
FDA
U.S. FOOD & DRUG
ADMINISTRATION

COMPLIANCE 101

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Compliance Branch
Human and Animal Food Operations
East Division 4 (FL, PR, & US VI)
Office of Regulatory Affairs

COMPLIANCE 101

FDA Compliance

Resources on www.fda.gov

FDA Compliance

- FDA's Mission
- Shared Responsibility
- FDA Compliance Activities

FDA Compliance

❖ FDA's Mission

Promoting and Protecting the Public Health

FDA Compliance

We cannot achieve this mission alone

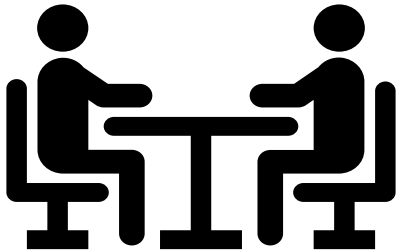
Federal, state, local agency partners

Regulated industry

Voluntary compliance

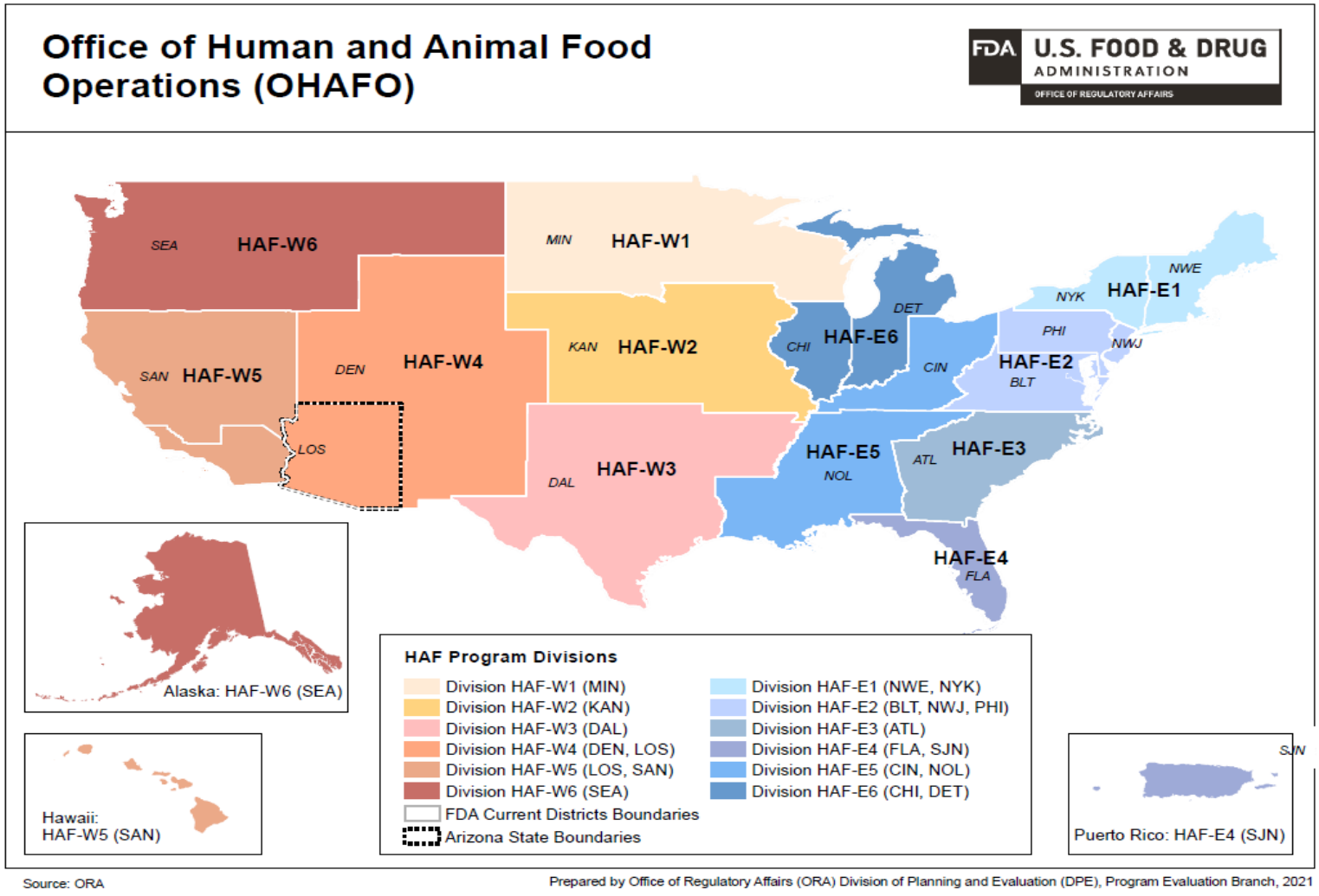
FDA Compliance

- Shared Responsibility



FDA + Regulated Industry

FDA Compliance



❖ FDA Compliance Activities

What are examples of when a regulated firm may interact with an FDA Compliance Officer?

- Notification of FDA sample results found to be out of compliance
- Product Recall
- Advisory actions
- Other actions

FDA Compliance

❖ FDA Compliance Activities

Advisory Actions

- Untitled Letter
- Warning Letter

FDA Compliance

Establishment inspection conducted

Establishment Inspection Report generated and inspection classified

FDA Compliance Branch
May issue advisory letter or make other recommendations

FDA Inspection Classification

The three classifications displayed are:

- **No Action Indicated (NAI)** no objectionable conditions or the objectionable conditions found do not justify further regulatory action
- **Voluntary Action Indicated (VAI) -** objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action
- **Official Action Indicated (OAI)** which means regulatory and/or administrative actions will be recommended.

❖ FDA Compliance Activities

Advisory Actions - Untitled Letter

- Does not meet the regulatory threshold of a warning letter
- Example, lack of food facility registration (FFR)

Tip - Renew FFR every other year
Link: Registration of food facility information

❖ FDA Compliance Activities

Advisory Actions - Warning Letter

- Issued to firms with expectation firm will achieve voluntary compliance
- Issued for violations of regulatory significance and to provide prior notice
- Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected

FDA Compliance

❖ FDA Compliance Activities

Advisory Actions - Warning Letter

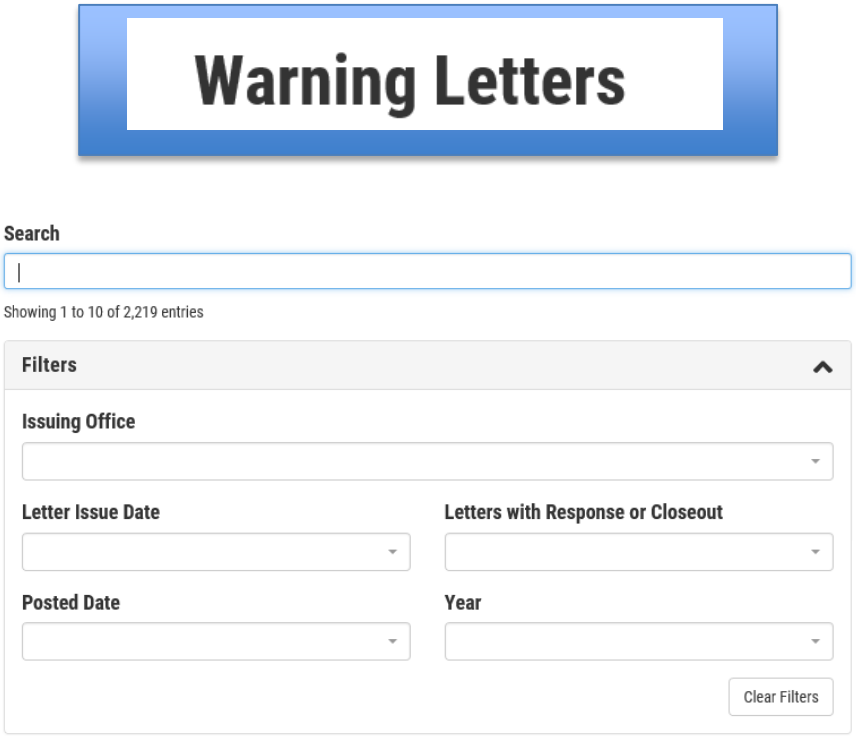
- Warning letters notify firm of violations of the FD&C Act
- Usually issued based on significant observations noted during an inspection tied to 21 CFR citations.
- May just quote the violation of the Act

FDA Compliance

❖ FDA Compliance Activities

Advisory Actions - Warning Letter

WL published/available online



❖ FDA Compliance Activities

Advisory Actions - Warning Letter

Tip – Should you receive a warning letter:

Do	Reconsider
✓ Respond within 15 working days ✓ Provide documentation to support corrective actions were taken and implemented ✓ Provide your proposed corrective action and prevention plan (CAPA) ✓ Report any delays/timeframe to complete CAPA	× Ignoring warning letter and not providing a response × Not taking any corrective actions × Not following through with commitments/failure to adequately implement proposed corrective actions

❖ FDA Compliance Activities

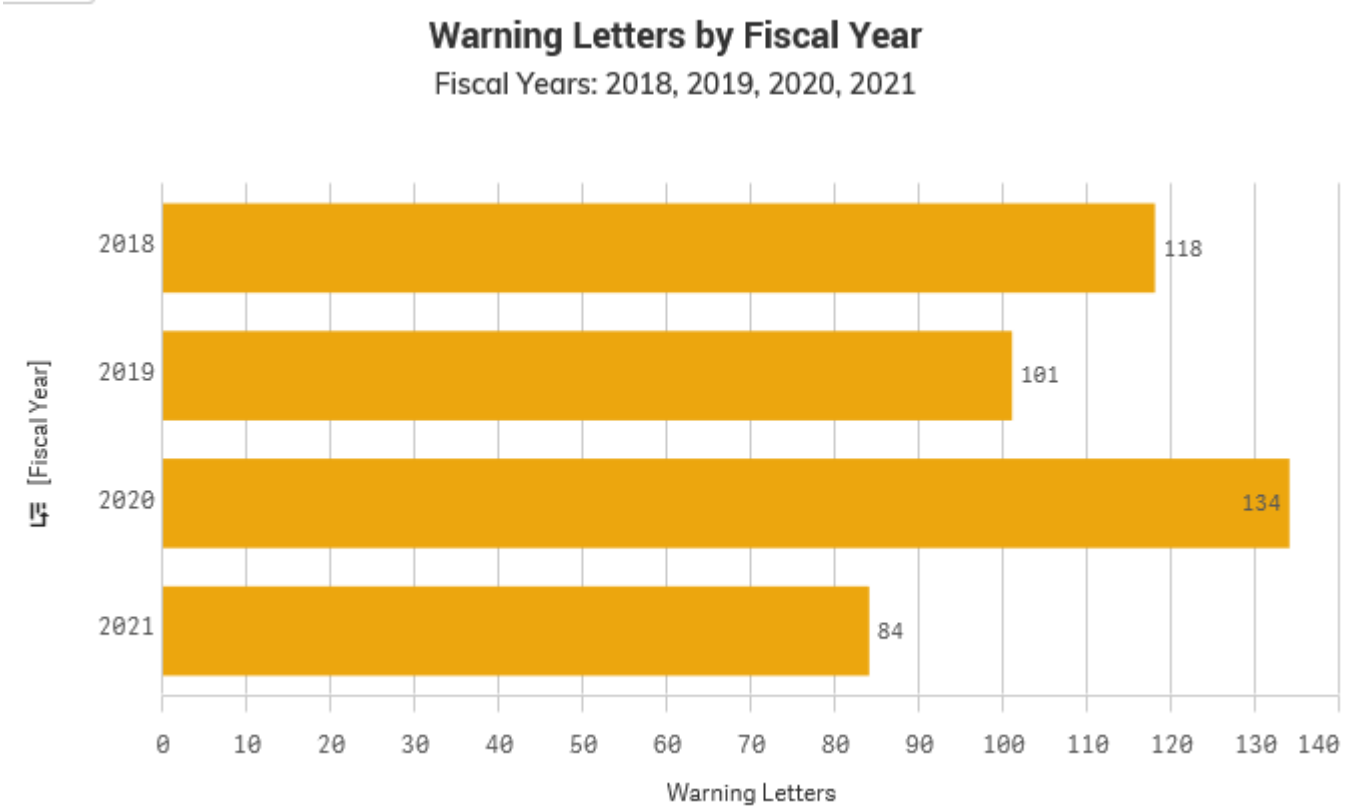
Advisory Actions - Warning Letter

Compliance Achievement

The observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the Acts enforced by the agency.

FDA Compliance

Warning Letter Count for Food and Cosmetic Products in US, FY18-FY21

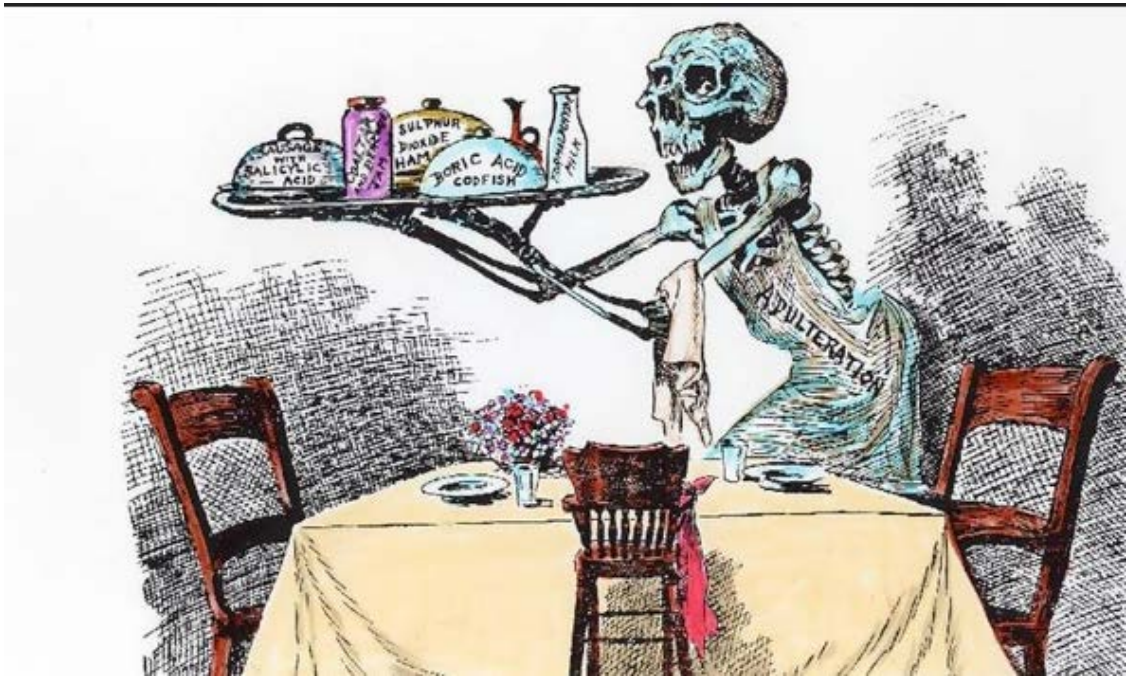


FDA Compliance

Warning Letter Count for Food and Cosmetic Products in Florida and Puerto Rico FY18-FY21

Food Adulteration

Section 402 [21 U.S.C. 342] of the
Federal Food and Drug Cosmetic Act



FDA Compliance

Example of 402 (Adulterated Food) "Charges"

402(a)(4), [21 U.S.C. 342(a)(4)]
-Adulterated food

A food shall be deemed to be adulterated

(a) Poisonous, insanitary, etc., ingredients
(4) if it 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

Example of 402 (Adulterated Food) “Charges”

402(g)(1), [21 U.S.C. 342(g)(1)]

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

FDA Compliance

What FDA regulations apply to your products?

FDA regulations: 21 CFR, Food and Drugs

FDA Compliance

21 CFR – Food & Drugs
Not an all inclusive list

Subchapter B - Food for Human Consumption **Parts 100-199**
Subchapter E - Animal Drugs, Feeds, and Related Products **Parts 500-589**
Subchapter G - Cosmetics **Parts 700-799**

21 CFR – Food & Drugs

Not an all inclusive list	
21 CFR Part 117 CGMP, HAZARD ANALYSIS, & RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD	21 CFR Part 101 FOOD LABELING **FOOD LABELING**
21 CFR Part 111 CGMP IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR **DIETARY SUPPLEMENTS** 	21 CFR Part 112 STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF **PRODUCE FOR HUMAN CONSUMPTION** 
21 CFR Part 113 HERMETICALLY PROCESSED **LOW-ACID FOODS** PACKAGED IN HERMETICALLY SEALED CONTAINERS 	 21 CFR Part 114 **ACIDIFIED FOODS**
21 CFR Part 120 **(Juice)** HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS	21 CFR Part 123 **FISH AND FISHERY PRODUCTS** 
21 CFR Part 118 PRODUCTION, STORAGE, AND TRANSPORTATION OF **SHELL EGGS** 	 21 CFR Parts 500-599 21 CFR Part 507- CGMP, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR **FOOD FOR ANIMALS**

Question for Participants

In addition to 21 CFR 117 (cGMP and PC for human food) and 21 CFR 101 (food labeling)

What other 21 CFR regulations are applicable to your food operations?

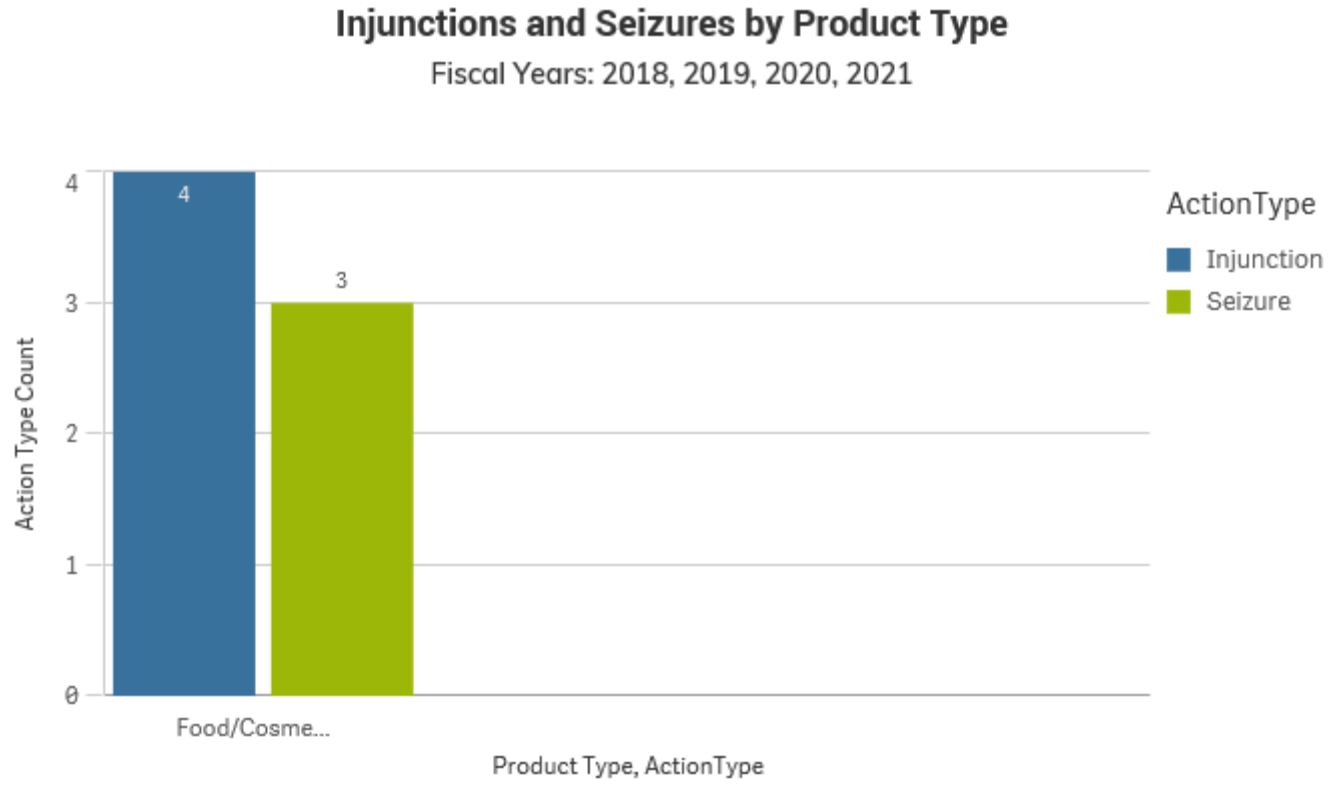
21 CFR Part 111 CGMP IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR **DIETARY SUPPLEMENTS**	21 CFR Part 112 STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF **PRODUCE FOR HUMAN CONSUMPTION**
21 CFR Part 113 HERMETICALLY PROCESSED **LOW-ACID FOODS** PACKAGED IN HERMETICALLY SEALED CONTAINERS	21 CFR Part 114 **ACIDIFIED FOODS**
21 CFR Part 120 **(Juice)** HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS	21 CFR Part 123 **FISH AND FISHERY PRODUCTS**
21 CFR Part 118 PRODUCTION, STORAGE, AND TRANSPORTATION OF **SHELL EGGS**	21 CFR Parts 500-599 21 CFR Part 507- CGMP, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR **FOOD FOR ANIMALS**

FDA Compliance Activities

Other Activities

- Administrative actions
- Judicial Actions such as seizure or injunction

FDA Compliance



Resources on www.fda.gov

Compliance Resources at www.fda.gov

Guidance Information

- Compliance Program Guidance Manual (CPGM)
- FDA Compliance Policy Guides (CPG)
- Regulatory Procedures Manual (RPM)

Resources on www.fda.gov

FDA Guidance Documents Link.

Not an all inclusive list. FDA recommendations (not legally binding)

Acidified & Low-Acid Canned Foods Guidance Documents & Regulatory Information	**Food Allergens**/Gluten-Free Guidance Documents & Regulatory Information	Eggs Guidance Documents & Regulatory Information
Bottled Water/Carbonated Soft Drinks Guidance Documents & Regulatory Information	Food Safety (FSMA): Questions and Answers Regarding Food Facility Registration (Seventh Edition) (August 2018)	Produce & Plant Products Guidance Documents & Regulatory Information
Dietary Supplements Guidance Documents & Regulatory Information	Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals	Reportable Food Registry Guidance Documents & Regulatory Information
Juice Guidance Documents & Regulatory Information	(DRAFT) Control of ***Listeria monocytogenes*** in Ready-To-Eat Foods (January 2017)	Salmonella Guidance Documents & Regulatory Information
Food Defense Guidance Documents & Regulatory Information	Imports & Exports Guidance Documents & Regulatory Information	Labeling & Nutrition Guidance Documents & Regulatory Information
Ingredients, Additives, GRAS & Packaging Guidance Documents & Regulatory Information	Sanitation & Transportation Guidance Documents & Regulatory Information	Seafood Guidance Documents & Regulatory Information

FDA CFSAN

The Center for Food Safety and Applied Nutrition, known as CFSAN,

- Field programs
- Agency administrative tasks
- Scientific analysis and support
- Policy, planning

Resources on www.fda.gov

CFSAN Training Videos

Food Safety: Application of Risk Analysis to Food Safety ***Available in:*** English **|** Spanish **cc (closed captioning)** **Tip ->** right click on your player and enable CC	**Food Safety: FDA's Role in the U.S. Food Safety System** ***Available in:*** English | Spanish cc
Food Labeling: Requirements for Labeling on Food & Dietary Supplements, Nutrition Labeling, & Allergen Labeling *Available in:* English | Spanish cc	**Dietary Supplements: Regulatory Approaches to Dietary Supplements and their Claims** *Available in:* English Closed captioning (cc) available in Spanish
Produce Safety: A Global Concern *Available in:* English | Spanish cc	**Food Defense:** *Available in:* English | Spanish cc
Food Safety: Reportable Food Registry *Available in:* English Closed captioning (cc) available in Spanish	**Food Safety: FDA's Pesticide Program** *Available in:* English Closed captioning (cc) available in Spanish
Food Safety: LACF and Acidified Foods Regulations and Requirements *Available in:* English Closed captioning (cc) available in Spanish	**Feed Safety: Animal Feed Safety** *Available in:* English Closed captioning (cc) available in Spanish

Resources on www.fda.gov

Question for participants

Name at least one video training you may find useful?

CFSAN Training Videos

Food Safety: Application of Risk Analysis to Food Safety	Food Safety: FDA's Role in the U.S. Food Safety System
Food Labeling: Requirements for Labeling on Food & Dietary Supplements, Nutrition Labeling, & Allergen Labeling	Dietary Supplements: Regulatory Approaches to Dietary Supplements and their Claims
Produce Safety: A Global Concern	Food Defense:
Food Safety: Reportable Food Registry	Food Safety: FDA's Pesticide Program
Food Safety: LACF and Acidified Foods Regulations and Requirements	Feed Safety: Animal Feed Safety

Summary

- It is recommended your firm provide a response when an FDA-483 is issued.
- Should you receive a warning letter, do respond in a timely manner
- Helps to provide documentation to support CAPA was implemented
- Utilize information available on www.fda.gov
- Consider hiring a qualified third party food consultant
- Attend training, for example:
  - FSMA training
  - Seafood HACCP

QUESTIONS?
CONTACT FDA

General food-related questions

Inquiries: Submit Your Question

Tel: **1-888-SAFEFOOD**

Center for Food Safety and Applied Nutrition (CFSAN)
Division of Education, Outreach & Information,
Information Center Branch
Food and Cosmetic Information Center
Hours: 10 AM - 4 PM ET
Closed Thursdays 12:30 PM – 1:30 PM ET

Small Business Assistance

ORA Small Business Representative
David Arvelo
FDA - Dallas District Office
1201 Main Street, Suite 7200
Dallas, Texas 75202
Phone: 214-253-4979

Human and Animal Food Operations East Division 4 Compliance Branch

Email: ORAHAFEAST4FirmResponses@fda.hhs.gov


Thanks!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