CONTENTS

Notice .......................................................................................................................... 3

1. Introduction ............................................................................................................. 4

2. About food inspections ............................................................................................ 5
   Food laws .................................................................................................................. 7
   Inspection authority ................................................................................................ 8
   Recordkeeping requirements and records access ..................................................... 10

3. Planning ahead .......................................................................................................... 15
   Establish an inspection team .................................................................................. 16
   Responding to requests for records ....................................................................... 18
   Put policies in writing ............................................................................................. 21
   Establish your protocols ......................................................................................... 28
   Conduct drills .......................................................................................................... 30

4. During the inspection ............................................................................................... 34
   The arrival of the inspector ..................................................................................... 35
   The opening conference .......................................................................................... 37
   Inspection procedures and assertion of your legal rights ......................................... 40
   Closing conference .................................................................................................. 44
   Inspection dos and don’ts ......................................................................................... 49

Appendix A: Notice of inspection form FDA 482 ...................................................... 52
Appendix B: Notice of inspection - request for records form FDA 482c .................. 56
Appendix C: Inspectional observations form FDA 483 ........................................... 58
Appendix D: Receipt of samples form FDA 484 ......................................................... 61
List of Worksheets ..................................................................................................... 64
This manual provides information and suggested guidelines for Produce Marketing Association (PMA) members to follow during food regulatory inspections. The manual has been developed by Keller and Heckman LLP (K&H) and represents PMA’s and K&H’s best efforts to provide information in a manner consistent with applicable regulations, standards, and guidelines.

This information is offered in good faith, but is made without warranty, express or implied, as to merchantability, fitness for particular purpose, or any other matter, as legal requirements are subject to change or interpretation over time. These guidelines are not necessarily exhaustive or exclusive, and were not designed to apply to any specific facility, farm, or process.

It is the responsibility of the user of this document to verify that these guidelines are appropriate for its operations. PMA, its members and contributors do not assume any responsibility for compliance with applicable laws and regulations, and recommend that users consult with their own legal and technical advisers to analyze the facts and ensure that the procedures for their companies meet applicable requirements.
INTRODUCTION

This PMA manual outlines suggested policies and procedures to serve as a resource for handling food regulatory inspections conducted by the U.S. Food and Drug Administration (FDA) and related state food regulatory agencies. (Reference to FDA or FDA inspectors in this manual is intended to include state and local counterparts, unless otherwise noted.)

The objectives of this manual are to provide:

- **Information** regarding the company’s and the food inspector’s rights and duties during a food inspection
- **Guidance** for handling food inspections at your facility or farm
- **A training reference tool** for employees responsible for handling food inspections

The goals of a food inspector are to determine compliance with regulatory requirements and/or the cause(s) of a possible violation. It is important for the company to respond to the inspector in a manner consistent with the law and the company’s policies, but the company should also protect confidential information to the extent permitted by law, and minimize disruptions to the business. Therefore, although this manual outlines the company’s and the inspector’s general rights and duties, difficult issues may arise and employees on site may be unable to make an informed decision on the basis of company policies and summaries of law alone. There should also be flexibility to assess potential options with respect to courses of action, typically after consultation with senior management and legal counsel.
If you operate a farm or secondary activities farm which grows, harvests, packs or holds produce for human consumption or a facility which manufactures, processes, packs or stores food products, an FDA inspection is inevitable. The frequency of inspection will depend primarily on the size of your business and the types of products involved. Large manufacturing, processing and warehouse facilities may be subject to annual inspections. If you operate a farm, the likelihood of inspection is lower, as farm inspections are not currently a high enforcement priority for FDA and generally are based on risk. Additionally, details and procedures regarding routine on-farm inspections by FDA and by state regulatory agencies under cooperative agreement or contract are still being developed. It is unclear at this point in time if FDA and state regulators will be using similar or different procedures and practices from those used during a food facility inspection when conducting routine on-farm inspections. In any case, every company should take steps to achieve successful FDA inspections. The risks of failing to do so are potentially severe: recalls, adverse publicity and potential loss of business, a shutdown of the facility, product liability lawsuits if products are linked to illnesses, reinspection fees, criminal fines, and possibly imprisonment.
An FDA inspection need not be a stressful experience. It should be viewed as a food safety audit performed by a government agency which places great emphasis on government-industry cooperation and voluntary correction of deficiencies, and FDA will resort to judicial remedies only in unusual situations. That said, it must be remembered that the inspector is searching for evidence of violations and other information regarding the actions and culture of corporate management which might form the basis for an enforcement action.

The approach followed by an FDA inspector will depend, to a great extent, on the inspector’s perception of the facility or farm and its operations. He or she will already have formed initial impressions based on a review of prior inspection reports, and perhaps additional information, such as recalls. Management should take all reasonable steps to ensure not only that the facility or farm is in compliance with the law, but also that the inspector can easily verify compliance.

The key to a successful inspection is preparation, which is particularly important in light of the fact that the inspector may arrive without prior notice. To be adequately prepared, the company should designate a company representative, and establish an Inspection Team comprised of selected employees from relevant departments, who will be responsible for supervising other employees and assisting the designated company representative in connection with FDA inspections. These employees should be prepared for their roles through a formal training program, based on a Company Inspection Manual that includes policies and procedures established by the company for handling FDA inspections.

The most useful and effective manual is practical and readily understandable. Employees’ understanding of company policies and individual responsibilities can be checked through mock inspections, and any concerns raised during that process can be addressed through further training or clarification of policies.

The purpose of this chapter is to explain the legal framework governing FDA inspections and to discuss the issues which should be considered in developing a Company Inspection Manual.
Food laws

The Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. §§ 302-399f, administered by FDA, is the primary food law of the United States. Among other violations, the FD&C Act prohibits the production and distribution of food that is adulterated or misbranded. In addition, most states have enacted food laws modeled on the FD&C Act. The FD&C Act also authorizes FDA to commission State agencies to carry out federal investigation functions. Moreover, State and local officials are responsible for enforcing their own food safety laws. And as a complement to FDA, State and local inspections, FDA plans to rely in part on farm audits by USDA and reliable, nongovernmental parties, with the goal of annual verification of farms subject to FDA regulations.

Food may be adulterated for a number of reasons. A food is adulterated if, among other reasons, it contains a poisonous, deleterious, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Food can also be considered adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health. If there is a finding of insanitary conditions, all products grown, processed, or stored during the time the insanitary conditions existed are deemed to be adulterated, and it is not necessary for FDA to show actual contamination.

The term “misbranded” includes products with false or misleading labeling, or with labeling which omits required or other material information. Undeclared major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) generally result in a food being both misbranded and adulterated.

With respect to violations, the FD&C Act authorizes enforcement actions including the following:

- Injunctive relief to prevent future violations
- Seizure of products shown to be violative
- Administrative detention while FDA investigates the need for seizure
- Suspension of FDA food facility registration
- Mandatory recall
- Criminal prosecution of a company and/or employees responsible for a serious violation

FDA frequently requests that companies voluntarily recall violative products, an action which is not formally authorized in the FD&C Act, but is a very effective option. FDA also issues warning letters seeking to have companies correct apparent apparent violations.
Inspection authority

FDA's main food inspection authority is set forth in Section 704 of the FD&C Act, and its authority to inspect records is found in Section 414. During a food inspection, FDA is authorized, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, to:

- Enter, at reasonable times, any factory, warehouse or establishment in which food is manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, in interstate commerce.

- Inspect, at reasonable times, within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling.

But although the FD&C Act defines FDA's inspection authority solely in reference to interstate commerce, FDA takes the position that it also has the authority to regulate a product that is never introduced or delivered into interstate commerce, as long as the product is intended for sale in the U.S. and has a “collective impact” on interstate commerce (unless a specific exemption applies, such as for very small businesses). Under this interpretation of its jurisdiction, FDA asserts the authority to inspect facilities, including farms, even if there is no direct connection to interstate commerce.

Prior notice to a company of an inspection is not required. A reasonable time for an inspection is certainly normal business hours, but it would be difficult to deny a food inspector access during any operating hours. As a practical matter, however, unless there is an emergency situation, food inspectors usually plan to inspect during normal business hours.

The inspector may inspect areas where finished products and ingredients are stored, processed, or packaged, as well as storage areas used for packaging and labeling. This authority does not extend beyond those areas of the plant, and access to offices and other areas not related to food processing or storage can be restricted unless required records are stored there and are inaccessible to FDA by other means within the required time frame for producing records.

There are two types of FDA inspections: (1) comprehensive; and (2) directed. A comprehensive inspection covers everything in the facility or on the farm subject to FDA jurisdiction. This type of inspection is undertaken in accordance with an overall administrative plan for food establishments within the jurisdiction of the responsible FDA District Office.

A directed inspection covers specific areas or issues. Examples are “for cause” inspections (in response to test results, a recall, an illness outbreak, a Reportable Food Registry filing, consumer complaints, an adverse event report, or other information indicating a potentially significant food safety problem which may call for immediate action), a reinspection based on previous findings of violations, a recall effectiveness check, or a criminal investigation.

FDA also offers guidance on nutrition labeling (NLEA) standards at: http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm.


FALCPA provides FDA with inspection authority to ensure that companies are complying with requirements to reduce or eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food, and to confirm that major food allergens that are intentional ingredients of the food are appropriately labeled.

FDA may take samples of products, raw materials, work in progress and labels. When samples are taken by FDA during an inspection, the company should take a duplicate sample. In recent years, FDA has focused to a great extent on environmental monitoring, to determine whether pathogens have become established in a facility or whether any positives are likely due to transient contamination from ingredients, employees, or equipment, which would probably be eradicated at the next cleaning and sanitation. FDA has noted that many major food illness outbreaks seem to be linked to facilities at which pathogens had become established, and therefore an important food safety goal for FDA is to identify facilities that harbor pathogens so that aggressive efforts can be pursued to destroy the environmental contamination. FDA may take hundreds of swabs during an inspection.

It is generally inadvisable to run tests of the company's samples, unless FDA gets positives and there is reason to believe that those results may be inaccurate. Decisions about whether and when a company should test samples taken during an inspection depend on the facts, and require careful consideration.

Under the Food Safety Modernization Act of 2011 (FSMA), which amended the FD&C Act, FDA is authorized to charge hourly fees for a reinspection at a facility that is due to violations materially related to food safety that were observed at the previous inspection. The fees approved for 2017, for example, are $221 per hour, per inspector for domestic facilities and $285 per hour, per inspector if foreign travel is required. Reinspection activities are broadly defined to include the reinspection at a facility, preparing for the reinspection (including communications with the company), traveling to and from the facility, analyzing samples, preparing reports, and conducting other activities until the facility is in compliance.
Recordkeeping requirements and records access

FSMA represents a sea change in the regulation of food, and shifts the focus for food safety from detection by regulators to prevention or correction by industry. FSMA regulations require industry to develop appropriate food safety programs based on risk assessments and verifications, and to maintain records demonstrating that the programs are being followed and are effective.

Prior to FSMA, FDA had very limited records access authority during a routine inspection, including interstate shipment records to establish FDA’s jurisdiction. As discussed above, however, FDA has asserted, long before FSMA, that it also has jurisdiction even if there is no evidence of interstate commerce. A company may, however, condition interstate records access on receipt of a written request from the inspector specifying the nature or type of food to which the request applies.

The reason to ask for a written request is that no information obtained by FDA pursuant to a written request, including any evidence which is directly or indirectly derived from the shipping records disclosed, may be used in a criminal prosecution of the company (or employees) which made the records available to FDA. This defense is not available, however, unless FDA’s request for shipping records is in writing. FDA does not have authority, as stated in the FD&C Act, to access recipes for food, financial data, pricing data, research data, or sales data.

Now, however, FDA may review and obtain copies of various records that food companies are required to maintain, even for routine inspections, if the appropriate criteria for access are met. The specific recordkeeping and records access requirements will depend on the FSMA regulations applicable to a company’s operations, such as the Produce Safety Rule, Hazard Analysis and Risk-Based Preventive Controls (HARPC), Current Good Manufacturing Practices (CGMPs), Foreign Supplier Verification Program (FSVP), Sanitary Transportation, and Intentional Adulteration.

The key routine records required to be maintained under FSMA, and the traceability records that must be provided under Bioterrorism Act and FSMA provisions in the event that FDA has serious food safety concerns about products or conditions, are summarized below. Regarding routine FSMA records, an assessment should be made for each operation as to the applicability of specific regulations.
a. Preventive Controls for Human Foods Rule (PCHFR)

- Hazard Analysis and Risk-Based Preventive Controls (HARPC)

FDA-registered food facilities are required to develop a written food safety plan under HARPC, unless an exemption applies. The plan must include the identification and analysis of known or reasonably foreseeable hazards that could affect food manufactured, processed, packed, or held at the facility (including hazards that occur naturally or may be unintentionally introduced, as well as intentionally introduced hazards). The plan must also include records that document: the monitoring of any preventive controls; corrective actions; validation (of monitoring, corrective actions, calibration of process monitoring and verification instruments, product testing, environmental monitoring, records review, and reanalysis), as well as records that document the supply-chain program and applicable training for the preventive controls qualified individual and the qualified auditor. HARPC facilities also must establish a written recall plan for any food with a hazard requiring a preventive control.

Required records must be retained at the facility for at least two years after the date they were prepared. Records that a facility relies on during the three-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption must be retained as long as necessary to support the facility’s status during the applicable calendar year. Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least two years after their use is discontinued.

- Current Good Manufacturing Practices (CGMPs)

Under FSMA, previously voluntary Current Good Manufacturing Processes (CGMPs), at 21 CFR Part 110, were revised and are now mandatory requirements, at Part 117. Farms must comply with Part 117 CGMPs or similar requirements in Part 112 under the Produce Safety Rule, depending on the type of operation. The CGMP regulations address personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels.

All facilities that manufacture, process, pack, or hold food for consumption in the United States are subject to the CGMP requirements unless an exemption applies. Thus, even if a facility is exempt from HARPC, it may still need to comply with CGMPs. Although there is no explicit regulatory requirement that policies and activities demonstrating compliance with mandatory CGMPs be documented in writing, FDA would have no way of determining compliance without reviewing records.
Training is required under Part 117 to ensure that all individuals who manufacture, process, pack, or hold food subject to CGMPs are qualified to perform their duties. Each individual must be a qualified individual, with education, training, or experience (or a combination) necessary to produce clean and safe food as appropriate to the duties, and must receive training in principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's duties. Responsibility for ensuring compliance must be assigned to supervisory personnel who are qualified to oversee this training. Records that document the required training, such as the date of training, a description of the training, and the name of the person trained, must be maintained for at least two years.

Details of the Preventive Controls for Human Foods Rule, including subparts pertaining to Hazard Analysis and Risk Based Preventive Controls and Current Good Manufacturing Practices, may be found in Title 21 Code of Federal Regulations (CFR) part 117. The most up-to-date version of 21 CFR part 117 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

b. Produce Safety Rule (PSR)

There are recordkeeping requirements associated with a number of different activities under the Produce Safety Rule, including regulations regarding: agricultural water, biological soil amendments of animal origin (BSAAO), sprouts, personnel training (such as date of training, topics covered, and persons trained); and equipment (such as date and method of cleaning and sanitizing equipment used in harvesting, packing, or holding activities).

Generally, records must be kept at least two years past the date the record was created. Records that a farm relies on during the three-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption (based on average monetary value of all food sold and direct farm marketing), must be retained as long as necessary to support the farm's status during the applicable calendar year. Records related to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least two years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

Details of the Produce Safety Rule may be found in Title 21 Code of Federal Regulations (CFR) part 112. The most up-to-date version of 21 CFR part 112 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.
c. Foreign Supplier Verification Program (FSVP)

Importers, as defined under FSMA, must establish and follow written procedures to verify that they only import food from approved suppliers, that the food was produced in a manner that provides the same level of public health protection as HARPC or the Produce Safety Rule, as appropriate, and that the imported food is not adulterated and not misbranded (with respect to allergen labeling). FDA did not mandate specific activities that must be conducted to verify the safety of imported food, but FDA’s examples include: (1) onsite audits of foreign suppliers; (2) sampling and testing of food; and (3) review of the foreign supplier’s relevant food safety records.

Records of all foreign supplier verification activities must be documented and maintained by the importer, including records regarding the hazard analysis, supplier evaluation and approval program, supplier verification activities, and any corrective actions taken to address any identified food safety problems. Any records relevant to an FSVP must be made available promptly to FDA upon request, and must be maintained for at least two years after their creation date, or for at least two years after their use is discontinued, whichever is longer. Offsite storage of records is permissible, provided that such records can be retrieved within 24 hours. Records can be maintained in an electronic format, and are considered to be located at a foreign facility if they can be accessed from that facility.

Details of the Foreign Supplier Verification Program rule may be found in Title 21 Code of Federal Regulations (CFR) part 1 subpart L. The most up-to-date version of 21 CFR part 1 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

d. Sanitary Transportation Rule

The extent of recordkeeping requirements under this rule depends on whether a company is acting as a shipper, loader, carrier, and/or receiver. The primary recordkeeping requirements apply to shippers and carriers. The rules generally require a shipper to provide a written document specifying the requirements that carriers (and loaders, where necessary) must meet in order to ensure that food is maintained under sanitary conditions, such as design requirements, cleaning procedures, and temperature requirements (including pre-cooling), as applicable. Measures to implement food safety procedures may be accomplished by the shipper, the carrier, or another party covered by the rule, pursuant to a written agreement, as appropriate.

With respect to carriers, there are mandatory recordkeeping requirements for training personnel to provide an awareness of potential food safety problems that may occur during transportation. Records under this rule must be maintained for a period of 12 months beyond the last effective date of those records.

Details of the Sanitary Transport of the Human and Animal Foods rule may be found in Title 21 Code of Federal Regulations (CFR) part 1 subpart O. The most up-to-date version of 21 CFR part 1 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.
e. Intentional Adulteration

Facilities subject to HARPC are required to prepare and implement a written food defense plan to mitigate the risk of intentional adulteration. **Upon completion of a vulnerability assessment companies must develop a written plan that identifies vulnerabilities and actionable process steps (if any), mitigation strategies, and procedures for food defense monitoring, corrective actions and verification.** A reanalysis is required every three years or when certain criteria are met, including mitigation strategies that are determined to be improperly implemented. Facilities are required to maintain documentation of personnel training for those assigned to vulnerable areas, and facilities must maintain records for food defense monitoring, corrective actions, and verification activities. The food defense plan must be stored onsite at the facility. Records must be retained for at least two years after the date of preparation.

Details of the Intentional Adulteration rule formally known as the Mitigation Strategies to Protect Food Against Intentional Adulteration rule may be found in Title 21 Code of Federal Regulations (CFR) part 121. The most up-to-date version of 21 CFR part 121 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

f. Traceability Records

The Bioterrorism Act of 2002, which amended the FD&C Act, applies to companies that manufacture, process, pack, transport, distribute, receive, hold or import food in the United States, and requires covered companies to establish and maintain records to facilitate traceability, through the identification of the immediate previous sources and immediate subsequent recipients of food, in order to address credible threats of serious adverse health consequences or death to humans or animals (“SAHCODHA” risk). Retail food establishments that distribute food to consumers are exempt from establishing and maintaining records as to the immediate subsequent recipients (consumers). Retail food establishments that distribute food to non-consumers must only maintain immediate subsequent recipient information if such information is reasonably available. Exemptions include farms, restaurants, persons that manufacture, process, transport, pack, distribute, receive, hold or import food that is regulated exclusively by USDA, and foreign persons (except those who transport food).

FDA can seek these traceability records if it has a reasonable belief that an article of food is adulterated and presents a SAHCODHA risk. Under FSMA, FDA may also access such records if FDA believes there is a reasonable probability that a food could cause serious harm (SAHCODHA risk). FDA can inspect all records relevant to determining whether the suspect food presents a serious food safety risk, including records for “related” products, if FDA reasonably believes that the other products are likely to be affected in a similar manner, such as having been produced on the same line without a sanitation between runs.

Under Section 204 of FSMA, FDA is authorized to request records from farms, during an active foodborne illness outbreak investigation or if necessary to protect the public health and prevent or mitigate a foodborne illness outbreak, to identify potential immediate recipients, other than consumers, of food if FDA reasonably believes such food is adulterated, and presents a SAHCODHA risk.
One cannot overemphasize the importance of advance preparation for inspections.

With proper planning, the company’s representatives will be in a position to respond to the inspector in an informed manner, demonstrate the company’s dedication to providing safe, quality food products, and protect the company’s rights to maintain the secrecy of its confidential information and to be free from excessive government interference.
Establish an inspection team

A food inspector will often arrive without prior notice. To ensure that a company is prepared and properly represented during all food inspections, a company should establish receiving procedures and a Company Inspection Team as part of its system for conducting inspections.

At least two employees should be available for any inspection, with one to take notes and the other designated as the Company Contact. The Company Inspection Team should include alternates in the event that any members are unavailable at the time of an inspection.

The Company Inspection Team, headed by the Company Contact, is responsible for:

- Greeting the inspector
- Participating in the opening (pre-inspection) conference
- Accompanying the food inspector throughout the inspection
- Participating in the closing (post-inspection) conference
- Supervising and providing the necessary communications, support personnel, and inspection follow-up

Choose an appropriate support group (e.g., plant manager, quality assurance director, etc.), as a subset of the Company Inspection Team, to be notified that an inspection is taking place so that they can take appropriate action before and during the inspection.

Ideally, members of the Company Inspection Team (or their alternates) should be present at the plant during all normal operating hours or available on an “on-call” basis within a short travel time from the facility. If this may not be practical, it would be sufficient to ensure that there is an employee at the plant, at all times, who is properly instructed on how to manage the situation until the Company Inspection Team arrives and is prepared to oversee the inspection.
WORKSHEET: ESTABLISH YOUR TEAMS

Record names and phone numbers on this page.

Company Inspection Team

- Company Contact: ____________________________
  Alternate: ________________________________

- Note Taker: _________________________________
  Alternate: ________________________________

Support Team

- Plant Manager: ________________________________

- Quality Assurance Director: _______________________
  ______________________ : __________________________
  ______________________ : __________________________
Responding to requests for records

A significant aspect of inspections under FSMA will be an audit of records to ensure that the facility or farm is meeting mandatory food safety requirements. Unless policies and activities are written, FDA will not have sufficient evidence of compliance. It is important that records be well organized, readily accessible (within 24 hours of a request), and comprehensive.

In addition to providing, upon request by FDA, records that must be maintained and made available to FDA, the Company Inspection Team and Company Contact are responsible for protecting the company’s rights, including trade secrets and other confidential information. For example, the inspection may include areas of a facility or farm in which trade secrets are maintained. Employees responsible for handling a food inspection should know, in advance of an inspection, what trade secrets exist within the facility or farm, where they are located, and whether redacted copies of trade secret documents have been prepared.

Importantly, FDA and state agencies may instruct inspectors to request information to which the agencies are not legally entitled. The inspector may pressure an employee to comply with a request by noting that cooperation can show that the company has “nothing to hide.” An FDA inspector may even indicate that non-compliance with a particular request may be considered a “refusal to permit inspection.” Accordingly, employees involved in an inspection must be in a position to handle such requests in a diplomatic manner consistent with company policy, and importantly, with a sound understanding of the inspector’s authority and the company’s rights.

Records must: be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records; contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities; be accurate, indelible, and legible; be created concurrently with performance of the activity documented; be as detailed as necessary to provide history of work performed; and include information adequate to identify the plant or facility, the date (and, when appropriate, the time) of the activity documented, the signature or initials of the person performing the activity, and the identity of the product and the lot code (if any and if appropriate).
### WORKSHEET: DISCLOSURE OF DOCUMENTS

**Receipt of Food Products Shipped in Interstate Commerce.**

<table>
<thead>
<tr>
<th>What kinds of receipts are kept?</th>
<th>Where are they?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Records Relevant to Bioterrorism Act.**

<table>
<thead>
<tr>
<th>What relevant records do you have (e.g., processing, storage, distribution)?</th>
<th>Where are they?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Records Required under FSMA.**

<table>
<thead>
<tr>
<th>What relevant records do you have to demonstrate FSMA compliance?</th>
<th>Where are they?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Records Subject to Disclosure in Your State.**

<table>
<thead>
<tr>
<th>What records must be disclosed to a state inspector but not to the FDA?</th>
<th>Where are they?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Records Not Subject to Disclosure.**

<table>
<thead>
<tr>
<th>What specific records should NOT be disclosed (including trade secrets)?</th>
<th>Where are they?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Put policies in writing

We recommend preparing a Company Inspection Manual that compiles all of the inspection policies so that the Company Inspection Team can show the policies during an inspection, if necessary. For example, if the inspector requests confidential information which the Company is not required to disclose, the Company Contact can show the written policy to the inspector and state:

“The information you seek is confidential. Company policy, based upon the advice of legal counsel, prohibits me from disclosing that information. If you wish to pursue the matter, however, you may submit a written request to me, the Company Contact, explaining why you believe you need the information, and I will forward it to the appropriate personnel for their consideration.”
The following sample policies are provided for your consideration. Appropriate company personnel and your legal counsel should help you determine your exact policies.

1. The inspector must be escorted at all times.

Sample policy:

The Company Contact and other appropriate members of the Company Inspection Team must accompany the inspector throughout the entire inspection period. This will ensure that the inspector does not accidentally place himself or herself in an unsafe situation or contaminate food products, examine confidential data, cause a significant interruption of operations, or engage in unauthorized conversations with other employees. If two inspectors are involved and decide to work independently, an Alternate Company Contact and Inspection Team will escort the second inspector.

Your company’s policy:  


2. Only designated personnel may respond to questions and requests.

*Sample policy:*

The inspector will be instructed that all questions should be addressed to the Company Contact or other designated company representatives. The inspector is not permitted to conduct private employee interviews on company property. Employees are reminded that they are not permitted to respond to the inspector’s questions without express authorization from the Company Contact, as to specific questions.

*Your company’s policy:*  

3. Confidential treatment for incidental exposure to trade secrets.

*Sample policy:*

Confidential treatment for all confidential information obtained from areas of the plant that contain trade secrets should be orally requested and confirmed in writing to the Investigator before the close of the inspection.

*Your company’s policy:*  

4. Disclosure of information, documents, and other records.

*Sample policy:*

Except when authorized by company policy or a supervisor, Company Inspection Team members will not permit the inspector to have access to or to obtain any confidential information. The following information is considered confidential (other than required training records):

- Corporate, unit, or department budgets or spending authority
- Corporate organizational structure
- Names or titles of any unit or corporate officers
- Names or titles of plant management

**Your company’s policy:**

---

---

---

5. Affidavits and similar documents.

*Sample policy:*

The inspector has no legal right to require the execution of an affidavit or any other document. Therefore, all employees should refuse to prepare or sign any document requested by the inspector.

**Your company’s policy:**

---

---

---
6. Sound recording equipment.

Sample policy:

The inspector is not authorized and, therefore, not permitted to take a tape recorder or other sound recording equipment beyond the reception area.

Your company’s policy: ________________________________________________________________

7. Photographic equipment.

Sample policy:

The inspector is not entitled and, therefore, not permitted, to take photographic equipment beyond the reception area. This includes cell phones with photographic capability.

Your company’s policy: ________________________________________________________________

8. Inspector’s compliance with the company’s health and safety rules.

Sample policy:

The inspector is expected to comply with all of the company’s safety and health rules at the facility or farm being inspected and he or she must wear and use appropriate protective clothing and equipment.

Your company’s policy: ________________________________________________________________

Sample policy:

Upon providing a written receipt (Form FDA-484 shown in Appendix D), and compensation, if requested, the inspector may take samples of raw materials, goods in process, finished goods, packaging, labeling, and swabs of environmental areas. If sampling is performed, these procedures are to be followed:

- The Company Contact will arrange for an employee familiar with sampling techniques to accompany the Contact and the inspector to examine the inspector’s techniques and to perform sampling on behalf of the company.

- The employee will determine and note the sampling procedure and technical instruments or equipment the inspector is using.

- The employee will ask the inspector if these procedures and equipment are formally approved by the agency and note his or her response.

- The employee will ask the inspector when and by what procedures the equipment was last calibrated and note his or her response.

- The employee will note the number of samples taken, when they were taken, and the operations and locations sampled.

- The employee will ask the inspector to take two of each sample. The second sample will be retained by the Company Contact.

- The employee will use company test equipment to take samples, in addition to the two taken by the inspector, duplicating the procedure used by the inspector and, where appropriate, using an alternative procedure which would provide similar data.

- The Company Contact will cause all samples to be labeled in a manner that will permit identification and will ensure that they do not become lost or contaminated.

- The Company will decide whether to analyze samples, and whether to retain samples, on a case-by-case basis.
Your company’s policy:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Establish your protocols

During the inspection, a company should, within reason, be able to duplicate every testing procedure or sampling procedure performed by the inspector. Therefore, the appropriate sampling equipment should be on hand and in good working order with all necessary supplies. For environmental sampling, FDA may take hundreds of swabs, and therefore, companies should have enough swabs on hand to take their own samples.

The Company Inspection Team should be aware of the status of any previous food inspections.

All reports from prior inspections will be on file with the inspecting agency and the inspector may ask to see any areas noted in the report as needing correction.

A reinspection should be handled by company personnel according to the same procedures used during the initial inspection. The Company Contact should be familiar with the company’s report on the initial inspection and know about the conditions noted as possible violations and how they have been handled or corrected.

Source: FDA
CHECKLIST: ESTABLISH YOUR PROTOCOLS

Consider –

- What are the likely tests the inspector may perform?
- What are the likely procedures he or she will use?
- What inspection reports will he or she read before the next inspection?

Do you have available –

- Appropriate sampling equipment?
- Appropriate sampling supplies?
- Previous food inspection reports?

Are your appropriate personnel trained on –

- How to use sampling equipment and supplies?
- What was noted as needing correction in prior inspection reports?
Conduct drills

Long before an inspection ever happens the Company should run drills. All roles should be clear. Teams need to be established, policies need to be in place, and safety programs need to be functioning.

“Every employee needs to buy in to the program.”
CHECKLIST: CONDUCT DRILLS

When an inspector calls –

- Who should take the call?
- Who else should be immediately notified?
- What other actions need to get under way immediately?

When an inspector arrives at the facility or farm –

- What should the receptionist do and not do?
- Who else should be immediately notified?
- What other actions need to get under way immediately?

If an inspector asks to see records –

- Who should take the request?
- How should the request be accepted?
- Which records are permissible to disclose?
- Which records should not be disclosed?
- When should a supervisor be notified?
If an inspector asks to take samples –

- Who should take the request?
- How should the request be accepted?
- Who else should accompany the inspector and witness the sampling?
- Who from the company should also take samples?
- When should a supervisor be notified?

If an inspector sees documents or a part of the plant not required to be disclosed –

- What assurances should be gotten from the inspector? By whom?
- When should a supervisor be notified?

What could or should be done in these scenarios?

- The designated Company Contact and alternate are both unavailable the day of the inspection.
- The inspector arrives after normal working hours.
- The inspector refuses to wear safety gear required for admittance to the plant.
- The inspector asks about items noted for improvement in previous inspection reports.
- The inspector puts pressure on an employee to reveal information not required for disclosure.
- An emergency occurs during the inspection:
  - Electrical blackout
  - Fire or security alarm
  - Earthquake or severe weather
  - Medical emergency for a team member or the inspector
The inspection team does not have key access to rooms where required records are kept.

The inspector overhears employees talking about a recent safety violation.

Evaluate how the drill went –

- Did everybody fulfill their roles according to team assignments?
- Were backup team members notified appropriately?
- Was management kept apprised of the inspection?
- Were appropriate notes taken throughout the inspection, from Opening Conference to Closing?
- Did the correct people respond to the inspector’s questions and requests?
- Did they respond appropriately?
- Was sampling conducted in accordance with company policy?
- Were documents disclosed in accordance with company policy?
- Were all other inspection-related policies followed?
- Did everybody involved with the inspection answer accurately?
- Did anybody reveal too much information?
Two important principles in handling a food inspection are:

- Make sure you are adequately prepared.
- Do not take any actions which would elevate a relatively minor violation into a serious matter.

The previous material has dealt with the first point. Preparation, as in anything else, is important. Food inspections are serious, and the issuance of a formal notice of alleged violations is serious. It is very important, however, not to let your desire to have a successful food inspection without any important violations lead you to do something, such as lying to an inspector or falsifying or destroying records, which could cause a very serious problem.
The arrival of the inspector

a. Responsibilities of the employee who greets the inspector

The receptionist or other person who typically greets visitors must know precisely what to do when the inspector arrives.

- Be sure that the inspector is escorted at all times.

- Know which employee has been designated as the Company Contact and which employees have been designated as the Alternate Company Contacts.

- During normal office hours, notify the Company Contact/Alternate Company Contact that the inspector has arrived.

- Other than normal office hours, make every effort to have him or her return during normal office hours. If the inspector insists on performing the inspection, advise him that he will have to wait for the Company Contact and then notify the Company Contact. If the inspector continues to insist on inspecting and the plant is operating, consult with company management and counsel.
b. Responsibilities of the Company Contact

- Examine and copy the inspector’s credentials; diplomatically confirm that he or she is, in fact, a food inspector.

- Ensure that the Support Team is notified that a food inspector has arrived and is informed of subsequent developments.

- Ensure that all working areas are prepared for an inspection and that all appropriate employees make themselves available for consultation with the Company Contact.

- Delay the inspection for a reasonable time if you feel it would be appropriate in order to provide sufficient time for preparation by the Company Inspection Team.
The opening conference

The formal part of the inspection begins with an opening conference, at which the inspector informs the company about the purpose and scope of the inspection and what it will involve. This can set the tone for the whole inspection and is a very important part of the inspection process.

From a company’s viewpoint, the main purpose of the opening conference is to learn, as much as possible, why the inspector is there and what the inspector plans to do. The FDA Investigations Operations Manual directs the inspector to outline in general terms the nature and scope of the inspection, including the physical inspection of the plant, records review, any complaints received, and any other relevant information. If the Company Contact does not believe the inspector has been sufficiently informative, he or she should not hesitate to ask for additional details.

The Company Contact should handle all conversations with the inspector.

FDA inspectors are required to present the Company Contact with a formal Notice of Inspection (Form FDA 482, shown in Appendix A or Form FDA 482c, shown in Appendix B) before they are authorized to continue the inspection. This is a printed form with spaces to be filled in, showing the date, the name and title of the responsible member of the firm to whom the notice is being issued, the firm name, and location of the plant. The Notice of Inspection also quotes the language from the FD&C Act which grants FDA its inspection authority. It should be signed by the inspector and should bear the name and address of the District Office from which he or she operates. This notice should be kept on file for later reference. Some state or local officials may not present this notice; in such cases, the Company Contact should write down all pertinent information provided regarding his or her inspection authority.

If an inspector arrives with a warrant, you are entitled to delay the inspection for a reasonable period of time necessary for you to read, analyze, and understand the warrant and consult legal counsel. You can allow the inspection, while at the same time preserving your rights to object to the validity of the warrant and the inspector’s authority to conduct the inspection, by presenting the inspector with a written notice of protest. The written protest should state that the inspector will be permitted to conduct the inspection under protest in light of the fact that he or she has presented the facility or farm with a warrant, which appears proper on its face and because refusal to honor the warrant may result in contempt proceedings against the company. By allowing the inspector to conduct the inspection under protest, the company avoids contempt proceedings and preserves its rights to object to the validity of the warrant and the inspection.

Inspectors will generally comply with established company procedures. Accordingly, during, or at the end of, the opening conference, the company representative should advise the inspector of these procedures and politely request his or her cooperation.
### WORKSHEET: OPENING CONFERENCE

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of inspection:</td>
<td></td>
</tr>
<tr>
<td>Time of opening conference:</td>
<td></td>
</tr>
<tr>
<td>Name of recorder:</td>
<td></td>
</tr>
<tr>
<td>Name of Company Contact:</td>
<td></td>
</tr>
<tr>
<td>Name of inspector:</td>
<td></td>
</tr>
<tr>
<td>Names of anyone else present:</td>
<td></td>
</tr>
<tr>
<td>What records has the inspector asked to review?</td>
<td></td>
</tr>
<tr>
<td>What physical parts of the plant has the inspector asked to inspect?</td>
<td></td>
</tr>
<tr>
<td>What, if any, complaints has the inspector asked about?</td>
<td></td>
</tr>
<tr>
<td>What, if any, other information has the inspector obtained that raises potential food safety concerns?</td>
<td></td>
</tr>
</tbody>
</table>
On what points, if any, did the Company Contact ask for further clarification?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Notice of Inspection (Form FDA 482 shown in Appendix A) or Request for Records (Form FDA 482c shown in Appendix B):

☐ Was it presented to the Company Inspection Team?

☐ Are all spaces filled in, including the date, name/title of person at the company to whom the notice is issued, the company name, and the plant location?

☐ Is it signed by the inspector?

☐ Does it bear the name and address of the inspector’s District Office?

If a state or local official does not present a Form FDA 482 or Form FDA 482c, record the pertinent information regarding his or her inspection authority:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Inspection procedures and assertion of your legal rights

As stated earlier, the Company Inspection Team and Company Contact are responsible for protecting a company’s right to maintain the secrecy of its trade secrets and other confidential information, and possibly other rights. To review, the policies you should have established regarding inspection procedures cover:

- Escorting the inspector at all times
- Who responds to questions and requests
- Disclosure of information, documents, and other records
- Affidavits and similar documents
- Sound recording equipment
- Photographic equipment
- Inspector’s compliance with the company’s Health and Safety Rules
- Sampling

a. Interacting with the inspector during the inspection

When accompanying the inspector, the Company Inspection Team should be courteous and respectful, while at the same time firmly standing up for the company’s rights and viewpoints. The Inspection Do’s and Don’ts in the Manual are useful as checklists.

b. Take detailed notes of the inspection

Accompanying an inspector can be a significant undertaking. For this reason, it is generally recommended that two employees accompany each inspector: one to answer questions, etc., and the other to carefully note all activities. The member of the Inspection Team who is not the Company Contact should carefully observe and note all activities of the inspector – including discussions, areas visited, sampling, records inspection, etc. Any notes taken by employees may later be used in legal proceedings. Therefore, it is important that the notes do not contain any statements which you would not want to be seen by people outside the company.
c. Immediate “correction” of alleged violations noted by the inspector

During the inspection, the inspector may point out conditions which he or she considers to be in violation of the FD&C Act or other applicable law. In appropriate situations, the Company Contact could direct employees to “correct” (modify) or begin modification of those conditions. Factors to be considered in making this determination are:

- The potential hazard presented by the condition.
- The likelihood that the condition noted does constitute a violation of the law.
- Whether the modification can be accomplished without undue interference with normal operations.

Source: FDA
WORKSHEET: DURING THE INSPECTION

Date of inspection: ______________________  Time of inspection: ______________________

Name of recorder: _____________________________________________________________________

Name of Company Contact: _____________________________________________________________________

Name of inspector: _____________________________________________________________________

Names of anyone else present: _____________________________________________________________________

What areas of the plant did the inspector inspect? __________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

What records did the inspector review? __________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

What samples did the inspector take (be sure to get a Form FDA 484 for each type of sample)?

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________
What else was discussed during the inspection?

What, if any, modifications were made immediately in response to the inspector’s comments?
Closing conference

After completing the walk-around phase of the inspection, the inspector will conduct a closing conference with the Company Contact. At least one other company employee designated by the Company Contact should attend the conference and take detailed notes of the discussion. The inspector will review:

- The conditions and practices which he or she believes could be improved.
- Conditions and practices which he or she deems to be citable violations.
- Applicable sections of the regulations which he or she feels have been violated.
- Consumer complaints received by the agency, to obtain an explanation for the condition cited in the complaint and to determine what, if any, corrective action has been taken by the company.

Any similar consumer complaints received by the company may also be referenced during the Opening Conference. If asked about consumer complaints, carefully discuss the condition complained of using the following approach:

- If the company has not received a similar complaint, so advise the inspector.
- Point out all reasonable explanations for the condition which might involve an event for which the company would not be responsible (for example, improper storage by retailer).

a. Formal notice of possible violations

Prior to leaving the premises, an FDA inspector may furnish the Company Contact with a Form FDA 483 (shown in Appendix C), listing objectionable conditions or practices observed. State and local food inspectors may leave a checklist-type form listing such conditions.

The Company Contact should review the Form FDA 483 or state form and clarify any differences of opinion during the closing conference, in a respectful manner, but advocating the company’s position.
b. Abatement of conditions noted as possible violations

If any conditions noted in the Form FDA 483 have been modified in the presence of the inspector or before he or she leaves, ask the inspector to include that fact on an “annotated 483” or in the inspection report. If it was not possible to modify these conditions before the inspector left, they should be modified as quickly as possible.

The Form FDA 483 is not a final agency action. The Company Inspection Team should draft a written response to the Form FDA 483, have it reviewed by Management, and send it to FDA within 15 business days. If received on time, FDA will review the response before deciding whether to issue a Warning Letter. Depending on the state where the facility or farm is located, written responses may also be accepted after state inspections if there were observations of possible violations.

c. FDA reports

In addition to the Form FDA 483, an FDA inspector will subsequently prepare, for internal FDA use, an Establishment Inspection Report (EIR). This is usually a detailed report of all aspects of the inspection, the answers to questions, a summary of all observations – favorable as well as unfavorable – test results and a recital of company responses to the inspector’s adverse observations.

Following an inspection, FDA will provide a copy of the EIR to the inspected Company, assuming FDA is not planning to take follow-up regulatory action. At the closing inspection, the Company Contact should confirm with the inspector that a copy of the EIR will be provided to the Company without the need to make a Freedom of Information Act request.

d. Internal company reports

The Company Contact, with the assistance of the other members of the Company Inspection Team, should prepare a complete report on the inspection shortly after the inspection. Copies of this report should be marked “CONFIDENTIAL” and distributed to appropriate firm personnel, including counsel.
WORKSHEET: CLOSING CONFERENCE

Date of inspection: ____________________  Time of inspection: ____________________

Name of recorder: ____________________________________________________________

Name of Company Contact: ___________________________________________________{

Name of inspector: _____________________________________________________________

Names of anyone else present: __________________________________________________

What, if any, conditions or practices did the inspector note for improvement?
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

What, if any, conditions or practices did the inspector deem to be in violation?
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

What, if any, sections of the regulations did the inspector deem to be violated?
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
What, if any, consumer complaints did the inspector reference?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

How did the Company Contact respond to the consumer complaint(s) referenced?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

If the inspector furnished a Form FDA 483, how did the Company Contact respond?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

If any modifications were made immediately in response to the inspector’s comments, was an annotated Form FD 483 provided?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Who will draft a written response to the Form FD 483? When? ________________________________

________________________________________

________________________________________

Did the Company Contact confirm with the inspector that a copy of the Establishment Inspection Report will be provided to the firm without the need to make a Freedom of Information Act request?

________________________________________

________________________________________

Who will draft an internal company report? When? ________________________________

________________________________________

________________________________________
Dos and Don'ts

Pre-inspection Do's:

- Have a Company Inspection Manual
- Have a trained Company Inspection Team
- Identify what FDA (or the state) may inspect
- Be familiar with relevant sections of FDA's Investigations Operations Manual
- Company Inspection Manual should include policies on:
  - Photographs
  - FDA record review
  - Complaint file review
  - Providing shipping records
  - Procedures boundaries (areas and interviews of employees)
  - Being accompanied
- Conduct mock inspections periodically
- Review prior inspection reports and check status of any promised corrective action

During the Inspection Do's:

- Notify Inspection Team
- Review credentials and make a copy
- Review FDA 482 – Notice of Inspection
- Review any FDA 482C presented – Request for Records
- Hold opening conference to determine purpose and scope
- Present inspection policies, including facility or farm safety procedures
- Be courteous, professional and firm
- Accompany inspector(s) at all times
- Inspection should be consistent with the stated scope
- Protect trade secrets
- Designated company spokesperson(s) must provide answers
- "I don't know" is acceptable, if accurate
- If you are uncertain whether to provide certain requested records or other information, inform the inspector that you need time to get guidance
- Use company “reporter” to take notes during the inspection
- Collect duplicate samples/swabs/records, but generally do not test products or environmental samples before getting FDA results and evaluating the implications.
During the Inspection Don'ts:

- Keep inspectors waiting
- Sign any documents
- Volunteer information
- Be untruthful or deceptive
- Be intimidated
- Admit any wrongdoing
- Allow inspector to go anywhere unaccompanied

Source: FDA
APPENDICES
APPENDIX A
NOTICE OF INSPECTION

FORM FDA 482
### INVESTIGATIONS OPERATIONS MANUAL 2016

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

<table>
<thead>
<tr>
<th>1. DISTRICT OFFICE ADDRESS &amp; PHONE NO.</th>
<th>3. DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1431 Harbor Bay Parkway</td>
<td>07/20/13</td>
</tr>
<tr>
<td>Alameda, CA 94502</td>
<td></td>
</tr>
<tr>
<td>(510)337-6700</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. NAME AND TITLE OF INDIVIDUAL</th>
<th>4. FIRM NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helen E. Castro, President</td>
<td>ABC Bread Company</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. NUMBER AND STREET</th>
<th>6. CITY AND STATE &amp; ZIP CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>579 Main Street</td>
<td>Richmond, CA 94805</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. PHONE NO. &amp; AREA CODE</th>
<th>8. PHONE NO. &amp; AREA CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(510)123-4567</td>
<td></td>
</tr>
</tbody>
</table>

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264].

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman. FDA has an Office of the Ombudsman that can directly assist small businesses with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8100 or by email at ombuds@oc.fda.gov. For industry information, go to www.fda.gov/foic/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s))

Sidney H. Rogers

10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))

Sidney H. Rogers, Investigator

---

1 Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this (Continued on Reverse))
FOOD REGULATORY INSPECTION MANUAL - APPENDIX A

Sec. 704. (d) 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.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the arrangements used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (h)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (a) is in effect, the applicant shall establish and maintain such records and make such reports to the Secretary of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (1) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whose regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

2 Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and

Sec. 361(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of

(Continued on Page 3)
Part F - Control of Radiation.

Sec. 360(a) A (a) "if the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 359(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

Part G - Quarantine and Inspection

Sec. 301(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."
APPENDIX B
NOTICE OF INSPECTION
REQUEST FOR RECORDS

FORM FDA 482C
INVESTIGATIONS OPERATIONS MANUAL 2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. FIRM NAME

5. HOUR

6. NUMBER AND STREET

6. NUMBER AND STREET

7. CITY AND STATE & ZIP CODE

8. PHONE & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(1)]. Written request is hereby given to access and/or copy the records described below, pursuant to the Federal Food, Drug and Cosmetic Act, Section 414(a) [21 U.S.C. 350c] and Title 21 Code of Federal Regulations, Section 1.361.

Applicable portions of Sections 704 and 414 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 374 and 350c) and Title 21 of the Code of Federal Regulations, are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 or (k), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(i). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 414(a) RECORDS INSPECTION. (1) ADULTERATED FOOD. - If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article, and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. (2) Use of or exposure to food of concern. - If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals. (3) Application. - The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packaging, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

321 CF CFR 1.361 What are the record availability requirements? When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374a) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

FOOD REGULATORY INSPECTION MANUAL - APPENDIX B

NOTICE OF INSPECTION - REQUEST FOR RECORDS

FORM FDA 482c (4/12)
APPENDIX C
INSPECTIONAL OBSERVATIONS
FORM FDA 483
INVESTIGATIONS OPERATIONS MANUAL 2016
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 Pharmaceuticals “T.L.P.”

STREET ADDRESS
2136 Elbe Place

CITY, STATE AND ZIP CODE
Jackson, MN 55326

TYPE OF ESTABLISHMENT INSPECTED
Tablet Repacker

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.

DURING AN INSPECTION OF YOUR FIRM (S) AND OBSERVED:

List your significant observations ranked in order of significance.

See IOM 5.2.3, 5.2.3.1, 5.2.3.2, and 5.2.3.3

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sidney H. Rogers

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Sidney H. Rogers, Investigator

DATE ISSUED
10/7/2008

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLET INSPECTIONAL OBSERVATIONS PAGE 1 of 1 PAGES
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."
APPENDIX D
RECEIPT OF SAMPLES
FORM FDA 484
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

850 Third Avenue
Brooklyn, NY 11232
718-340-7000

Richard A. Frost, General Manager

Quality Wholesale Drug Co.

3146 Front Street
Brooklyn, NY 11232

AB3632918

1. DISTRICT ADDRESS & PHONE NUMBER
2. NAME AND TITLE OF INDIVIDUAL
3. DATE
4. SAMPLE NUMBER
5. FIRM NAME
6. FIRM’S DEA NUMBER
7. NUMBER AND STREET
8. CITY AND STATE (Include Zip Code)
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and/or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.

NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.

One Box of 25 - 1 cc ampoules, Dilaudid HCl (hydromorphone) 2 mg/cc, lot # 0103213 manufactured by Knoll Pharmaceutical Co., Orange NJ.

10. SAMPLES WERE
☐ PROVIDED AT NO CHARGE
☒ PURCHASED
☐ BORROWED (To be returned)

11. AMOUNT RECEIVED FOR SAMPLE
☒ CASH
☐ BILLED
☐ VOUCHER
☐ CREDIT CARD

$15.00

12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.)

Richard A. Frost

13. COLLECTOR’S NAME (Print or Type)

Sylvia H. Rogers

14. COLLECTOR’S TITLE (Print or Type)

Investigator

15. COLLECTOR’S SIGNATURE

Sylvia H. Rogers
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.”
# List of Worksheets

<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishing your teams</td>
<td>17</td>
</tr>
<tr>
<td>Disclosure of documents</td>
<td>19</td>
</tr>
<tr>
<td>Establishing your policy</td>
<td>22</td>
</tr>
<tr>
<td>Opening conference</td>
<td>38</td>
</tr>
<tr>
<td>During the inspection</td>
<td>42</td>
</tr>
<tr>
<td>Closing conference</td>
<td>46</td>
</tr>
</tbody>
</table>