Compliance & Enforcement (Food)

To protect public health, FDA monitors domestic firms and the foods that they produce. FDA also has multiple initiatives for monitoring imported products and foreign firms exporting to the United States. FDA protects consumers from unsafe foods through:

- Research and methods development
- Inspection
- Voluntary Destruction
- Sampling
- Recall
- Seizure
- Injunction
- Criminal prosecution

This section provides access to FDA's warning and untitled letters, information about inspection and compliance programs, and the Reportable Food Registry.

CFSAN Adverse Event Reporting System (CAERS) (/food/compliance-enforcement/cfsan-adverse-event-reporting-system-caers)

A database that contains information on adverse event and product complaint reports submitted to FDA for foods, dietary supplements, and cosmetics.

Economically Motivated Adulteration - Food Fraud (/food/compliance-enforcement-food/economically-motivated-adulteration-food-fraud)

FDA works on several fronts to protect consumers from the potential health risks and economic harm from food fraud.

Food Compliance Programs (/food-compliance-programs)

FDA's compliance programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the laws administered by FDA.

Inspections (/inspections)

Learn how the FDA helps to keep food safe through inspections. The agency's approach is risk-based and seeks to form a complete understanding of a facility’s or farm’s food safety system.

Reportable Food Registry (/reportable-food-registry)

The Reportable Food Registry is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Reportable Food Registry helps FDA better protect public health by tracking patterns and targeting inspections.

Sampling (/sampling)

The FDA Food Safety Modernization Act is based on preventing problems before they happen, rather than solely responding to outbreaks of foodborne illness. But in order to

develop prevention-based systems, you need data and other information to help identify hazards that need to be addressed and minimized. Sampling is an important method for gathering data and information.

Untitled Letters (/untitled-letters)

Untitled letters address violations from manufacturing controls or labeling that do not meet the threshold of regulatory significance for a Warning Letter. Untitled letters can also be issued to websites.

Warning Letters (/warning-letters)

When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter.

Voluntary Destruction

On February 21, 2018, the FDA announced the voluntary destruction and recall of a large volume of kratom-containing dietary supplements manufactured and distributed nationwide under the brand names Botany Bay, Enhance Your Life and Divinity by Divinity Products Distribution of Grain Valley, Missouri. For more details: FDA oversees destruction and recall of kratom products; and reiterates its concerns on risks associated with this opioid (/news-events/press-announcements/fda-oversees-destruction-and-recall-kratom-products-and-reiterates-its-concerns-risks-associated).

Compliance Resources

- Compliance Policy Guidance Manual (/compliance-policy-guides)
- Compliance Program Manual (/compliance-program-guidance-manual)
- Regulatory Procedures Manual (/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual)
- Investigations Operations Manual (/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual)

Enforcement Resources

- Recalls, Market Withdrawals, & Safety Alerts (/recalls-market-withdrawals-safety-alerts)
- Warning Letters (/warning-letters-1)
- Untitled Letters (/untitled-letters)
- Guidance for Industry: Product Recalls, Including Removals and Corrections (/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections)

Analytical Resources

- Bacteriological Analytical Manual (BAM) (/food/laboratory-methods/bacteriological-analytical-manual-bam)
- Macroanalytical Procedures Manual (MPM) (/food/laboratory-methods/macroanalytical-procedures-manual-mpm)
- Pesticide Analytical Manual (PAM) (/food/laboratory-methods/pesticide-analytical-manual-pam)

- Bad Bug Book: Introduction (/bad-bug-book)
- CFSAN Laboratory Quality Assurance Manual (/food/laboratory-methods-food/cfsan-laboratory-quality-assurance-manual)

Additional Resources

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program (/medwatch-fda-safety-information-and-adverse-event-reporting-program)
- Dockets Management (/dockets-management)