# Introduction to Food Law & Regulation: Inspection and Enforcement Authority

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MORRISON FOERSTER

FDLI

# Agenda

- Inspections
  - What is the scope of FDA's authority?
  - How do you handle an FDA inspection?
  - What is entailed in post-inspection follow-ups?

- Enforcement
  - What tools does FDA have?
  - When and how does it use them?

- State Law and Its Relationship to Federal Law
  - Do states have additional authorities?
  - How do state attorneys general protect consumers from risks in the food supply?

# Overview

- CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.
- FDA regulates about 78 percent of the U.S. food supply. This includes everything we eat except for meat, poultry, and some egg products.
- FDA regulations cover about 35,000 produce farms, 300,000 restaurant chain establishments, and 10,500 vending machine operators.
- FDA products are manufactured or handled at nearly 270,000 registered facilities, more than half of which are overseas.

# FDA's Authority to Inspect

- Section 704 of the FDCA authorizes FDA to conduct inspections
  - at reasonable times,
  - within reasonable limits, and
  - in a reasonable manner.
- Although the FD&C Act does not specifically define "reasonable," FDA has long maintained that the inspectional authority under Section 704 "extends to what is reasonably necessary to achieve the objective of the inspection."

# Frequency of Inspection

- FSMA established a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately.
  - All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter.
  - Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.

# What is an inspection?

A “careful, critical, official examination of a facility to determine its compliance with certain laws and regulations administered by the FDA.”

*FDA, Investigations Operations Manual, Section 5.1.2, Inspectional Approach (2014).*

# What can FDA inspect?

- Section 704 specifically provides
  - right to enter, at reasonable times, any factory, warehouse, or establishment in which food . . . [is] manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food . . . in interstate commerce
  - Includes
    - all pertinent equipment, finished and unfinished materials, containers, and labeling therein
    - all records related to an article of food if:

      (1) the Secretary 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, and

      (2) the records are necessary to assist the Secretary in making such a determination.
    - Does not include restaurants or farms

# What else can FDA do during an inspection?

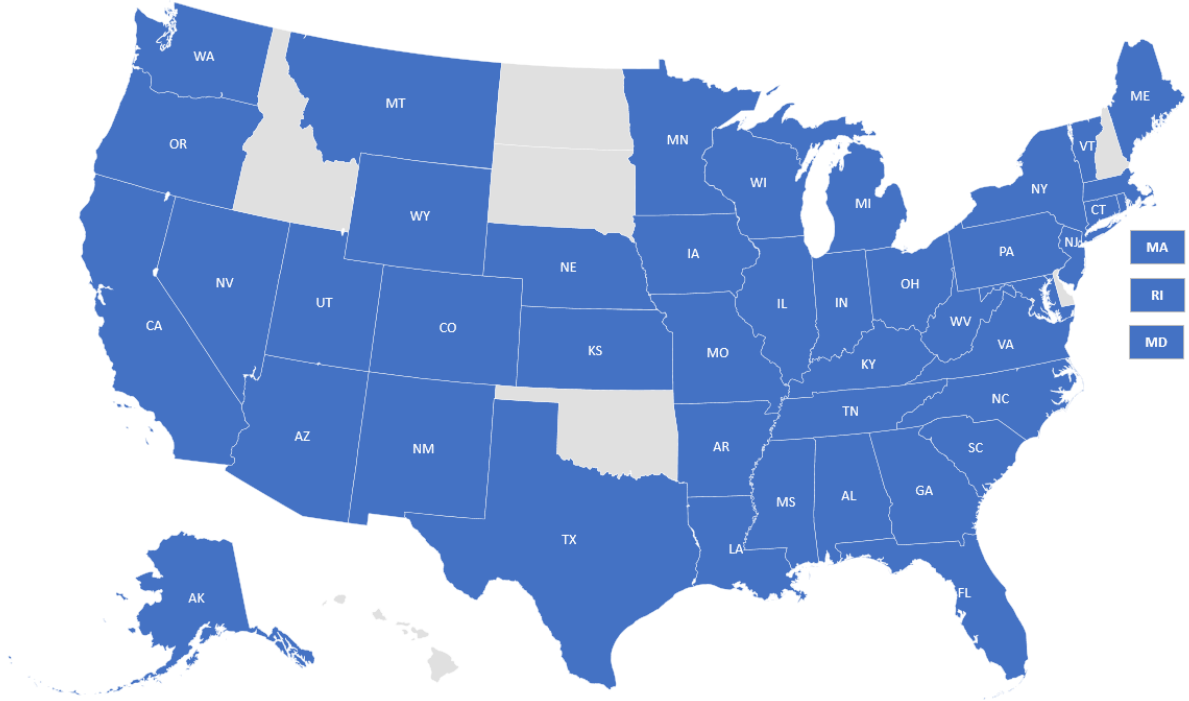
- Take photographs and recordings
  - FDA maintains that *Dow Chemical v. United States*, 476 U.S. 227 (1986), invests a regulatory agency with the right to take photographs and recordings to aid its enforcement of the law.
- Take samples*
  - In-lines
  - Packaged finished products
- Make copies of certain records

** Manufacturers are to be paid for all product or ingredient samples, except those collected under authority of a court order or decree. Reports of analysis of food samples are required under Section 704(d) of the FDCA [21 U.S.C. 374 (d)] to be furnished to the firm. After samples are collected or the inspection is completed, the investigator will provide a receipt (FDA Form 484) for all samples collected.*

# Can FDA show up in the middle of the night to inspect my food manufacturing facility?

A. Yes, because FDA's inspection authority is limitless!
B. No, Congress has asked them to show up at a "reasonable time."
C. Maybe, because I've been intentionally adulterating batches of contaminated pasta sauce, and several people have gotten sick.

# FDA Contracts with States to Perform Some Food Facility Inspections



# Inspection of Foreign Food Establishments

- Section 306 of the FDA Food Safety Modernization Act (FSMA) directs FDA to refuse admission of food into the U.S. when that food is from a foreign factory, warehouse or other establishment that refuses to allow inspection.
  - Depending on the nature of the "refusal," FDA may also consider other regulatory options in determining whether such products are subject to refusal of admission into U.S. commerce, such as increasing sampling or examination at the border.
  - Note: Failure to respond to FDA's notice of intent to conduct an inspection may be considered a refusal!

*FDCA Section 807(b)*

# Bioterrorism Act Authority

- Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188) created a new section 414, "Maintenance and Inspection of Records," in the FD&C Act.
- Under this authority, the Secretary of Health and Human Services (and FDA, by delegation) may *by regulation* establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain **food records** that identify the immediate previous sources and the immediate subsequent recipients of food.
  - FDA has issued rules implementing this authority at 21 CFR Part 117.

# Infant Formula Act of 1980

- Extended the definition of adulteration to include specific nutritional, quality and good manufacturing control requirements.
- Mandates a firm make available batch records, quality control records, nutrient test data and methodology, and similar documents for examination and copying.

*FDCA Sections 412, 704(a)(3) (21 USC 350a, 374(a)(3))*

# What to expect when FDA inspects

- FDA may conduct an inspection of your operation for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem.

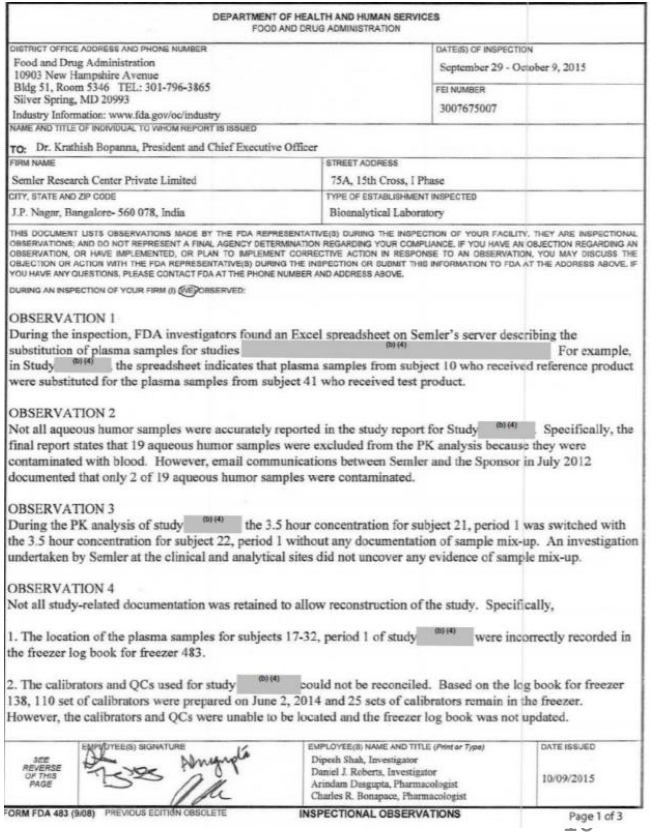
- The FDA investigator who arrives will present their agency credentials and a "Notice of Inspection" (FDA Form 482).
  - Note: Some FDA investigators may be in uniform when they arrive to conduct sampling. They are members of the Commissioned Corps of the U.S. Public Health Service (USPHS) and are required 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. (USPHS is a component of the Department of Health and Human Services and is directed by the U.S. Surgeon General.)

# What to expect when FDA inspects (cont'd)

- A knowledgeable person in your firm, such as the plant or production manager, preferably designated ahead of time, should accompany the investigator at all times.
- Usually, the investigator will examine your production process, look at certain records and collect samples.
- At the conclusion of the inspection, the investigator will discuss with your firm's management any significant findings and concerns; and leave with your management a written report of any conditions or practices, which, in the investigator's judgment, indicate objectionable conditions, or practices. (FDA Form 483)

# FDA Form 483

- An FDA Form 483 is issued to firm management at the conclusion of an inspection when investigators observe conditions that may constitute violations of the FDCA
  - specify the objectionable conditions and reference the violated regulations
  - require written responses within 15 business days, and responses should include the company's plan for corrective and preventive actions



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
Food and Drug Administration
10903 New Hampshire Avenue
Bldg 51, Room 5346 TEL: 301-796-3865
Silver Spring, MD 20993
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
September 29 - October 9, 2015

FEI NUMBER
3007675007

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Dr. Krathish Bopanna, President and Chief Executive Officer

| FIRM NAME | STREET ADDRESS |
|---|---|
| Semler Research Center Private Limited | 75A, 15th Cross, I Phase |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| J.P. Nagar, Bangalore- 560 078, India | Bioanalytical Laboratory |

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) (X) OBSERVED:

OBSERVATION 1
During the inspection, FDA investigators found an Excel spreadsheet on Semler's server describing the substitution of plasma samples for studies [redacted]. For example, in Study [redacted] the spreadsheet indicates that plasma samples from subject 10 who received reference product were substituted for the plasma samples from subject 41 who received test product.

OBSERVATION 2
Not all aqueous humor samples were accurately reported in the study report for Study [redacted]. Specifically, the final report states that 19 aqueous humor samples were excluded from the PK analysis because they were contaminated with blood. However, email communications between Semler and the Sponsor in July 2012 documented that only 2 of 19 aqueous humor samples were contaminated.

OBSERVATION 3
During the PK analysis of study [redacted] the 3.5 hour concentration for subject 21, period 1 was switched with the 3.5 hour concentration for subject 22, period 1 without any documentation of sample mix-up. An investigation undertaken by Semler at the clinical and analytical sites did not uncover any evidence of sample mix-up.

OBSERVATION 4
Not all study-related documentation was retained to allow reconstruction of the study. Specifically,

1. The location of the plasma samples for subjects 17-32, period 1 of study [redacted] were incorrectly recorded in the freezer log book for freezer 483.

2. The calibrators and QCs used for study [redacted] could not be reconciled. Based on the log book for freezer 138, 110 set of calibrators were prepared on June 2, 2014 and 25 sets of calibrators remain in the freezer. However, the calibrators and QCs were unable to be located and the freezer log book was not updated.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | | Dipesh Shah, Investigator<br>Daniel J. Roberts, Investigator<br>Arindam Dasgupta, Pharmacologist<br>Charles R. Bonapace, Pharmacologist | 10/09/2015 |

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 1 of 3

# Responding to FDA Form 483

- can be used by your firm's management as a guide for corrective action, since the FDA representative will not usually recommend specific corrective measures
- Firms can and should respond to the FDA-483 during the discussion with the investigator.
  - Corrective actions or procedural changes that are accomplished immediately in the presence of the investigator are regarded as positive indications of your concern and desire to voluntarily correct discrepancies.
- If you disagree with any of the observations or question whether FDA has jurisdiction over a matter, you may:
  - Seek advice of counsel
  - Discuss it with the investigator while they are onsite
  - Respond in writing with rationale and documentation
  - Contact FDA's Office of the Ombudsman
- A written 483 response can have a significant impact on whether FDA takes further compliance action, and the response can go beyond the specific observations and address the firm's overall corrective action plan and commitment to quality and compliance.
- The 483 response should address **all** of FDA's observations.
  - It should indicate which ones have been corrected already and provide a timetable and plan for correcting the others.
- A firm may request that FDA post the 483 response on FDA's website, if FDA has posted the 483.

# Establishment Inspection Report (EIR)

- The final written FDA report, describing the observations, is known as the establishment inspection report (EIR), and is usually available to the site approximately 3-6 months after the inspection.
- Following the inspection, if an inspector did not issue a Form FDA 483, inspectional observations, the inspection will be classified as no action indicated (NAI).
- If a Form FDA 483 was issued, the inspection will be classified either as voluntary action indicated (VAI) or official action indicated (OAI).
  - VAI means one or more inspection observations (non-compliance with regulations) were noted, but the observations do not justify further regulatory actions and any action to correct the issue(s) noted is left to the investigator to take voluntarily.
  - OAI requires FDA Compliance Branch review and may result in regulatory and/or administrative actions by the FDA.
-

# What happens in a virtual inspection?

- To date, FDA has only issued guidance with respect to remote/virtual inspections of facilities that manufacture drugs, including biologics.
- The global COVID-19 pandemic significantly impacted FDA's ability to conduct traditional on-site inspections of human food facilities.
- Although mission-critical inspections have continued throughout the public health emergency, the agency resumed surveillance inspections in July 2020 following a temporary postponement in March 2020.
- In response to the challenges to on-site inspections presented during the global pandemic, and in preparation for future such emergencies, FDA's Office of Human and Animal Foods Operations introduced a new study for selected human food facilities to voluntarily participate in Remote Regulatory Assessments (RRA) of their records. An RRA is a request for a remote review of records that a firm is required to maintain for FDA's review under normal circumstances.
  - RRAs are not considered FDA inspections under the FDCA, and firms who do not wish to voluntarily participate may opt out without penalty
  - FDA selects firms with a good compliance history who, after previous inspections, had promised corrective actions that the agency has determined can be verified through a remote review of records documenting that those corrective actions have been implemented
- FDA has requested that importers send records required under the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) rule electronically (or through other prompt means) to the Agency
  - The FSVP rule requires importers to perform certain risk-based activities to verify that their foreign supplier is producing the food in accordance with U.S. food safety standards. Until now, FSVP inspections to review FSVP records typically have been conducted at an importer's place of business.

# RRA Process

- A letter, sent via email, is provided to the facility requesting voluntary participation in RRA.
- If a facility voluntarily agrees to participate, the facility selects a designee to work with FDA staff to provide the requested information.
- FDA staff sets up a meeting via audio or video call with the firm's designee to explain the process.
- Information, including a facility's required records, is shared electronically and securely.
- FDA staff reviews information in the firm's records that help the FDA assess current compliance with applicable regulatory requirements; FDA staff also interviews the firm via audio or video call, if necessary, to clarify information on the records.
- If a firm wishes to provide context about the records provided to the agency, FDA is willing to meet with the firm via audio or video call upon receipt of the firm's records.
- FDA staff and the facility's most responsible person or designee hold a close-out meeting to verbally explain any concerns.
- RRAs do not result in an Establishment Inspection Report (EIR) or 483; written documentation will not be provided to the firm during the close-out meeting.

# Someone in a uniform just showed up and says they want to conduct an inspection of my factory. What do I do?

A. Try to figure out if the uniform is legit by searching Google Images
B. Quiz them on food safety regulations
C. Ask them for their credentials
D. Ask for a copy of their FDA Form 482

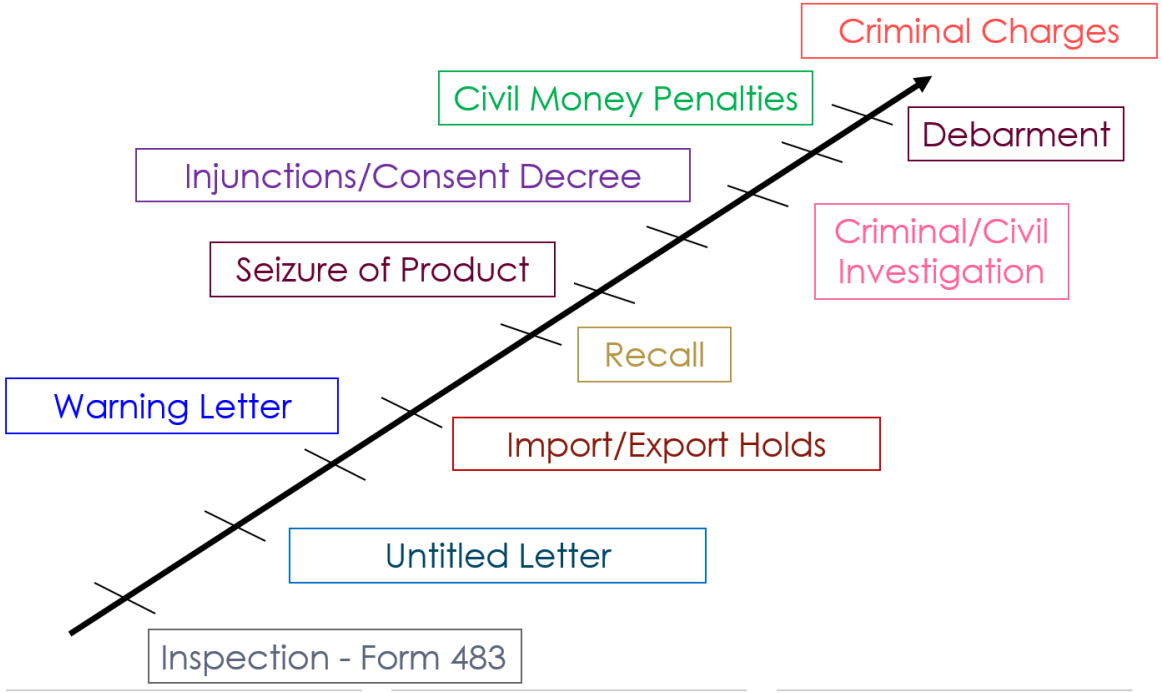
# USDA Authority

- The Food Safety and Inspection Service (FSIS), an agency of the United States Department of Agriculture (USDA), is the public health regulatory agency responsible for ensuring that United States' commercial supply of meat, poultry, siluriformes (catfish), and egg products is safe, wholesome, and correctly labeled and packaged.
- Authorities derived from:
  - Federal Meat Inspection Act
  - Poultry Products Inspection Act, and
  - Egg Products Inspection Act

- USDA has similar authorities to inspect, and ingredients or manufacturing processes common to both USDA and FDA regulated products should generally be inspected by FDA, according to an agreement between the agencies.

- USDA's Animal and Plant Health Inspection Service (APHIS) oversees the import of plants, animals, and related products into the United States. This includes fruits and vegetables, plants and seeds, meat, live animals, hides, trophies, and other agricultural items.

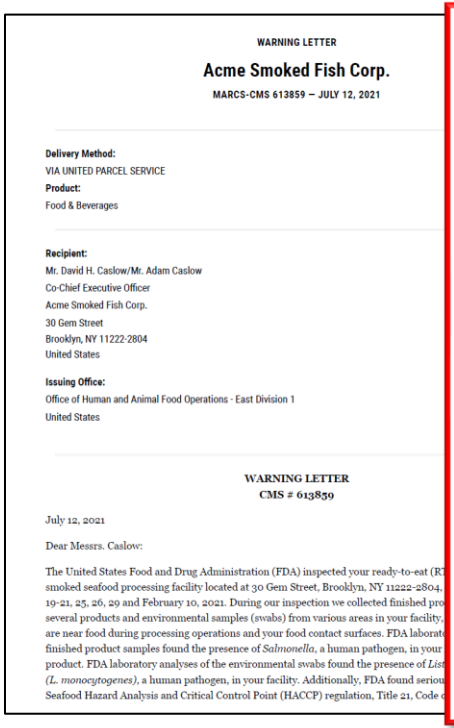
# FDA Enforcement Tools



# FDA Warning Letters

- Warning Letters are intended to provide written notice/warning.
  - They are used only for violations of "regulatory significance" – possible enforcement actions if not corrected.
- According to FDA's Regulatory Procedures Manual § 4-1-1, Warning Letters are the "principal means of achieving prompt voluntary compliance with the [FDCA]."
- Warning Letters allow for corrective action.
  - Written responses must be provided to FDA within 15 business days, and again must outline the proposed corrective and preventive actions.
- FDA publishes redacted Warning Letters publicly.

# FDA Warning Letters – Example



WARNING LETTER

**Acme Smoked Fish Corp.**

MARCS-CMS 613859 – JULY 12, 2021

**Delivery Method:**
VIA UNITED PARCEL SERVICE
**Product:**
Food & Beverages

**Recipient:**
Mr. David H. Caslow/Mr. Adam Caslow
Co-Chief Executive Officer
Acme Smoked Fish Corp.
30 Gem Street
Brooklyn, NY 11222-2804
United States

**Issuing Office:**
Office of Human and Animal Food Operations - East Division 1
United States

**WARNING LETTER**
**CMS # 613859**

July 12, 2021

Dear Messrs. Caslow:

The United States Food and Drug Administration (FDA) inspected your ready-to-eat (RT
smoked seafood processing facility located at 30 Gem Street, Brooklyn, NY 11222-2804,
19-21, 25, 26, 29 and February 10, 2021. During our inspection we collected finished pro
several products and environmental samples (swabs) from various areas in your facility,
are near food during processing operations and your food contact surfaces. FDA laborat
finished product samples found the presence of *Salmonella*, a human pathogen, in your
product. FDA laboratory analyses of the environmental swabs found the presence of *List*
*(L. monocytogenes)*, a human pathogen, in your facility. Additionally, FDA found seriou
Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code

"During our inspection we collected finished product samples of several products and environmental samples (swabs) from various areas in your facility, including areas that are near food during processing operations and your food contact surfaces. FDA laboratory analyses of the finished product samples found the presence of *Salmonella*, a human pathogen, in your RTE cold smoked tuna product. FDA laboratory analyses of the environmental swabs found the presence of *Listeria monocytogenes (L. monocytogenes)*, a human pathogen, in your facility. Additionally, FDA found serious violations of the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations (CFR), Part 123 (21 CFR Part 123) and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (CGMP & PC rule), Title 21, Code of Federal Regulations, Part 117 (21 CFR Part 117)."

# FDA Warning Letters v. Untitled Letters

**Warning Letters**

- Generally sent under the following circumstances:
  - Significant observations
  - Inadequate 483 response
- Key distinction between 483 and Warning Letter
  - 483 represents opinion of investigator(s)
  - Warning Letter states position of U.S. FDA that product is violative
  - May address issues not cited in the 483 (i.e., approval status; promotion)
- Typically addressed to CEO
- Publically available

**Untitled Letters**

- Does not include statement that U.S. FDA will advise other federal agencies of issuance of letter so that they may take information into account when considering awarding of contracts
- Does not include warning statement that failure to take prompt correction may result in enforcement action
- Does not evoke mandated district follow-up
- Requests (rather than requires) a written response within reasonable amount of time (e.g., "Please respond within 30 days"), unless more specific instructions are provided
- Rarely sent in the GMP context

# Administrative Detention

- Administrative detention provides a means through which FDA can hold adulterated or misbranded food and prevent it from reaching the marketplace
  - FSMA authorized detention“if there is reason to believe that an article of food is adulterated or misbranded”
    - FDA has issued a final rule adopting this standard at 21 CFR Part 1, Subpart K.
- FDA also has authority to administratively detain food that is regulated by USDA
- FDA may detain an article of food for a reasonable period
  - not to exceed 20 calendar days, after the detention order is issued. However, an article of food may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The entire detention period may not exceed 30 calendar days (21 CFR 1.379).
  - If FDA initiates a seizure under section 304(a) of the FD&C Act [21 U.S.C. 334(a)] against a perishable food that is subject to an administrative detention order, FDA will send the seizure recommendation to the Department of Justice within four (4) calendar days after the administrative detention order is issued, unless extenuating circumstances exist (21 CFR 1.383).

# Food Facility Registration Withdrawal

- if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:
  - Created, caused, or was otherwise responsible for such reasonable probability; or
  - Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

# Withdrawal of a Qualified Facility Exemption

- Qualified facilities are subject to provisions that relate to conditions under which FDA could withdraw their exemption, thus requiring the qualified facility to come into compliance with the full Preventive Controls Rule.
- There are two situations under which FDA can withdraw a qualified facility exemption:
  1. In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or
  2. If FDA determines that [withdrawal] is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.
- However, before FDA can issue an order to withdraw a qualified facility exemption, FDA must:
  1. Notify the owner or operator – in writing – of the circumstances that may lead FDA to withdraw the exemption;
  2. Provide an opportunity for the owner or operator to respond in writing (within 15 calendar days) to FDA's notification, and;
  3. Consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.
- FDA says in the rule that withdrawing the qualified facility exemption would be a "rare event," and that is more customary for the agency to work with a food facility to address problems before taking enforcement actions.

# Debarment from Food Importation

- FDA is authorized to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

*FDCA Section 306(b)(1)(C) (21 U.S.C. 335a(b)(1)(C)).*

# Import Alerts

- Import alerts inform the FDA's field staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of the FDA's laws and regulations.
  - These violations could be related to the product, manufacturer, shipper and/or other information.
  - Can be country/area-wide
  - Stoplight rating system
- DWPE allows the agency to detain a product without physically examining it at the time of entry.
  - Before importing into the United States, importers should know if their products are subject to DWPE.

# Import Alert Ratings

| Type of List | Description | Example |
|---|---|---|
| Red List | Firms, products and/or countries are subject to Detention without Physical Examination (DWPE) under an import alert. | EXAMPLE: A food that previously was shown to contain deadly bacteria that can cause a food-borne illness. |
| Green List | Firms, products and/or countries that have met criteria for exemption from Detention without Physical Examination (DWPE) under an import alert. | EXAMPLE: Import Alert 12-03 indicates that all soft cheeses from France are subject to DWPE. However, there are some soft cheeses from firms that received an exemption based on the guidance in the import alert. The firms/ products that are allowed to be imported are on the green list of this import alert. |
| Yellow List | Firms, products and/or countries subject to intensified surveillance; or firms that may have satisfied GMP issues but where the nature of violations may warrant further field examinations of individual entries and/or additional analyses. | EXAMPLE: Import Alert 21-11 indicates that all ackee products except from firms listed on the green list are subject to DWPE. This alert includes a green list and a yellow list.<br><br>As the FDA identifies foreign facilities to have food safety controls in place to control for the toxin, hypoglycin A, in their ackee products, the firm and product(s) will be identified on the Yellow List. All entries of ackee products imported by the firms or manufactured/shipped by the firms on the Yellow List will continue to be subject to DWPE and require a private laboratory analysis until the FDA has confidence the firm's products are in compliance. |

# FDA Recalls

- FDA has authority to order a mandatory recall for adulterated or misbranded food. [Section 423 of the FD&C Act]
  - FDA issued a guidance document in November 2018 providing further clarification: "Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff"
  - The FDA recalls database can be found here: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

# USDA Enforcement

- Noncompliance Records (NRs)
- Recalls
- Other Actions

# What is FDA's primary goal when it takes enforcement action?

A. Punishment
B. Entertainment
C. Compliance
D. Revenge

# When DOJ Gets Involved

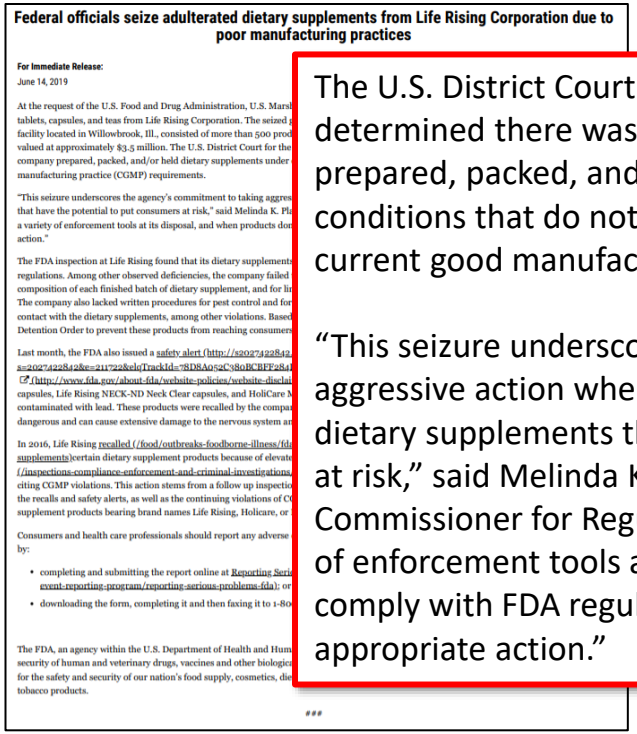
- Seizures
- Injunctions
- Civil Penalties
- Criminal Prosecutions

# FDA Seizures

- Seizure is defined as, “a judicial civil action directed against specific offending goods, in which goods are "arrested." Originally designed to remove violative goods from consumer channels, it was intended primarily as a remedial step; however, the sanction often has a punitive and deterrent effect.” [2021 Investigations Operations Manual (IOM), Chapter 2.2.6]

- “FDA may initiate seizure against detained foods, devices, and drugs, and/or injunction under sections 304(a) and 302 of the FD&C Act, respectively. In addition, FDA may consider instituting other action against detained foods, such as mandatory recall under section 423 of the FD&C Act, suspension of a food facility’s registration under section 415(b) of the FD&C Act, or emergency permit control under section 404 of the FD&C Act.” [2021 Investigations Operations Manual (IOM), Chapter 2.7.1]

# Seizure – Example



**Federal officials seize adulterated dietary supplements from Life Rising Corporation due to poor manufacturing practices**

**For Immediate Release:**
June 14, 2019

At the request of the U.S. Food and Drug Administration, U.S. Marsh
tablets, capsules, and teas from Life Rising Corporation. The seized p
facility located in Willowbrook, Ill., consisted of more than 500 prod
valued at approximately $3.5 million. The U.S. District Court for the
company prepared, packed, and/or held dietary supplements under
manufacturing practice (CGMP) requirements.

"This seizure underscores the agency's commitment to taking aggres
that have the potential to put consumers at risk," said Melinda K. Pla
a variety of enforcement tools at its disposal, and when products don
action."

The FDA inspection at Life Rising found that its dietary supplement
regulations. Among other observed deficiencies, the company failed
composition of each finished batch of dietary supplement, and for lin
The company also lacked written procedures for pest control and for
contact with the dietary supplements, among other violations. Based
Detention Order to prevent these products from reaching consumers

Last month, the FDA also issued a safety alert (http://s2027422842
s=2027422842&e=211722&elqTrackId=8D8A052C980BCBFF284
(/http://www.fda.gov/about-fda/website-policies/website-disclai
capsules, Life Rising NECK-ND Neck Clear capsules, and HoliCare
contaminated with lead. These products were recalled by the compa
dangerous and can cause extensive damage to the nervous system an

In 2016, Life Rising recalled (/food/outbreaks-foodborne-illness/fd
supplements)certain dietary supplement products because of elevate
(/inspections-compliance-enforcement-and-criminal-investigations/
citing CGMP violations. This action stems from a follow up inspectio
the recalls and safety alerts, as well as the continuing violations of C
supplement products bearing brand names Life Rising, Holicare, or

Consumers and health care professionals should report any adverse
by:

- completing and submitting the report online at Reporting Seri
event-reporting-program/reporting-serious-problems-fda); or
- downloading the form, completing it and then faxing it to 1-80

The FDA, an agency within the U.S. Department of Health and Hum
security of human and veterinary drugs, vaccines and other biologic
for the safety and security of our nation's food supply, cosmetics, die
tobacco products.

###

The U.S. District Court for the Northern District of Illinois determined there was probable cause that the company prepared, packed, and/or held dietary supplements under conditions that do not conform to the dietary supplement current good manufacturing practice (CGMP) requirements.

"This seizure underscores the agency's commitment to taking aggressive action when manufacturers distribute adulterated dietary supplements that have the potential to put consumers at risk," said Melinda K. Plaisier, the FDA's Associate Commissioner for Regulatory Affairs. "The FDA has a variety of enforcement tools at its disposal, and when products don't comply with FDA regulations, we will not hesitate to take appropriate action."

# Injunctions

- Courts may:
  - enjoin certain conduct
  - Issue consent decrees
  - Impose other equitable remedies??
    - Disgorgement?
    - Restitution?

# Civil Penalties

- Introduction of an adulterated food into interstate commerce or noncompliance with a food recall order can incur fines of up to $500,000
- If civil penalties are assessed, this can limit seizure and criminal penalty authorities.

*21 USC 333(f)(2)*

# FDA's Office of Criminal Investigations (OCI)

- FDA's criminal law enforcement arm established in 1991 in the wake of a generic drug scandal
- conducts criminal investigations of illegal activities involving FDA-regulated products, arresting those responsible, and bringing them before the Department of Justice for prosecution.
- provides its special agents with numerous resources to support investigations, including an experienced staff of investigative analysts, technical equipment specialists, polygraph examiners, information technology specialists, special agents trained in computer forensics.

# Criminal Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,[1] if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

*21 USC 333(a)*

# *Park* Doctrine

- Imposes strict liability upon individual corporate officers for misdemeanor violations of the FDCA
  - Also known as the "responsible corporate officer" doctrine.
- To date, prosecutors largely have limited enforcement actions to individuals with alleged knowledge of or involvement in corporate misconduct.
- However, there have been some examples in recent years:
  - In 2020, Indivior Exec Shaun Thaxter pled guilty to one count of misbranding in response to the charge that he failed to prevent and correct the distribution of false and misleading pediatric exposure data about its suboxone film to the Massachusetts Medicaid program. He received a sentence of six months of incarceration, one year of supervised release, a $100,000 fine, and $500,000 in forfeiture.
  - In 2014, in *United States v. DeCoster*, executives of Quality Egg LLC, which suffered a salmonella outbreak, were sentenced to three months' imprisonment following convictions under the *Park* doctrine. The U.S. Court of Appeals for the Eighth Circuit upheld those sentences on appeal, rejecting the defendants' argument that the prison sentences violated due process in light of the defendants' plea as responsible corporate officers.

# Recent Criminal Prosecution Examples


Agreed to $25 million criminal fine and three-year deferred prosecution agreement related to the company's involvement in foodborne illness outbreaks 2015-2018

Company agreed to plead guilty to two misdemeanor counts of distributing adulterated ice cream products in the 2015 listeriosis outbreak and pay a criminal fine and forfeiture amount totaling $17.25 million.

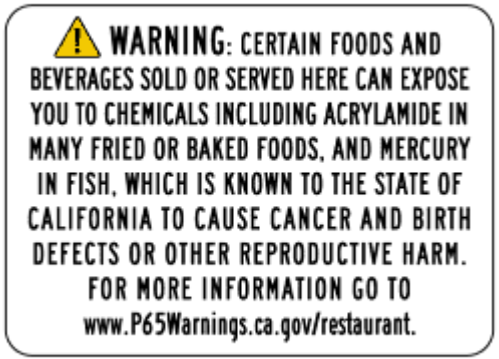
Former president charged with 7 felony counts.

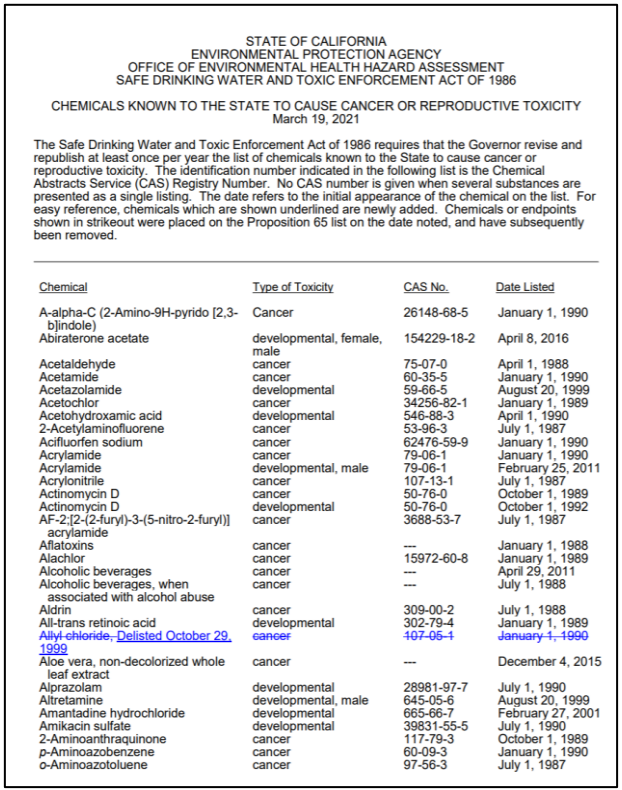
# State FDCA Authority

- Most states have their own mini-FDCA that parallels the provisions of the Federal FDCA
  - Attorneys general of states have authority to enforce these laws, as well as other consumer protection laws that cover food products, to the extent they are not preempted by federal law
  - Consumer litigation can also raise these issues, especially where the state law grants a right of private enforcement

# California's Proposition 65

- officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986
- Seeks to protect the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals.



STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY
March 19, 2021

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. The identification number indicated in the following list is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing. The date refers to the initial appearance of the chemical on the list. For easy reference, chemicals which are shown underlined are newly added. Chemicals or endpoints shown in strikeout were placed on the Proposition 65 list on the date noted, and have subsequently been removed.

| Chemical | Type of Toxicity | CAS No. | Date Listed |
|---|---|---|---|
| A-alpha-C (2-Amino-9H-pyrido [2,3-b]indole) | Cancer | 26148-68-5 | January 1, 1990 |
| Abiraterone acetate | developmental, female, male | 154229-18-2 | April 8, 2016 |
| Acetaldehyde | cancer | 75-07-0 | April 1, 1988 |
| Acetamide | cancer | 60-35-5 | January 1, 1990 |
| Acetazolamide | developmental | 59-66-5 | August 20, 1999 |
| Acetochlor | cancer | 34256-82-1 | January 1, 1989 |
| Acetohydroxamic acid | developmental | 546-88-3 | April 1, 1990 |
| 2-Acetylaminofluorene | cancer | 53-96-3 | July 1, 1987 |
| Acifluorfen sodium | cancer | 62476-59-9 | January 1, 1990 |
| Acrylamide | cancer | 79-06-1 | January 1, 1990 |
| Acrylamide | developmental, male | 79-06-1 | February 25, 2011 |
| Acrylonitrile | cancer | 107-13-1 | July 1, 1987 |
| Actinomycin D | cancer | 50-76-0 | October 1, 1989 |
| Actinomycin D | developmental | 50-76-0 | October 1, 1992 |
| AF-2;[2-(2-furyl)-3-(5-nitro-2-furyl)] acrylamide | cancer | 3688-53-7 | July 1, 1987 |
| Aflatoxins | cancer | --- | January 1, 1988 |
| Alachlor | cancer | 15972-60-8 | January 1, 1989 |
| Alcoholic beverages | cancer | --- | April 29, 2011 |
| Alcoholic beverages, when associated with alcohol abuse | cancer | --- | July 1, 1988 |
| Aldrin | cancer | 309-00-2 | July 1, 1988 |
| All-trans retinoic acid | developmental | 302-79-4 | January 1, 1989 |
| ~~Allyl chloride.~~ Delisted October 29, 1999 | ~~cancer~~ | ~~107-05-1~~ | ~~January 1, 1990~~ |
| Aloe vera, non-decolorized whole leaf extract | cancer | --- | December 4, 2015 |
| Alprazolam | developmental | 28981-97-7 | July 1, 1990 |
| Altretamine | developmental, male | 645-05-6 | August 20, 1999 |
| Amantadine hydrochloride | developmental | 665-66-7 | February 27, 2001 |
| Amikacin sulfate | developmental | 39831-55-5 | July 1, 1990 |
| 2-Aminoanthraquinone | cancer | 117-79-3 | October 1, 1989 |
| *p*-Aminoazobenzene | cancer | 60-09-3 | January 1, 1990 |
| *o*-Aminoazotoluene | cancer | 97-56-3 | July 1, 1987 |

https://oehha.ca.gov/proposition-65

# Slack-Fill Laws

- Misleading containers, “Slack-fill is the difference between the actual capacity of a container and the volume of product contained therein. Nonfunctional slack-fill is the empty space in a package that is filled to less than its capacity…”

  *21 CFR 100.100*

# Q&A

# Further Questions?

- Please feel free to contact me by email at bbondoc@mofo.c.om