



Food and Dietary Supplement Regulation Year in Review

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Quiz



FDA by the Numbers: Inspections

FY2022 as of March 1:

- **Limited Scope**
 - Domestic Limited Scope PCHF: 1154
 - Foreign Limited Scope PCHF: 23
 - State Limited Scope PCHF: 1246
- **Full Scope**
 - Domestic Full Scope PCHF: 147
 - Foreign Full Scope PCHF: 8
 - State-Full Scope PCHF: 96
- **Intentional Adulteration**
 - Domestic Intentional Adulteration: 48
 - Foreign Intentional Adulteration: 5
- **Sanitary Transportation Human Food: 35**
- **FSVP-Human Food: 425**
 - This work is primarily conduct by OEIO-Import Divisions and not OHAFO

FDA by the Numbers: Warning Letters

- FY 2022: ~73 [FYTD]
- FY 2021: ~196 Warning Letters
- FY 2020: ~150 Warning Letters
- FY 2019: ~119 Warning Letters

Warning Letter Trends

- Allergen controls
 - March 2020-21: 11 WL
 - Since March 2021: 6 WL
- Environmental pathogens
- GMPs
- FSVP
 - Most common WL (~56)

Significant Warning Letters



Use of the Enforcement Tool Box



Role of GMPs



Environmental Monitoring

Whole Genome Sequencing: Cracking the Genetic Code for Foodborne Illness

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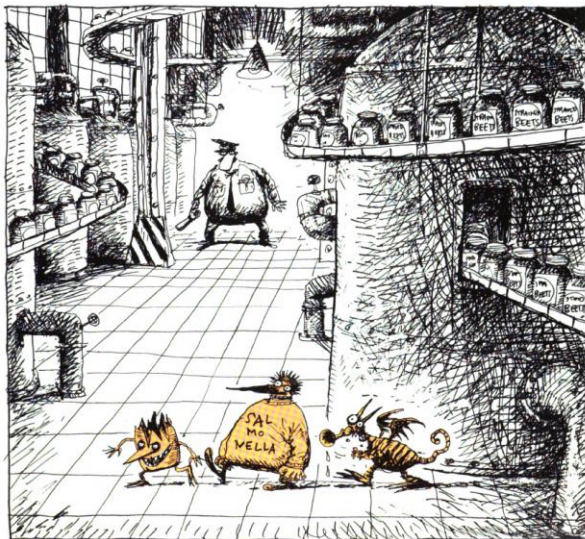
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Bacteria that cause disease have millions of different genomes, or sequences of genetic code, each as unique as a fingerprint.

Content current as of:

06/23/2016

Regulated Product(s)

Food & Beverages

Multipronged Approach



Plaintiff, the United States of America, on behalf of the United States Food and Drug Administration (“FDA”) alleges:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), to halt the manufacture and distribution of adulterated and/or



Food Labeling



Timeline for Revoking French Dressing:

- 1998: Citizen Petition
- 2020: Proposed Rule
- 2022: Final



Timeline for Revoking Frozen Cherry Pie

- 2005: Citizen Petition
- 2020: Proposed Rule
- Unknown*: Final

Musings on 2021 and 2022





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