


Western Growers Science

# GROWER/SHIPPER/ HANDLER GUIDE TO FOOD AND DRUG ADMINISTRATION ASSIGNMENT SAMPLING VISITS

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Version 1

**DISCLAIMER**

This guide is intended to provide information and suggested guidelines for Western Growers Association members to follow during FDA Assignment Sampling Visits. The guide represents Western Growers' best efforts to provide information based on current regulations and guidelines with the understanding that federal and state requirements and interpretations can change as new regulations and guidance are issued. This guide does not constitute legal advice, nor does it create or imply the existence of an attorney-client relationship. The recommendations are not exhaustive and may not apply in every situation. It is the sole responsibility of the reader to verify that the recommendations are appropriate for its company and facility. Western Growers does not assume any responsibility for members' compliance with applicable laws and regulations, and recommends that users consult with their own legal and technical advisers to ensure that their procedures and operations meet relevant federal, state, and local requirements.

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## A. PURPOSE

The purpose of this document is to provide background, direction, and guidance to growers, shippers, handlers, and similarly-situated firms regarding the Food and Drug Administration (FDA or the agency) sampling of product at the growing operation or at an FDA-regulated commercial cooler, or cold storage facility for a processing facility under a sampling assignment.[1],[2]

It is intended as a resource for purposes of activities conducted under a sampling assignment, but is not intended to capture every scenario that may be presented by the agency, address formal inspections[3] carried out by the agency, or address formal investigations by FDA.[4]

## B. BACKGROUND FOR REGULATORY SAMPLING

### 1. Under what legal authority is sampling conducted?

The Federal Food, Drug and Cosmetic Act (FFDCA) gives FDA the authority to conduct investigations and collect samples.[5]

### 2. When might FDA collect samples, i.e., what are the different types of sampling?

FDA collects various types of samples to further its goals to oversee and maintain public health.

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1 Note, we use the terms "investigator" and "inspector" interchangeably throughout. Where helpful, we include an example of the form referenced.

2 To the extent applicable, we use the terms "farm," "FDA-regulated commercial cooler," and "cold storage facilities for a processing facility" subject to sampling assignments interchangeably.

3 The 2018 Western Growers manual on FDA inspections provides information and suggested guidelines to follow during food regulatory inspections.

4 There are two primary reasons for conducting on-farm investigation: 1) an outbreak and trace back investigation that implicated the farm and related operations; and/or follow-up to a positive produce sample. For a reference guide to produce farm investigations, see FDA Guide to Produce Farm Investigations (Nov. 18, 2014), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/guide-produce-farm-investigations-1105.

5 21 USC § 372(a)(1)(A) (stating "The Secretary is authorized to conduct examinations and investigations for the purposes of this Act . . . .").

There are two basic sample types:

**Official Samples.** An Official Sample is one taken from a lot for which Federal jurisdiction can be established. If violative, the Official Sample provides a basis for administrative or legal action.

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

Official samples and investigational samples are collected during authorized sampling activities that include routine, for-cause, or surveillance sampling:

**Routine Sampling.** Routine inspections and sampling are routinely scheduled investigations conducted according to a random selection process and/or according to FDA's inspectional frequency. Samples collected during routine inspections can be either official samples or investigational samples.

**For-Cause Inspection Sampling.** For-cause inspections and sampling are those conducted in response to a current or previous outbreak or during an emergency. Samples collected during for-cause inspections can be either official samples or investigational samples.

**Surveillance Sampling.** Surveillance sampling is only conducted as part of a surveillance assignment for specific commodities generally in or from certain regions. Samples collected during surveillance sampling can be either official samples or investigational samples. Under sampling assignments, FDA typically selects certain commodities for a larger sampling exercise of approximately 1,600 samples of each over 12 to 24 months. Specific instructions have been developed for the collection of surveillance samples on farms or from on-farm packinghouses or processors, including pre-notification, interaction with personnel, payment for samples collected, and sample size(s). Though these instructions only apply to surveillance samples, they may also be considered for illness investigations or for cause sampling but are not required. This type of sampling should be limited to instances where it is specifically mentioned in an assignment.

### 3. What is the purpose of surveillance sampling and are assignments part of FSMA?

The FDA Food Safety Modernization Act (FSMA) is focused on prevention rather than responding to outbreaks of foodborne illness. Although sampling assignments existed before FSMA, since FSMA was enacted FDA has focused its use of sampling assignments to help gather the data and other information needed to help identify and address hazards.

As part of the FDA's risk-based and preventive approach, FDA began developing a new, more robust approach to deploying its sampling resources in 2014.

The goals of the surveillance sampling are to keep contaminated products from reaching consumers and to facilitate a greater understanding of hazards before they become a problem.

### 4. What is the FDA approach to establishing and executing a sampling assignment?

The FDA's past approach to surveillance sampling was to collect a relatively small number of samples of many different commodities over many years.

Under FDA's "new" sampling approach, the agency collects a large number of samples (~1,600) of targeted foods over a relatively short period—12 to 24 months—to ensure that enough data are available to inform decisions. This approach seeks to help the FDA determine if there are common factors among positive findings, such as origin, variety, or season.

The sampling design for each food is intended to represent what U.S. consumers are likely to find in the marketplace. Accordingly, the agency considers the volume of the target food that is imported and produced domestically and the number of states/countries that produce the target food, and develops the assignment from there.

### 5. How does FDA develop a sampling assignment?

Staff in the FDA's Office of Compliance and the Division of Risk and Decision Analysis begin by developing a list of food-pathogen combinations that are good candidates for sampling, based largely on the history of detection in foods, recalls, and outbreak history. In prioritizing sampling efforts, other factors are considered, including the severity of illness, the characteristics of the food and its manufacturing process, and whether large-scale sampling is an appropriate tool for filling current knowledge gaps.

Assignments are intended to be designed in a way that minimizes impact on industry operations. FDA is aware of the economic concerns of industry, and that time is of the essence in obtaining test results when it comes to produce and other perishable foods. As part of FDA's outreach, it works with industry to make sampling, analytical testing, and reporting back of findings more efficient, and incorporate industry suggestions into planning.

### 6. What types of samples might be collected?

**Product Sampling.** The FDA collects samples of food products ready to go to market and in-process and raw ingredient samples. Finished product sampling occurs to ensure products don't reach consumers with harmful contaminants, or to verify that they contain ingredients at levels as declared on product labeling.

**Environmental Sampling.** The FDA collects samples from the environment surrounding the food. This type of sampling is important because environmental contamination may contribute to contamination of finished product.

**Emergency Response/Emerging Issues Sampling.** This type of sampling can take the form of either environmental sampling or product sampling, and often involves both. Emergency response sampling is routinely conducted in response to outbreaks of foodborne illness to help identify the source of the disease-causing pathogen. Emerging issues sampling helps the agency to gather information about potential food safety issues based on trends or intelligence the FDA might have.

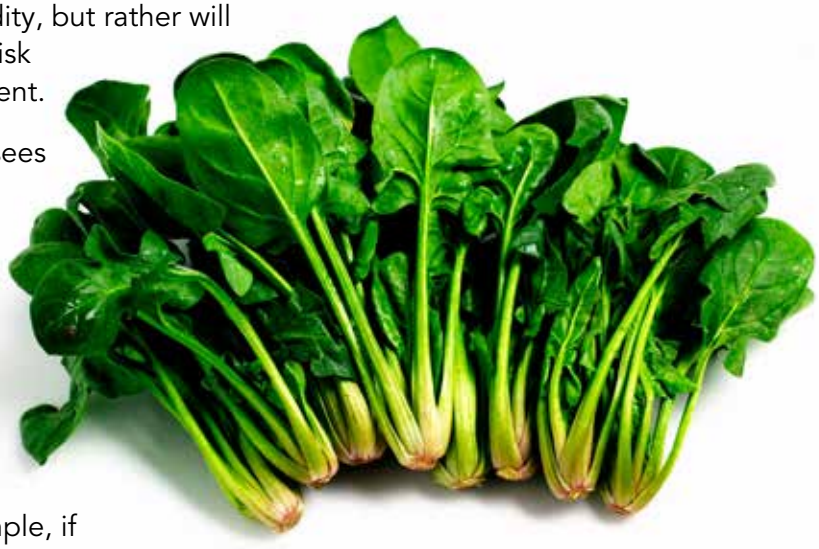
## 7. What is the difference between FDA sampling assignments and sampling at import into the US?

As described, surveillance sampling is only conducted as part of a surveillance assignment for specific commodities generally in or from certain regions. To ensure sampling is representative, FDA collects samples in approximate proportion to their U.S. market share based on origin (i.e., domestic vs. import). For example, if 60 percent of a commodity eaten by U.S. consumers is imported, then about 60 percent of the samples of that commodity should be from imported products. This approach is intended to approximate the products and relative risks that consumers are likely to encounter.

Assignment sampling is different than routine sampling of imported products to determine if the products meet public health standards. Import samples are not limited to specific commodities, regions, or companies. Reasons FDA would conduct a physical examination of an import to collect a sample include risk associated with product, product history (e.g., violations), manufacturer, shipper, importer history (e.g., violations), and random sampling.

## 8. Can the FDA target specific producers or production sites (fields) for sampling (under a general sampling assignment)?

Generally, FDA considers the volume of the target food produced and the number of states/counties that produce the target food. It's unlikely FDA would select for a sampling assignment a small-volume rarely-consumed commodity, but rather will continually identify higher-profile higher-risk products as part of the sampling assignment.



However, depending on the trends FDA sees as results become available and purpose of the sampling, FDA may narrow the scope of the sampling assignment to more specific producers/locations/sites. This is unlikely to occur at the front-end of the assignment, but may occur after FDA evaluates initial sample data. Depending on results, FDA may implement more targeted sampling if trends are identified; for example, if

positive samples come from a specific geographic region, a specific facility, or during a particular season.

## C. PREPARING FOR A SAMPLING VISIT BY FDA

### 1. Why are some sampling assignments announced and others unannounced?

FDA does not share the specific locations where it will be sampling, or which business' products might be collected for testing. FDA believes it is important to get an unbiased snapshot of the frequency of contamination in the commodity, and that this is achieved with unannounced collection visits.

However, when an investigator is planning to collect surveillance samples, the investigator will call at least 24 hours in advance to notify the firm of FDA's intent to collect samples and share the commodity of interest. There may be instances when responsible management will not be available on the planned date and time and FDA instructs its investigators to use their judgment in negotiating alternate dates as appropriate.

Further, due to the ongoing COVID-19 pandemic,[6] FDA is preannouncing all visits/inspections well in advance of visiting to ensure the safety of all personnel. We would expect any sampling that occurs during the ongoing pandemic to continue to be announced in advance of 24 hours.

### 2. How does FDA define a "lot" for the purpose of sampling?

**FDA Definition of "Lots."** We understand FDA defines a lot to mean commodity from a specific field that is harvested by one crew on one day, i.e., product harvested from the same field on Day 2 (with or without a different crew) is a different lot than Day 1.

**Grower, Handler, and Shipper Definition of "Lots."** We understand growers (and their downstream handlers and shippers) define a lot to mean that product grown on the

6 However, FDA has issue numerous guidances and made statements alluding to the importance of appropriate COVID-19 considerations, and all employees are expected to act respectfully professionally. See Section D.3. and D.4. for additional information. If an investigator refuses to comply with COVID-19 protocols, contact Western Growers or legal counsel. Also note the refusal in the post-sampling detailed report

same field is part of the same lot regardless of harvesting day (i.e., the same field is the same lot whether it was harvested on Day 1 or Day 5).

The differing definition of lots can create confusion and potential negative ramifications for the grower, handler, or shipper depending on test results and the amount of product it chooses to hold while awaiting test results. We recommend growers, handlers, or shippers subject to a sampling assignment explain to FDA investigators how the grower, handler, and shipper defines a lot and respectfully suggest the investigator test accordingly. We recommend the grower, handler, or shipper explain to FDA the implications of testing product from several lots. If FDA is not being cooperative or willing to engage in further discussions regarding this definition, escalate the issue by contacting Western Growers or legal counsel.

### 3. How do you prepare contracted sites or other (non-company owned) sites for sampling of your product?

Companies should provide contracted or other sites with this manual ahead of time to allow for review and follow-up questions. Engage with and train these sites on what to expect if an investigator comes for surveillance samples.

Require that they contact you as soon as practicable after they receive notice of FDA coming to sample.

Request that their management (or a company representative) be present throughout the sampling (and to follow the practices as outlined under Section D below).

### 4. What actions should be taken when the FDA announces a sampling assignment involving a product category you produce?

All companies should prepare their teams and operations as a potential sampling location. Management and personnel should review this manual, direct clarification questions to Western Growers or legal counsel (as applicable), and identify all responsible personnel for oversight and management during a visit from FDA investigators. This includes identifying the persons who will accompany FDA throughout the visit and who will be able to answer questions.

Companies should also prepare, refresh, and retrain on operational documentation, standard operating procedures (SOPs), plans, documentation, and records (including shipments) in the event FDA presents a form Notice of Inspection (See Appendix 1 – FDA Form 482: Notice of Inspection) or if test results indicate that a recall is required.

### 5. What are your rights and responsibilities during a sampling assignment (Should the company samples? What if the investigator requests pictures?)?

Below is a broad overview of activities to be aware of or watch out for during a sampling assignment. Most of the issues are discussed in further detail under Section D.

**Responsibilities.** FDA has the authority to conduct sampling as part of its investigation authority under the FFDCA. Firms should comply with sampling assignment requests to the extent practical, i.e., allowing FDA to collect finished product and environmental samples.

If FDA's activities go beyond the scope of surveillance sampling, personnel accompanying the investigator should engage in a dialogue inquiring for further information. If activities go beyond the scope of sampling or the firm refuses to allow sampling, FDA will likely issue a FDA Form 482 – Notice of Inspection.

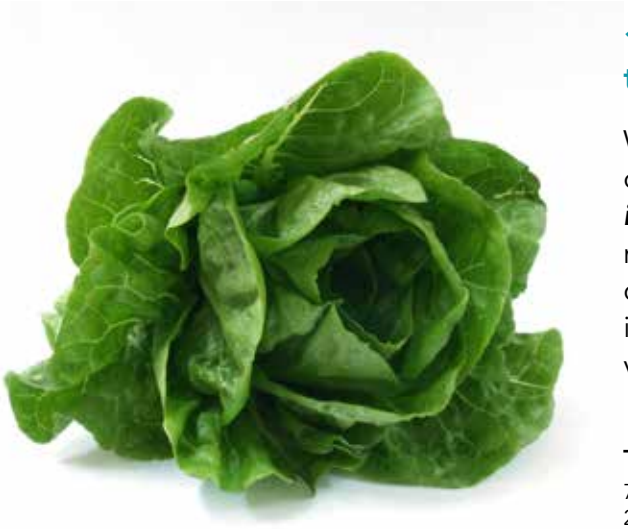
Once FDA provides the Notice of Inspection, it has broad authority to access facilities, and the inspection may include an examination of the building, equipment, raw ingredients and materials, in-process or finished products, containers, labeling, and certain records. Courts have upheld the legality of an FDA inspection if it is conducted at a reasonable time, within reasonable limits and in a reasonable manner. Consent is not the basis upon which a FDA inspection is conducted, and permission or authorization to inspect is not required from the firm to be inspected. The FFDCA provides criminal penalties for refusal to permit a lawful inspection.[7]

**Company Samples.** The company has the right to take duplicate samples of all samples collected by FDA. The company should decide ahead of time whether it plans to do this and instruct employees accordingly.

**Photos.** The FDA believes it has the authority under the statute to take photographs. There is no express authority under the FFDCA to do so. Some states have express provisions giving the authority to take photographs. Therefore, firms should be familiar with the company's policies on photographs and the state laws on the issue in which the firm is located. Depending on these two things, you may be in a position to refuse photographs, though it's important to keep in mind that this can lead to a contentious interaction with the investigator. Contact legal counsel with questions or concerns on this issue.

**Affidavits.** In the event FDA presents you with documentation to sign, you are ***not required to sign affidavits*** or any other documentation presented to you. You are also under no obligation to confirm or deny any statements the FDA presents to you. The FDA can and will use these documents and/or statements as part of the regulatory record and in Court against your firm. Do not sign or otherwise confirm/deny any statements without first checking and confirming with legal counsel.

## D. CONDUCT DURING THE VISIT AND SUPPORTING THE SAMPLING PROCESS



### 1. Pre-notification: What should the site expect before the investigator comes to sample?

When an investigator is planning to collect surveillance samples on a farm or from packinghouses or processors or coolers, ***the investigator will call the firm at least 24 hours in advance*** to notify the firm of FDA's intent to collect samples and share the commodity of interest. While the COVID-19 pandemic continues, it is highly likely FDA will contact the firm in advance of coming to visit.

7 FDA CPG Sec. 130.100 Inspectional Authority; Refusal to Permit Inspection (March 9, 2015), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-130100-inspectional-authority-refusal-permit-inspection.

There may be instances when responsible management will not be available on the planned date and time and the investigator will need to use his/her judgment in negotiating alternate dates as appropriate. During the pre-notification call, the investigator should also determine an estimate of what the sample(s) will cost if the firm decides to charge for the samples.

## 2. Are there documents that should be presented by the investigators? Should you sign the documents?

**FDA Credentials.** Review for authenticity to confirm identity, but no signature is required.

**FDA Form 482 – Notice of Inspection.** No signature is required.

**FDA Form 482c – Request for Records (Appendix 2).** No signature is required. (Note, this form can only be served to registered facilities, not farms).

**Form 484 – Receipt for Samples (Appendix 3).** This is the only document company employees should be authorized to sign. (Note, this form may not be provided if a Form 482 is not issued, but you may request one).

**Affidavits or Other Documents.** As described above, do not sign affidavits or other documentation, or otherwise confirm/deny statements made by the agency without approval of legal counsel.

## 3. What is the recommended approach to a growing operation/cooler sampling event?

**After Notification and Prior to Arrival.**

- Review Section C. above "Preparing for a Sampling Event."
- If you become aware that FDA is coming, to the extent possible, engage in best inventory management practices to ensure there are no "partial" lots that may be sampled that are in commerce. This will allow you to "hold" any product that is subject to sampling.

**FDA Arrival.**

- When the investigator arrives, security, a receptionist, or other first point of contact should welcome the investigator as any other business visitor and treat the investigator with courtesy.
- If there are COVID protocols upon entry to the area (e.g., temperature check, routine question forms), inform the investigator of these protocols, request the ability to complete them, and complete them.[8]
- The entry point of contact should notify the manager on duty and/or other person(s) assigned to greet and accompany the investigator throughout the visit.

8 There are no FDA statutory references or regulations requiring investigators to follow a firm's COVID-19 policies and procedures. However, FDA has issue numerous guidances and made statements alluding to the importance of appropriate COVID-19 considerations, and all employees are expected to act respectfully and professionally. See Section D.3. and D.4. for additional information. If an investigator refuses to comply with COVID-19 protocols, contact Western Growers or legal counsel. Also note the refusal in the post-sampling detailed report.

**Engagement with Investigator.**

- Have a senior manager or other responsible person greet the investigator promptly. Do not keep FDA waiting for more than 20 minutes.[9]

- The FDA investigator who arrives to collect samples will present his or her agency credentials. Note, some FDA investigators may be in uniform when they arrive to conduct sampling. They are members of the Commissioned Corps of the U.S. Public Health Service (USPHS) – professionals dedicated to protecting and promoting public health and safety. They are required to be in uniform when on duty. Though their uniform is similar to military dress, these health professionals are not members of the armed forces and work only in the interest of health promotion and disease prevention.

  – The investigator may at this point (or any other point throughout) give you a "Notice of Inspection" (FDA Form 482). For sampling assignments, an investigator will generally not present the Notice of Inspection. If he/she presents credentials with the designation "200-D" (these are criminal investigators) or if he/she presents a FDA Form 482c (Form 482c Request for Records) contact legal counsel.

- **Request a pre-sampling conference.** Ask the investigator to explain the purpose of the sampling, including where sampling will occur, and how many samples will be collected.

- **Explain the company's policies and procedures regarding visitors/inspections.** For example, investigators are expected to follow company policy regarding GMPs and COVID-19, and obey all safety signs and precautions. Discuss the company's policy regarding the use of photographic equipment.

  – If company policy prohibits the use of photographic equipment—

    o Be prepared for the investigator to insist that he/she has the authority to take photographs. Ask what the investigator wishes to photograph and elevate the

9 Note, 20 minutes is not a required timeframe, but illustrates the importance of prompt response and attitude towards the inspection generally. Waiting longer than 20 minutes to greet the investigator may be perceived negatively, and the firm should plan on doing approaching the visit in a cordial and smooth manner.

request to legal counsel.

- Make it clear the company is not denying FDA access to sampling, only the ability to take photographs.

– If the Company policy authorizes the use of photographic equipment—ask the investigator to mark all photos as "confidential commercial information." The Company should take both a similar photograph to the one the invesigator takes, as well as a broader photograph depicting the surrounding area.

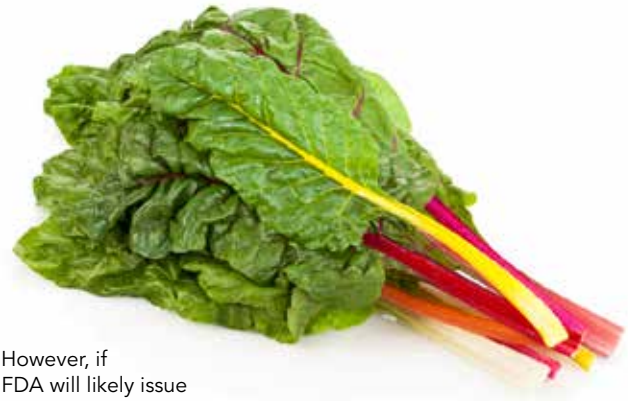
- Ask the investigator to direct any questions to the company's designated representatives accompanying the investigator.

**Collecting Samples.**

- **Knowledgeable, trained, and previously designated employees should accompany the investigator at all times.** No exceptions. If there is more than one investigator, each must be accompanied by a designated employee, preferably two. Questions and requests for information should be directed to the designated employees.
- **One of the designated employees accompanying the investigator should take copious notes of the entire visit** including questions asked and answered, observations and comments made, and from where the samples are taken. Only answer questions that are asked – do not offer extra information.
- Ask the investigator why he/she is collecting particular samples, which tests are to be performed, and when results are expected.
- After samples are collected or the inspection is completed, the investigator will provide a receipt (FDA Form 484) for all samples collected. (Note, this form may not be provided if a Form 482 is not issued,[10] but you may request one).
- **All finished product that is sampled should be placed on hold pending results.** Communicate to the investigator that all products sampled will be held pending results provided by FDA.
- **At the time of sampling or during the exit interview, request the FDA investigator to provide a written report on the sample analysis via Form 1551** (See Appendix 4 – Form 1551).

**Post-Sampling.**

- **The manager and other appropriate facility employees should conduct an exit interview with the investigator,** and ask if there are any questions that the investigator may have.
- This is also an opportunity for the site to ask



10 As noted above, Form 482s are not required for surveillance sampling visits. However, if activities go beyond the scope of sampling or the firm refuses to allow sampling, FDA will likely issue a FDA Form 482 – Notice of Inspection.

questions of the investigator.

- ***Do not sign or initial any affidavits.*** If the investigator insists, forward the unsigned affidavit to legal counsel. Do not sign any affidavits or otherwise confirm/deny any statements without the clear consent from legal counsel.

**After the FDA Visit.**

- **After the investigator leaves, prepare a detailed report of the sampling for internal purposes.** Key information from this report should be shared with all relevant operational contacts that may be affected by the sampling (e.g., if growers have released lots to coolers that were part of the sampling), and legal counsel (as appropriate). Firms also should submit a copy of the report to Western Growers to assist with providing an overview of FDA surveillance activity, as well as facilitating direct feedback to the agency from industry in an anonymized way regarding investigator conduct and industry impact.
- The report should contain:
  - Date(s) and time(s) of sampling
  - Investigator's name and credentials
  - Company personnel accompanying the investigator(s)
  - Details on samples taken and testing to be performed
  - Questions asked by the investigator and answers provided
  - Whether photographs were taken and areas photographed
  - Observations and comments by the investigator
  - Records requested, reviewed and copied
- This internal report should include copies of the Form FDA 482, 482c, 484, or 1551; images of any photographs taken; and, a list of all information provided to the investigator (whether oral or written) including documents or records provided.

## 4. What if the investigators' requests seem unexpected, unreasonable, and/or their tone or tenor is unexpected or difficult?

Very few limits are placed on FDA's ability to conduct activities in the interest of public health, but there are some. All government employees are expected to act within the Standards of Ethical Conduct for Employees of the Executive Branch and present themselves with decorum and courteousness.

During sampling, FDA is to make every effort to restore the lot to its original state, and must be prepared to purchase a whole unit to avoid leaving broken cases. FDA should also reimburse the firm for additional labor costs incurred as a result of sampling. If any of these issues are concerns for the firm, raise it with the investigator.

If any of the requests seem unexpected or unreasonable, ask the investigator to clarify the request and its purpose. The firm is also within its rights to ask FDA its authority to engage in or

conduct a specific activity. If a particular FDA employee is not acting in a professional manner, if a request is beyond the bounds or scope of sampling (when a Notice of Inspection is not provided), or if the firm believes requests are unreasonable, you should contact Western Growers and legal counsel (as appropriate) to discuss the current situation. Firms should document unreasonable requests or unprofessional activities in the detailed visit report (to be shared with Western Growers and/or legal counsel as appropriate).

## 5. What are the investigators conducting the sampling allowed to do?

**General Authorization.** As noted, the FFDCA gives FDA the authority to conduct investigations and collects samples (environmental and/or product). Further, under formal inspections after issuance of a Form 482, FDA investigators are lawfully authorized to enter and inspect any facility, warehouse, and/or establishment in which foods are manufactured, processed, packed or held for shipment into interstate commerce or any vehicle used to transport or hold such food. An inspection may include an examination of the building, equipment, raw ingredients and materials, in-process or finished products, containers, labeling, and certain records.

**Assignment Sampling Versus Inspection.** If FDA does not present a Notice of Inspection (FDA Form 482), the activities should be limited to sampling activities for the commodity that was communicated in the pre-call. However, the investigator can at any time present the Notice of Inspection. This gives them broad authority to inspect any part of the facility or operations.

**Inventory Considerations.**

When an investigator is on site and viewing the inventory of product to be collected, the investigator should determine if the sample size needed will exhaust the supply of the product or may cause the firm to not be able to meet customer needs.

If so, investigators should consider whether to not collect the sample or if possible modifying the sample collection. If the sample collection will exhaust the entire inventory, the investigator should discuss this with responsible management and determine how soon inventory will be restored and if the responsible individual believes the sample collection will impose an economic disadvantage.

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

## 6. What if the investigators ask to see other areas of the site?

If the investigator has not presented a Form 482

Notice of Inspection and requests to see other areas of the site, the responsible person should engage with FDA and ask the purpose of the additional review. The responsible person should not be combative or otherwise defensive if FDA continues to push.

FDA's activities should be limited to just sampling, but there is a very fine line here. If the investigator continues to push and the firm is comfortable allowing him/her to see additional areas, the firm has the ability to allow the investigator to see other areas without more or to request formal issuance of a Form 482 – Notice of Inspection. A firm should be prepared to undergo a formal inspection by the agency if it requests the Notice of Inspection. As noted, this gives FDA broad authority to inspect any facility, warehouse and/or establishment in which foods are manufactured, processed, packed or held for shipment into interstate commerce or any vehicle used to transport or hold such food. An inspection may include an examination of the building, equipment, raw ingredients and materials, in-process or finished products, containers, labeling, and certain records.

### 7. What happens if the investigator does not believe the site is cooperating with the sampling request? What can the site do in response?

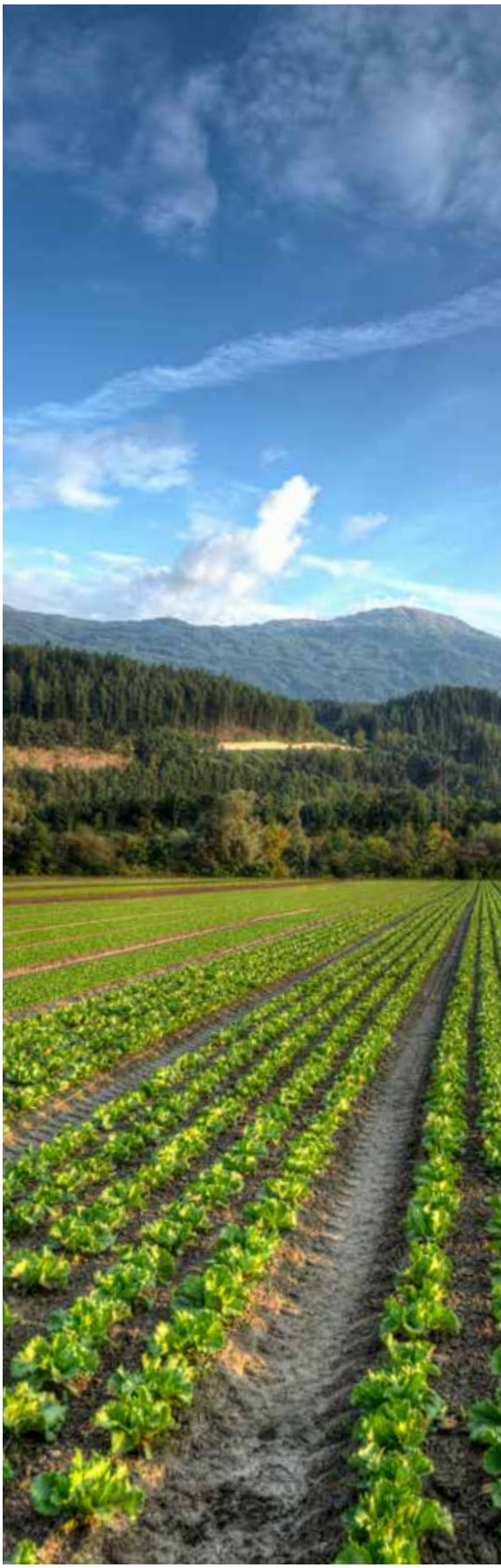
Continue to be courteous throughout all interactions with the FDA, and answer all questions reasonably expected to be part of sampling. If activities go beyond the scope of sampling, or if the company refuses to allow sampling, FDA will likely present a Notice of Inspection (FDA Form 482).

The site can request FDA to present this Notice if they feel the investigator is going beyond the scope of surveillance sampling, but cannot reject the inspection (regardless of whether it is surveillance sampling or a broader inspection). If the site is concerned about the conduct of the investigator, contact Western Growers and legal counsel (as appropriate).

## E. AFTER THE SAMPLES ARE TAKEN

### 1. Should firms save and test their own samples too?

Section C.5. ("Preparing for an FDA Visit, Company Samples") discusses how firms have the right to take duplicate samples of all samples collected by FDA. The company should decide ahead of time whether it plans to do this and instruct employees accordingly.



If samples are collected, the firm should decide whether it will test the samples (and for which tests). Firms that collect and test their own samples should be prepared to take action in accordance with their procedures in the event positive results are received (e.g., recall, destruction).

## 2. How should you expect to hear about the results?

The timing to receive results is dependent on the location of the laboratories FDA chooses to use for the analysis of the samples. It can take several days to receive results. The FDA will notify firms of positive samples once confirmed.

- Sample results should be shared via Form 1551 – Report of Sample Analysis.
- The district will call the firm management or its designee to discuss test results and may follow up with an e-mail or fax.

If potentially harmful contaminants are found in a product that has been distributed or is actually on the market, the FDA will consider regulatory and enforcement options. These include:

- encouraging a voluntary recall,
- ordering a mandatory recall,
- ordering administrative detention to prevent the product from being distributed,
- and/or issuing public warnings to alert consumers to the potential danger.

If potentially harmful contaminants are found in samples taken from imported food, the shipment(s) may be detained and refused entry, and future shipments may be subject to an Import Alert (detention without physical examination) as warranted.

## 3. What if there is no response from the FDA representative or if the sample results are late?

If FDA does not provide sample results in a timely manner (e.g., if results are not obtained in two weeks), the firm (or legal counsel) can independently inquire as to the results by asking the investigators that came to sample.

## 4. What should you do if a sample tests positive for a pathogen, exceeds an allowable threshold for a pesticide and/or is in any other way considered violative?

**Pathogen Positives.**

When a pathogen is detected, the FDA will notify both the operator of the commercial cooler from which it was collected and the management of the growing operation where it originated (as applicable). The FDA will work with them, as well as with state regulatory partners, to take action as warranted to protect the public health, and identify the cause of the contamination.

Enforcement activities may include actions to correct and prevent microbial contamination or to remove violative food from the market (i.e., a recall), as necessary. Whole genome sequencing (WGS) will be conducted on detected pathogens to identify the organism's genetic pattern and determine whether it may be linked to known human illness events.

Per the directions above, firms should hold all finished product that is sampled pending notification of test results. FDA supports this action to help prevent recalls of any contaminated product that could have entered commerce.

FDA will engage with industry on conducting root cause analyses for any positive samples found during this assignment. ***But firms should not wait to hear from FDA and should be conducting internal reviews and root cause analyses to identify potential sources and routes of contamination, inform what preventive measures are needed, and implement corrective actions as appropriate.***

These measures should be carefully implemented and clearly documented to demonstrate to FDA that the firm is responding appropriately. FDA will also likely conduct a formal follow-up inspection and follow-up sampling to determine the adequacy of the root cause analysis and corrective actions.

**Other Violative Samples.**

Depending on the type of violation, FDA may follow the same procedures for positive pathogen findings, e.g., elevated levels of heavy metals or toxic pesticides. The firm should work with its management, quality assurance team, and legal counsel to address situations where product results suggest violations of the FFDCA.

## 5. What happens to the data collected from the assignment?

The FDA will evaluate the data or results generated throughout the sample collection period and use the data to inform the agency's short and longer term decision making. It can take months (or years) for the agency to analyze the data sets into usable information, and to publish a publicly available report. By developing these data sets, the FDA seeks to identify potential vulnerabilities and ways to enhance the food safety system.

Depending on the interim and long-term results, the FDA may react or take certain steps, such as:

- Decreasing sampling, if few positive samples are obtained;
- Implementing more targeted sampling if trends are identified; for example, if positive samples

come from a specific geographic region, a specific facility, or during a particular season;

- Conducting follow-up inspections (for locations with positive results);
- Working with state or international regulatory partners to take corrective actions and implement preventive controls;
- Developing new or enhanced industry guidance; and
- Conducting outreach and information sharing to better protect consumers.

### 6. Can a site receive a formalized copy of the results?

Yes. The site should request FDA to provide sample results on Form 1551 in addition to any informal communication the FDA provides.

### 7. For product sampling assignments, why are there delays of many months in providing information to the public? Is there any other way to access the information?

FDA analyzes a large number of sample results into usable data sets and information. It often takes months (or years) to aggregate and analyze the information in a usable way. It can take FDA even longer to formally assemble the information into a formal report.

There is no way to access this information prior to release to the public other than submitting a request through the Freedom of Information Act (FOIA). FDA will likely deny this request until it makes its findings and report publicly available.

### 8. What should I do if FDA identifies a product positive through surveillance sampling? What should I do if FDA believes produce from my growing operation or commercial cooler is implicated in an outbreak?

The answer to both of these questions is the same—a firm should proceed the same way if there is a product positive and/or if FDA otherwise believes product from your growing operation/ cooler is implicated in an outbreak.

When pathogens are identified through sampling assignments or through any other means (e.g., internal testing), growers, shippers, and handlers should conduct their own root cause analyses and investigations to determine how the contamination likely occurred and then implement appropriate prevention and verification measures. In particular, FDA expects growers, shippers, and handlers to identify possible sources of contamination and possible routes of contamination. If the positive was identified via a sampling assignment, growers, shippers, and handlers should not wait for further communications from FDA, or for FDA to follow-up or revisit the farm or cooler—firms should plan on conducting root cause analyses/investigations and implementing corrective and preventive actions regardless of whether the agency is involved in these actions.

Growers, shippers, and handlers should be prepared for follow-up activities by FDA including visits and questions regarding the preventive measures put in place to prevent contamination and their effectiveness. FDA has broad investigational authority under 21 USC § 372 to conduct its own investigation via inspections and collection of additional or other samples. Farms also

should be prepared for inspections for compliance with the Produce Safety Rule (See Question #9 below).

Last, growers, shippers, and handlers also should be prepared for enhanced supply chain oversight from customers. For example, customers may require additional supply chain audits or revise current audits to address potential sources and routes of contamination (e.g., adjacent land use) or require additional testing. Similarly, customers may modify their product specifications or impose additional traceability recordkeeping requirements on supply chain partners, including growers, shippers, and handlers.

## 9. What should I expect if FDA conducts an inspection for compliance under the Produce Safety Rule?

FDA or a state regulatory agency may conduct an inspection of a growing operation (farm) for a variety of reasons, such as a routine or follow-up inspection. FDA created a Fact Sheet detailing what growing operations should expect during a Produce Safety Rule inspection.[11] At a high level, grower operations can expect the following if subject to one of these inspections:

**Scheduling an Announced Inspection.** For announced inspections, the investigator will call the most responsible person to schedule the inspection. During the pre-inspection call, the investigator will ask questions and use the FDA decision tree entitled "Standards for Produce Safety, Coverage and Exemptions/Exclusions" to make a preliminary determination about whether the Produce Safety Rule applies.[12] For purposes of this manual, we assume grower operations are subject to the Produce Safety Rule.[13]

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11 FDA Fact Sheet, Produce Safety Rule, ""What to Expect of a Regulatory Inspection" Informational Handout for Farmers," https://www.fda.gov/media/124328/download.

12 See Standards for Produce Safety, Coverage and Exemptions for 21 Part 112 (Nov. 13, 2015), https://www.fda.gov/media/94332/download.

13 If, however, during the pre-call your farm is determined to be eligible for a qualified exemption or your produce is determined to be eligible for the commercial processing exemption, the inspector will review records that support this status.

If the grower operation is covered by the Produce Safety Rule, the investigator will schedule an inspection date, typically within five (5) business days (note, this time may be longer depending on the status of COVID-19 in your geographic region).

**Scheduling an Unannounced Inspection.** While most inspections will be announced, there are some circumstances in which unannounced inspections may be conducted:

1. If there have been produce safety issues in the past and the issues have not been corrected;
2. If a follow-up inspection is needed and an unannounced inspection may work best to observe the necessary changes being made;
3. If your operation is unresponsive (no contact within five (5) business days after reasonable contact attempts have been made) or is unwilling to set a date for the inspection; or
4. In response to a complaint, recall, or foodborne outbreak investigation.

**The Day of the Inspection.**

Grower operations should follow many of the same practices as outlined under Section D.3. above. The procedures below follow closely with Section D.3. but are catered to appropriate actions while FDA conducts inspections (versus a sampling assignment).

**After Notification and Prior to Arrival.**

- If you become aware that FDA is coming, to the extent possible, engage best inventory management practices to ensure there are no "partial" lots that may be sampled that are in commerce. This will allow you to "hold" any product that is subject to sampling.
- Ensure practices, SOPs, training, and any other requirements under the Produce Safety Rule are current, accurate, and able to be reviewed by FDA.

**FDA Arrival.**

- When the investigator arrives, security, a receptionist, or other first point of contact should welcome the investigator as any other business visitor and treat the investigator with courtesy.
- If there are COVID protocols upon entry to the area (e.g., temperature check, routine question forms), inform the investigator of these protocols, request the ability to complete them, and complete them.[14]
- The entry point of contact should notify the manager on duty and/or other person(s) assigned to greet and accompany the investigator throughout the visit.

**Engagement with Investigator.**

- Have the senior manager or other responsible person **greet the investigator promptly**. Do

14 As noted above, there are no FDA statutory references or regulations requiring investigators to follow a firm's COVID-19 policies and procedures. However, FDA has issue numerous guidances and made statements alluding to the importance of appropriate COVID-19 considerations, and all employees are expected to act respectfully and professionally. See Section D.3. and D.4. for additional information. If an investigator refuses to comply with COVID-19 protocols, contact Western Growers or legal counsel. Also note the refusal in the post-sampling detailed report.

not keep FDA waiting for more than 20 minutes.[15]

- The FDA investigator who arrives to conduct the inspection will present his or her agency credentials. Note, some FDA investigators may be in uniform when they arrive. They are members of the Commissioned Corps of the U.S. Public Health Service (USPHS)—professionals dedicated to protecting and promoting public health and safety. They are required to be in uniform when on duty. Though their uniform is similar to military dress, these health professionals are not members of the armed forces and work only in the interest of health promotion and disease prevention.
  - The investigator may at this point (or any other point throughout) give you a "Notice of Inspection" (FDA Form 482). For Produce Safety Rule inspections, an investigator may not present the Notice of Inspection. If he/she presents credentials with the designation "200-D" (these are criminal investigators) or if he/she presents a FDA Form 482c (Form 482c Request for Records) contact legal counsel.
- **Request an initial interview (if not offered).** Ask the investigator to explain the purpose for and scope of the inspection and activities to be conducted during the inspection.
- **Explain the company's policies and procedures regarding visitors/inspections.** For example, investigators are expected to follow company policy regarding GMPs and COVID-19, and obey all safety signs and precautions. Discuss the company's policy regarding the use of photographic equipment.
- Ask the investigator to direct any questions to the company's designated representatives accompanying the investigator. These representatives should be persons knowledgeable in growing, harvesting, packing and holding activities, preferably the person responsible for produce safety.

15 As noted above, 20 minutes is not a required timeframe, but illustrates the importance of prompt response and attitude towards the inspection generally. Waiting longer than 20 minutes to greet the investigator may be perceived negatively, and the firm should plan on doing approaching the visit in a cordial and smooth manner.

**Conducting the Inspection.**

- **Knowledgeable, trained, and previously designated employees should accompany the investigator at all times.** No exceptions. If there is more than one investigator, each must be accompanied by a designated employee, preferably two. Questions and requests for information should be directed to the designated employees.
- During the inspection, the investigator will observe your growing operation. The investigator may ask questions about farming practices and operations that cannot be observed during the inspection. Growing operations can expect investigators to take notes (may take pictures depending on the operation's policies), may collect samples, and will review and may copy records, such as training and biological soil amendment records.
- **One of the designated employees accompanying the investigator should take copious notes of the entire visit** including questions asked and answered, observations and comments made, and from where samples are taken (if taken). Only answer questions that are asked – do not offer extra information.
- If the investigator makes an observation or otherwise notes a non-compliance, the responsible persons should make reasonable efforts to immediately rectify the non-compliance via corrections. Responsible persons should document and confirm the corrections are sufficient for purposes of the deviation(s).
- If the investigator collects samples, ask the investigator why he/she is collecting particular samples, which tests are to be performed, and when results are expected.
- After samples are collected or the inspection is completed, the investigator will provide a receipt (FDA Form 484) for all samples collected. (Note, this form may not be provided if a Form 482 is not issued, but you may request one).
- **All finished product that is sampled should be placed on hold pending results.** Communicate to the investigator that all products sampled will be held pending results provided by FDA.
- **At the time of the inspection or during the exit interview, request the FDA investigator to provide a written report of the sample analysis via Form 1551.**

**Post-Inspection.**

- **The investigator will conduct an exit interview with the responsible persons and other appropriate facility employees. If the investigator does not prompt the exit interview, the operation should request one.**
- The investigator will go over any regulatory concerns and findings via FDA Form 4056 Produce Farm Inspection Observations (See Appendix 5).
  - If the operation is able to make corrections during the inspection, the investigator will document them.
  - If the deficiency cannot be corrected during the inspection, the inspector or investigator will note the Observation on Form 4056.

- This is also an opportunity for the site to ask questions of the investigator.
- ***Do not sign or initial any affidavits.*** If the investigator insists, forward the unsigned affidavit to legal counsel. Do not sign any affidavits or otherwise confirm/deny any statements without the clear consent from legal counsel.

**After the FDA Inspection.**

- **After the investigator leaves, prepare a detailed report of the inspection for internal purposes.** If in accordance with company policy and/or if approved by legal counsel, this report can be submitted to all relevant operational contacts that may be affected by the inspection, as well as to Western Growers.
- This report should contain:
  - Date(s) and time(s) of inspection
  - Investigator's name and credentials
  - Company personnel accompanying the investigator(s)
  - Details on the inspection, including any samples taken and testing to be performed
  - Questions asked by the investigator and answers provided
  - Whether photographs were taken and areas photographed
  - Observations and comments by the investigator
  - Records requested, reviewed and copied
- This internal report should include copies of the Form FDA 482, 482c, 484, 1551, or 4056; images of any photographs taken; and, a list of all information provided to the investigator (whether oral or written) including documents or records provided.

**Additional Potential Resource.**

FDA issued a Field Management Directive (FMD) 152, *Produce Safety Dispute Mitigation and Resolution Procedures*, which outlines a process that can be used to resolve disputes between agencies with Product Safety regulatory authority.[16] The document does not address disputes between a regulator and the industry.

However, the document includes pre-dispute procedures and protocol, which include FDA and states collaborating to promote uniformity and consistency of inspections. While the document is directed to FDA inspectional staff, growing operations should review the documents as it provides additional insight into what they can expect during a Produce Safety Rule inspection.

16 FDA FMD-152 Produce Safety Dispute Mitigation and Resolution Procedures (Jan. 13, 2019), https://www.fda.gov/media/124312/download.

## F. APPENDICES

Appendix 1 – FDA Form 482

Appendix 2 – Form 482c Request for Records

Appendix 3 – FDA Form 484 Receipt for Samples

Appendix 4 – Form 1551 Report of Sample Analysis

Appendix 5 – Form 4056 Produce Farm Inspection Observations

## Appendix 1 – FDA Form 482

**EXHIBIT 5-1** **INVESTIGATIONS OPERATIONS MANUAL 2021**

### 5-1 FORM FDA 482 NOTICE OF INSPECTION

| | |
|---|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION | 1. DISTRICT OFFICE ADDRESS & PHONE NO.<br>1431 Harbor Bay Parkway<br>Alameda, CA 94502<br>(510)337-6700 |

| | | | |
|---|---|---|---|
| TO | 2. NAME AND TITLE OF INDIVIDUAL<br>Helen E. Castro, President | | 3. DATE<br>07/28/13 |
| | 4. FIRM NAME<br>ABC Bread Company | 5. HOUR | 7:30 a.m. |
| | 6. NUMBER AND STREET<br>579 Main Street | | p.m. |
| | 7. CITY AND STATE & ZIP CODE<br>Richmond, CA 94805 | | 8. PHONE NO. & AREA CODE<br>(510)123-4567 |

**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)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]**

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 business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

| 9. SIGNATURE(S) *(Food and Drug Administration Employee(s))* | 10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))* |
|---|---|
| *Sidney H. Rogers* | 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)*

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). 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. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) 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 judgment, indicate that any food, drug, device, tobacco product, 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.

Sec. 704. (c) 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.

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 procedures 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 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) 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) (4) 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 whom such 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. 351(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

*(Continued on Page 3)*

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 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 358(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)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(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 2 – Form 482c Request for Records

### 5-10 FORM FDA 482c NOTICE OF INSPECTION – REQUEST FOR RECORDS

| | | |
|---|---|---|
| **DEPARTMENT OF HEALTH AND HUMAN SERVICES**<br>FOOD AND DRUG ADMINISTRATION | | 1. DISTRICT OFFICE ADDRESS & PHONE NO. |
| TO | 2. NAME AND TITLE OF INDIVIDUAL | 3. DATE |
| | 4. FIRM NAME | 5. HOUR a.m. / p.m. |
| | 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)][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][2] and Title 21 Code of Federal Regulations, Section 1.361[3].**

| 9. SIGNATURE *(Food and Drug Administration Employee(s))* | 10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))* |
|---|---|
| | |

**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:**

[1]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(i) 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(j). 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.

[2]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, packing, 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.

[3]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 374(a)) 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.

**FORM FDA 482c (4/12)** **NOTICE OF INSPECTION - REQUEST FOR RECORDS**

## Appendix 3 – FDA Form 484 Receipt for Samples

**INVESTIGATIONS OPERATIONS MANUAL 2021** **EXHIBIT 4-5**

### 4-5 RECEIPT FOR SAMPLES - FDA 484

| | |
|---|---|
| **DEPARTMENT OF HEALTH AND HUMAN SERVICES**<br>FOOD AND DRUG ADMINISTRATION | 1. DISTRICT ADDRESS & PHONE NUMBER<br>850 Third Avenue<br>Brooklyn, NY 11232<br>718-340-7000 |

| 2. NAME AND TITLE OF INDIVIDUAL | 3. DATE | 4. SAMPLE NUMBER |
|---|---|---|
| Richard A. Frost, General Manager | 12-4-06 | 25563 |

| 5. FIRM NAME | 6. FIRM'S DEA NUMBER |
|---|---|
| Quality Wholesale Drug Co. | AB3632918 |
| **7. NUMBER AND STREET** | **8. CITY AND STATE** *(Include Zip Code)* |
| 3146 Front Street | Brooklyn, NY 11232 |

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(**NOTE**: *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.*)

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

| 10. SAMPLES WERE | 11. AMOUNT RECEIVED FOR SAMPLE | 12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)* |
|---|---|---|
| ☐ PROVIDED AT NO CHARGE<br>☒ PURCHASED<br>☐ BORROWED *(To be returned)* | ☒ CASH ☐ BILLED<br>☐ VOUCHER ☐ CREDIT CARD<br>$15.00 | Richard A. Frost |

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

FORM FDA 484 (3/06) PREVIOUS EDITION MAY BE USED RECEIPT FOR SAMPLES PAGE 1 OF 1 PAGES

PSC Media Arts (301) 443-1090 EF

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

## REPORT OF SAMPLE ANALYSIS

FROM: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

☞ *REFERENCE TO THE REPORT OF ANALYSIS IS PROHIBITED IN LABELING, ADVERTISING, OR OTHER SALES PROMOTION.*

FDA SAMPLE NUMBER

TO:

DATE SAMPLE COLLECTED

COLLECTING INSPECTOR

DESCRIPTION OF SAMPLE

ESTABLISHMENT WHERE SAMPLE COLLECTED (*If other than addressee*)

| REASON FOR SUBMISSION OF REPORT | ☐ SECTION 704 *(d)* OF THE FEDERAL "FOOD, DRUG, AND COSMETIC ACT"<br>☐ OTHER *(Specify)*: _____ |
|---|---|

REPORT OF ANALYSIS

## Appendix 4 – Form 1551 Report of Sample Analysis

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

### REPORT OF SAMPLE ANALYSIS

| | |
|---|---|
| FROM: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES | ☞ *REFERENCE TO THE REPORT OF ANALYSIS IS PROHIBITED IN LABELING, ADVERTISING, OR OTHER SALES PROMOTION.* |
| TO: | FDA SAMPLE NUMBER |
| | DATE SAMPLE COLLECTED |
| | COLLECTING INSPECTOR |

DESCRIPTION OF SAMPLE

ESTABLISHMENT WHERE SAMPLE COLLECTED (*If other than addressee*)

| | |
|---|---|
| REASON FOR SUBMISSION OF REPORT | ☐ SECTION 704 *(d)* OF THE FEDERAL "FOOD, DRUG, AND COSMETIC ACT"<br>☐ OTHER *(Specify)*: _____ |

REPORT OF ANALYSIS

| SIGNATURE | TITLE | DATE |
|---|---|---|
| | | |

**FORM FDA 1551 (5/11)** PSC Publishing Services (301) 443-6740 EF

## Appendix 5 – Form 4056 Produce Farm Inspection Observations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FDA

### PRODUCE FARM INSPECTION OBSERVATIONS

| Name of State and Department *(if acting under commission with FDA)* | DISTRICT OFFICE ADDRESS |
|---|---|
| | |

| DISTRICT OFFICE PHONE NUMBER | DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|---|
| | | |

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED *(Most responsible individual present) TO:*

FARM NAME *(include business name, if different)*

OWNER/OPERATOR

| FARM MAILING ADDRESS | FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS (*e.g., location identifiers such as GPS coordinates)* |
|---|---|
| | |

| TYPE OF INSPECTION: | CROPS OBSERVED DURING INSPECTION |
|---|---|
| ☐ Initial ☐ Routine ☐ Follow-up ☐ For-cause<br>☐ Other *(please specify)* | |

This form lists factual observations made by the FDA representative(s) during the inspection of the farm's operation.

**This is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule *(21 CFR Part 112)* or any other legal requirement.**

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the topic area listed below that, in the representatives' judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farm's operation during an inspection, so a topic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirements related to that topic area.

Representatives of the regulatory agency should discuss all observations with the management of the farm or their representative as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when this form is issued. Discussion should include those observations which may be written on the form and those that will only be discussed with management during the closeout meeting. This form should be issued during the exit conference of all produce inspections, including when no observations have been recorded.

The farm may use this opportunity to ask questions about the observations or to request clarification. If the farm has implemented, or plans to implement, corrective action in response to an observation, this may be discussed with the representatives of the regulatory agency during the inspection. Representatives of the regulatory agency should annotate the form, as applicable, with any completed or promised corrections discussed during the inspection. FDA representatives are encouraged to verify the farm's completed corrective actions during the inspection as long as the verification does not unreasonably extend the duration of the inspection. Inclusion of annotations regarding corrective actions does not signify any conclusion by the regulatory agency regarding the sufficiency of the actions.

**FORM FDA 4056 (01/19)** **Page 1 of 9** PSC Publishing Services (301) 443-6740 EF

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

If you have any questions, please contact the regulatory agency at the phone number and address above.

Representatives of the regulatory agency should record observations consistent with procedures established for conduct of inspections, including additional instructions that appear in Chapter 5 of the IOM, available at https://www.fda.gov/ICECI/Inspections/IOM.

**REPORTABLE OBSERVATIONS MADE DURING THE INSPECTION**

Representatives of the regulatory agency should check one of the following options. As noted above, this is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.

☐ During an inspection of the operation (I) (we) did not observe any conditions and/or practices to be reported on this form.

☐ During an inspection of the operation (I) (we) observed the following conditions and/or practices as described below.

**Personnel Qualifications and Training *(21 CFR Part 112, Subpart C)***

1. §§ 112.21 and 112.22: Qualifications and training for personnel who handle (contact) covered produce or food contact surfaces
   ☐ Observation ☐ Corrective action taken
   Description:
2. § 112.23: Assignment or identification of supervisors
   ☐ Observation ☐ Corrective action taken
   Description:
3. § 112.30: Record-keeping
   ☐ Observation ☐ Corrective action taken
   Description:

**Health and Hygiene *(21 CFR Part 112, Subpart D)***

4. § 112.31: Measures to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance
   ☐ Observation ☐ Corrective action taken
   Description:
5. § 112.32: Hygienic practices of personnel
   ☐ Observation ☐ Corrective action taken
   Description:

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

6. § 112.33: Measures to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance

☐ Observation ☐ Corrective action taken

Description:

**Agricultural Water *(21 CFR Part 112, Subpart E)***

7. § 112.41: Quality of agricultural water

☐ Observation ☐ Corrective action taken

Description:

8. § 112.42: Agricultural water sources, water distribution system, and pooling of water

☐ Observation ☐ Corrective action taken

Description:

9. § 112.43: Treating agricultural water

☐ Observation ☐ Corrective action taken

Description:

10. § 112.44: Microbial quality criteria applicable to agricultural water used for certain intended uses

☐ Observation ☐ Corrective action taken

Description:

11. § 112.45: Corrective measures if agricultural water does not meet requirements of § 112.41 or § 112.44.

☐ Observation ☐ Corrective action taken

Description:

12. §§ 112.46 and 112.47: Testing agricultural water that is subject to the requirements of § 112.44.

☐ Observation ☐ Corrective action taken

Description:

13. § 112.48: Water that is used during harvest, packing, and holding activities

☐ Observation ☐ Corrective action taken

Description:

14. § 112.50: Record-keeping

☐ Observation ☐ Corrective action taken

Description:

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

**Biological Soil Amendments of Animal Origin and Human Waste *(21 CFR Part 112, Subpart F)***

15. § 112.52: Handling, conveyance, and storage of biological soil amendments of animal origin
☐ Observation ☐ Corrective action taken
Description:

16. § 112.53: Use of human waste
☐ Observation ☐ Corrective action taken
Description:

17. §§ 112.51, 112.54, 112.55, and 112.56: Determining status of biological soil amendment of animal origin; acceptable treatment processes; applicable microbial standards for such treatment processes; and, application requirements and minimum application intervals for biological soil amendments of animal origin
☐ Observation ☐ Corrective action taken
Description:

18. § 112.60: Record-keeping
☐ Observation ☐ Corrective action taken
Description:

**Domesticated and Wild Animals *(21 CFR Part 112, Subpart I)***

19. § 112.83: Measures related to grazing animals, working animals, or animal intrusion
☐ Observation ☐ Corrective action taken
Description:

**Growing, Harvesting, Packing, and Holding Activities *(21 CFR Part 112, Subpart K)***

20. § 112.111: Measures related to growing, harvesting, packing, or holding both covered and excluded produce
☐ Observation ☐ Corrective action taken
Description:

21. § 112.112: Measures to be taken immediately prior to and during harvest activities
☐ Observation ☐ Corrective action taken
Description:

22. § 112.113: Handling harvested covered produce
☐ Observation ☐ Corrective action taken
Description:

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

23. § 112.114: Disposition of dropped covered produce
☐ Observation ☐ Corrective action taken
Description:

24. § 112.115: Measures related to packaging covered produce
☐ Observation ☐ Corrective action taken
Description:

25. § 112.116: Measures related to food-packing (including food-packaging) material
☐ Observation ☐ Corrective action taken
Description:

**Equipment, Tools, Buildings, and Sanitation *(21 CFR Part 112, Subpart L)***

26. § 112.123: Equipment and tools
☐ Observation ☐ Corrective action taken
Description:

27. § 112.124: Instruments and controls used to measure, regulate, or record
☐ Observation ☐ Corrective action taken
Description:

28. § 112.125: Equipment used in the transport of covered produce
☐ Observation ☐ Corrective action taken
Description:

29. § 112.126: Buildings
☐ Observation ☐ Corrective action taken
Description:

30. § 112.127: Domesticated animals in and around a fully-enclosed building
☐ Observation ☐ Corrective action taken
Description:

31. § 112.128: Pest control in buildings
☐ Observation ☐ Corrective action taken
Description:

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

32. § 112.129: Toilet facilities
☐ Observation ☐ Corrective action taken
Description:

33. § 112.130: Hand-washing facilities
☐ Observation ☐ Corrective action taken
Description:

34. § 112.131: Control and disposal of sewage
☐ Observation ☐ Corrective action taken
Description:

35. § 112.132: Control and disposal of trash, litter, and waste
☐ Observation ☐ Corrective action taken
Description:

36. § 112.133: Plumbing
☐ Observation ☐ Corrective action taken
Description:

37. § 112.134: Control of animal excreta and litter from domesticated animals
☐ Observation ☐ Corrective action taken
Description:

38. § 112.140: Record-keeping
☐ Observation ☐ Corrective action taken
Description:

**Sprouts *(21 CFR Part 112, Subpart M)***
☐ Check here if entity does not engage in growing, harvesting, packing, and/or holding of sprouts

39. § 112.142: Seeds or beans used to grow sprouts
☐ Observation ☐ Corrective action taken
Description:

40. § 112.143(a): Fully-enclosed buildings
☐ Observation ☐ Corrective action taken
Description:

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

**Continuation Sheet**

Additional Observations and/or Comments

FARM NAME *(include business name, if different)*

| DATE(S) OF INSPECTION | FEI NUMBER |
|---|---|
| | |

**Continuation Sheet**

Additional Observations and/or Comments

Continue

| FARM NAME *(include business name, if different)* | |
|---|---|
| DATE(S) OF INSPECTION | FEI NUMBER |

The observations of conditions and practices listed on 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 applicable laws and regulations.

Any reference to this report in labeling, advertising, or other sales promotion by any person is prohibited under Section 301(n) of the Federal Food, Drug and Cosmetic Act.

WESTERN GROWERS®

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