



U.S. Food and Drug Administration

Glenn Bass, Deputy Director, West

Office of Regulatory Affairs

Office of Human and Animal Food Operations

U.S. Food & Drug Administration | FDA

2020 Northeast Center to Advance Food Safety (NECAFS)

Topic: FSMA Update: Preventive Controls Human Food

February 11, 2020

Center for Safety and Applied Nutrition

Core business processes:

- Provide **Policy** for oversight of regulated products
- Provide **Program** development
- Provide Program **Priorities**
- Enforcement action where appropriate



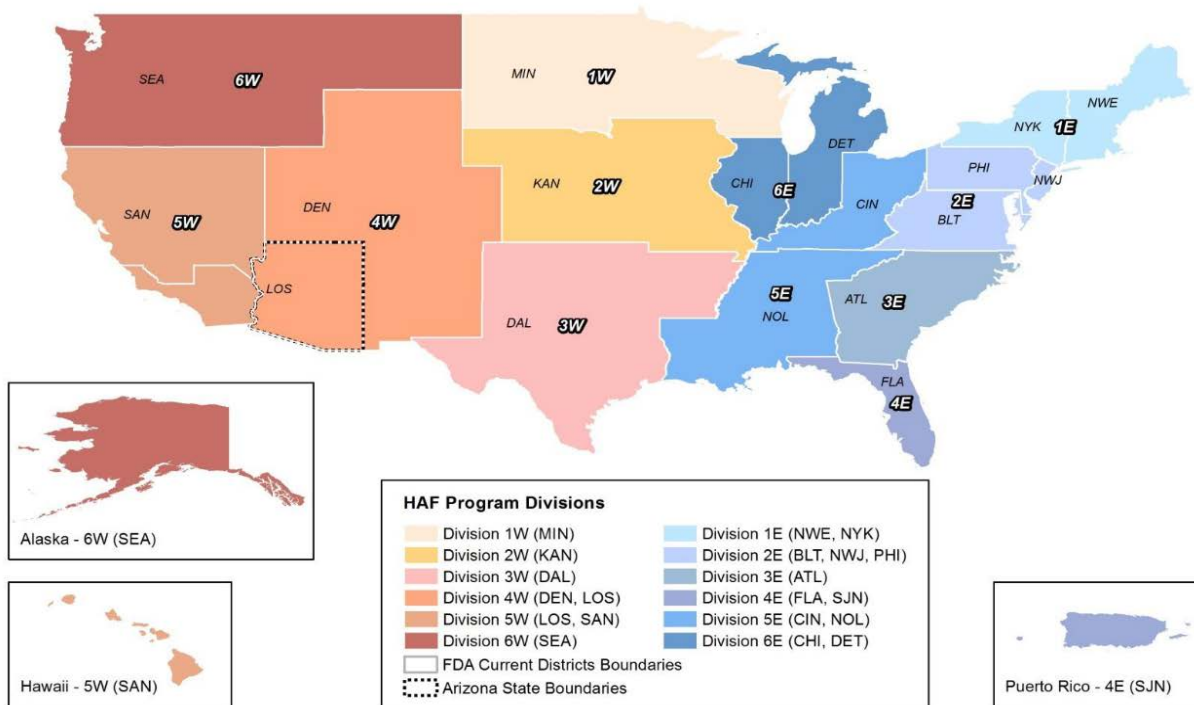
Office of Regulatory Affairs

Core business processes:

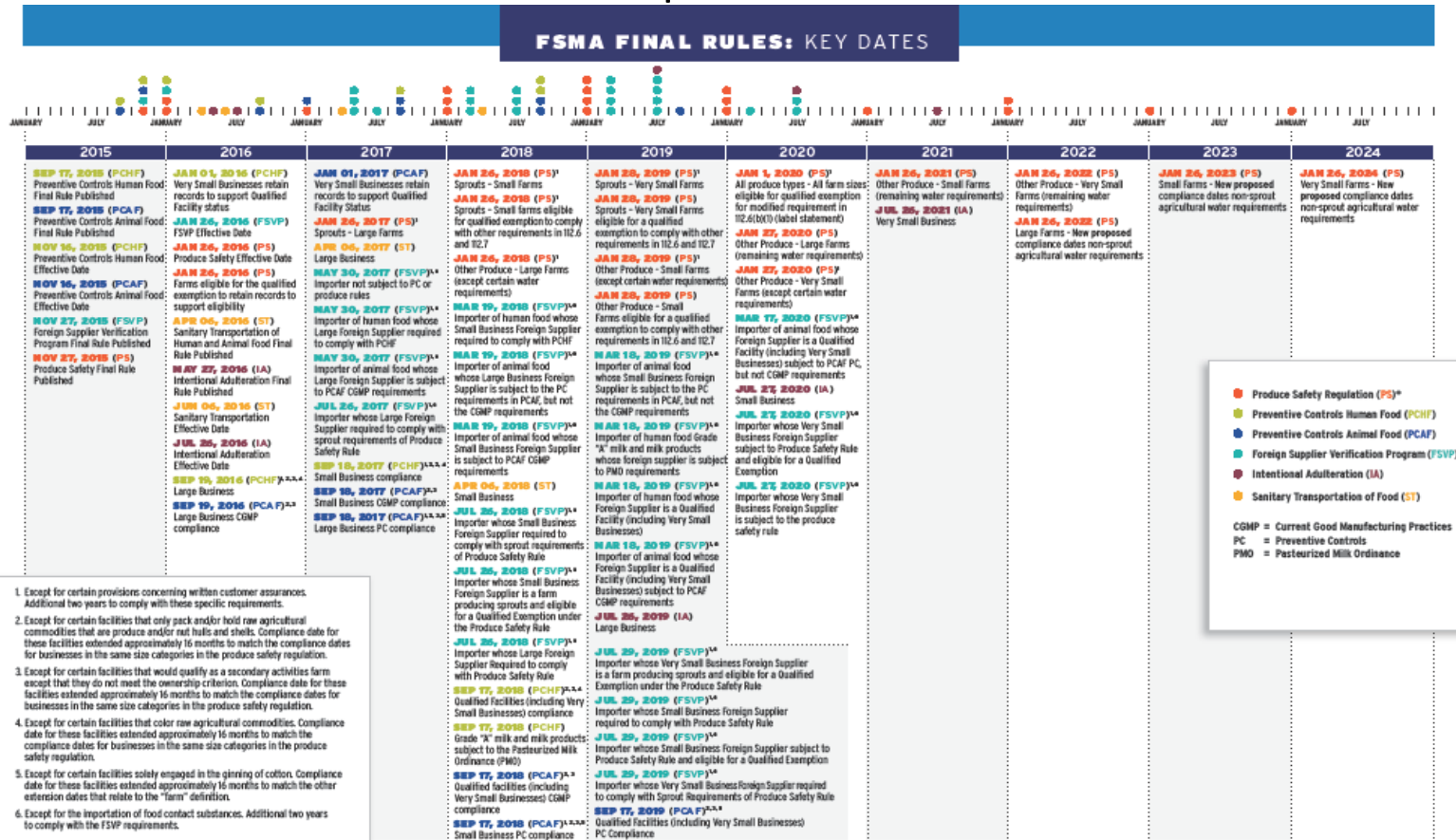
- Conduct Inspection/Investigation
- Conduct Sample Collection
- Conduct Sample Analyses
- Enforcement Action where appropriate



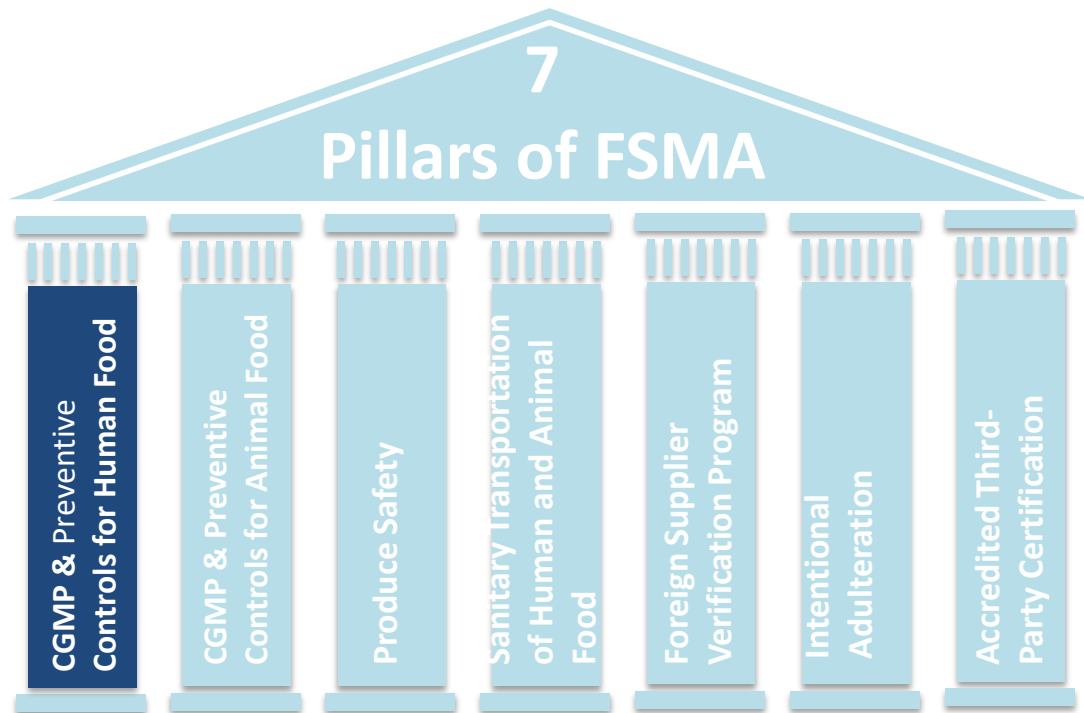
ORA – Office of Human and Animal Food Operations



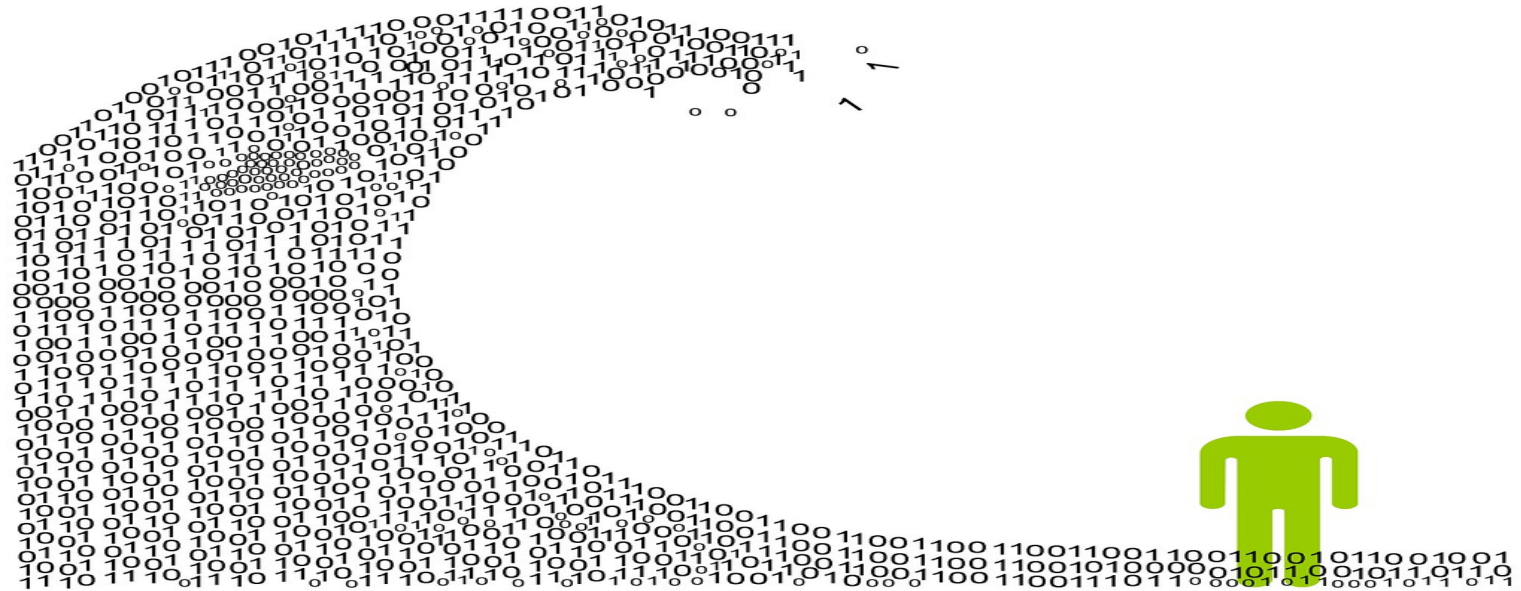
Overview of FSMA Final Rules: KEY DATES



Food Safety Modernization Act (FSMA)



Data Overload



Preventive Controls and Sanitary Human Food Operations



Browser address bar: <https://www.fda.gov/media/131744/download> fda.gov

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FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM GUIDANCE MANUAL

PROGRAM **7303.040**

CHAPTER 03: FOODBORNE MICROBIOLOGICAL HAZARDS

SUBJECT: PREVENTIVE CONTROLS AND SANITARY HUMAN FOOD OPERATIONS		IMPLEMENTATION DATE: 10/17/2019
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES (PAC)	
USE APPROPRIATE PRODUCT CODES	REPORT PROGRAM ACTIVITIES UNDER THE FOLLOWING PAC CODES: 03040 (FOOD CGMP INSPECTIONS)	

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Preventive Controls and Sanitary Human Food Operations



1. Food CGMP Inspection
2. Limited Scope Inspection
3. Full Scope Inspection
4. **Modified Requirement of Qualified Facilities**
5. Modified Requirement at facilities solely engaged of unexposed packaged food that require time/temp controls for food safety



FDA 2020 Inspections To Date: 02.02.2020

	Planned	Accomplished
CGMP/Limited Scope PC Human Food	Not Planned	Domestic: 1035 Foreign: 282 State: 874
CGMP/ Full Scope PC Human Food	812 (domestic) 444 (state) 150 (foreign)	FDA: 211 State: 35 47
FSVP	1325	290
Sanitary Transportation	144	43



Assignment Update: 02.01.2020

	Planned	Accomplished
Produce Safety	180 – Domestic 40 - Foreign	19 (130)=149 (83%) 28 (27)=30 (125%)
Frozen Berries	1000 – Domestic 1000 - Import	811 (81%) 284 (28%)
RAC: Romaine Lettuce	270	52 (19%)
Intentional Adulteration	300 (D & F) QUICK CHECK	Issues in March 2020

**Most
Common
FDA
Observations
(2017-2019)**

PC HF (21 CFR 117, Subpart C)

- Hazard Analysis – Identification of Hazard
- Sanitation Controls Verification Procedures
- Sanitation Controls Monitoring Procedures
- Allergen Controls Monitoring Procedures

Estimated Inspection Hours (2017-2019)

	NAI	VAI	OAI
FDA	40 – 65 hours	47 – 90 hours	50 – 134 hours
State	29 hours	32 hours	-

FDA Regulatory Activities (2017 – 2019)



23 Warning Letters



44 Regulatory Meetings



4 Injunctions

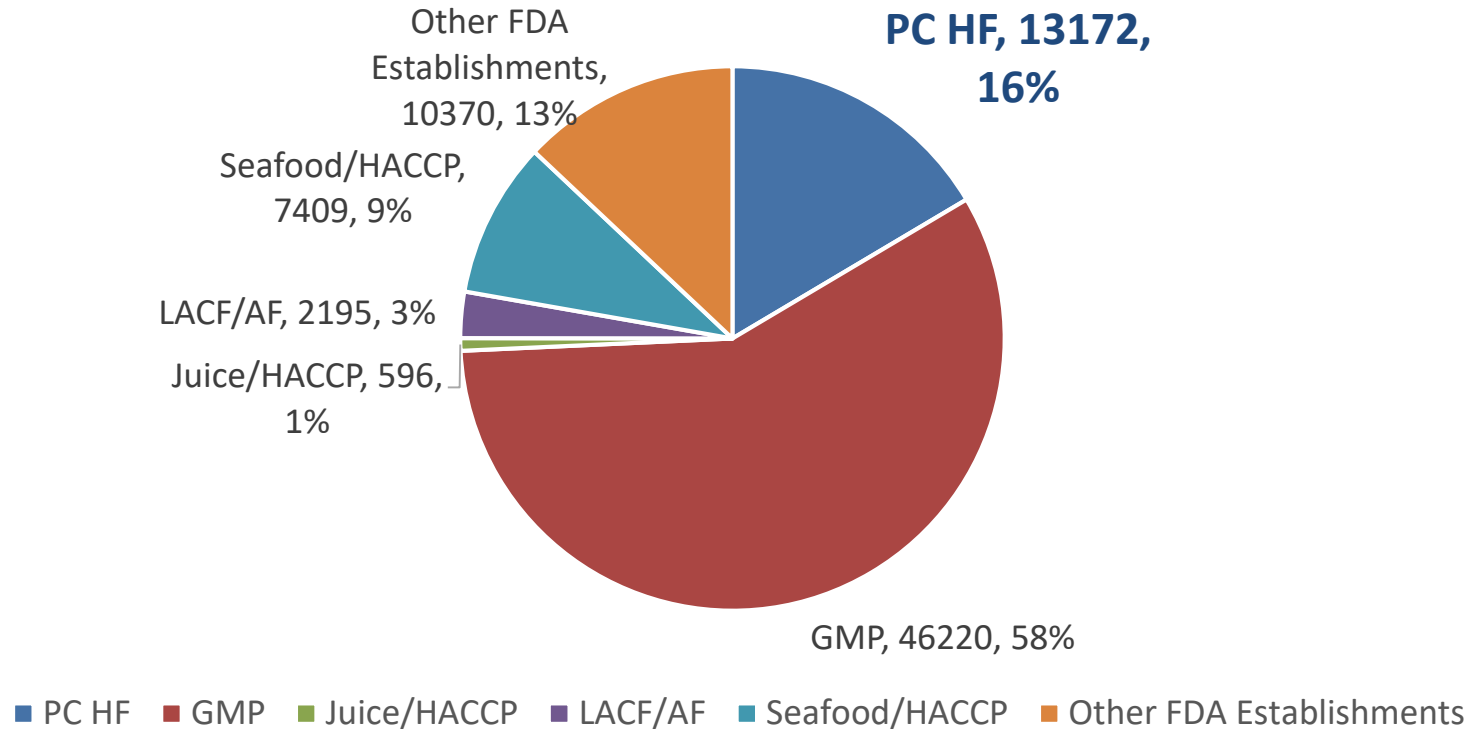
Preventive Control Human Food Inventory



Row Labels	HR	NHR	Grand Total	Inspection Frequency Each Year HR/NHR		Total Full PC Inspection Frequency
Full PC	6686	6486	13172	2229 HR	1297 NHR	3,526
GMP	7761	38459	46220			
Juice HACCP	552	44	596			
LACF/ACD	1647	548	2195			
Not Eligible for State Contract	4521	5849	10370			
Seafood HACCP	3531	3878	7409			
(blank)						
Grand Total	24698	55264	79962			

FDA Inventory by Inspection Scope

N = 79,962



Data Source: CFSAN OC algorithm applied 12-15-

2019

Inspection Scope

Full Scope PC Eligible	19949
GMP	27180
Modified - Refrigerated Warehouse	10676
Modified (Qualified Attestation)	1206
Modified Eligible (No attestation)	17002
Null Sales/Employee	3949
(blank)	
Grand Total	79962

FSMA Inflation Adjusted Cut Offs

- <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>
- Qualified Facility- Very Small: 2018
- Human Food: 1.1M;
- Animal Food: 2.75M

- How can I obtain information a list of businesses that submitted attestations, [Form FDA 3942a](#) (for Human Food) or [Form FDA 3942b](#) (for Animal Food)?
- There are various ways to access the information. Available information is based on fields from [Form FDA 3942a](#) (for Human Food) or [Form FDA 3942b](#) (for Animal Food).
- **Option 1.** If you have the ability to customize ORADSS reports, then Qualifying Facility Self-Attestation objects are available to query in ORADSS FIRM universe under Firms - QFA folder (Screen shot below).

PC.16 Does the final rule include provisions to appeal the withdrawal of a qualified facility exemption?

Yes. The final rule provides procedures for a facility to appeal the withdrawal order and request an informal hearing. And there is a procedure for reinstating an exemption that was withdrawn. Attaching Subpart E relative to withdrawal.

Section 6 – STATUS CHANGE (If applicable)

Human food facilities that have changed status from a "qualified facility" to "not a qualified facility" must notify FDA of that change in status by July 31 of the applicable calendar year. Check the box below to indicate a status change.

- ☐ The above-named facility is no longer a "qualified facility" as defined in 21 CFR 117.3 based on the annual determination.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

- ☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 (Street address, P.O. box, etc.)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

State/Province/Territory

Country

ZIP or Postal Code

Implementation Continues

- Coordinating OJE
- Dynamic workforce
- Maintaining accurate inventory
 - Limited to no data of business e.g. sales, products (unable to determine inspection scope for planning)

FDA Data Dashboard

Compliance Dashboards

[Inspections](#)

[Compliance Actions](#)

[Recalls](#)

[Imports Summary](#)

[Import Refusals](#)

FSMA Data Search

Find firm compliance and enforcement information.

[Search Firm Information](#)

[TPP Participants](#)

Transparency – [FDA Data Dashboard](#)

Industry Technical Assistance Network (TAN)



Browser window showing the FDA website: <https://www.fda.gov/food/food-safety-mo> (FSMA Technical Assistance N...)

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Total	10,828
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Inquiries Received by FSMA Topic

FSMA Topic	Inquiries Received
Preventive Controls-Human Food	4,156
Foreign Supplier Verification Program (FSVP)	2,479
Produce Safety	1,302
Sanitary Transportation for Human and Animal Food	1,292
Preventive Controls-Animal Food	743
Accredited Third-Party Certification (3rd Party)	339
Other	210
Intentional Adulteration	206
Lab Accreditation	52
Voluntary Qualified Importer Program (VQIP)	49
Total	10,828

Inquiries Received, Domestic vs. International

Country of Origin	Inquiries Received
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References

- Realizing FDA's website is not as intuitive as one would hope, I am also adding links based on common questions from external stakeholder
-
- NEW Compliance Program for Preventive Controls: <https://www.fda.gov/media/131744/download>
- General Compliance Programs for Food Safety Programs: <https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs>
- Investigations Operations Manual,
 - Chapter 4 – Sampling, affidavits <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/chapter-4-sampling>
 - Chapter 5 – Establishment Inspections, Section 5.3 - Photographs: <https://www.fda.gov/media/76769/download>
-
- ORA District Directors <https://www.fda.gov/about-fda/contact-ora/ora-district-directors>
- Intentional Adulteration Blog, September 2019 (Quick Checks) <https://www.fda.gov/food/conversations-experts-food-topics/protecting-food-supply-intentional-adulteration-such-acts-terrorism>
- Facility Risk based on FSMA Factors (archived, CFSAN is publishing an update soon): <https://wayback.archive-it.org/7993/20170723070159/https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm295345.htm>
- FDA Data Dashboard: <https://www.fda.gov/about-fda/transparency/fda-data-dashboard>
- Field Management Directives: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/field-management-directives>

Thank You, Questions?

Working Together for safe food