Preparing for a US FDA Food Facility Inspection

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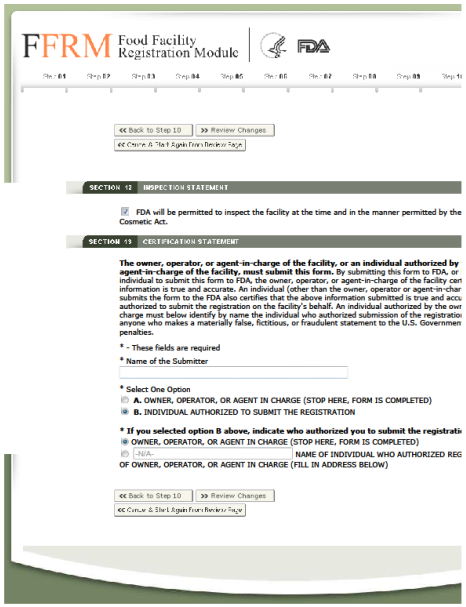
Seminar Overview

- Why me?
- The Process
- How to Prepare
- Questions & Answers

Why Me and Why Now?

- Once registered with US FDA, you are under their “inspectional jurisdiction”
- In your Food Facility Registration, you “consent” to FDA inspection



Why Me and Why Now?

- Facility's risk profile:
  - Commodity specific
  - Manufacturing process
  - Compliance history
- Could be as simple as you are located near another facility FDA will inspect

High Risk Foods

- Acidified Foods
- Low-Acid Foods
- Seafood
- Custard Filled Bakery Product
- Modified Atmosphere Packaging
- Dairy Products
- Soft; Semi-soft; Soft Ripened Cheese and Cheese Products
- Unpasteurized Juices
- Sprouts Ready-to-Eat
- Fresh Fruits and Vegetables
- Processed Fruits and Vegetables
- Spices
- Shell Eggs
- Sandwiches
- Prepared Salads
- Infant Formula
- Others

Why does FDA Inspect?

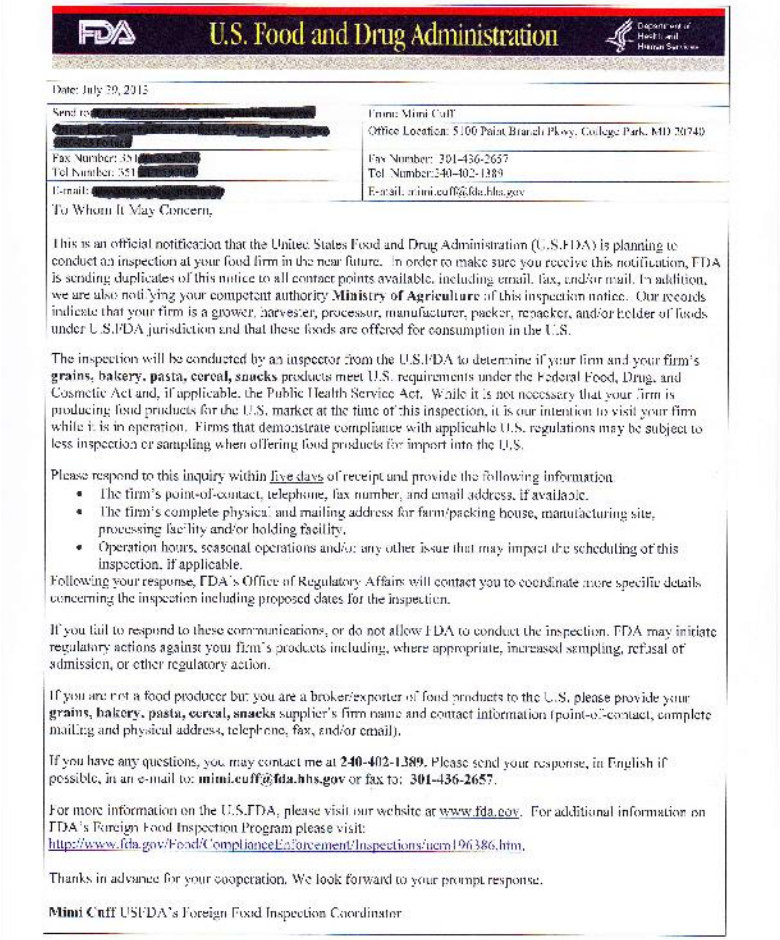
- FDA inspections are designed to:
  - Identify food safety problems before products arrive in the U.S.
  - Determine compliance status of facilities and ensure they meet the requirements under the Food, Drug and Cosmetic Act
  - Help FDA make admissibility decisions

Inspection Process: "Notice of Inspection"

- Notice is sent by email to registrant's email as indicated in the food facility's FDA registration
- Notice is also sent to U.S. Agent via email
- Email will come from: @fda.hhs.gov

Inspection Process: "Notice of Inspection" (hand-out)

- In English:



FDA U.S. Food and Drug Administration — Department of Health and Human Services

Date: July 29, 2015

Send to: [redacted]
Fax Number: 35[redacted]
Tel Number: 351[redacted]
E-mail: [redacted]

From: Mimi Cuff
Office Location: 5100 Paint Branch Pkwy, College Park, MD 20740
Fax Number: 301-436-2657
Tel Number:240-402-1389
E-mail: mimi.cuff@fda.hhs.gov

To Whom It May Concern,

This is an official notification that the United States Food and Drug Administration (U.S.FDA) is planning to conduct an inspection at your food firm in the near future. In order to make sure you receive this notification, FDA is sending duplicates of this notice to all contact points available, including email, fax, and/or mail. In addition, we are also notifying your competent authority **Ministry of Agriculture** of this inspection notice. Our records indicate that your firm is a grower, harvester, processor, manufacturer, packer, repacker, and/or holder of foods under U.S.FDA jurisdiction and that these foods are offered for consumption in the U.S.

The inspection will be conducted by an inspector from the U.S.FDA to determine if your firm and your firm's **grains, bakery, pasta, cereal, snacks** products meet U.S. requirements under the Federal Food, Drug, and Cosmetic Act and, if applicable, the Public Health Service Act. While it is not necessary that your firm is producing food products for the U.S. market at the time of this inspection, it is our intention to visit your firm while it is in operation. Firms that demonstrate compliance with applicable U.S. regulations may be subject to less inspection or sampling when offering food products for import into the U.S.

Please respond to this inquiry within five days of receipt and provide the following information:

- The firm's point-of-contact, telephone, fax number, and email address, if available.
- The firm's complete physical and mailing address for farm/packing house, manufacturing site, processing facility and/or holding facility.
- Operation hours, seasonal operations and/or any other issue that may impact the scheduling of this inspection, if applicable.

Following your response, FDA's Office of Regulatory Affairs will contact you to coordinate more specific details concerning the inspection including proposed dates for the inspection.

If you fail to respond to these communications, or do not allow FDA to conduct the inspection, FDA may initiate regulatory actions against your firm's products including, where appropriate, increased sampling, refusal of admission, or other regulatory action.

If you are not a food producer but you are a broker/exporter of food products to the U.S. please provide your **grains, bakery, pasta, cereal, snacks** supplier's firm name and contact information (point-of-contact, complete mailing and physical address, telephone, fax, and/or email).

If you have any questions, you may contact me at **240-402-1389.** Please send your response, in English if possible, in an e-mail to: **mimi.cuff@fda.hhs.gov** or fax to: **301-436-2657.**

For more information on the U.S.FDA, please visit our website at www.fda.gov. For additional information on FDA's Foreign Food Inspection Program please visit:
http://www.fda.gov/Food/ComplianceEnforcement/Inspections/ucm196386.htm.

Thanks in advance for your cooperation. We look forward to your prompt response.

Mimi Cuff USFDA's Foreign Food Inspection Coordinator

Inspection Process: "Notice of Inspection"

- Key Points:
  - 5 Days to Respond
  - Provide additional data
  - Refusal to respond or refusal to allow an inspection may cause "increased sampling, refusal of admission, or other regulatory action."

Inspection Process: "Factory Profile Information" Form (hand-out)

- Once you reply, FDA's Office of Regulatory Affairs will contact you:
  - May take days, weeks, or months (or never)
  - Coordinate inspection date
  - Ask you to complete and return a "Factory Profile Information" form to FDA
  - FDA will then come back with name of investigator, their flight info, ask you to make hotel reservations, and maybe even ask you to provide ground transportation.

Inspection Process: Day 1

- Inspection is typically 2 days
- Day 1:
  - Introductions
  - Opening Meeting
  - Quick Tour
  - Document Review

Inspection Process: Day 2

- Day 2:
  - Most time spent in factory
  - Closing meeting with management
  - Delivery of form “483” “Inspectional Observations”

Inspection Process

- Process Design:
  - Hazard Analysis
  - HACCP Plan
  - Food Safety Plan
  - Process Filing

- Process Delivery:
  - Training of personnel and suitability of equipment and facility to deliver the process
  - Post-process handling
- Process Monitoring and Documentation

Inspection Process: Personnel Requirements

- Disease Control
  - Illness, open lesions, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination
- Cleanliness
  - Outer garments, washing hands, unsecured jewelry, hair restraints, gloves, eating, etc.
- Education & Training
- Supervision

Inspection Process: Plant and Grounds

- Plant construction and design
  - Sufficient space for placement of equipment and storage of materials; separation of operations in which contamination is likely to occur; outdoor bulk storage; working space between equipment and walls; good repair of floor, walls, and ceiling
- Grounds
  - Removal of litter and waste; eliminating anything that may constitute an attractant, breeding place, or harborage for pests; adequate draining; proper maintenance

Inspection Process: Sanitary Operations and Controls

- Maintenance, cleaning and sanitizing
- Pest control
- Storage of toxic materials
- Water supply and Plumbing
- Toilet facilities
- Hand-washing facilities
- Sewage, rubbish and offal disposal

Inspection Process: Equipment and Utensils

- Design and construction
  - Seams
  - Surface finish
  - Cleanable
- Maintenance and calibration
  - Does it work?
  - Does it work properly?

Inspection Process: Warehousing and Distribution

- Storage Conditions
  - Facilitates proper rotation
  - Protection against deterioration or adulteration
  - Container integrity
  - Presence of insects and rodent damage
- Transportation
  - Protection against deterioration or adulteration
  - Presence of insects and rodent damage
- Distribution
  - Review of distribution and shipment records

Inspection Process: Records Review

- Employee Training
- Hazard Analysis and HACCP
- Sanitation Schedules
- Disposition of non-conforming product
- Equipment Maintenance & Calibration
- Labeling
- Pest Control

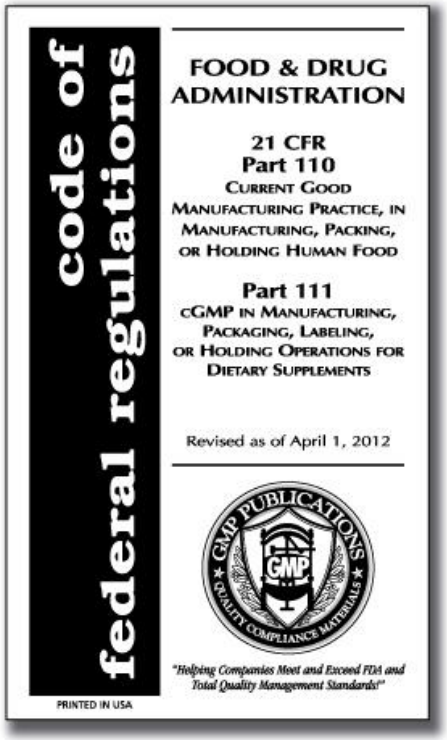
- Customer Complaints & Recalls
- Corrective Actions
- Internal & External Laboratory Test Results
- Production Records
- Distribution Records

Records Review – Product Specific

- Low Acid/ Acidified Foods:
  - Process filings, pH, Aw, thermal process, deviations, critical equipment, other critical factors
- Seafood HACCP:
  - Hazard analysis, critical control points, time/temperature requirements, monitoring activities, aquaculture drug residue, etc.

Inspection Process: Applicable FDA Regulations

- Federal Food, Drug, and Cosmetic Act
- Title 21 Code of Federal Regulation (not all inclusive):
  - Food Labeling (21 CFR 101)
  - Current GMP (21 CFR 110)
  - Dietary Supplement (21 CFR 111)
  - Low-Acid Foods (21 CFR 113)
  - Acidified Foods (21 CFR 114)
  - Juice HACCP (21 CFR 120)
  - Seafood HACCP (21 *CFR* 123)
  - Bottled Water (21 CFR 129)



Applicable FDA Regulations

- A single inspection may focus on multiple requirements
- For example, canned sardines may be inspected for compliance with:
  - Seafood HACCP (21 CFR 123)
  - Low Acid Canned Foods (21 CFR 1
  - Current GMP (21 CFR 110)
  - Food Labeling (21 CFR 101)

End of Inspection

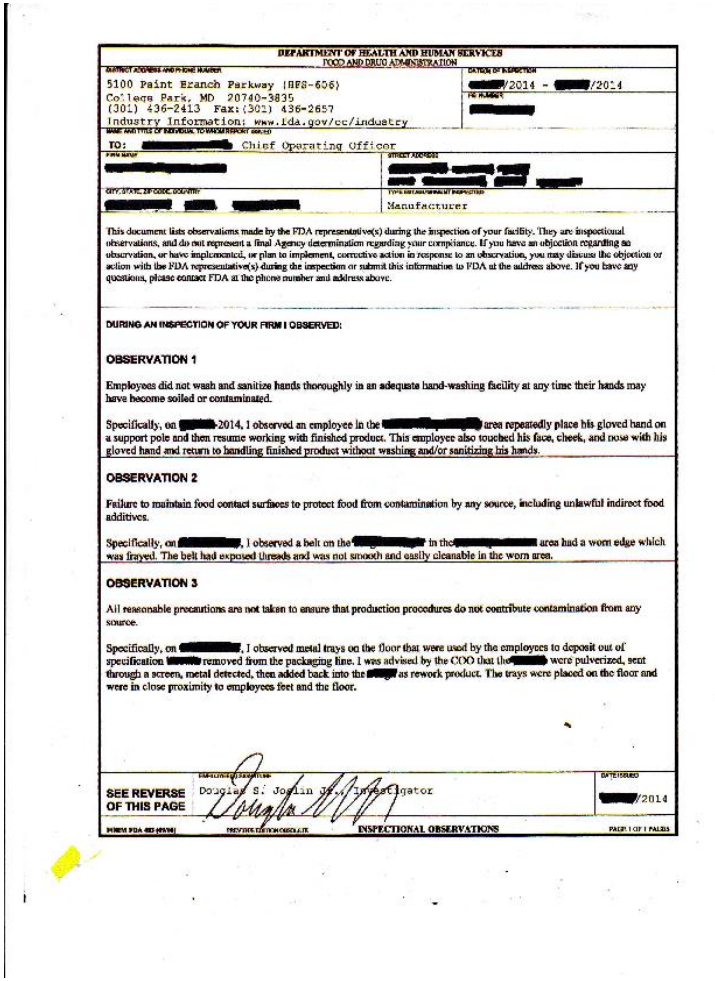
- Closing Meeting: Discussion of observations with management (CEO, Plant Manager, QA / QC Managers)
- Opportunity to have corrective actions of the deficiencies identified by FDA Investigator reviewed before they are added to the 483

End of Inspection (hand-out)

- Inspector departs with no observations

or…

- Form FDA 483 (Inspectional Observations) is issued
  - Outlines Observations / Deficiencies
  - Inspector departs



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

5100 Paint Branch Parkway (HFS-606)
College Park, MD 20740-3835
(301) 436-2413 Fax:(301) 436-2657
Industry Information: www.fda.gov/cc/industry

TO: [redacted] Chief Operating Officer

Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically, on [redacted]2014, I observed an employee in the [redacted] area repeatedly place his gloved hand on a support pole and then resume working with finished product. This employee also touched his face, cheek, and nose with his gloved hand and return to handling finished product without washing and/or sanitizing his hands.

OBSERVATION 2

Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives.

Specifically, on [redacted], I observed a belt on the [redacted] in the [redacted] area had a worn edge which was frayed. The belt had exposed threads and was not smooth and easily cleanable in the worn area.

OBSERVATION 3

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically, on [redacted], I observed metal trays on the floor that were used by the employees to deposit out of specification [redacted] removed from the packaging line. I was advised by the COO that the [redacted] were pulverized, sent through a screen, metal detected, then added back into the [redacted] as rework product. The trays were placed on the floor and were in close proximity to employees feet and the floor.

SEE REVERSE OF THIS PAGE

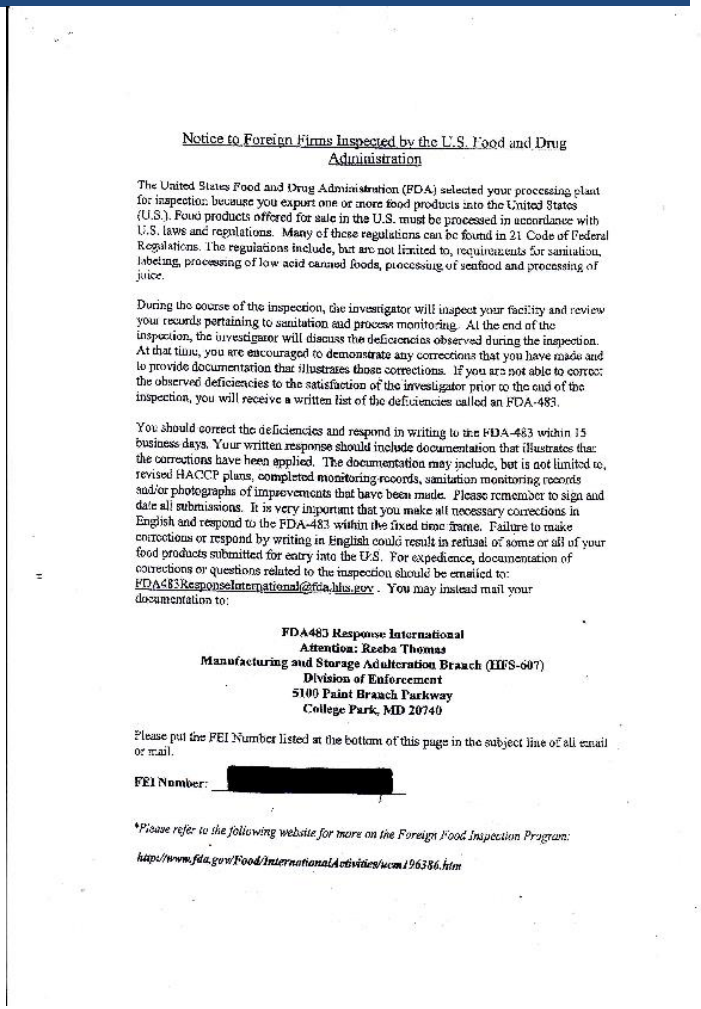
Douglas S. Joslin Jr., Investigator

[redacted]/2014

INSPECTIONAL OBSERVATIONS

End of Inspection

- 483 advises you have 15 days to respond to FDA to explain how you will correct the deficiencies
- Corrective actions should be substantiated by evidence (photos, receipts, etc)



Notice to Foreign Firms Inspected by the U.S. Food and Drug Administration

The United States Food and Drug Administration (FDA) selected your processing plant for inspection because you export one or more food products into the United States (U.S.). Food products offered for sale in the U.S. must be processed in accordance with U.S. laws and regulations. Many of these regulations can be found in 21 Code of Federal Regulations. The regulations include, but are not limited to, requirements for sanitation, labeling, processing of low acid canned foods, processing of seafood and processing of juice.

During the course of the inspection, the investigator will inspect your facility and review your records pertaining to sanitation and process monitoring. At the end of the inspection, the investigator will discuss the deficiencies observed during the inspection. At that time, you are encouraged to demonstrate any corrections that you have made and to provide documentation that illustrates those corrections. If you are not able to correct the observed deficiencies to the satisfaction of the investigator prior to the end of the inspection, you will receive a written list of the deficiencies called an FDA-483.

You should correct the deficiencies and respond in writing to the FDA-483 within 15 business days. Your written response should include documentation that illustrates that the corrections have been applied. The documentation may include, but is not limited to, revised HACCP plans, completed monitoring records, sanitation monitoring records and/or photographs of improvements that have been made. Please remember to sign and date all submissions. It is very important that you make all necessary corrections in English and respond to the FDA-483 within the fixed time frame. Failure to make corrections or respond by writing in English could result in refusal of some or all of your food products submitted for entry into the U.S. For expedience, documentation of corrections or questions related to the inspection should be emailed to: FDA483ResponseInternational@fda.hhs.gov . You may instead mail your documentation to:

FDA483 Response International
Attention: Reeba Thomas
Manufacturing and Storage Adulteration Branch (HFS-607)
Division of Enforcement
5100 Paint Branch Parkway
College Park, MD 20740

Please put the FEI Number listed at the bottom of this page in the subject line of all email or mail.

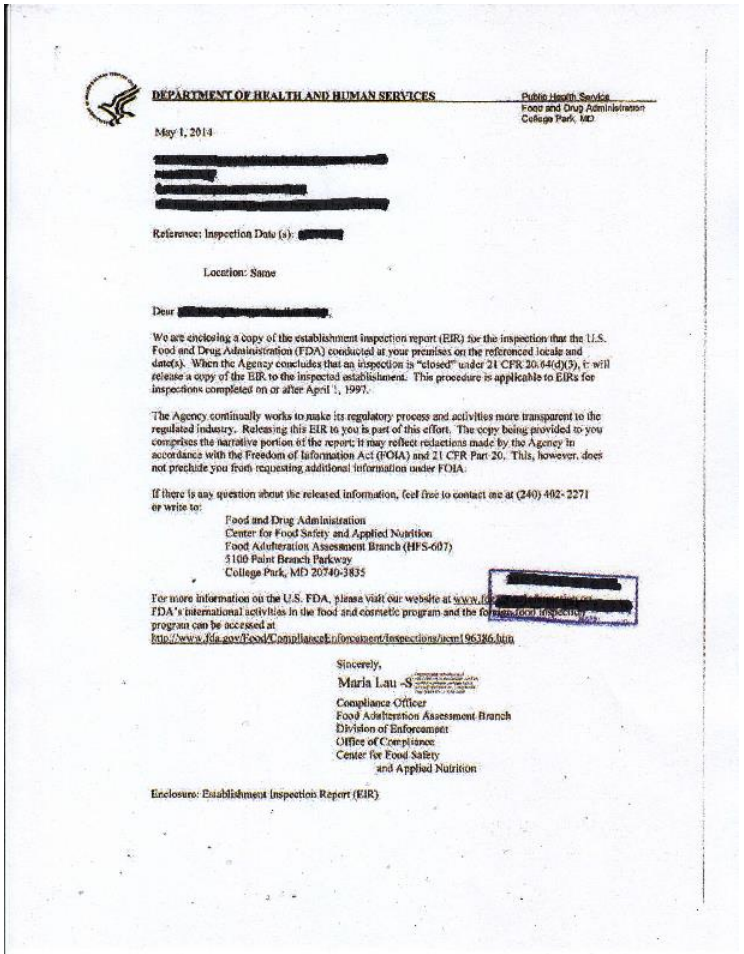
FEI Number: [redacted]

Please refer to the following website for more on the Foreign Food Inspection Program:

http://www.fda.gov/Food/InternationalActivities/ucm196386.htm

After the Inspection (hand-out)

- Facility responds to FDA 483
- FDA reviews response to FDA 483
- FDA issues an Establishment Inspection Report ("EIR")



DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service, Food and Drug Administration, College Park, MD

May 1, 2014

[redacted]

Reference: Inspection Date (s): [redacted]

Location: Same

Dear [redacted],

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at (240) 402- 2271 or write to:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Food Adulteration Assessment Branch (HFS-607)
5100 Paint Branch Parkway
College Park, MD 20740-3835

For more information on the U.S. FDA, please visit our website at www.[redacted]. FDA's international activities in the food and cosmetic program and the foreign food inspection program can be accessed at http://www.fda.gov/Food/ComplianceEnforcement/Inspections/ucm196386.htm

Sincerely,

Maria Lau -S

Compliance Officer
Food Adulteration Assessment Branch
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition

Enclosure: Establishment Inspection Report (EIR)

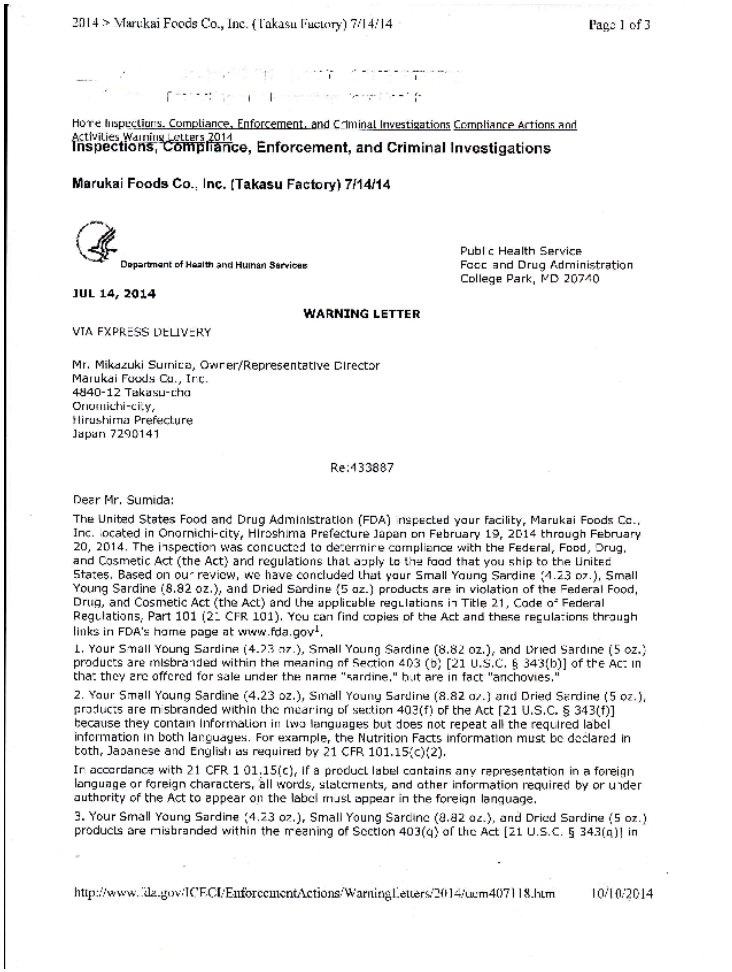
After the Inspection

- FDA will eventually classify the inspection:
  - No Action Indicated (NAI)
  - Voluntary Action Indicated (VAI) -
  - ***Official Action Indicated (OAI)***
- FDA discloses the final inspection classification in an online database

http://www.accessdata.fda.gov/scripts/inspsearch/

OAI Actions (hand-out)

- Warning Letter (which you could respond to) and perhaps a “Close Out Letter”
- Detentions at the port
- Registration suspension
- Re-inspection under FSMA



2014 > Marukai Foods Co., Inc. (Takasu Factory) 7/14/14 Page 1 of 3

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters 2014

Inspections, Compliance, Enforcement, and Criminal Investigations

Marukai Foods Co., Inc. (Takasu Factory) 7/14/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

JUL 14, 2014

WARNING LETTER

VIA EXPRESS DELIVERY

Mr. Mikazuki Sumida, Owner/Representative Director
Marukai Foods Co., Inc.
4840-12 Takasu-cho
Onomichi-city,
Hiroshima Prefecture
Japan 7290141

Re:433887

Dear Mr. Sumida:

The United States Food and Drug Administration (FDA) inspected your facility, Marukai Foods Co., Inc., located in Onomichi-city, Hiroshima Prefecture Japan on February 19, 2014 through February 20, 2014. The inspection was conducted to determine compliance with the Federal, Food, Drug, and Cosmetic Act (the Act) and regulations that apply to the food that you ship to the United States. Based on our review, we have concluded that your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.), and Dried Sardine (5 oz.) products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find copies of the Act and these regulations through links in FDA's home page at www.fda.gov[1].

1. Your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.), and Dried Sardine (5 oz.) products are misbranded within the meaning of Section 403 (b) [21 U.S.C. § 343(b)] of the Act in that they are offered for sale under the name "sardine," but are in fact "anchovies."

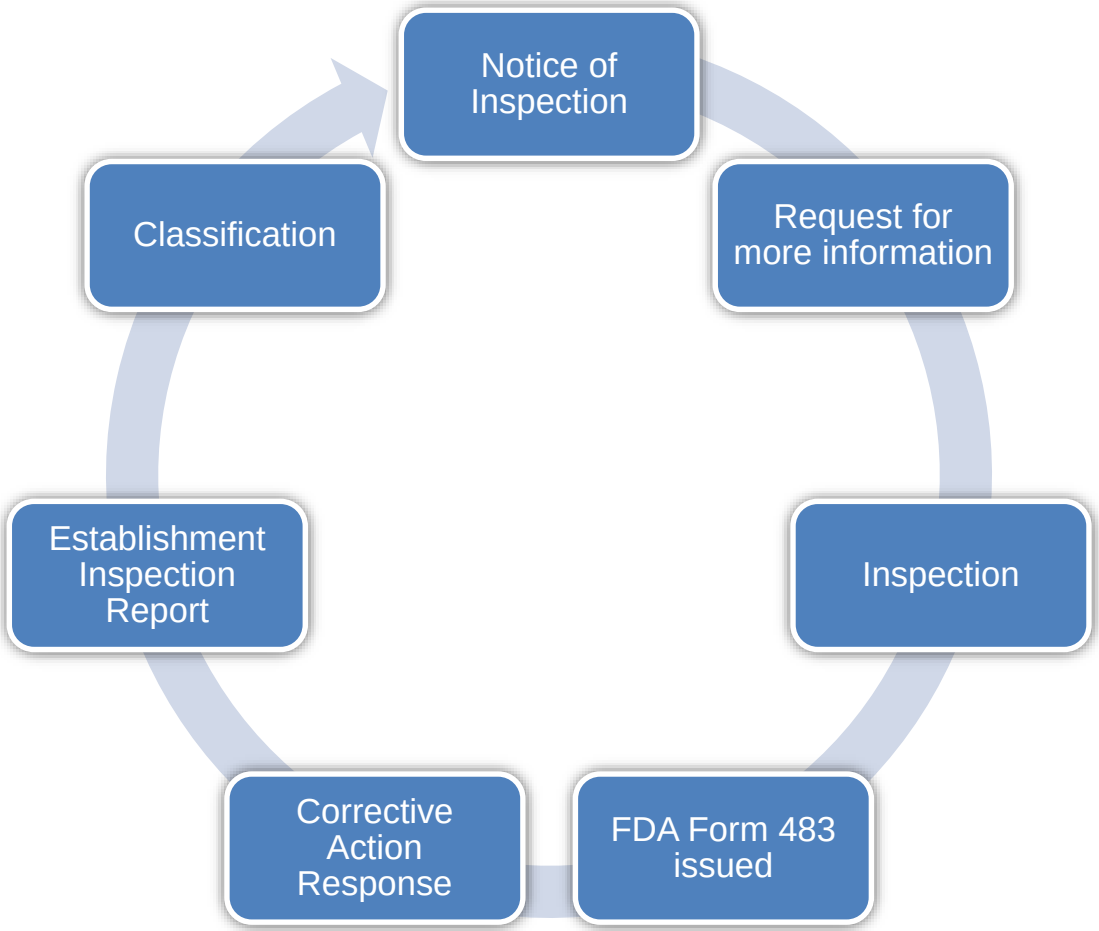
2. Your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.) and Dried Sardine (5 oz.), products are misbranded within the meaning of section 403(f) of the Act [21 U.S.C. § 343(f)] because they contain information in two languages but does not repeat all the required label information in both languages. For example, the Nutrition Facts information must be declared in both, Japanese and English as required by 21 CFR 101.15(c)(2).

In accordance with 21 CFR 101.15(c), if a product label contains any representation in a foreign language or foreign characters, all words, statements, and other information required by or under authority of the Act to appear on the label must appear in the foreign language.

3. Your Small Young Sardine (4.23 oz.), Small Young Sardine (8.82 oz.), and Dried Sardine (5 oz.) products are misbranded within the meaning of Section 403(q) of the Act [21 U.S.C. § 343(q)] in

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm407118.htm 10/10/2014

Inspection Process: Summary



Common Sense Tips

- Don’t try to cancel or reschedule the inspection just to avoid inspection (“We think it would be better next year”)
- Take the inspection serious: your export business could be at risk by refusing or “failing” an inspection
- Be courteous and professional with the inspector
- Don’t be offended or defensive of their findings: their job
- Do offer to correct deficiencies promptly, but be realistic in your promises and provide evidence to support the changes
- Don’t give gifts or other compensation even if small in nature: inspectors are not your friends

How can facilities prepare?

- Review and stay current with applicable FDA rules and regulations
- Ensure that food safety systems are current and validated, especially LACF processes
- Conduct internal audits and employee training, especially as outlined in your documents
- Consider a Registrar Corp “Mock FDA Inspection” or other third party consultative audits
- Review common findings before FDA arrives

http://www.fda.gov/ICECI/EnforcementActions/ucm326984.htm#foods

Questions?

Registrar Corp's Office in Europe
16 Rue Jean Marie Barre – Auray -France

Phone: +33-(0)-2-97-56-60-65
Fax: +33-(0)-2-72-68-57-24
Email: europe@registrarcorp.com

Web: www.registrarcorp.com