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

informa markets

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.

Heather Fairman
CEO
DF Guardian Consulting, Inc.

Marc Ullman
Of Counsel
Rivkin Radler

October 25, 2023

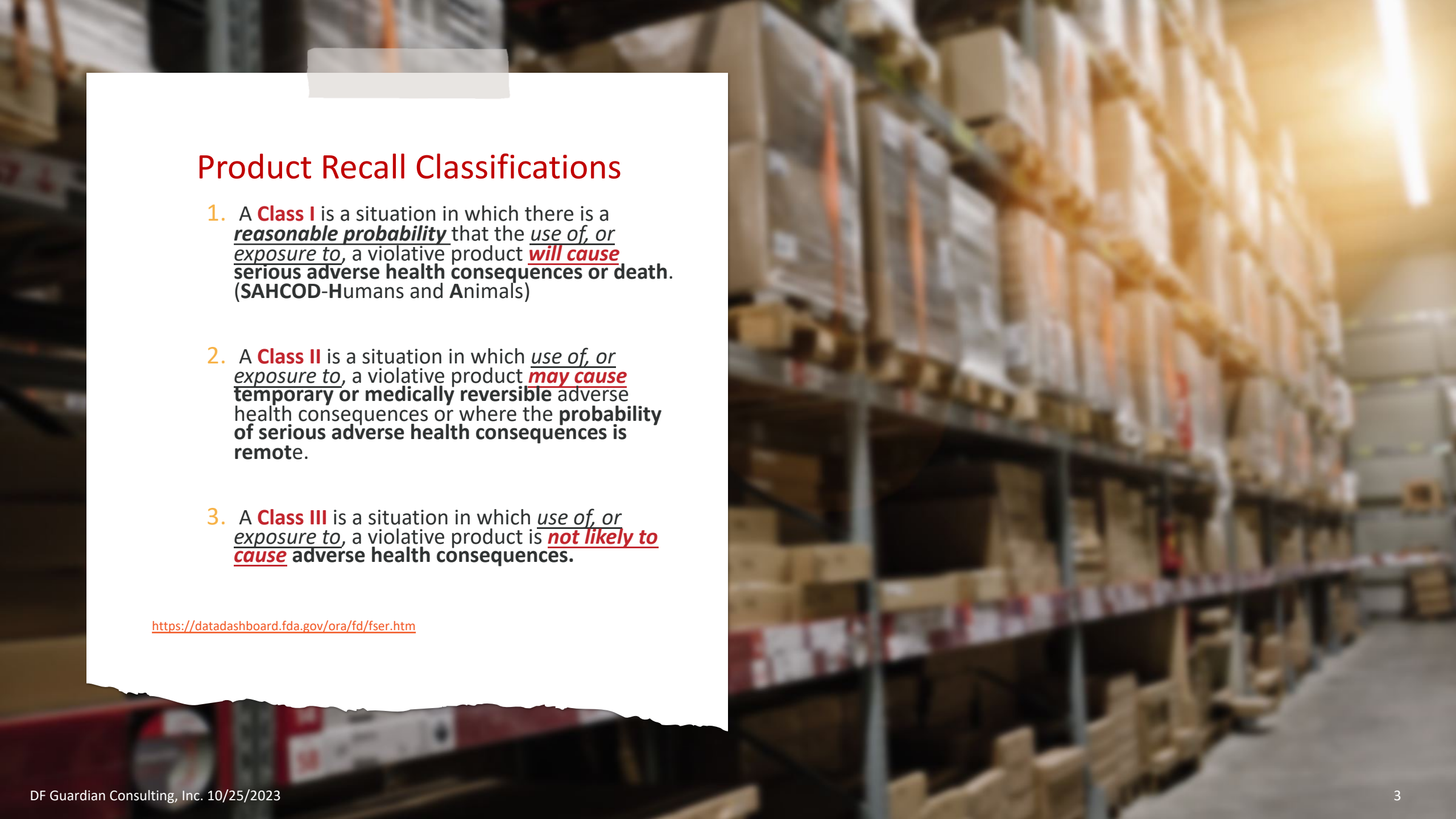
What is a Product Recall?

“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**-**H**umans and **A**nimals)

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 remot**e.

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

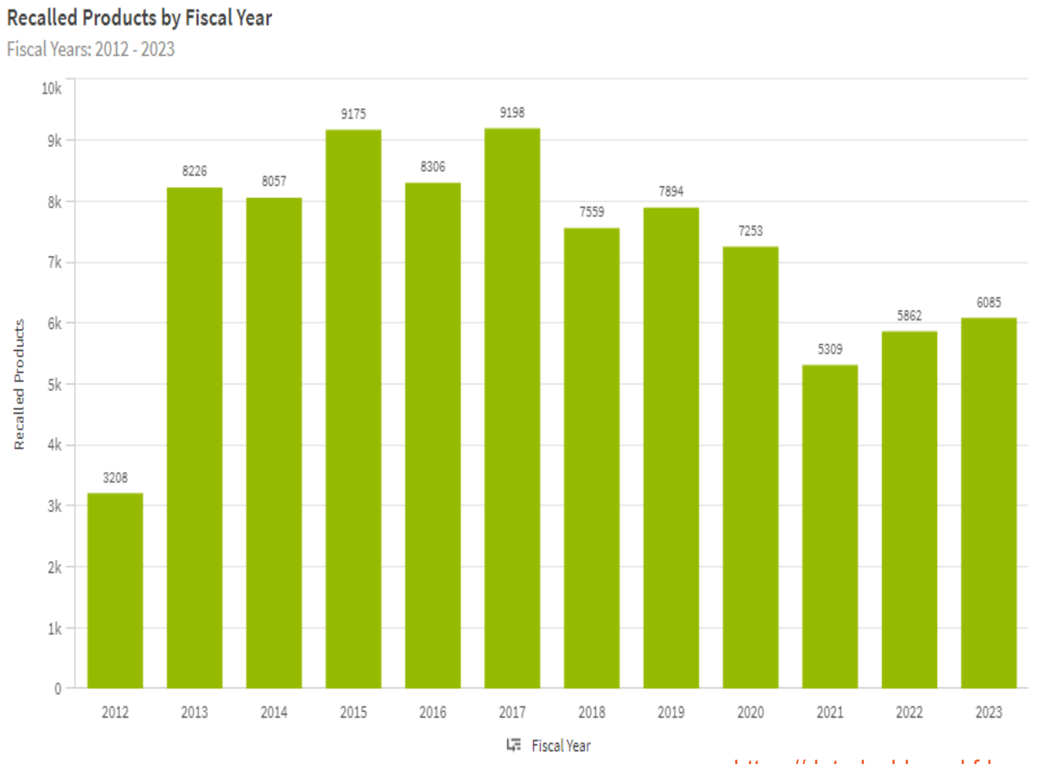
21 CFR Part 507.38 Recall Plan (Animal Food)

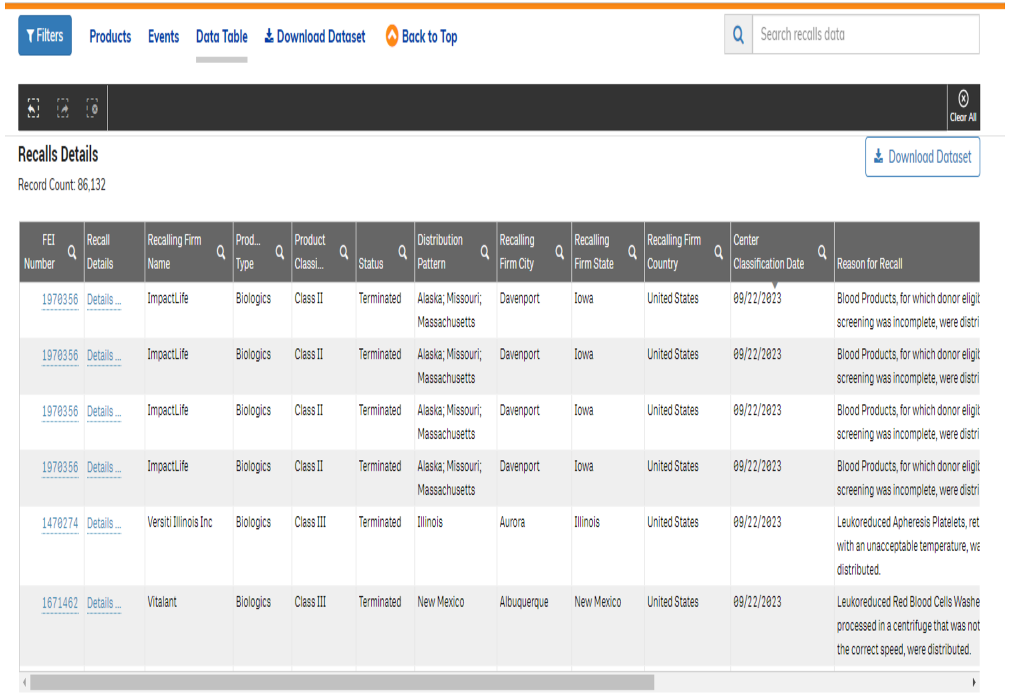
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-507/subpart-C/section-507.38

21 CFR Part 107 Subpart E – Infant Formula Recalls

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

FDA Data Dashboard





FEI Number	Recall Details	Recalling Firm Name	Prod... Type	Product Classi...	Status	Distribution Pattern	Recalling Firm City	Recalling Firm State	Recalling Firm Country	Center Classification Date	Reason for Recall
1970356	Details ...	ImpactLife	Biologics	Class II	Terminated	Alaska; Missouri; Massachusetts	Davenport	Iowa	United States	09/22/2023	Blood Products, for which donor eligit screening was incomplete, were distri
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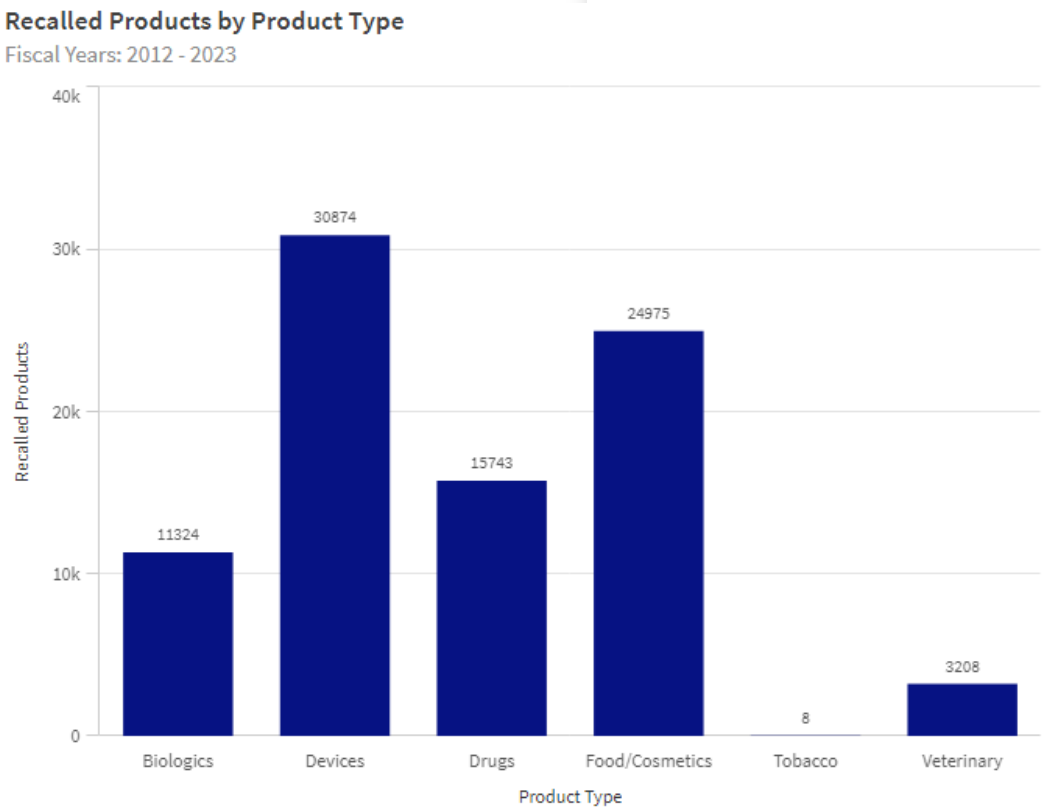
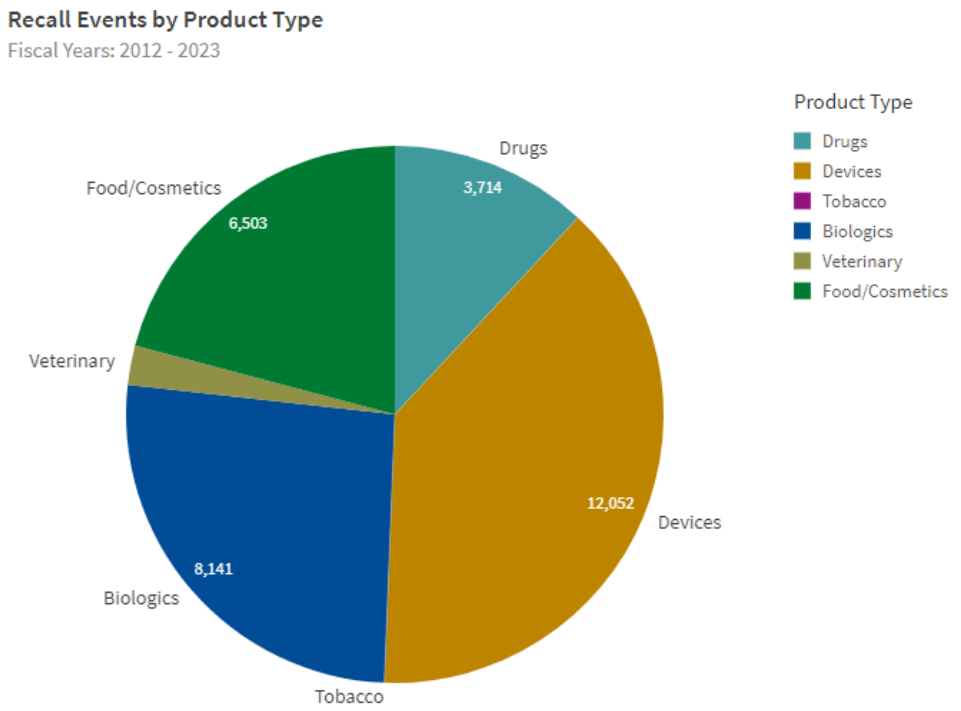
1470274	Details ...	Versiti Illinois Inc	Biologics	Class III	Terminated	Illinois	Aurora	Illinois	United States	09/22/2023	Leukoreduced Apheresis Platelets, ret with an unacceptable temperature, wa distributed.
1671462	Details ...	Vitalant	Biologics	Class III	Terminated	New Mexico	Albuquerque	New Mexico	United States	09/22/2023	Leukoreduced Red Blood Cells Washe processed in a centrifuge that was not the correct speed, were distributed.

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

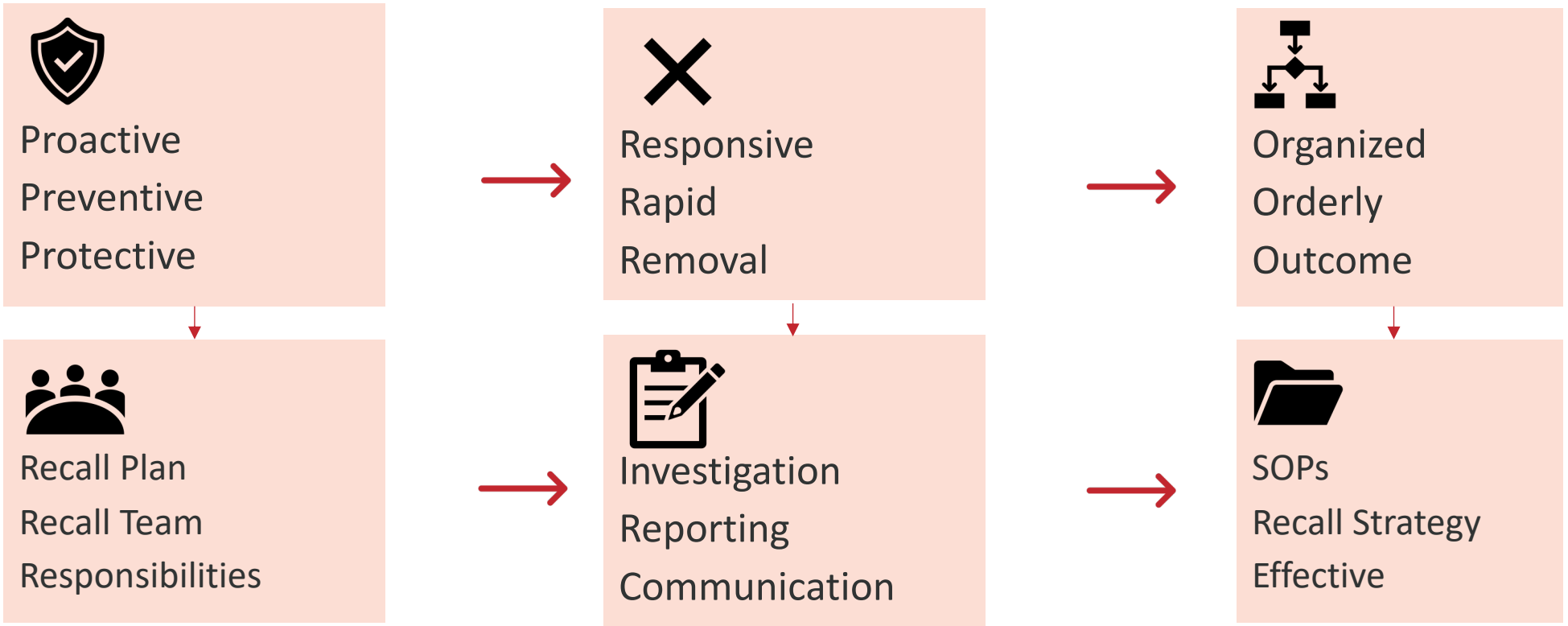
FDA Data Dashboard





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

Proactive → Responsive → Organized



Discussion and Q & A

Marc Ullman
Of Counsel
(516) 357-3240
marc.ullman@rivkin.com

Thank You

DF GUARDIAN
CONSULTING INC.

Come meet us at
Booth #1876

Thank You

Heather N.D. Fairman

info@dfguardianconsulting.com | 516-381-8799

www.dfguardianconsulting.com

FSPCA Lead Instructor

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