring devices, and testing devices (i.e. flow meters, weighing scales, temperature sensors, pH meters, etc.).

Laboratory Tests

In cases where the facility conducts laboratory tests on site, the FDA inspector will evaluate routine tests or examinations performed by the firm's laboratory, including a review of pertinent laboratory records. They will determine what equipment is available in the laboratory and if it is adequate for the purpose intended and properly calibrated. If you are using a consulting laboratory, the FDA inspector will want to review the records from the lab to determine what tests are performed and how often. The laboratory records will likely be reviewed for the period immediately preceding the inspection. These should be made accessible to the FDA inspector, upon request, at the time of the inspection. The FDA may ask you to describe the controls that prevent in-house laboratories from becoming a source of contamination to production areas and products. In addition, be prepared to describe the controls for non-conforming product ("HOLD") procedures.

Packaging and Labeling

The FDA inspector will also evaluate packaging and labeling operations. The storage of packaging materials will be inspected to ensure adequate protection from contamination by rodents, insects, toxic chemicals or other materials. The FDA inspector will appraise the manner in which containers are handled and delivered to the filling/production areas. If slack fill is suspected, the FDA inspector will likely weigh a representative number of finished packages. The inspector will verify that the weighing equipment is properly calibrated. Furthermore, they will look to evaluate the integrity of the packaging materials for chipping, denting, puncturing, tearing, etc. The preparation of containers prior to filling will also be observed to evaluate any risk of contamination. Any washing, steaming, or other cleaning processes will be evaluated for effectiveness. When manufacturing products with a known potential for metals contamination, measures should be in place to tests for such contamination in finished product.

The FDA inspector may obtain specimens of representative labels and promotional materials including pamphlets, booklets, etc., to ensure compliance with labeling requirements. For more information concerning the requirements for labeling materials, please refer to the Review of Records section of this guidance.

Sanitation

The conditions under which food products are processed, packed, or stored is a major part of the FDA inspection and will be reviewed to determine if the firm's compliance with the law. This involves the determination of whether or not insanitary conditions contribute to the product being adulterated with filth, rendered injurious to health, or whether it consists in whole or in part of a filthy, putrid or decomposed substance.

Observations that dirt, decomposed materials, feces or other filthy materials are present in the facility and there is a reasonable possibility these filthy materials will be incorporated in the food are ways of determining products may have become contaminated and will be reviewed by the FDA inspector. If there is an existence of insanitary or filthy conditions, the FDA inspector will evaluate how these conditions contribute or may contribute to contaminating the finished product. Potential routes of contamination and all means by which filth or hazardous substance may be incorporated into the finished product will be reviewed.

Pest Control

Measures should be in place prior to the inspection to prevent insect and rodent contamination. The company should have a functioning, documented pest control program. Every effort should be made to ensure building exterior is protected against the entry of rodents and other pests. Any incidents that are uncovered during inspection will be noted in the final report. If the company stores pesticides on the premise, ensure they are authorized for use around food, properly labeled, and stored securely.

Chemical Control

The FDA Inspector will try to determine if the company properly manages the use, storage, and handling of all chemicals. Ensure Material Safety Data Sheets (MSDS) or non-USA equivalents are available for all chemicals.

Pesticide contamination of the finished product may be the result of mishandling of food products at any stage in manufacturing or storage. The use of toxic rodenticides or insecticides in a manner that may result in contamination constitutes an insanitary condition. During the inspection, the FDA inspector will likely want to speak with person in charge of the firm's rodent and insect control program. The FDA inspector in their final report will note any careless use of these toxic chemicals. Additional guidance can be found in 40 CFR Part 180 - Tolerances and Exemptions from Tolerances for Pesticides in Food Administered by The Environmental Protection Agency.

Articles containing Polychlorinated biphenyl (PCBs) (e.g., transformers, PCB containers stored for disposal, electrical capacitors) must be marked with prescribed labeling to show they contain PCBs. No PCB-containing heat exchange fluids, hydraulic fluids or lubricants are allowed used in food plants. All PCB storage areas must be marked to show the presence of PCBs. The FDA inspector will look to determine whether PCBs are being used and if so whether they are properly labeled. They will also look to determine if there is any possible leakage.

In addition, the FDA inspector will also look for the following evidence of mishandling of pesticides. Measures should be in place prior to the inspection to ensure none of these mishandlings occurs.

- Possible mix-up of pesticides or industrial chemicals with food raw materials.
- Improperly stored pesticides or industrial chemicals (lids open, torn bags in close proximity to foods, signs of spillage on floors, pallets, shelves, etc.).
- Incorrect application methods including excessive use. Many pesticide labels give instructions for use and precautions on the container.
- Improper disposal or reuse of pesticide or industrial chemical containers.
- Evidence of tracking powder or improper use of bait stations or baited traps.
- Improper handling of equipment. Movable or motorized equipment used for handling possible chemical contaminants should not be used for handling food products unless they are thoroughly decontaminated. For example, forklifts moving pallets of pesticides should not also be used to move pallets of flour, etc.
- Use of unauthorized pesticides.
- Use of foods treated with pesticides and marked "Not for Human Consumption" (e.g., treated seed wheat, etc.).
- Likely sources and possible routes of contamination of the product with pathogenic microorganisms.

Defect Action Levels

Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action. Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

Compliance with defect action levels does not excuse violation of the requirement that food not be prepared, packed, or held under unsanitary conditions or the requirements that food manufacturers, distributors, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. The FDA inspector will review these defect levels and the records of the control of these.

Storage and Food Transport Vehicles

The storage of finished products will be evaluated in the same manner as the raw materials. Products should be stored in a manner with which to minimize container abuse, facilitate proper rotation, and adhere to the storage requirements. This includes refrigeration temperatures, critical temperature tolerance, aging of products, and proper disposition of distressed stock.

During the inspections, the FDA inspector will conduct inspections of not only the storage facilities for the finished products, but also the food transport vehicles, to include:

1. Evidence of insanitary conditions.
2. Conditions which might lead to food adulteration.
3. Physical defects in the vehicle.
4. Poor industry handling practices.
5. Presence of insect and rodent damage.

The FDA inspector will likely evaluate the process by which these vehicles and the goods within are loaded and unloaded to look for signs of adulteration. Regulatory actions are possible if unfit transport vehicles are loaded and, as a result of loading, adulteration occur. Any violations will be documented with appropriate samples and photographs taken.

Distribution

During the inspection, the FDA inspector will also review the distribution and shipment of the finished product. They will likely review shipping records or invoices that report shipment of specific lots. They will also likely observe shipping cartons, loading areas, order rooms, etc., to determine customer names, addresses and destination of shipments. During the inspection, the general distribution pattern of the finished product should be made available to the FDA inspector, upon request, as well as a listing of the manufacturer's larger consignees.

Product Complaints and Recalls

The FDA inspector will likely want to review the product complaint files. They will look to identify who reviews the complaints and what their qualifications are. The criteria used by the firm in evaluating the significance of complaints and how they are investigated will also be reviewed by the FDA inspector. Complaint records should be kept in one place and made available to the FDA inspector, upon request.

In case of a severe defect or contamination a proper recall procedure should be in place. Records will likely be audited to determine the effectiveness of established procedures. In cases where no recall procedure exists, the FDA inspector will likely note this in their final report.

A recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which FDA would initiate legal action, such as seizure, according to 21 CFR Section 7.3(c).

The facility should have a documented, systematic traceability and recall plan that indicates how the organization will track and recall food manufactured, processed, packed, or held in their facility. The system should enable trace back one-step and trace forward one-step to occur in the event of a recall. Forward traceability allows processors to determine the number of cases produced on a given date and where those cases were shipped. Backward traceability allows managers to determine the supplier and lot number of all ingredients included in a finished product code. The plan should include a designated recall coordinator, written traceability procedures, recall team roles with contact information, and ready-to-use example documents such as press releases, customer contact forms, product reconciliation forms, etc.

The FDA inspector may evaluate the effectiveness of your traceability plan, by asking you to conduct a mock recall during the inspection. A mock recall is an internal exercise to test a company's ability to trace and recall product or ingredients using their documented traceability and recall plan. A mock recall exercise should be completed, with documentation, on at least an annual basis to ensure the traceability/recall systems work and all parties within the organization know what to do. After a mock recall, all personnel should come together to assess effectiveness by identifying and correcting deficiencies. Begin a mock recall by developing a scenario (real or fictional) in reference to an affected lot or affected trailer load and then follow the traceability and recall plan. The mock recall should be completed within a reasonable time (e.g. within 2 hours) having as close to 100% reconciliation of all implicated lots as possible. Make copies of all supporting materials (shipping records, production records, etc.) to show how reconciliation occurred. Be sure to write or stamp the phrase "MOCK RECALL" across all copies of supporting materials. There is no need to cause anxiety or a market crash because fictional information got into the wrong hands.

REVIEW OF RECORDS

Record Review

The plant must have detailed policies and procedures relevant to the receiving, handling, manufacturing, shipping, control and evaluation of food products to assure that they meet appropriate food safety and regulatory requirements. These policies must be well organized, available, current, dated and signed by management. Changes should be clearly identified and appropriately signed and dated.

Bioterrorism Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Secretary of Health and Human Services to issue final regulations that establish requirements regarding the establishment and maintenance of records – for not longer than two years – by persons (excluding farms, restaurants, and certain others) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging.

Examples of Documents to Review and/or Update (not all-inclusive):

1. Employee Training
2. Hazard Analysis and Preventive Controls
3. Sanitation Schedules
4. Disposition of non-conforming product
5. Laboratory tests
6. Equipment maintenance and calibration
7. Labeling
8. Pest Control
9. Customer Complaints and Recalls
10. Corrective Actions Taken When Deviations occur

For non-transporters (i.e., persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation), the records have to:

1. Identify the immediate non-transporter previous *sources*, whether foreign or domestic, of all foods received, including:
 - The name of the firm; address; telephone number; fax number and e-mail address, if available.
 - Type of food, including brand name and specific variety (e.g., Brand X cheddar cheese, not just cheese; romaine lettuce, not just lettuce).
 - Date received.
 - Quantity and type of packaging (e.g., 12 oz. bottles).
2. Identify the immediate transporter previous sources, including the name, address, telephone number – and, if available, fax number and e-mail address. Persons who manufacture, process, or pack food also must include lot or code number or other identifier, if the information exists. Identify the immediate non-transporter subsequent *recipients* of all foods released, including:

- The name of the firm; address; telephone number; fax number and e-mail address, if available.
- Type of food, including brand name and specific variety.
- Date released.
- Quantity and type of packaging.
- Identify the immediate transporter subsequent recipients, including the name, address, telephone number – and, if available, fax number and e-mail address. Persons who manufacture, process, or pack food also must include lot or code number or other identifier, if the information exists.
- Information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

The term *transporters* include persons who have possession, custody, or control of an article of food in the U.S. for the *sole* purpose of transporting the food, whether by road, rail, water, or air. The term *transporters* also include foreign persons that transport food in the U.S., regardless of whether the foreign persons have possession, custody, or control of food for the sole purpose of transporting it.

For transporters, records must include names of the transporter’s immediate previous source and transporter’s immediate subsequent recipient; origin and destination points; date shipment received and date released; number of packages; description of freight; route of movement during the time the food was transported; and, transfer point through which the shipment moved.

Preventive Controls and Sanitation Records

For specific foods, including juice and seafood, facilities are required to develop and maintain a Hazard Analysis and Critical Control Points (HACCP) plan. For Low-Acid Canned Food (LACF) and Acidified foods, the manufacturer must also conform to the requirements of 21 CFR 113 and 21 CFR 114, respectively. Other commodities also have specific sections of the CFRs that apply. Please note that Section 103 of the Food Safety Modernization Act (FSMA) gives FDA an expressed statutory mandate to require hazard analysis and risk-based preventive controls at registered facilities that manufacture, process, pack, and hold regulated foods that are not already covered by a mandatory HACCP plan. FSMA does not change the requirements for facilities already required to operate under preventive control programs such as HACCP (e.g., seafood and juice) or foods subject to the low-acid canned food (LACF) regulation. FSMA will, however, require all other registered foreign and domestic facilities to implement preventive controls and maintain a written preventive control plan.

The entirety of this record keeping requirement includes the development of a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing, a hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type product processed by that processor and to identify control measures that the processor can apply to control those hazards, and a written HACCP or

FSMA's preventive controls plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing. The food safety plan (e.g., HACCP or FSMA's preventive controls) is required to identify the potential hazards, critical control points, critical limits, list of procedures and frequency for monitoring the critical limits, corrective action procedures, lists of validation and verification procedures, and the record keeping measures and the personnel involved.

For foods subject to the low-acid canned food (LACF) regulation, all departures from scheduled processes having a possible bearing on public health or the safety of the food should be noted and the affected portion of the product identified; these departures must be recorded and made the subject of a separate file (or log identifying the appropriate data) delineating them, the action taken to rectify them, and the disposition of the portion of the product involved. FDA will evaluate these deviations to determine if proper management of such situation was conducted and whether the deviation corrective actions in place are appropriate and meet FDA regulations.

FDA will review all of the aforementioned records to ensure compliance with the corresponding regulations outlined in this guidance. In preparation for the inspection, it would be prudent to review your facility's HACCP or FSMA's preventive control plan to ensure that it incorporates all potential critical control points and to ensure your records are being maintained and are readily available, complete, and in compliance prior to the inspection date. Any deviations not properly addressed or failure to produce substantiating records will be noted on the FDA Inspector's final report.

Label Review

At the time of inspection, upon request, all labeling must be made available to the FDA Inspector, at which point the labeling will be evaluated for compliance with FDA regulations. The sanitary condition of labelers and equipment feeding cans to, and away from, the labeler will be inspected to determine if old product is present on any equipment that touches the can end seams in the presence of moisture carry-over from the can cooling operation. Floor drains in the labeling area will also be evaluated for sanitary conditions. Absence of floor drains could indicate infrequent cleaning of the equipment unless it is physically moved to another area for cleaning. The FDA Inspector will also look to determine what labels are used and what labeling is prepared or used to accompany or promote the product. The FDA inspector will also want to determine the methods used to promote products and how the products reach the ultimate consumer. They will likely want to review the printed promotional materials used and determine whether they accompany the products or are distributed under a separate promotional scheme.

Labeling on finished products will be reviewed for compliance with all FDA labeling regulations, including allergen labeling. The Nutrition Labeling and Education Act of 1990 (NLEA) provides FDA with specific authority to require nutrition labeling of most foods regulated by the Agency, and to require that all nutrient content claims (e.g., 'high fiber', 'low fat', etc.) and health claims be consistent with agency regulations. Furthermore, FDA has established food standards of identity that specific food products must comply with in order to bear that specific name. FDA food standards establish the common or usual name for a food and define the nature of the food, generally in terms of the types of ingredients that it must contain (mandatory ingredients), and that it may contain (optional ingredients). FDA food standards may specify minimum levels of the valuable constituents and maximum levels for fillers and water.

They also may describe the manufacturing process when that process has a bearing on the identity of the finished food. Finally, FDA food standards provide for label declaration of ingredients used in the food and may require other specific labeling, such as the declaration of the form of the food, packing medium, and flavorings or other characterizing ingredients, as part of the name of the food or elsewhere on the principal display panel of the label (70 FR 29217).

The FDA inspector will likely examine final food products to ensure that proper sanitation, nutrition, and standard of identity labeling has been completed. We recommend you review the FDA Guide to The Nutrition Labeling and Education Act found in appendix A. When the labeling is suspect or when the FDA Inspector requests to collect labels/labeling, usually, 3 copies of all labels and accompanying literature will be collected for further review at FDA offices after the inspection has been completed.

Requesting Information

While undergoing an inspection you will likely be required to provide some if not all records regarding the aforementioned information to the FDA Inspector. The FDA Inspector can request records by issuing a written demand for records referred to as Form 482(a). The Demand for Records must identify the specific records requested and must be signed by the FDA Inspector.

The FDA Inspector may also issue a written request for information. The form known as Form 482(b) is issued to request the firm's copies of scheduled processes, supporting documentation from a processing authority (e.g., letter or bulletin) and the documentation that delineates the venting or retort operational procedures. The FDA 482(b) is not routinely issued to request detailed supporting documentation (e.g., heat penetration or temperature distribution test data) from a processing authority. However, when situations are encountered where an FDA Inspector may believe control of certain factors are critical to the process, and there is no evidence to document that these factors (e.g., a change in formulation that could affect consistency) were considered by the processing authority or listed on the filed scheduled process, the FDA Inspector may issue the request.

Note: FDA 482, 482(a) and 482(b) are not issued during foreign inspections.

All FDA Inspectors have an obligation to uphold confidentiality. Under FD&C Act Section 301(j) Sections 359(d) and 306(e) of the Public Health Service Act, and Section 1905 of the Federal Confidential Statute (18 U.S.C. 1905), FDA Inspectors are required to protect confidential material obtained during your official duties. The management of the firm under inspection is permitted to request copies of any documents or records obtained from their firm. Furthermore, FDA Inspectors are not permitted to remove the firm's only copy of records. They may photocopy or mechanically copy records if duplicates are not available.

EMERGENCY PERMIT CONTROL

When FDA determines that a class of foods may be contaminated with microorganisms and be injurious to health, and the injurious nature of the product cannot be determined after shipment in interstate commerce, the agency can issue regulations governing the issuance of permits (21 CFR 108). Whenever the Commissioner determines, after investigation, that a manufacturer, processor, or packer of a food for which a regulation has been promulgated does not meet the mandatory conditions or requirements of that regulation, the Commissioner will issue to such manufacturer, processor, or packer an order stating that a permit is required before the food may be introduced or delivered for introduction into interstate commerce by that person. The order will specify the mandatory conditions and requirements with which there is a lack of compliance.

The manufacturer, processor, or packer will have 3 working days after receipt of such order in which to file objections. If objections are filed, the determination is stayed pending a hearing to be held within 5 working days after the filing of objections on the issues involved unless the Commissioner determines that the objections raise no genuine and substantial issue of fact to justify a hearing. If the Commissioner finds that there is an imminent hazard to health, the order will contain this finding and the reasons therefor, and will state that the determination of the need for a permit is effective immediately pending an expedited hearing. Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner will determine whether a permit is required and will inform the manufacturer, processor, or packer, in writing, with the reasons for his decision. The Commissioner will not stay a determination of the need for a permit pending court appeal except in unusual circumstances, but will participate in expediting any such appeal (21 CFR 108.5(a)-(c)).

A permit will be required only during a temporary period as is necessary to protect the public health. Whenever the Commissioner has reason to believe that a permit holder is in compliance with the mandatory requirements and conditions and is likely to remain in compliance, he will, on his own initiative or on the application of the permit holder, revoke both the determination of need for a permit and the permit that had been issued. If denied, the applicant will, upon request, be allowed a hearing.

After a determination and notification that a manufacturer, processor, or packer requires a permit, the manufacturer, processor, or packer may not thereafter introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by him unless he holds a permit issued by the Commissioner or obtains advance written approval of the FDA. Any manufacturer, processor, or packer for whom the determination was made that a permit is necessary may apply to the Commissioner for the issuance of a permit. The application will contain such data and information to show that all mandatory requirements and conditions for the manufacturer, processing, or packing of a food for which regulations are met and, in particular, will show that the deviations specified in the Commissioner's determination of the need for a permit have been corrected or suitable interim measures established. Within 10 working days after receipt of such application (except that the Commissioner may extend such time an additional 10 working days where necessary), the Commissioner will issue a permit, deny the permit, or offer the applicant a hearing as to whether the permit should be issued. If the Commissioner finds that a permit holder is not in compliance with the mandatory requirements

and conditions established by the permit, he will immediately suspend the permit and so inform the permit holder, with the reasons for the suspension (21 CFR 108.6-7).

A manufacturer, processor, or packer may continue, at its own risk, to manufacture, process, or pack without a permit a food for which the Commissioner has determined that a permit is required. All food so manufactured, processed, or packed during such period without a permit must be retained and may not be introduced or delivered for introduction into interstate commerce without the advance written approval of the FDA. Approval may be granted only upon an adequate showing that such food is free from microorganisms (21 CFR 108.12).

For any foreign commercial processor engaged in the processing of acidified foods and offering those foods for import into the United States, in lieu of providing for the issuance of an emergency permit, as described above, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, under section 801 of the Act, to any acidified foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health.

Any acidified food so refused admission shall not be admitted until the Commissioner determines that the commercial processor offering the food for import has complied with the requirements and that the food is not injurious to health. To assist the Commissioner in making this determination, a duly authorized employee of the FDA shall be permitted to inspect the commercial processor's manufacturing, processing, and packing facilities.

END OF INSPECTION

FDA Inspectors will make every reasonable effort to discuss all observations with the management of the establishment:

- as they are observed during the course of the inspection, and/or
- on a daily basis before leaving the facility, and
- during the inspection closeout meeting at the facility.

This is done to minimize surprises, errors, and misunderstandings when or if the FDA 483 (Inspectional Observations form) is issued and/or inspectional deviations are discussed (please see Appendix B for an example of the form). These discussions may include observations, which may be written on the FDA-483, and those that will only be discussed with management during the inspection closeout meeting at the facility. Firms may use these discussion opportunities to ask questions about the observations, request clarification, and inform the FDA inspection team what corrections have already been made or will be made at a later time. FDA Inspectors will verify the completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection.

Upon completing the inspection and before leaving the premises, the FDA Inspector will provide you with a copy of the inspectional findings on an FDA 483 - Inspectional Observations form. The form is intended to notify the inspected establishment's top management in writing of significant objectionable conditions relating to products and/or processes, or other violations of the FD&C Act and related Acts, which were observed during the inspection. It is possible to have the FDA 483 form annotated at the time of the final meeting with the FDA Inspector. The annotations are succinct comments about the statuses of the FDA 483 items. If the facility's management has promised and/or completed a corrective action to an FDA 483 observation prior to the completion of the inspection, the FDA 483 should be annotated with one or more of the following comments, as appropriate:

1. Reported corrected, not verified.
2. Corrected and verified.
3. Promised to correct.
4. Under consideration.

If the firm's management promises corrections and furnishes a date or timeframe (without a specific date) for completion, then a date may be added to the FDA 483 as "by xxx date" or "within xxx days or months" in the annotation. You should carefully review all annotations prior to closure of your meeting with the FDA Inspector. You normally have 15 working days to respond to FDA in writing with your corrective actions for any observation listed on the FDA 483 (please see flowchart on page 11). If FDA deems that your corrective actions are not sufficient to address or correct a finding, they can issue a warning letter. You normally have 15

working days to respond to the warning letter in writing. The FDA Inspector will instruct the firm on how to respond in writing to FDA. It is important that you follow through with the inspector to confirm the receipt of all documents that are both sent and received to ensure adequate follow-through.

Once all corrective actions are reviewed and accepted by FDA, the Inspector will then complete an Establishment Inspections Report (EIR). The EIR is a detailed narrative of observations made by the FDA Inspector during the inspection of the facility. The EIR is reviewed by the Center for Food Safety and Applied Nutrition (CFSAN) for any compliance issues in order to determine the next course of action, if any. A copy of the EIR will be provided to the manufacturer within four to six weeks of the inspection date.

CFSAN reviews foreign inspection EIRs and classifies each inspection. Regulatory actions, such as Detention without Physical Examination (DWPE), may be recommended by CFSAN if significant deviations from the regulations are revealed. If the violations found at the facility are severe, a warning letter will likely be issued. If you receive a warning letter, you will have a 15-day window to respond with the corrective actions that will be taken to correct the violations. If no response is received within the 15-day period, FDA may choose to move to seizure of products and goods at the inspected facility. In some instances, a reinspection will be deemed necessary if critical violations are uncovered. If FDA re-inspects to determine whether a deficiency has been corrected, the agency will charge re-inspection fees, currently at the rate of \$289 per hour where travel is required, plus expenses. Additionally, if an FDA Inspector determines that an adulterated or misbranded product is already on the U.S. market they may ask that a recall be issued for a specific product.

If you require assistance, please contact Registrar Corp by phone, email, or by using the “Live Help” on our web site: www.registrarcorp.com. Our nineteen offices worldwide are also available to assist you.

Appendix A: Resources

1. Investigations Operations Manual: Chapter 5 Establishment Inspection

- <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf>

2. Foreign Food Inspection Program at a Glance

- <http://www.fda.gov/Food/InternationalActivities/ucm212024.htm>

3. 21 CFR 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

- http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=7a96e78de0597eff3dfce80e103973e9&tpl=/ecfrbrowse/Title21/21cfr110_main_02.tpl

4. FDA Standards of Identity for Foods

- http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=12dbb027a152c5ac4031218a6d351f48&c=ecfr&tpl=/ecfrbrowse/Title21/21cfrv2_02.tpl

5. Establishment and Maintenance of Records Guidance

- <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/UCM113920.pdf>

6. Defect Levels Handbook

- <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitization/ucm056174.htm>

7. FDA Guide to The Nutrition Labeling and Education Act

- [http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm#GUIDE FOR REVIEW OF NUTRITION](http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm#GUIDE_FOR_REVIEW_OF_NUTRITION)

8. Commodity Specific Guidance

- <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074967.htm>
- <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074988.htm>
- <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm>
- <http://www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm>

9. Allergy Inspection Guide

- <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm>

10. Fish and Fishery Products Hazards and Controls Guidance

- <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm>

11. Guidance for Industry: Juice HACCP Hazards and Controls Guidance

- <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Juice/ucm072557.htm>

Appendix B: Forms

Example of: FDA Notice of Inspection Email Attachment

 U.S. Food and Drug Administration 	
Date:	
Send to:	From:
Office Location:	Office Location:
Fax Number:	Fax Number:
Tel Number:	Tel Number:
E-mail:	E-mail:
<p>To Whom It May Concern,</p> <p>This is an official notification that the United States Food and Drug Administration (U.S.FDA) is planning to conduct an inspection at your food firm in the near future. In order to make sure you receive this notification, FDA is sending duplicates of this notice to all contact points available, including email, fax, and/or mail. In addition, we are also notifying your competent authority (APEDA) of this inspection notice. Our records indicate that your firm is a grower, harvester, processor, manufacturer, packer, repacker, and/or holder of foods under U.S.FDA jurisdiction and that these foods are offered for consumption in the U.S.</p> <p>The inspection will be conducted by an inspector from the U.S.FDA to determine if your firm and your firm's (Produce) products meet U.S. requirements under the Federal Food, Drug, and Cosmetic Act and, if applicable, the Public Health Service Act. While it is not necessary that your firm is producing food products for the U.S. market at the time of this inspection, it is our intention to visit your firm while it is in operation. Firms that demonstrate compliance with applicable U.S. regulations may be subject to less inspection or sampling when offering food products for import into the U.S.</p> <p>Please respond to this inquiry within <u>five days</u> of receipt and provide the following information:</p> <ul style="list-style-type: none"> • The firm's point-of-contact, telephone, fax number, and email address, if available. • The firm's complete physical and mailing address for farm/packing house, manufacturing site, processing facility and/or holding facility. • Operation hours, seasonal operations and/or any other issue that may impact the scheduling of this inspection, if applicable. <p>Following your response, FDA's Office of Regulatory Affairs will contact you to coordinate more specific details concerning the inspection including proposed dates for the inspection.</p> <p>If you fail to respond to these communications, or do not allow FDA to conduct the inspection, FDA may initiate regulatory actions against your firm's products including, where appropriate, increased sampling, refusal of admission, or other regulatory action.</p> <p>If you are not a food producer but you are a broker/exporter of food products to the U.S. please provide your (Produce) supplier's firm name and contact information (point-of-contact, complete mailing and physical address, telephone, fax, and/or email).</p> <p>If you have any questions, you may contact me at _____ . Please send your response, in English if possible, in an e-mail to: _____ or fax to: _____</p> <p>For more information on the U.S.FDA, please visit our website at www.fda.gov. For additional information on FDA's Foreign Food Inspection Program please visit: http://www.fda.gov/Food/InternationalActivities/ucm196386.htm.</p> <p>Thanks in advance for your cooperation. We look forward to your prompt response.</p> <p style="text-align: center;">_____, USFDA's Foreign Food Inspection Coordinator</p>	

Example of FDA Form 482a: Demand for Records

INVESTIGATIONS OPERATIONS MANUAL

EXHIBIT 5-2

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS AND PHONE NO. 6751 Steger Dr. Cincinnati, OH 45237 (513) 679-2700	
TO	2. NAME AND TITLE OF INDIVIDUAL Michael Campbell, President		3. DATE 8/20/2007
	4. FIRM NAME ABC Soup Company		5. HOURS 8:30
	6. NUMBER AND STREET 3114 Mapleleaf Ave		A.M. P.M. XXX
	7. CITY AND STATE Cincinnati, OH		8. ZIP CODE 45213
Written demand for examination and/or copying of the records required by 21 CFR 113.100, 21 CFR 114 and 21 CFR 500.23 is hereby given, pursuant to 21 CFR 108.25(g), 21 CFR 108.35(h) and 21 CFR 500 for the records described below in order to verify the pH, adequacy of processing, the integrity of container closures, and the coding of the products processed by your firm.			
9. RECORDS NECESSARY All thermal process and production records mandated by 21 CFR 113 and 114 for the manufacture of Mighty Good Vegetable Soup in 303 cans from May 1, 2004 to the present. This includes pH records, calibration record, formulation, batch records, etc.			
10. SIGNATURE <i>(Food and Drug Administration Employee(s))</i> Sydney H. Rogers		11. TITLE FDA EMPLOYEE Investigator	

FORM FDA 482a (10/03)

PREVIOUS EDITION IS OBSOLETE

DEMAND FOR RECORDS

Example of FDA Form 482b: Request for Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS AND PHONE NO. 6751 Steger Dr. Cincinnati, OH 45237 (513) 679-2700	
TO	2. NAME AND TITLE OF INDIVIDUAL Michael Campbell, President		3. DATE 8/20/2007
	4. FIRM NAME ABC Company		5. HOURS 8:00
	6. NUMBER AND STREET 3114 Mapleleaf Ave.		A.M. P.M. XXX
	7. CITY AND STATE Cincinnati, OH		8. ZIP CODE 45213
Written request is hereby given pursuant to 21 CFR 108.25(c)(3)(ii), 21 CFR 108.35(c)(3)(ii) and 21 CFR 500.23 for the information described below, concerning processes and procedures which is deemed necessary by the Food and Drug Administration to determine the adequacy of the processes for products processed by your firm.			
9. RECORDS NECESSARY All written supporting documentation from a process authority or other source which specify the scheduled process and critical factors for the processing of Mighty Good Vegetable Soup in 303 cans to include pH records, calibration records, formulation and batch records, etc			
10. SIGNATURE (Food and Drug Administration Employee(s)) <i>Sydney H. Rogers</i>		11. TITLE FDA EMPLOYEE Investigator	

Example of FDA Form 483: Inspectional Observations

EXHIBIT 5-5 **INVESTIGATIONS OPERATIONS MANUAL**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Minneapolis District 250 Marquette Ave. South, Suite 600 Minneapolis, MN 55401 Industry information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 10/5-7/2008	
		FEI NUMBER 0000112233	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED to: William S. Gundstrom, Vice President, Production			
FIRM NAME Topline "T.L.P."		STREET ADDRESS 2136 Elbe Place	
CITY, STATE AND ZIP CODE Jackson, MN 55326		TYPE OF ESTABLISHMENT INSPECTED Tablet Repacker	
<p><small>THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.</small></p> <p><small>DURING AN INSPECTION OF YOUR FIRM (I) (H) OBSERVED:</small></p>			
<p>List your observations in a logical manner</p>			
<small>SEE REVERSE OF THIS PAGE</small>	EMPLOYEE(S) SIGNATURE <i>Sidney H. Rogers</i>	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Sidney H. Rogers, Investigator	DATE ISSUED 10/7/2008

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

Example of FDA Form 484- Receipt of Samples

EXHIBIT 4-5		INVESTIGATIONS OPERATIONS MANUAL	
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER 850 Third Avenue Brooklyn, NY 11232 718-340-7000	
2. NAME AND TITLE OF INDIVIDUAL Richard A. Frost, General Manager		3. DATE 12-4-06	4. SAMPLE NUMBER 25563
5. FIRM NAME Quality Wholesale Co.		6. FIRM'S DEA NUMBER AB3632918	
7. NUMBER AND STREET 3146 Front Street		8. CITY AND STATE (Include Zip Code) Brooklyn, NY 11232	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification) The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form. (NOTE: if you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)			
10. SAMPLES WERE <input type="checkbox"/> PROVIDED AT NO CHARGE <input checked="" type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> CASH <input type="checkbox"/> BILLED <input type="checkbox"/> VOUCHER <input type="checkbox"/> CREDIT CARD \$15.00	
		12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) <i>Richard A. Frost</i>	
13. COLLECTOR'S NAME (Print or Type) Sylvia A. Rogers		14. COLLECTOR'S TITLE (Print or Type) Investigator	
		15. COLLECTOR'S SIGNATURE <i>Sylvia A. Rogers</i>	

Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

(1) ****

(2) ****

(3) ****

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form FDA 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

Appendix C: Checklist

I: Personnel

- Measures in place to ensure control of communicable disease.
 - Procedures to ensure no ill persons are in processing area.
 - Required hygiene practices for all persons on duty.
 - Education and training in proper food handling procedures in place.
 - Supervisors are assigned to ensure compliance with cleanliness procedures.

II: Inspection of Grounds and Sanitary Operations

- Grounds
 - Equipment properly stored.
 - Litter and waste removed.
 - Weeds or grass cut within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
 - Roads, yards, and parking lots are maintained so that they do not constitute a source of contamination in areas where food is exposed.
 - Draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests are adequate.
 - Systems for waste treatment and disposal are operating in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
- Plant Construction and Design
 - Sufficient space is provided for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
 - Take proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material by separation of operations in which contamination is likely to occur,

by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

- Protect food in outdoor bulk fermentation vessels by any effective means, including:
 - Using protective coverings.
 - Controlling areas over and around the vessels to eliminate harborage for pests.
 - Checking on a regular basis for pests and pest infestation.
 - Skimming the fermentation vessels, as necessary.
- Floors, walls, and ceilings can be adequately cleaned and kept clean and kept in good repair.
- Drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials.
- There is adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned.
- There is adequate ventilation or control equipment to minimize odors and vapors.
- Provide, where necessary, adequate screening or other protection against pests.

- Sanitation Operations
 - Buildings, fixtures, and other physical facilities at the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated.
 - Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination.
 - Substances used in cleaning and sanitizing procedures must be free from undesirable microorganisms and be safe and adequate under the conditions of use.
 - Storage of toxic materials are properly identified through labeling, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

 - No pests are in any area of a food plant.

- All food-contact surfaces, including utensils and food-contact surfaces of equipment are cleaned as frequently as necessary to protect against contamination of food.
- Cleaned and sanitized portable equipment with food-contact surfaces and utensils are stored in a location and manner that protects food-contact surfaces from contamination.

- Sanitary Facilities and Controls
 - Water supply is sanitary and provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
 - Plumbing is adequate to support all needs of the facility.
 - Sewage Disposal is made into an adequate sewerage system or disposed of through other adequate means.
 - Toilet Facilities are accessible to all employees, fully stocked, sanitary, have self closing doors, doors that do not open into areas where food is exposed to airborne contamination.
 - Hand washing Facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands. Facilities are fully stocked with sanitizers and drying devices, employee hand washing signs posted, and provided with devices designed to protect against recontamination of hands.
 - Rubbish is conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protected against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

III: Equipment and Utensils

- All plant equipment and utensils are designed and made of material and workmanship that can be adequately cleaned and is properly maintained.
- Seams on food-contact surfaces are smoothly bonded and maintained.
- Equipment that is in the manufacturing or food-handling area and that does not come into contact with food is constructed so it can be kept in a clean condition.

- Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms is fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device.
- Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms are in place.
- Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment is sanitary.

IV: Production and Process Controls

- HACCP and FSMA's risk-based preventive controls, include;
 - Conduct a comprehensive hazard analysis.
 - Identify and implement risk-based preventive controls.
 - Monitor performance of controls.
 - Maintain records of monitoring activities.
 - Verify the controls are implemented and working.
 - Validate that controls are adequate to produce safe foods.
- Ingredients are handled in a manner to prevent contamination
 - Cleaning and inspectional operations performed on the materials prior to or while adding to the process and specific trimming or sorting operations performed on low quality or questionable material.
 - Acceptance examination and inspection practices are in place including washing and disposition of rejected lots.
 - Raw materials used are appropriate for their intended use and their effect on the finished product.
 - Any formulation changes have been documented and the formulation of a product is compliant with FDA regulations.
 - All food and color additives used are legal and used within their regulated conditions of use.

- Raw material examination factors are recorded and made part of the daily process records.
- Raw agricultural products are handled and cleaned to remove excess soil from the surface of the product.
- All raw materials are held under conditions which prevent contamination.
- Suppliers guarantees (if any) of all raw materials on hand verifying suitability.

- Manufacturing Operations
 - All food manufacturing, including packaging and storage, are conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food.
 - Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms are in place and documented.
 - Measures in place and documented to protect against the inclusion of metal or other extraneous material in food.
 - Food, raw materials, and other ingredients that are adulterated are disposed of in a manner that protects against the contamination of other food or are reconditioned effectively and are reexamined.
 - Mechanical manufacturing steps such as washing and peeling are performed so as to protect food against contamination.
 - Batters, breading, sauces, gravies, dressings, and other similar preparations are treated or maintained in such a manner that they are protected against contamination.
 - Filling, assembling, packaging, and other operations are performed in such a way that the food is protected against contamination.
 - Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms are processed to and maintained at a safe moisture level.
 - Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms are monitored and maintained at a pH of 4.6 or below.

- Ice used in contact with food, is made from water that is safe and of adequate sanitary quality.
- Food-manufacturing areas and equipment used for manufacturing human food are not used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

- Facility and Product Inspections
 - Responsibility for specific operations regarding preventive controls, sanitation procedures, and good manufacturing practices are established and that critical controls concerning the safety of, ingredients, work-in-process, and the finished product are carefully monitored.
 - Periodic random internal inspections are conducted to determine whether the food safety system conforms to planned arrangements, are up-to-date and meet regulatory requirements.
 - Inspectional controls, including effectiveness, maintenance and calibration, as applicable, of critical equipment, measuring devices, and testing devices.

- Laboratory Tests
 - In house laboratory testing or examinations records are adequate and accurate.
 - If a consulting laboratory is used, records are maintained from the lab and include what tests are performed and how often.
 - Review technician training, laboratory procedures and equipment calibration.

- Packaging and Labeling
 - The storage of packaging materials are protected from contamination by rodents, insects, toxic chemicals or other materials.
 - Weighing equipment is appropriately maintained and there is no evidence of slack fill.
 - Packaging materials are handled in a manner to prevent damage and contamination to the materials.
 - Old products are not present on any equipment which touches the can end seams.

- Sanitary conditions are maintained for labelers and equipment feeding cans to, and away from, the labeler.
- Floor drains in labeling area are accessible.

- Sanitation
 - Dirt, decomposed materials, feces or other filthy materials are not present in the facility.
 - Measures are in place to prevent potential routes of contamination and all means by which filth or hazardous substances may be incorporated into the finished product.

- Pest Control
 - Measures are in place prior to the inspection to prevent insect and rodent contamination.
 - Building exteriors protect against the entry of rodents and insects.
 - Pesticides are authorized for use around food, properly labeled, and stored securely.

- Chemical Control
 - Articles containing Polychlorinated biphenyl (PCBs) are marked with prescribed labeling to show they contain PCBs.
 - Pesticides or industrial chemicals are clearly labeled and properly stored to ensure they are not mixed-up with food raw materials.
 - Pesticide labels give instructions for use and precautions.
 - Pesticide or industrial chemical containers are properly disposed of.
 - Movable or motorized equipment used for handling possible chemical contaminants are not used for handling food products unless they are thoroughly decontaminated.
 - Foods treated with pesticides are marked "Not For Human Consumption."
 - Material Safety Data Sheets (MSDS) or non-USA equivalent are available for all chemicals.

- Defect Action Levels
 - Measures are in place to ensure compliance with defect action levels for particular foods and records of verification of compliance are maintained.

- Storage and Food Transport Vehicles
 - Products are stored in a manner with which to minimize container abuse, facilitate proper rotation, and adhere to the storage requirements.
 - There is no evidence of insanitary conditions, conditions which might lead to food adulteration, physical defects in the vehicle, or poor handling practices in the transport vehicles.

- Distribution
 - Shipping records and invoices that report shipment of specific lots are maintained.
 - The general distribution pattern of the finished product is maintained as well as a listing of the manufacture's larger consignees.

- Product Complaints and Recalls
 - Complaint records are maintained, addressed, and kept on file.
 - An effective recall procedure is documented and maintained.
 - Mock recalls are conducted to evaluate effectiveness of recall system.

V: Review of Records

- Bioterrorism Act
 - Identify the immediate non-transporter previous *sources*.
 - Identify the immediate non-transporter subsequent *recipients*.
 - Transporters, records.

- Production Records
 - Frequency of measurement and recording of critical factors.
 - Evidence of critical factors not within established limits.
 - HACCP or Preventive Controls Plan and Hazard Analysis.
 - A diagram or detailed description of the firm's systems is on file and documentation that the systems are effectively implemented.
 - Preventive controls records.
 - Disposition of non-conforming product.
 - Sanitation Standard Operating Procedures (SSOPs).