Best Practices for Drug Product Recalls

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U.S. Food and Drug Administration

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Learning Objectives

- When to conduct a human drug recall
- Reporting to FDA
- Implementing a recall
- Evaluating effectiveness

CDER Office of Compliance's Mission

To shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement action.

Office of Drug Security, Integrity, and Response

- Imports Compliance Branch
- Exports Compliance Branch
- Supply Chain Security Branch
- Incidents, Recalls, and Shortages Branch

Recalls and Shortages Team

Recalls

Shortages

When to Conduct a Recall

Recall

Market Withdrawal

Considerations of a Recall

1. I’m not sure a recall is necessary.
2. I’m concerned about a drug shortage.

Consider Drug Shortage Situations

Cause or Exacerbate a Shortage

drugshortages@fda.hhs.gov

Be Prepared…

- Establish and maintain recall SOPs
- Identify and train staff
- Establish recall communications plan
- Know your FDA recall tools and contacts

Thought Question #1

What has been the number one reason for recalls in the past three years?

A. Failed dissolution specifications

B. Lack of sterility assurance

C. Sub-potent drug

D. Failed impurities/degradation specifications

E. Current Good Manufacturing Practices (CGMPs) deviations

Major Reasons for Human Drug Recalls

FY2020	FY2021	FY2022
• CGMP deviations	• CGMP deviations	• CGMP deviations
• Failed impurities/degradation specifications	• Failed impurities/degradation specifications	• Lack of Assurance of Sterility
• Lack of sterility assurance	• Lack of sterility assurance	• Failed dissolution specifications
• Sub-potent drug	• Failed dissolution specifications	• Failed Impurities/Degradation Specifications

Identifying Problems

- Product specification deviation or OOS
- Consumer complaints about products
- Adverse reactions, disease, injury, death
- Inspectional observations

Thought Question #2

What is the most common form of initiation for human drug recalls?

A. Firm initiated

B. FDA recommended

C. FDA requested

D. FDA mandated

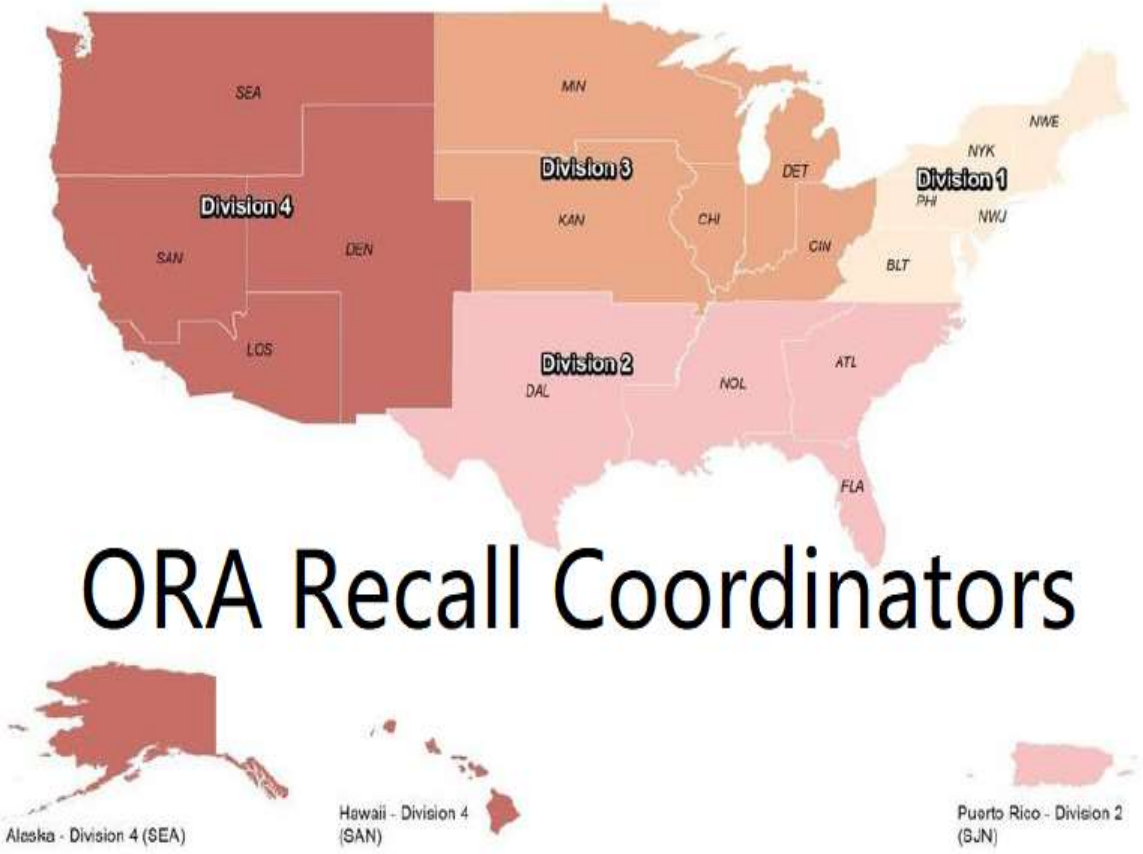
Ways Recalls Can Be Initiated

- Firm Initiated
- FDA Recommended
- FDA Requested Recall
- Mandatory Recalls

Reporting to FDA

1. Who should I contact?
2. What if FDA contacts me first?
3. What information should I provide?

Who do I contact at FDA to initiate a recall?



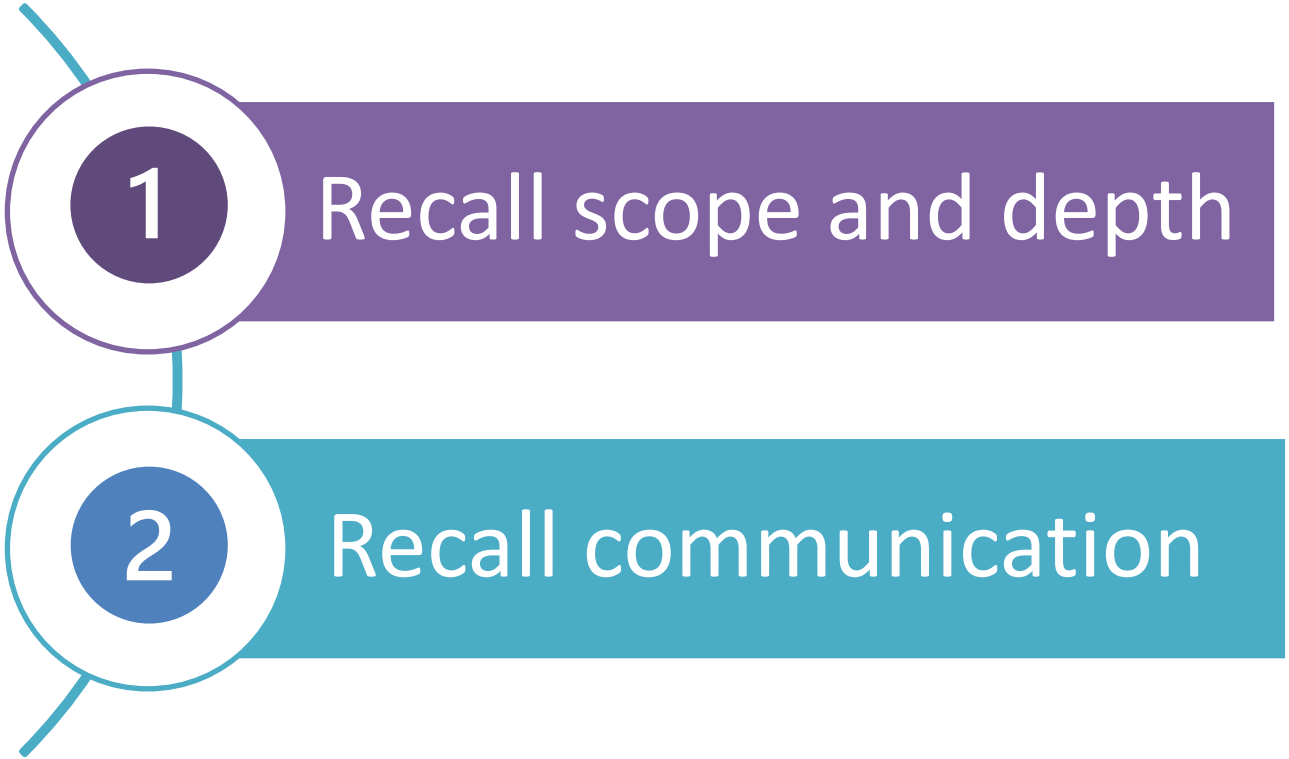
What if FDA contacts me first?

- Typically coordinated by ORA Pharm
- Adulteration and/or Misbranding Charge
- Products, issue, changes, recall guidance
- Written response within 24-hours

Recall Information to FDA

- Product Information
- Firm Information
- Reason for Recall and Health Hazard
- Volume, distribution, proposed recall strategy

Recall Implementation



Recall Classifications

- A **reasonable probability** of serious adverse health consequences or death.
- **Temporary or medically reversible** adverse health consequence or probability of serious adverse health consequences is **remote**.
- **Not likely** to cause adverse health consequences.

Recall Strategy

Depth of Recall

Scope of Recall

Firm Recall Communications

Firm Recall Letters/Response Forms

Firm Recall Press Release

FDA Recall Communications

- CDER Alert
- CDER Immediate Public Notification
- FDA Press Release
- FDA Enforcement Report

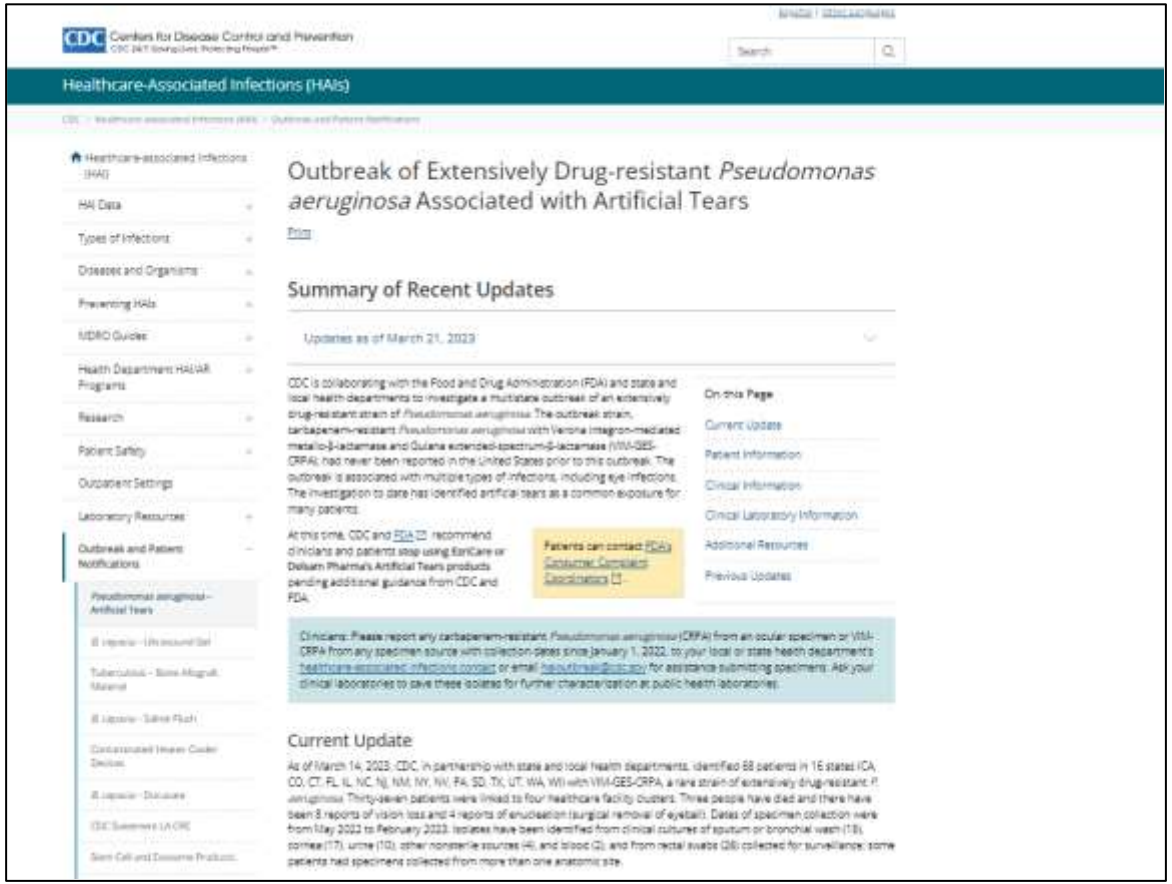
Evaluating Effectiveness

- Effectiveness checks
- Effectiveness check letters/response forms
- Communicate with your consignees
- Communicate with ORA Pharm Recall Coordinator

High-Profile Recalls

- Contaminated ophthalmic recalls
- Hand sanitizer recalls during COVID-19 pandemic

Contaminated Ophthalmic Drug Product Recalls



Ophthalmic Drug Products

- Review manufacturing processes
- Review your formulation
- Manufactured under CGMPs
- If there is a problem, quarantine, and stop distribution

Hand Sanitizer Drug Product Recalls

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Takes Action to Warn, Protect Consumers from Dangerous Alcohol-Based Hand Sanitizers Containing Methanol

Share Tweet LinkedIn Email Print

For Immediate Release: July 02, 2020

See this webpage for a full list of hand sanitizers we urge consumers not to use: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol

Hand Sanitizer Drug Products

- Know your suppliers
- Manufactured under CGMPs
- If there is a problem, quarantine, and stop distribution
- Does the issues impact your product

Challenge Question #1

Which of the following ways of initiating a recall is NOT considered voluntary?

A. Firm initiated

B. FDA recommended

C. FDA requested

D. FDA mandated

Challenge Question #2

If I have a product that I am not sure if I should recall, I should …

A. Contact my local ORA Pharm Recall Coordinator to obtain guidance

B. Wait until I am inspected and let the investigators ask me why I didn't take a market action

C. Do nothing and hope for the best

D. Wait until there are adverse events reported

Challenge Question #3

Which of these scenarios is NOT considered a recall?

A. Distributed product that failed impurity specifications

B. Product lot that obtained out of specification results for dissolution but is now expired

C. Lots were tested that meet specification but are supported by a stability lot that failed for assay

D. Liquid product that was manufactured using water that was found to be contaminated but finished product testing did not find contamination

Closing Thoughts

- Effective recalls
- Establish recall procedures and train staff
- Know FDA contacts and resources for guidance
- Communicate early and transparently to FDA

Thank You!

If you have questions, contact

cder-OC-recallsandshortages@fda.hhs.gov