Almond Board of California's Food Quality & Safety Symposium

FDA Food Facility Inspections & Enforcement

Akin Gump
STRAUSS HAUER & FELD LLP

June 13, 2019

Howard R. Sklamberg
Partner

Presentation Overview

- FDA Inspections: Background
- FDA Inspections: Best Practices
- FDA Compliance & Enforcement Actions
- FDA Recalls & Inspection Implications
- Current Compliance & Enforcement Trends

FDA Inspections: Background

FDA Inspections: Background

- FDA is responsible for ensuring the safety of almost all food products sold in the United States (except meat, poultry, and some egg products)
- FDA Food Inspections
  - Intended to protect consumers from unsafe foods
  - Conducted by Consumer Safety Officers (investigators) in FDA's Office of Regulatory Affairs (ORA) and by state regulatory authorities on behalf of FDA through FDA's Human Food Inspection Contract Program
    - California's Departments of Health & Agriculture both participate in FDA's Contract Program
- An FDA inspection for growers, hullers/shellers and processors may involve evaluation of the following (as applicable):
  - Current Good Manufacturing Practices (CGMPs)
  - Preventive controls
  - Unsanitary conditions and practices
  - Any specific regulations for growing, harvesting, packing or holding almonds FDA chooses to issue in the future

FDA Inspections: Background

- Types of FDA inspections for food
  - Surveillance inspections
    - Routine assessments of whether a facility is complying with FDA's rules and regulations
    - FDA conducts these inspections after a product is on the market
    - Risk-based model for determining site selection
  - For-cause inspections
    - Occur in response to a specific trigger, such as a recall, an outbreak, laboratory testing results or information from a whistle-blower
    - FDA also performs for-cause inspections to verify that a firm has taken corrective actions that rectify a problem that FDA had previously identified
- Inspections are not necessarily announced in advance and make take place over a period of several days
  - FDA investigators may enter at "reasonable times"
  - Investigators will present credentials and a "Notice of Inspection" (FDA Form 482)

FDA Inspections: Best Practices

FDA Inspections: Pre-Inspection Preparation

- Designate a lead person for interacting with FDA or have a standard operating procedure in place for representative selection
  - Ensure a sufficient technical background to explain and answer agency questions
- Have an internal communications plan
  - Clearly establish how regulatory inquiries should be handled/referred
- Have relevant records/documents organized and accessible
  - Have a designated location where FDA will review and be able to copy documents
- Review and implement latest applicable FDA guidance documents
- Consider doing a mock FDA inspection, particularly if internal quality monitoring identifies potential regulatory departures or deviations
  - Consider using a third-party regulatory consultant if additional feedback is needed

FDA Inspections: During the Inspection

- Have the designated lead person and other appropriate employees accompany the FDA investigator during facility tour and records review
  - Should be able to speak with authority on the product, manufacturing process, equipment, facility, packaging, testing, etc.
  - Should be prepared to respond to investigator questions and information requests
    - Should document what information is requested and the responsive information provided
  - May be able to rapidly resolve or respond to issues highlighted by the investigator
- Engage with inspector during the "daily wrap up"
  - At the end of each day, the investigator usually summarizes any detected problems
    - Critical to point out any areas of disagreement as soon as the investigator raises the issue

FDA Inspections: Post-Inspection Response

- At the conclusion of the inspection, the investigator will issue a form entitled "Inspectional Observations" (FDA Form 483)
  - Form 483s contain "Inspectional Observations" based on investigator findings of facility conditions or practices that may cause a food to be:
    - adulterated, or
    - prepared, packed, or held under conditions where food might become adulterated or rendered injurious to health.
  - Form 483s are not a final FDA determination of a violation of law but are considered when the agency determines whether compliance action is warranted
  - FDA releases Form 483s under the Freedom of Information Act upon request or FDA may release the document proactively
    - Release of a Form 483 can result in media and stakeholder attention
- Firms have 15 working days to respond to FDA's Form 483 in writing
  - Response must be truthful and complete
  - Complex responses may warrant consultation with counsel and experts
  - Regular additional communication with FDA is recommended until resolution

FDA Inspections: Post-Inspection Response

- After issuing a Form 483:
  - FDA investigator prepares a detailed narrative of the inspection in an Establishment Inspection Report (EIR)
  - FDA conducts laboratory analysis on any product or environmental samples taken during the inspection
- Subsequently, FDA classifies each inspection into one of three categories:
  - No Action Indicated (NAI)
    - No objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action)
  - Voluntary Action Indicated (VAI)
    - Objectionable conditions or practices were found but FDA is not prepared to take or recommend any administrative or regulatory action
  - Official Action Indicated (OAI)
    - Regulatory and/or administrative actions will be recommended by FDA

FDA Compliance & Enforcement Actions

FDA Compliance & Enforcement Actions

- Agency advisory & compliance actions
  - Warning letter
    - Issued when FDA finds serious compliance violations
    - Indicates that FDA may take more serious enforcement action if the violations are not promptly and adequately corrected
    - A firm has 15 working days to respond to FDA
    - Issuance of a warning letter can result in media and stakeholder attention
  - Untitled letter
    - Issued when the violations less serious than the criteria required for a warning letter
    - FDA requests a response within 30 working days
  - Regulatory meetings
    - FDA-requested meeting with representatives of a facility to inform them that its products, practices, processes, or other activities are considered to be a compliance violation
    - May be requested when violations do not warrant a warning letter, or in combination with the issuance of a warning letter

FDA Compliance & Enforcement Actions

- Administrative enforcement tools
  - Detention of food product
    - –FDA can hold adulterated or misbranded food, preventing it from reaching the marketplace
    - –Detention may not exceed 20 calendar days after the detention order is issued
    - –An article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action
  - Mandatory recall authority
    - –FDA may order a recall when there is a reasonable probability that the article of food (other than infant formula) is adulterated or misbranded and that the use of or exposure will cause serious adverse health consequences or death to humans or animals (SAHCODHA)
  - Suspension of a company's registration (prohibiting facility from distributing food)
    - –FDA may order suspension when food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing SAHCODHA

FDA Compliance & Enforcement Actions

- Judicial enforcement actions
  - Seizure of unlawful product
  - An injunction (usually ordering a firm to cease operations, abide by rigorous conditions or disgorge profits)
  - Criminal prosecution
- Park Doctrine (criminal prosecution)
  - Government may prosecute corporate officials for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA)
  - No proof required that the corporate official acted with intent or negligence
    - Corporate official does not need any actual knowledge of, or participation in, the specific offense
  - Theory derived from *United States v. Park*, 421 U.S. 658 (1975)
  - Intended to deter continued FDCA violations by holding individuals legally responsible
  - First-time misdemeanor prosecution, with subsequent felony prosecution possible

FDA Compliance & Enforcement Actions

- Park Doctrine (cont'd)
  - FDA's criteria for referral of a case for prosecution under the Park Doctrine includes:
    - the individual's position in the company and relationship to the violation, and whether the official had authority to correct/prevent the violation;
    - whether the violation involves actual or potential harm to the public;
    - whether the violation is obvious;
    - whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
    - whether the violation is widespread;
    - whether the violation is serious;
    - the quality of the legal and factual support for the proposed prosecution; and
    - whether the proposed prosecution is a prudent use of agency resources.

FDA Recalls & Inspection Implications

FDA Recalls & Inspection Implications

- A recall occurs when a firm removes or corrects a marketed product that violates FDA-administered laws and regulations and would be subject to FDA legal action
  - Recalls are intended to protect the public from products that are harmful, deceptive or defective
- May be initiated:
  - through a firm's own decision-making process, such as via an internal audit, safety or quality control programs, employee reporting or consumer feedback;
  - by FDA's informal recommendation, based on information available to the agency, such as consumer complaints or results from an inspection, an outbreak investigation or laboratory tests;
  - by FDA's formal request for voluntary action by a firm, providing the firm with a letter explaining the violation and associated health hazards, the need for an immediate recall, and recommendations for a recall strategy; or
  - by FDA's mandatory recall authority for food.
    - Issued only once since FDA gained the authority in 2011

FDA Recalls & Inspection Implications

- FDA may initiate a variety of compliance and enforcement measures during or immediately following a recall, such as:
  - conducting "for cause" facility inspections;
  - issuing a warning letter; or
  - initiating administrative or judicial actions, such as import bans, injunctions, seizures and criminal prosecution.
- For food recalls, FDA may suspend a firm's registration of a food facility, immediately halting any food from leaving the facility for sale or distribution
  - A suspension continues until FDA believes that the relevant compliance problem has been resolved
- FDA recently released draft guidance for conducting recalls:
  - *Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C*; Draft Guidance for Industry (April 2019)
- Providing recall notification to FDA does not eliminate other reporting requirements
  - Reportable Food Registry notification

Current Compliance & Enforcement Trends

FDA Food/Cosmetics Inspection Statistics

Food/Cosmetics Establishment Inspection Totals (FY 2017-2019)*			
Fiscal Year	**2017**	**2018**	**2019 (based on available data)**
FDA Inspections in California	1,422 (14.3%)	1,151 (12.0%)	465 (13.8%)
Total Domestic Inspections	9,922	9,570	3,380
FDA Food/Cosmetics Inspections in California: Establishment Inspection Classifications			
Fiscal Year	**2017**	**2018**	**2019 (based on available data)**
No Action Indicated (NAI)	992 (69.7%)	687 (59.7%)	294 (63.2%)
Voluntary Action Indicated (VAI)	398 (28.0%)	442 (38.4%)	170 (36.6%)
Official Action Indicated (OAI)	32 (2.3%)	22 (1.9%)	1 (0.2%)
*Does not include inspections conducted by state regulators			

Source: FDA

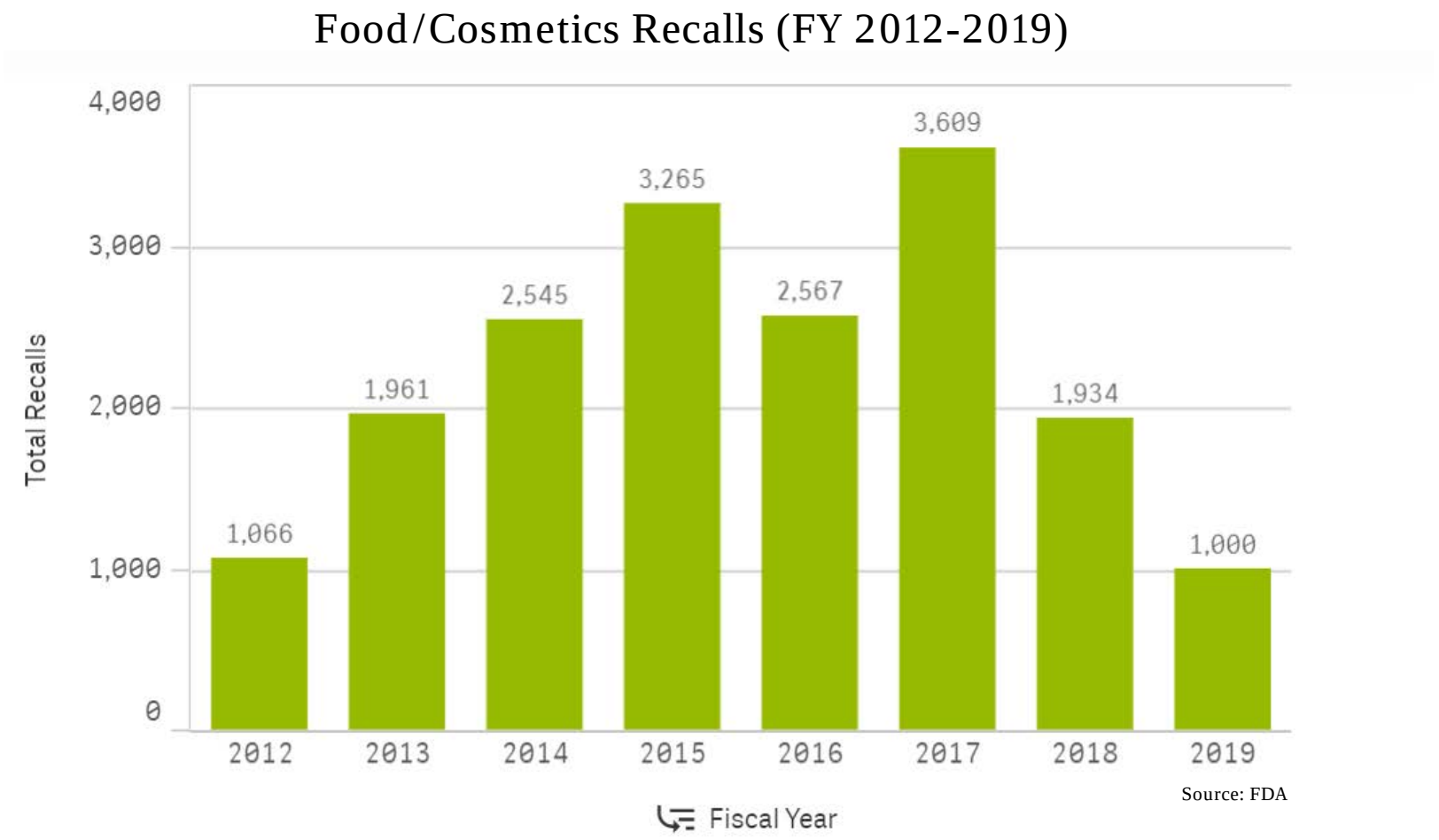
*Excludes inspections conducted by states

FDA Form 483: Inspectional Observations

Most Common FDA Food Observations, Part 110 (FY 2017)			
Category	**Description**	**Obs. Frequency**	**CFR**
Lack of effective pest exclusion	Effective measures are not being taken to [exclude pests from the processing areas] [protect against the contamination of food on the premises by pests].	330	21 CFR 110.35(c)
Screening	Failure to provide adequate screening or other protection against pests.	211	21 CFR 110.20(b)(7)
Floors, walls and ceilings	The plant is not constructed in such a manner as to allow [floors] [walls] [ceilings] to be [adequately cleaned and kept clean] [kept in good repair].	192	21 CFR 110.20(b)(4)
Cleaning and sanitizing operations	Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of [food] [food-contact surfaces] [food-packaging materials].	157	21 CFR 110.35(a)
Manufacturing conditions	Failure to [manufacture] [package] [store] foods under conditions and controls necessary to minimize [the potential for growth of microorganisms] [contamination].	156	21 CFR 110.80(b)(2)

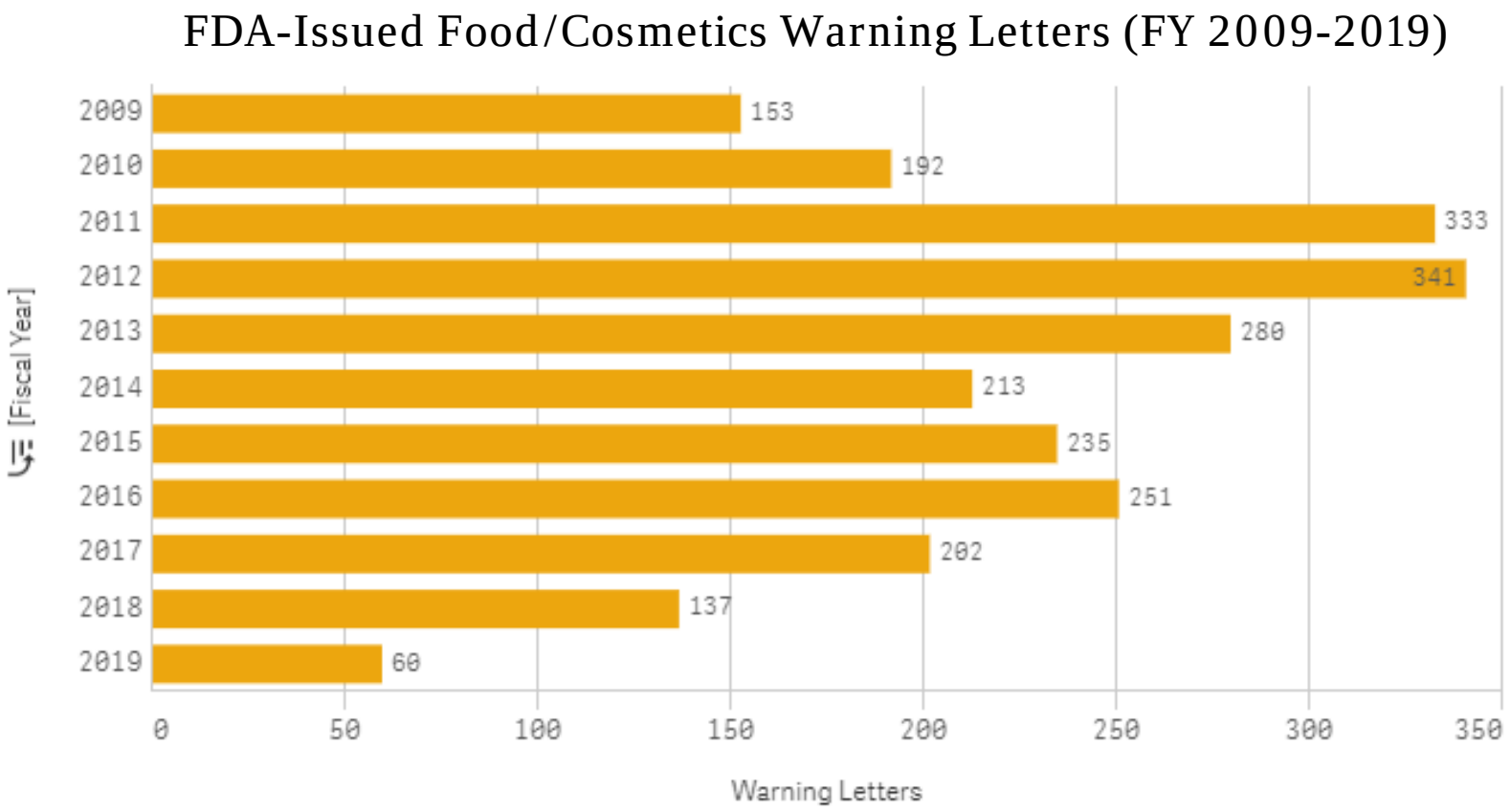
Source: FDA

FDA Recalls: Food/Cosmetics Statistics



Source: FDA

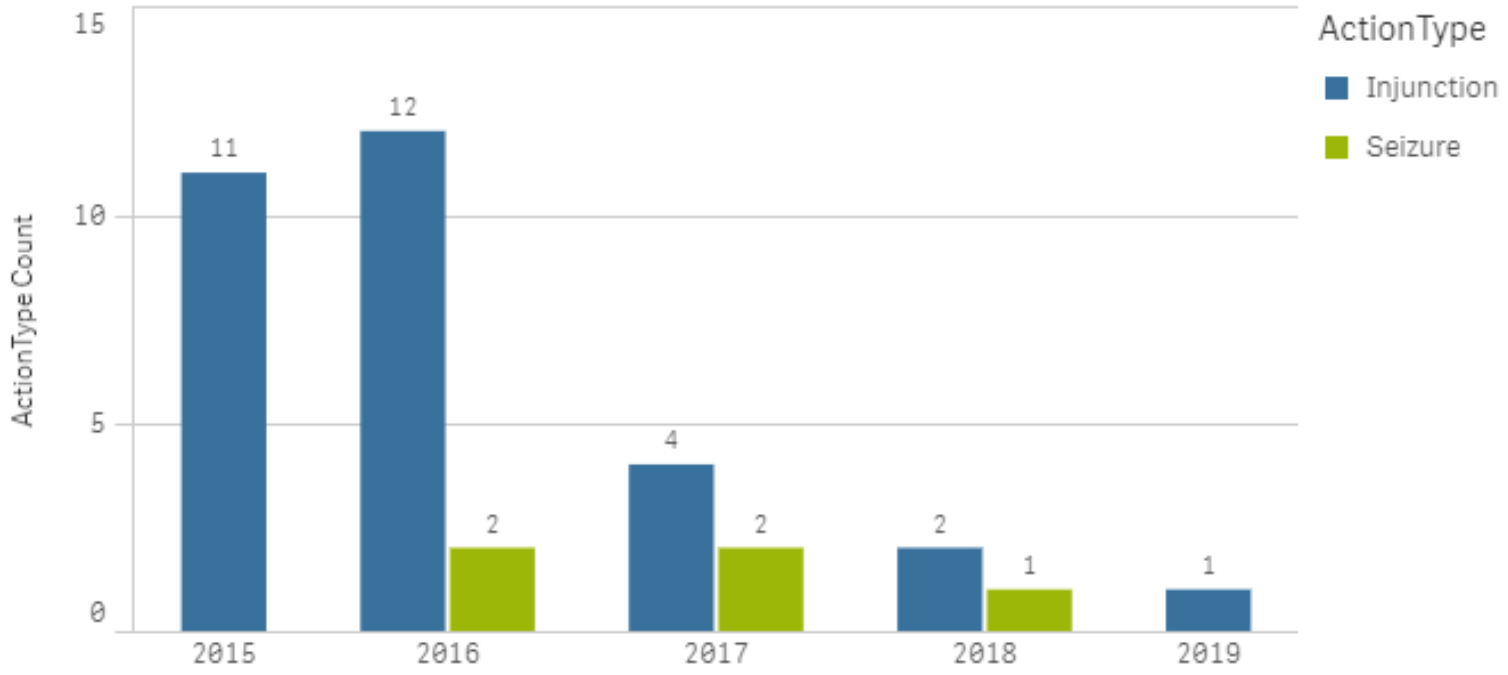
FDA Warning Letters: Food/Cosmetics Statistics



Source: FDA

FDA Injunctions & Seizures: Food/Cosmetics

FDA Food/Cosmetics Injunctions & Seizures (FY 2015-2019)



Source: FDA

Questions?

Howard R. Sklamberg
hsklamberg@akingump.com
Follow us on Twitter
@FDAReport

Additional Resources:
A Client's Guide to FDA Inspections
A Client's Guide to FDA Recalls