

Best Practices for Drug Product Recalls

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Office of Drug Security, Integrity, and Response

CDER Office of Compliance

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

- **CGMP deviations**
- Failed impurities/degradation specifications
- Lack of sterility assurance
- Sub-potent drug

FY2021

- **CGMP deviations**
- Failed impurities/degradation specifications
- Lack of sterility assurance
- Failed dissolution specifications

FY2022

- **CGMP deviations**
- Lack of Assurance of Sterility
- 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?

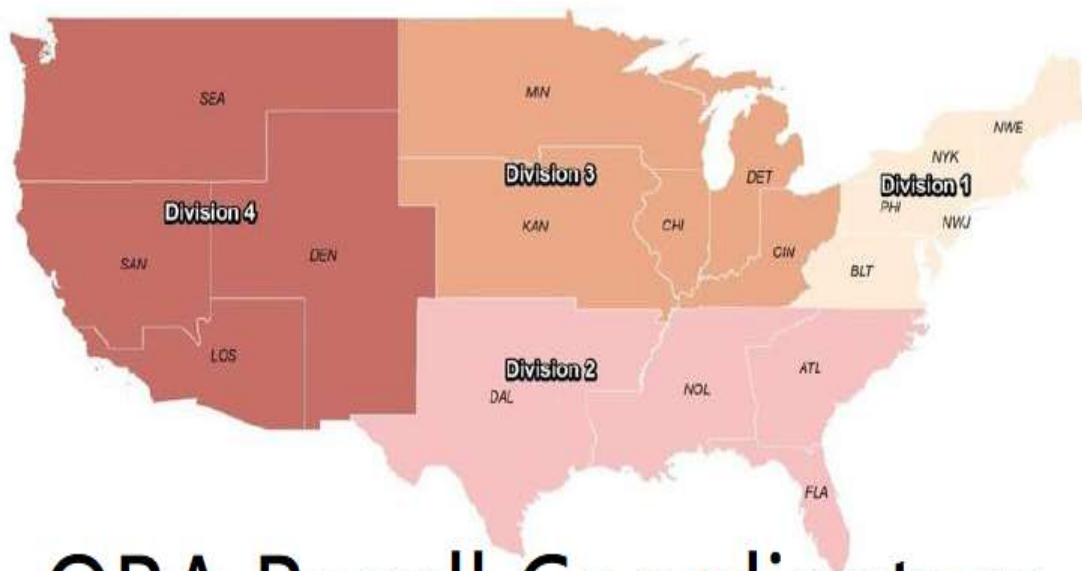
2

What if FDA contacts me first?

3

What information should I provide?

Who do I contact at FDA to initiate a recall?



ORA Recall Coordinators



Alaska - Division 4 (SEA)



Hawaii - Division 4 (SAN)



Puerto Rico - Division 2 (SJN)

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

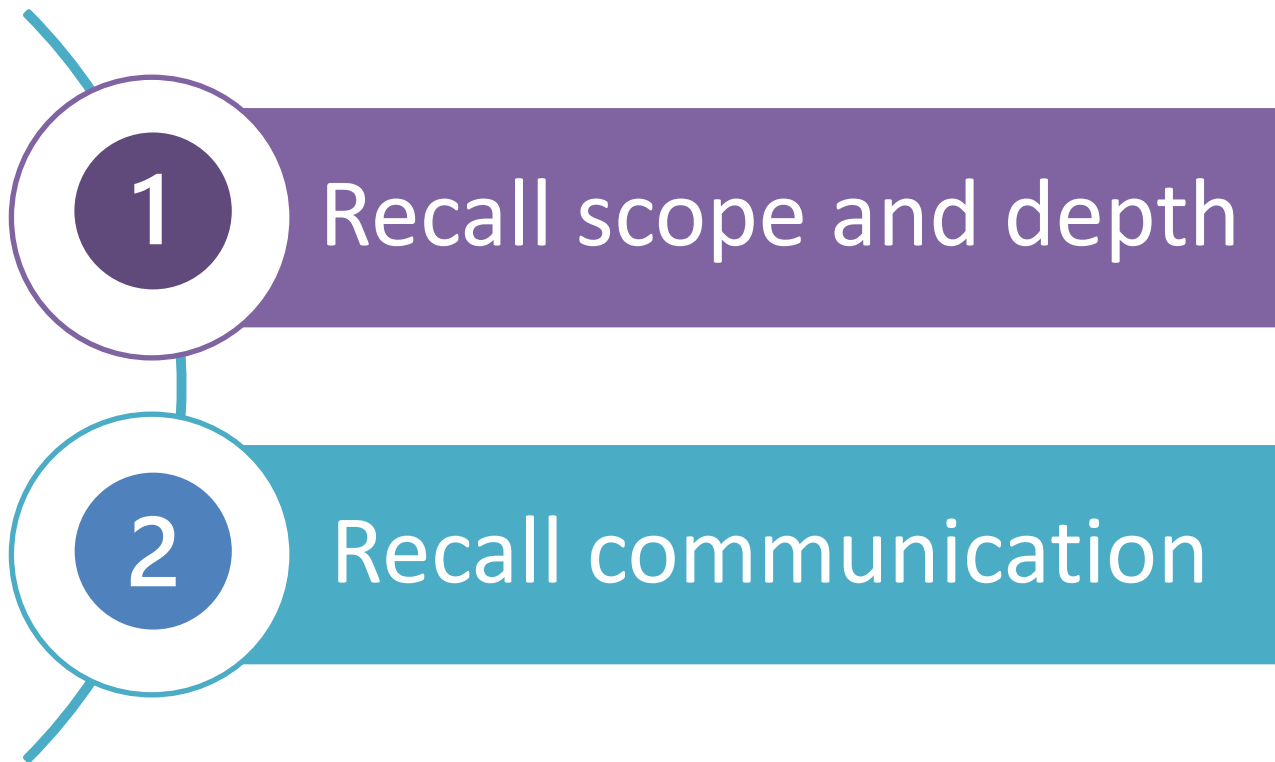
Product Information

Firm Information

Reason for Recall and Health Hazard

Volume, distribution, proposed recall strategy

Recall Implementation



Recall Classifications



Class I

- A **reasonable probability** of serious adverse health consequences or death.

Class II

- **Temporary or medically reversible** adverse health consequence or probability of serious adverse health consequences is **remote**.

Class III

- **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



CDC Center for Disease Control and Prevention
CDC | All Services, Promoting Health

Search

Healthcare-Associated Infections (HAIs)

CDC > Healthcare-associated Infections (HAIs) > Outbreaks and Patient Notifications

- Healthcare-associated Infections (HAI)
- HAI Data
- Types of Infections
- Diseases and Organisms
- Preventing HAIs
- MDRO Guides
- Health Department HAIIR Programs
- Research
- Patient Safety
- Outpatient Settings
- Laboratory Resources
- Outbreak and Patient Notifications**

Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears

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Summary of Recent Updates

Updates as of March 21, 2023

CDC is collaborating with the Food and Drug Administration (FDA) and state and local health departments to investigate a multistate outbreak of an extensively drug-resistant strain of *Pseudomonas aeruginosa*. The outbreak strain, carbapenem-resistant *Pseudomonas aeruginosa* with Verona Integron-mediated metallo- β -lactamase and *Gulana* extended-spectrum- β -lactamase (VIM-GES-CRPA), had never been reported in the United States prior to this outbreak. The outbreak is associated with multiple types of infections, including eye infections. The investigation to date has identified artificial tears as a common exposure for many patients.

At this time, CDC and FDA recommend clinicians and patients stop using BionCare or Delum Pharmaceuticals Artificial Tears products pending additional guidance from CDC and FDA.

Patients can contact CDC's Consumer Complaint Coordinator

On this Page

- Current Update
- Patient Information
- Clinical Information
- Clinical Laboratory Information
- Additional Resources
- Previous Updates

Clinicians: Please report any carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) from an ocular specimen or VIM-GEs-CRPA from any specimen source with collection dates since January 1, 2022, to your local or state health department's [healthcare-associated infections contact](#) or email [hainfo@cdc.gov](#) for assistance submitting specimens. Ask your clinical laboratories to save these isolates for further characterization at public health laboratories.

Current Update

As of March 14, 2023, CDC, in partnership with state and local health departments, identified 58 patients in 15 states (CA, CO, CT, FL, IL, IN, NJ, NM, NY, OH, PA, SD, TX, UT, WA, WI) with VIM-GEs-CRPA, a rare strain of extensively drug-resistant *P. aeruginosa*. Thirty-seven patients were linked to four healthcare facility outbreaks. Three people have died and there have been 8 reports of vision loss and 4 reports of enucleation (surgical removal of eyeball). Dates of specimen collection were from May 2022 to February 2023. Isolates have been identified from clinical cultures of sputum or bronchial wash (18), cornea (17), urine (10), other nonsterile sources (4), and blood (2), and from dental swabs (2) collected for surveillance; some patients had specimens collected from more than one anatomic site.

II Update - Resource Set

Tuberculosis - Bone Marrow, Material

II Update - Saline Flush

Contaminated Heine Code

II Update - Database

CDC Surveys LA-CRE

Stem Cell and Exosome Products

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

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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
cderr-OC-recallsandshortages@fda.hhs.gov