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How to handle a product recall like a P.R.O.

Show Announcements:

- Download the Mobile App to view the Exhibitor List, Show Schedule, Floor Plan and our Sponsors.
 - Thank you to our Mobile App sponsor: **Epicor (Booth 4465)**
- Wi-Fi – Sponsored by **Cactus Botanicals (Booth 4237)**
 - Select network: **SupplySideWest23**
 - On the splash page, agree to terms & conditions
 - Enter access code: **cactus4237** (access code is case sensitive)
- Please place all devices on silent mode
- The Expo Hall is open today from 10am – 5:30pm.
- There is an LGBTQ + Allies Networking reception tonight from 5:30-7:30pm in South Pacific Ballroom F.
This reception is in partnership with the Naturally Proud Network.



How to Handle a Product Recall Like a P.R.O.



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Of Counsel
Rivkin Radler

October 25, 2023



What is a Product Recall?

“A recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. [*]

Most recalls are voluntarily initiated by a firm though some may not be. One of FDA's roles in a recall is its classification which is a numerical designation, i.e., I, II, or III, assigned to a particular product recall to indicate the relative degree of *health hazard* presented by the product being recalled”.

* A market withdrawal or a stock recovery ***is not*** considered a recall, nor are either of these a replacement for a recall.

<https://datadashboard.fda.gov/ora/fd/fser.htm>

Product Recall Classifications

1. A **Class I** is a situation in which there is a **reasonable probability** that the **use of, or exposure to,** a violative product **will cause** **serious adverse health consequences or death.** (SAHCOD-Humans and Animals)
2. A **Class II** is a situation in which **use of, or exposure to,** a violative product **may cause** **temporary or medically reversible** adverse health consequences or where the **probability of serious adverse health consequences is remote.**
3. A **Class III** is a situation in which **use of, or exposure to,** a violative product is **not likely to cause** adverse health consequences.

<https://datadashboard.fda.gov/ora/fd/fser.htm>

Covered Food Product Categories

Ingredients

Foreign and Domestic



Food & Beverage



Dietary Supplements



Infant Formula



FDA Regulations

21 CFR Part 7 Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7/subpart-C>

21 CFR Part 117.139 Recall Plan (Human Food)

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117/subpart-C/section-117.139>

21 CFR Part 507.38 Recall Plan (Animal Food)

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-507/subpart-C/section-507.38>

21 CFR Part 107 Subpart E – Infant Formula Recalls

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-107/subpart-E>

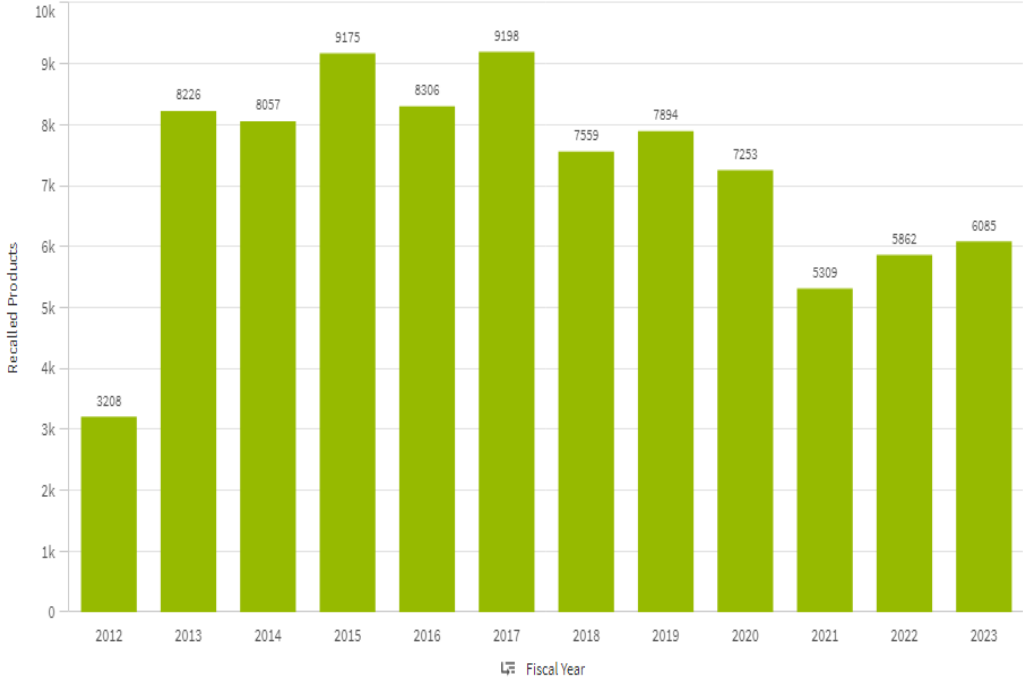
The screenshot shows the Code of Federal Regulations website interface. At the top, there is a navigation bar with links for Home, Browse, Search, Recent Changes, Corrections, Reader Aids, My eCFR, and a search box. Below the navigation bar is the National Archives logo and the title "Code of Federal Regulations" with the subtitle "A point in time eCFR system". To the right is the Department of Health and Human Services seal. A blue banner indicates "Title 21". Below this, a message states "Displaying title 21, up to date as of 9/27/2023. Title 21 was last amended 9/26/2023." with a link to "view historical versions". A purple notification box highlights "New Agency Features" regarding search filters and agency subscriptions. A search bar is present with the placeholder text "Enter a search term or CFR reference (eg. fishing or 1 CFR 1.1)". Below the search bar, the breadcrumb "Title 21 / Chapter I / Subchapter B" is shown, along with "Previous / Next / Top" links. The main content area is titled "ECFR CONTENT" and displays a table of contents for Title 21, Chapter I, Subchapter B, Part 107.

	Part / Section
▼ Title 21 Food and Drugs	1 – 1299
▼ Chapter I Food and Drug Administration, Department of Health and Human Services	
▼ Subchapter B Food for Human Consumption	100 – 199
▶ Part 100 General	100.1 – 100.155
▶ Part 101 Food Labeling	101.1 – 101.108
▶ Part 102 Common or Usual Name for Nonstandardized Foods	102.5 – 102.57
▶ Part 104 Nutritional Quality Guidelines for Foods	104.5 – 104.47
▶ Part 105 Foods for Special Dietary Use	105.3 – 105.66
▶ Part 106 Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications	106.1 – 106.160
▶ Part 107 Infant Formula	107.1 – 107.280

FDA Data Dashboard

Recalled Products by Fiscal Year

Fiscal Years: 2012 - 2023



<https://datadashboard.fda.gov/ora/cd/recalls.htm>

Y Filters Products Events Data Table Download Dataset Back to Top

Search recalls data

Clear All

Recalls Details Download Dataset

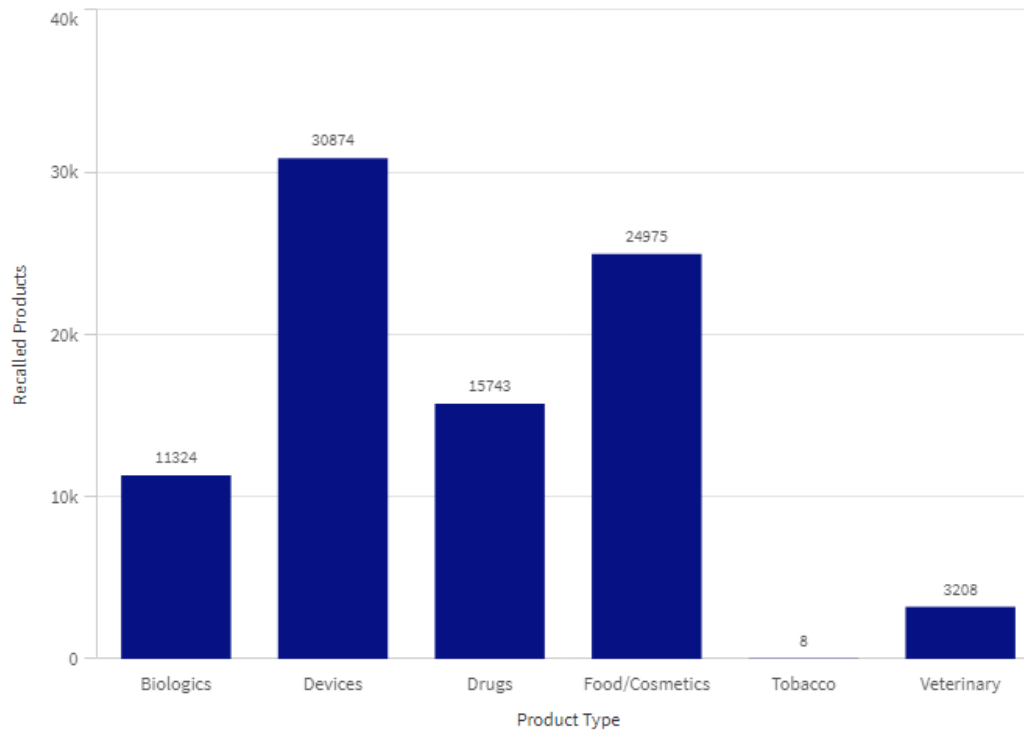
Record Count: 86,132

FEI Number	Recall Details	Recalling Firm Name	Prod... Type	Product Class...	Status	Distribution Pattern	Recalling Firm City	Recalling Firm State	Recalling Firm Country	Center Classification Date	Reason for Recall
1978356	Details...	ImpactLife	Biologics	Class II	Terminated	Alaska; Missouri; Massachusetts	Davenport	Iowa	United States	09/22/2023	Blood Products, for which donor eligi screening was incomplete, were distri
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1478274	Details...	Versiti Illinois Inc	Biologics	Class III	Terminated	Illinois	Aurora	Illinois	United States	09/22/2023	Leukoreduced Apheresis Platelets, ret with an unacceptable temperature, we distributed.
1671462	Details...	Vitalant	Biologics	Class III	Terminated	New Mexico	Albuquerque	New Mexico	United States	09/22/2023	Leukoreduced Red Blood Cells Washe processed in a centrifuge that was not the correct speed, were distributed.

FDA Data Dashboard

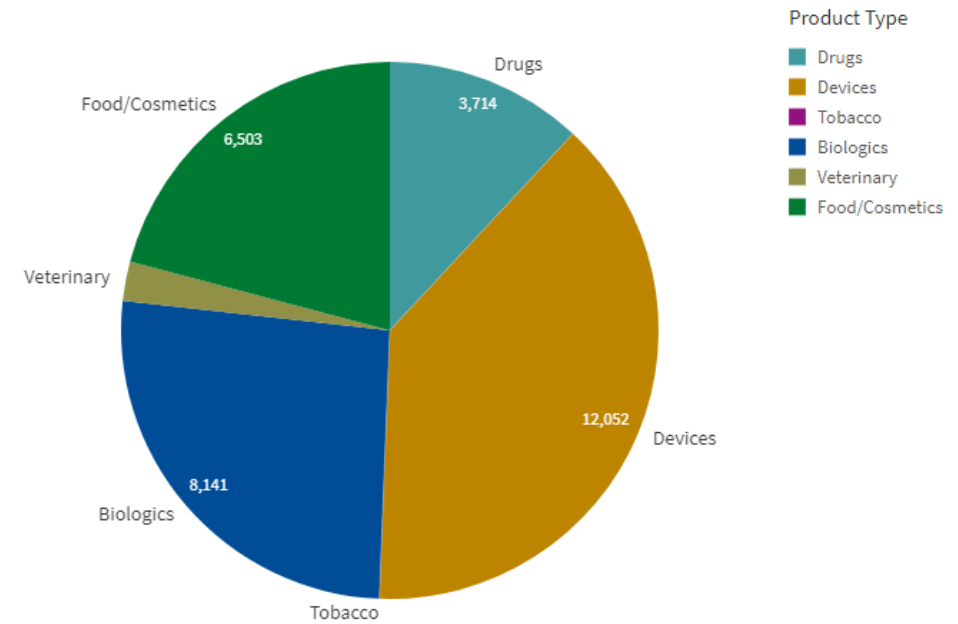
Recalled Products by Product Type

Fiscal Years: 2012 - 2023



Recall Events by Product Type

Fiscal Years: 2012 - 2023




<https://datadashboard.fda.gov/ora/cd/recalls.htm>


Proactive → Responsive → Organized



Proactive
Preventive
Protective



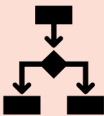
Recall Plan
Recall Team
Responsibilities




Responsive
Rapid
Removal



Investigation
Reporting
Communication



Organized
Orderly
Outcome



SOPs
Recall Strategy
Effective



Discussion and Q & A



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Thank You



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FSPCA Lead Instructor

- Preventive Controls for Human Food (PCHF)
Food Safety Plan (FSP) Preparation and Training
- Foreign Supplier Verification Program (FSVP)

**Come meet us at
Booth #1876**

Thank You