Anatomy of an FDA Food Inspection

Consumer Brands Association

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Objectives

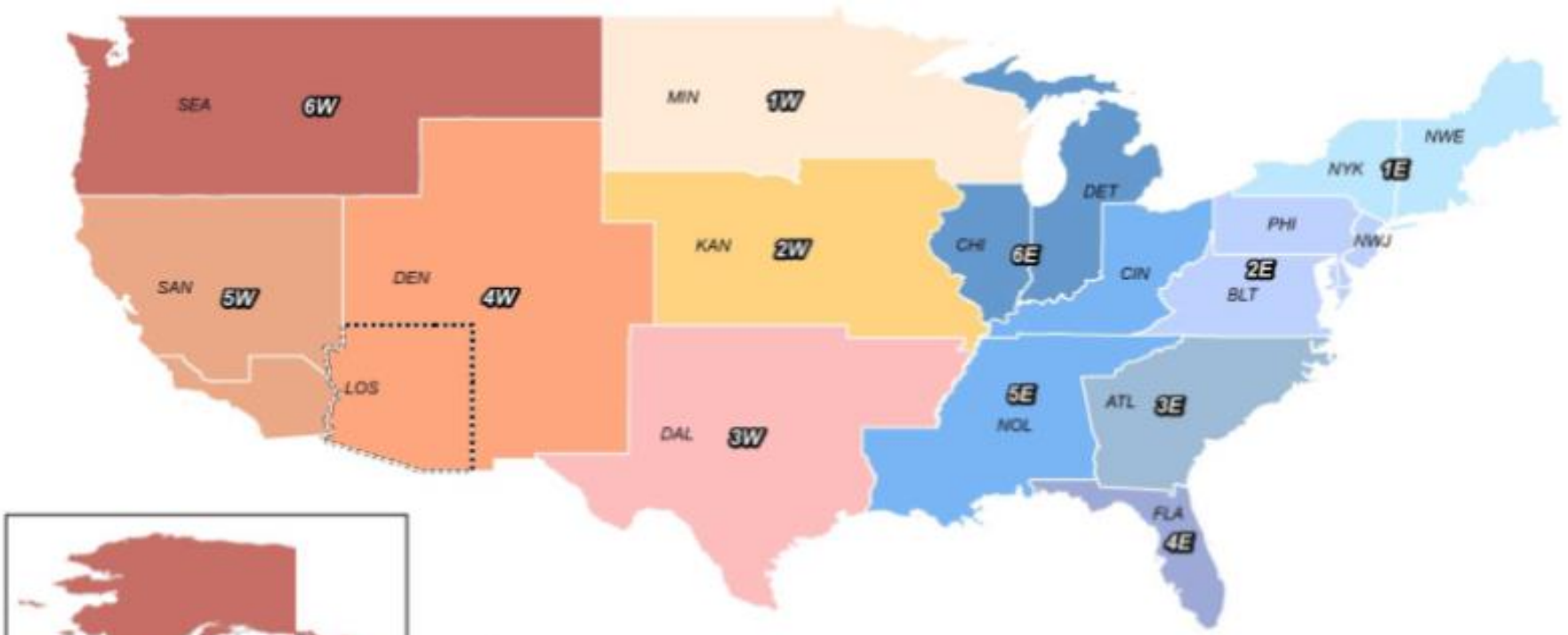
- Describe how establishments inspections are selected.
- Describe how FDA Consumer Safety Officers prepare for an inspection.
- Describe how FDA conducts an inspection.
- Discuss what happens after the inspection.

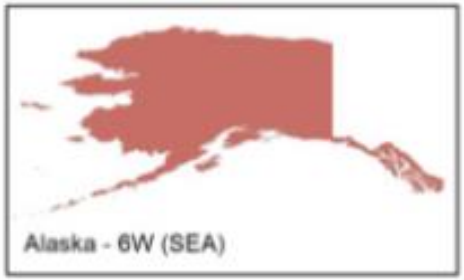
Office of Regulatory Affairs

The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts.

Office of Human and Animal Food Operations (OHAFO)

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS





HAF Program Divisions

- Division 1W (MIN)
- Division 2W (KAN)
- Division 3W (DAL)
- Division 4W (DEN, LOS)
- Division 5W (LOS, SAN)
- Division 6W (SEA)
- Division 1E (NWE, NYK)
- Division 2E (BLT, NWJ, PHI)
- Division 3E (ATL)
- Division 4E (FLA, SJN)
- Division 5E (CIN, NOL)
- Division 6E (CHI, DET)
- FDA Current Districts Boundaries
- Arizona State Boundaries

Source: ORA

Prepared by Office of Regulatory Affairs (ORA) Division of Planning, Evaluation & Management (DPEM), Program Evaluation Branch, 2017

How Establishments are Selected for Inspection?

- FDA analyzes internal and external data regarding relative risk.
  - Establishments identified for routine surveillance based on factors for inspection frequency mandates; or
  - Center priorities (directed assignments).
- Other considerations such as foodborne illness investigation, consumer complaint, congressional inquiry, or Class 1 recall.

What is FDA's focus while conducting a routine surveillance inspection?

- The purpose of an FDA inspection is to determine a facility's compliance with the Federal Food, Drug, and Cosmetic Act and relevant regulations of Title 21 of the U.S. Code of Federal Regulations (CFR), when applicable, any other U.S. regulations applicable to the specific type of food produced.

- A single inspection may focus on multiple requirements, such as a canned tuna product that may be inspected for compliance with seafood hazard analysis and critical control point (HACCP) systems, canning regulations, labeling requirements, and current GMPs.

Authority to Enter and Inspect

Section 704(a) of the FD&C Act provides authority for FDA to conduct inspections.

> "upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge."

Be reasonable (time) in order to achieve the objective(s) of the inspection.

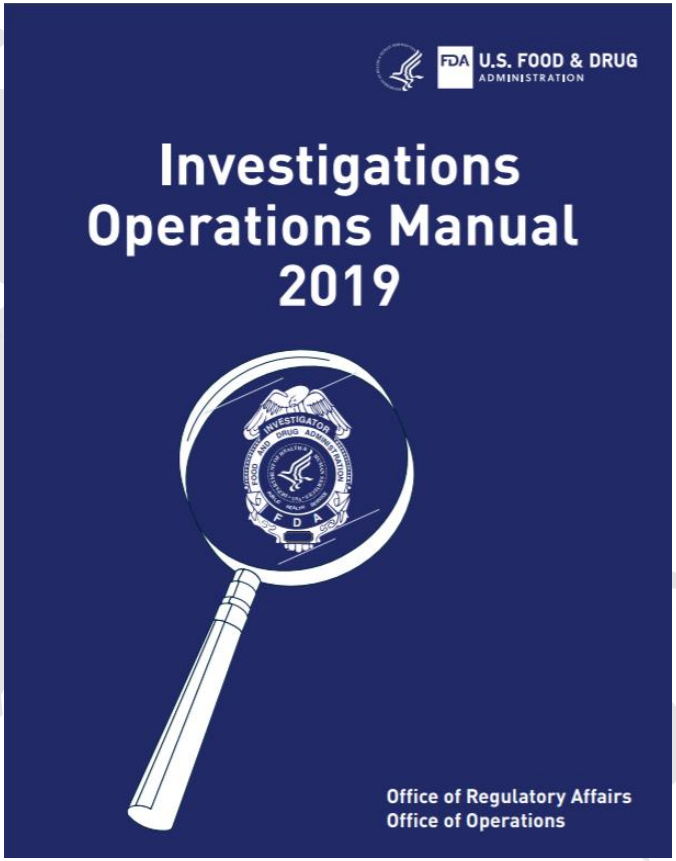
FDA Inspections

- FDA inspections can be contracted to credentialed and commissioned State public health and regulatory partners.

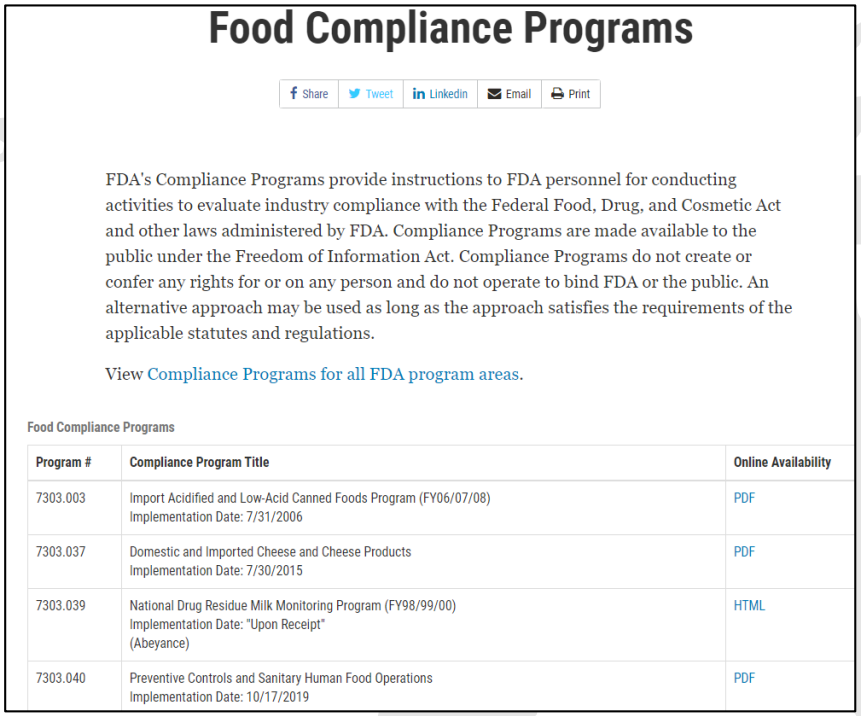
- Industry may see team inspections, more than one Consumer Safety Officer.

Investigations Operation Manual

The *Investigations Operations Manual* (IOM) is the primary operational guide for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.



Compliance Program Guidance Manuals



Food Compliance Programs

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FDA's Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. Compliance Programs are made available to the public under the Freedom of Information Act. Compliance Programs do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used as long as the approach satisfies the requirements of the applicable statutes and regulations.

View Compliance Programs for all FDA program areas.

Food Compliance Programs

Program #	Compliance Program Title	Online Availability
7303.003	Import Acidified and Low-Acid Canned Foods Program (FY06/07/08) Implementation Date: 7/31/2006	PDF
7303.037	Domestic and Imported Cheese and Cheese Products Implementation Date: 7/30/2015	PDF
7303.039	National Drug Residue Milk Monitoring Program (FY98/99/00) Implementation Date: "Upon Receipt" (Abeyance)	HTML
7303.040	Preventive Controls and Sanitary Human Food Operations Implementation Date: 10/17/2019	PDF

- FDA's Food Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA.
- Compliance Programs do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

Compliance Program Guidance Manuals

- Food Compliance Programs
  - ***NEW*** Preventive Controls (21 CFR 117)
  - Seafood Processor Inspection Program
  - Acidified and Low-Acid Canned Foods
  - Cheese and Cheese Products
  - Dietary Supplements

Guidance Documents

- Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

Investigator's Tool Kit

- Sampling supplies (for swabs, filth, product)
- Digital camera
- Reference materials
- Temperature devices
- Federal forms

FDA Inspection

- Interview to gather information on current business operations.
- Walk-through based on flow of operations.
  - Receiving, Storage, Manufacturing, Packaging
- May talk with staff to better understand operations.

During an Inspection

- ORA investigators may observe conditions they deem to be objectionable. These observations, are listed on an FDA Form 483 when, in an investigator's judgment, the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA's requirements.
- Discuss any observations and ask the investigator for clarification if you do not fully understand.
- Business management should display a willingness to correct problems. FDA encourages ***voluntary corrections***.

Close-Out Meeting

- Meeting held with management official.
- Summarize inspection and discuss any Objectionable Conditions (Should not be a surprise).
  - Issuance of the Form FDA 483, Inspectional Observations
- Document Management's Response/Intent to Correct Deficiencies.

FDA Form 483, Inspectional Observations

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

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

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

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

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 Consumer Safety Officer** during the inspection **or submit information to** the address provided on the form **(District Office).**

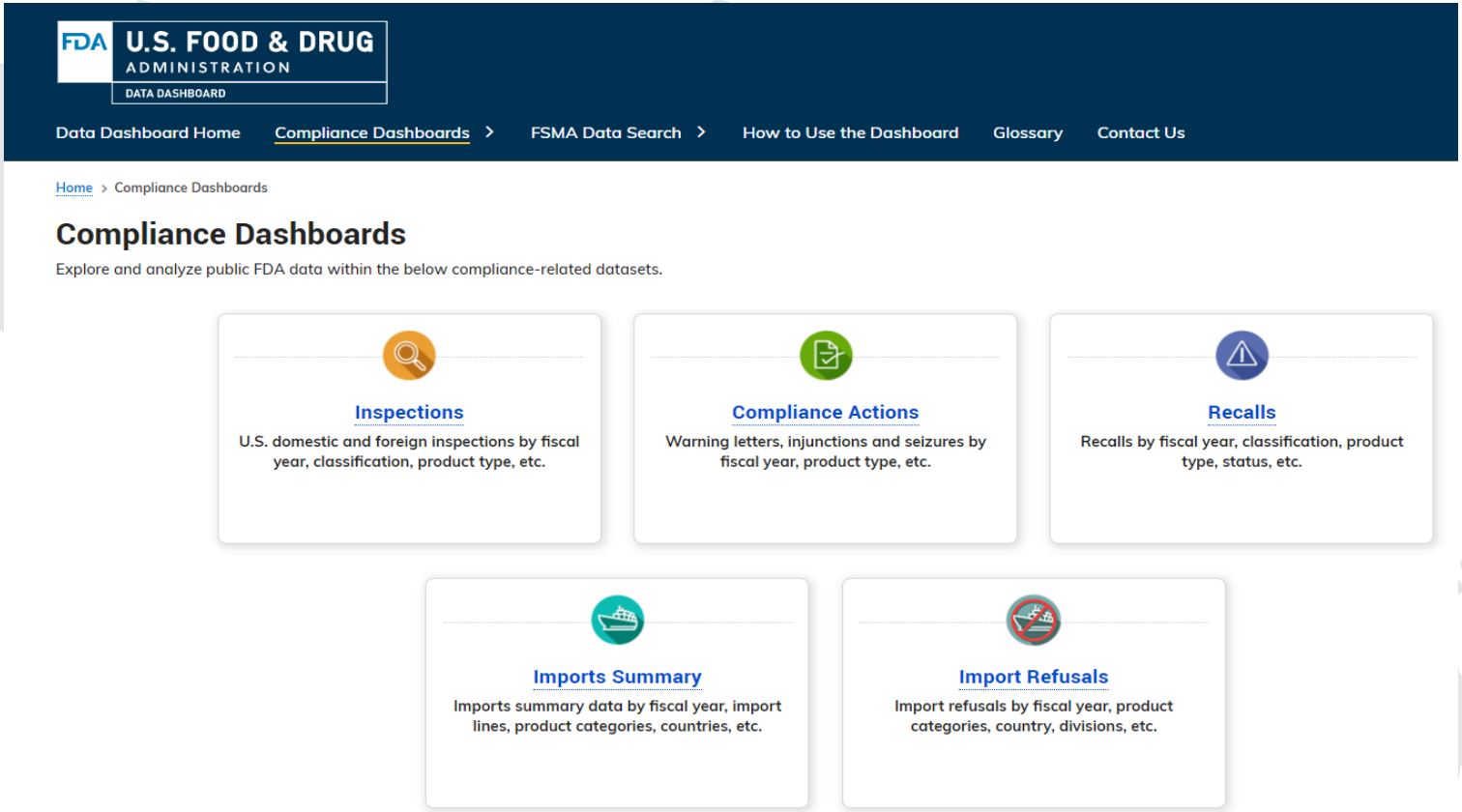
After the Inspection

- Responding to observations cited on the FDA 483 or written correspondence.
- The most responsible person will receive a copy of the inspection report.
- Inspections are generally classified into one of three categories (NAI, VAI, or OAI).
- If egregious conditions were observed, the agency may take appropriate regulatory actions (advisory, administrative, or judicial).

ORA District Directors

District Office	District Director	States Covered
Atlanta (ATL-DO)	Ingrid Zambrana ingrid.zambrana@fda.hhs.gov Office: 404-253-1284	• Georgia • North Carolina • South Carolina
Baltimore (BLT-DO)	Evelyn Bonnin evelyn.bonnin@fda.hhs.gov Office: 410-779-5424	• District of Columbia • Maryland • Virginia • West Virginia
Chicago (CHI-DO)	William Weissinger william.weissinger@fda.hhs.gov Office: 312-596-4200	• Illinois
Cincinnati (CIN-DO)	Steven Barber steven.barber@fda.hhs.gov Office: 513-679-2700 x2116	• Kentucky • Ohio
Dallas (DAL-DO)	Edmundo Garcia edmundo.garcia@fda.hhs.gov Office: 214-253-5201	• Arkansas • Oklahoma • Texas
Denver (DEN-DO)	LaTonya Mitchell latonya.mitchell@fda.hhs.gov Office: 303-236-3016	• Colorado • New Mexico • Utah • Wyoming

FDA Data Dashboard



Other FDA Contacts

- ORA Ombudsman

  1-844-871-4536

  ORA Ombudsman@fda.hhs.gov

Resources: Field Management Directives

- Release of Establishment Inspection Report, FMD-145
- Establishment Inspections and Conclusions and Decisions, FMD-86

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Thank you