



**U.S. FOOD & DRUG
ADMINISTRATION**

Preventive Controls: *Food Safety into the 21st Century*

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

Association for Food & Drug Officials (AFDO)

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FDA Food Safety Modernization Act

Intended to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system.

FY2018 FDA Assignments

FSMA	Date of Issuance	Planned Number of Inspections
Preventive Controls in Human Food	Issued December 18, 2017	Domestic (400), Foreign (100) Businesses within staggered compliance dates
Foreign Supplier Verification Program	Issued November 15, 2017	Importers (2275)
Preventive Controls in Animal Food (Limited to CGMP)	Issued October 16, 2017	Domestic (304)
Sprout Inspections	Issued September 15, 2017	Domestic (90), Foreign (1)
Other Center directed assignments	Issued throughout year(s)	Inspections, Sample Collections (Product or Environmental)

Regulators Training

In addition to Alliance Courses

- Preventive Controls for Human Food for Regulators (FD254)
- Preventive Controls for Animal Food for Regulators (VM220)
- Modernized GMP Inspections broadcast (FD8000R)
- [Sanitary Transportation Carriers Training Module](#) (FDA's Public webpage)
- FSMA Chats; FSMA and PC Rule Readiness
- Training schedule available on ORA [OTED](#) web page, Pathlore Learning Management System

FDA Inspections – FY2017



	Planned	Accomplished
Human Food Modernized GMP	450	621
Comprehensive PC	240 (Domestic) 60 (Foreign)	123* 46
Animal Food CGMP	250	224
FSVP	325	285

**Conducted by cadre; includes On-the-Job Experience*



FDA Inspections - FY2018 to date

	Planned	Accomplished*
Human Food Modernized GMP	Not Planned	3,234
Comprehensive PC	400 (domestic) 100 (foreign)	210** 101
Animal Food CGMP	304	235
FSVP	2,275	242
Sprout Facilities	90	25

**Data as of 5/1/2018. ORA OISM.*

***Conducted by CSO's completing regulators course, includes On-the-Job Experience.*



Average Number of Days in Facility

Type of Inspection	Number of Days
Full Requirements of the Preventive Controls Human Food	4 – 5 Days
Facilities Exempt from full requirements of the Preventive Controls Human Food	3 - 4 Days
CGMP of the Preventive Controls Animal Food	3 Days

Challenges in calculating average hours due to team inspections.

Educating Before and While We Regulate

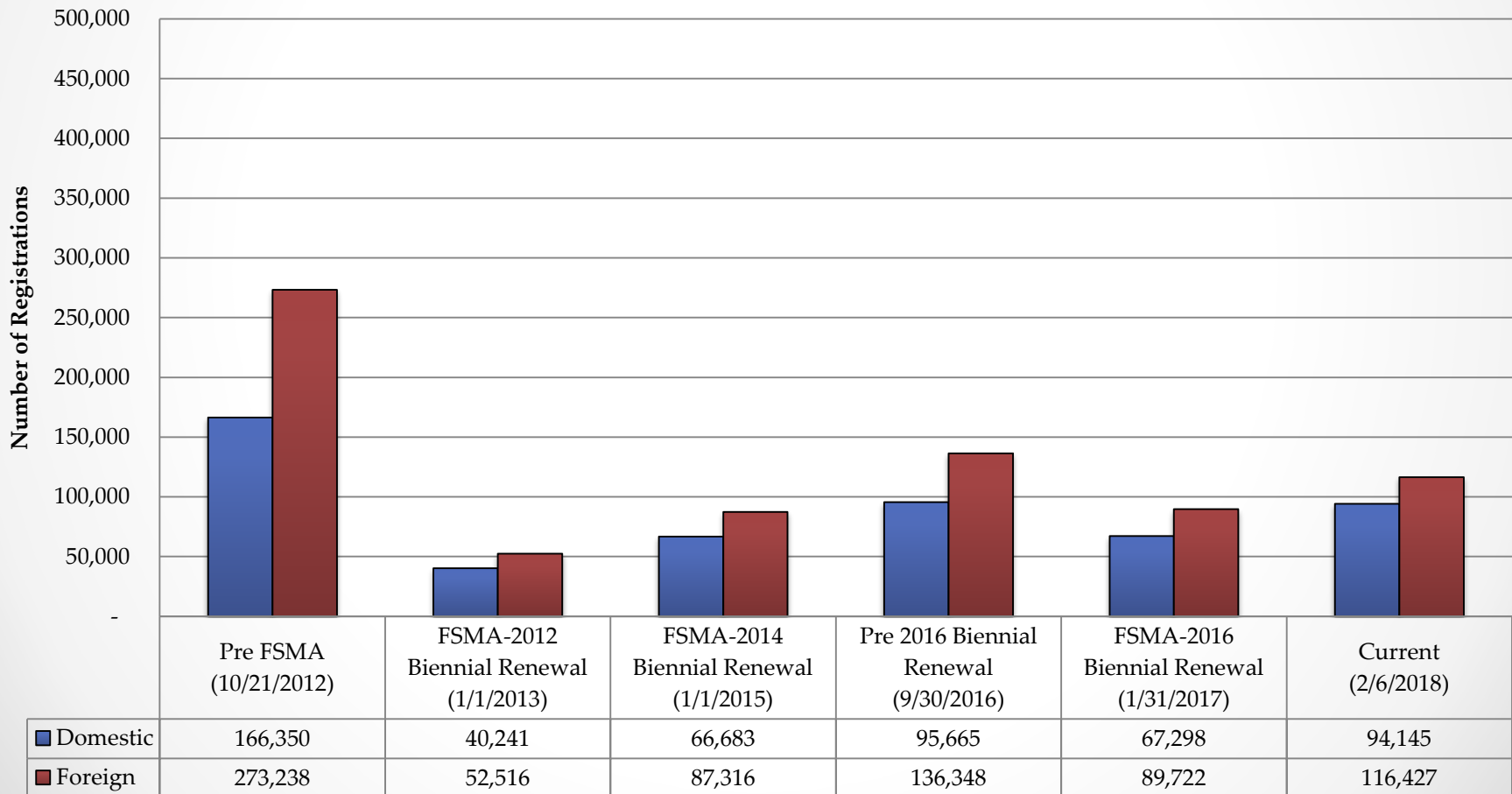
FDA Issues Warning Letters

- Human Food – 21 CFR CGMP Regulations, History of violations from GMP requirements
- Animal Food – 21 CFR CGMP Regulations, Misbranding Charges, Medicated Feed, and History of violations

Scope of Work



Food Facility Registration Inventory



Qualified Facilities

- Business with average annual sales of <\$500,000 and at least half the sales to consumers or local retailers or restaurants (w/in same state or w/in 275 miles); or,
- Very small business (including any subsidiaries and affiliates) averaging less than \$1 million, adjusted for inflation, per year, etc.
- Modified requirements apply. Notification through attestation, and must be submitted every two years. See DRAFT Guidance Document (May 2016).



What's Next?

September 17, 2018: Very small businesses (averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food

Qualified facility attestations can be submitted during food facility registration cycle.

Working together, learning together