



# FDA's Drug Shortage Role and Patient Resources

2025 Annual Joint Meeting—FDA Patient Engagement  
Collaborative (PEC) and European Medicines Agency (EMA)  
Patients' and Consumers' Working Party (PCWP)

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CDR Robert Kosko, PharmD, MPH, RAC-Drugs, CPH  
US Food and Drug Administration

# Outline

- FDA's role in working with drug supply
- Definitions and reasons for drug shortages
- Sources of information and how the Agency assists with drug shortages
- Locating drug supply updates and reporting a drug shortage



# **FDA'S ROLE IN WORKING WITH DRUG SUPPLY**

# Drug Shortage Staff Overview and Mission

## Drug Shortage Staff (DSS)

- FDA group that is designated to oversee and facilitate the resolution of all drug shortage situations

## Mission

- Prevent, mitigate, and alleviate drug shortages
- Patient and practitioner access to life-saving medications is our priority

# Drug Shortage Staff Role

DSS supports FDA's mission of ensuring that safe and effective drugs are available to patients

- Facilitate short-term and long-term strategies
- Coordinate a timely and comprehensive risk/benefit analysis
- Distribute information

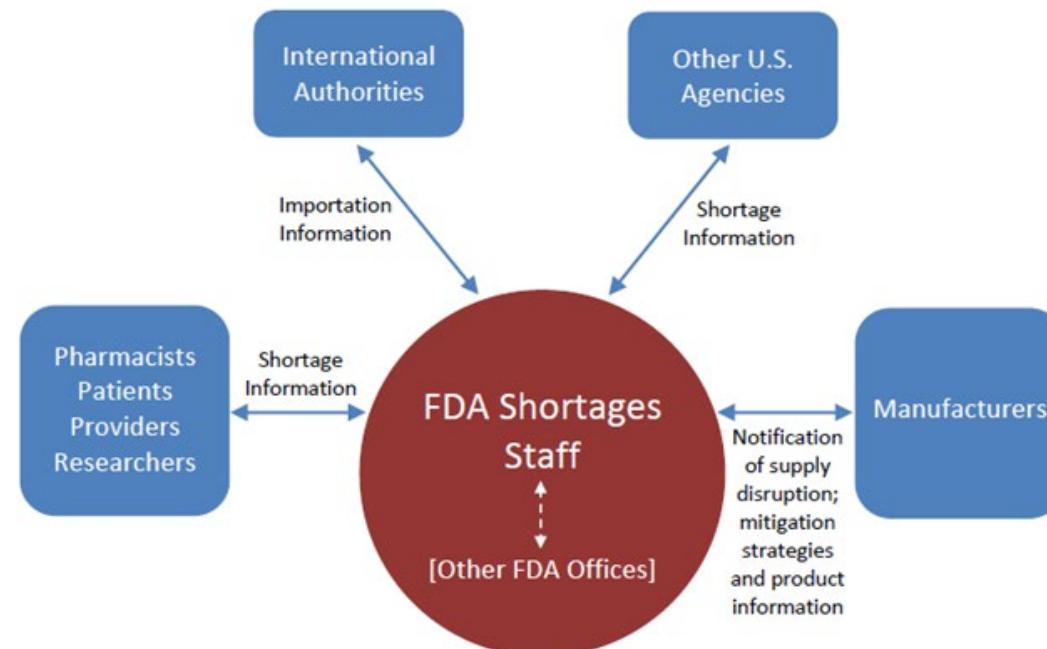
# Drug Shortage Staff Role

DSS works with key stakeholders within the FDA:

- Office of New Drugs (OND)
- Office of Pharmaceutical Quality (OPQ)
- Office of Generic Drugs (OGD)
- Office of Compliance (OC)
- Office of Regulatory Affairs (ORA) Field Inspectors
- Others

# Drug Shortage Staff Role

DSS works with key stakeholders from other government agencies, industry, and the public:



# **DEFINITIONS AND REASONS FOR DRUG SHORTAGES**

# Drug Shortage Definition

A period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

- In general, the DSS focuses on shortages of medically necessary products that have a significant effect on public health.

# Medically Necessary Drug Definition

Any drug product used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other drug that is judged by CDER medical staff to be an appropriate substitute or there is an inadequate supply of an acceptable alternative as determined by the DSS.

- Although the agency focuses on medically necessary drugs, all potential shortages are evaluated to help determine the possible public health impact.
- Manufacturers are required to notify DSS of potential manufacturing interruptions regardless of their own determination of medical necessity.

# Causes of Drug Shortages

## Quality and Manufacturing Issues

- Sterility
- Particulates
- Crystallization
- Precipitate
- Impurities
- Degradants
- Equipment breakdown

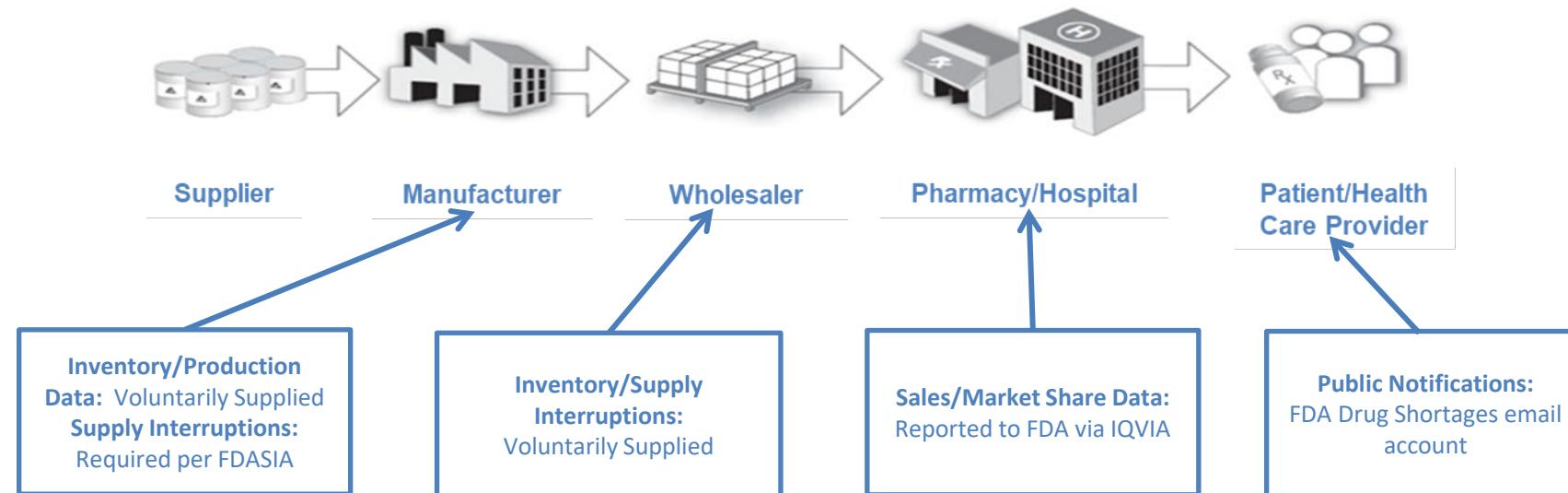
# Causes of Drug Shortages

## Other Issues

- Discontinuations
- Raw material and component supply
- Inability of other manufacturers to increase supply
- Natural disasters

# **SOURCES OF INFORMATION AND HOW THE AGENCY ASSISTS WITH DRUG SHORTAGES**

# Supply and Demand Information Sources



# Opportunities and Challenges

What we **CAN** require:

- Notification by manufacturers

What we **CANNOT** require:

- Manufacturers make a drug
- Manufacturers make more of a drug
- How much drug is distributed and who receives it

# Approach to Prevention and Mitigation

- Prioritize products that are medically necessary
- Risk/benefit analysis
- Maintain availability while minimizing risk
- Work with manufacturers to address problems
- Drug shortages cannot always be prevented

# Our Toolbox

- Communicate possible shortage concerns to other suppliers
- Prompt manufacturers to look at supply and demand
- Regulatory flexibility and discretion
- Expedite review of proposals and regulatory submissions
- Temporary importation of an unapproved product



# **LOCATING DRUG SUPPLY UPDATES AND REPORTING A DRUG SHORTAGE**

# Drug Shortage Database



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[Drug Shortages](#) can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Manufacturers provide FDA most drug shortage information, and the agency works closely with them to prevent or reduce the impact of shortages. When a shortage is listed as current on the Drug Shortage Database, the FDA is aware of the supply situation and is working with the manufacturers on efforts to mitigate the supply disruption. FDA also continue to work with manufacturers on shortage prevention efforts for drugs not yet listed on the Drug Shortage Database.

Current and resolved drug  
shortages and discontinuations.

List of extended use dates to  
assist with drug shortages.

[Search Drug Shortage Database](#)

[Search Extended Use Dates](#)

Content current as of:  
01/10/2025

Regulated Product(s)  
Drugs

# Drug Shortage Database

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Current and Resolved Drug Shortages and Discontinuations Reported to FDA

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Search by Generic Name or Active Ingredient: Enter at least three characters

SELECT A CATEGORY CURRENT/RESOLVED SHORTAGES DISCONTINUATIONS THERAPEUTIC CATEGORIES NEW AND UPDATED

The Drug Shortages Staff will update the webpage to show a shortage has been resolved when it determines that supply is no longer exceeded by demand or projected demand. After a shortage has been resolved, DSS will continue to monitor supply and demand for the drug.

Generic Name or Active Ingredient	Status
Albuterol Sulfate Solution	Currently in Shortage
Amino Acid Injection	Currently in Shortage
Amoxapine Tablet	Resolved
Amoxicillin Powder, For Suspension	Currently in Shortage
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	Currently in Shortage

# Drug Shortage Database

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SELECT A CATEGORY CURRENT/RESOLVED SHORTAGES **DISCONTINUATIONS** THERAPEUTIC CATEGORIES NEW AND UPDATED

#### Discontinuations Listed by Generic Name or Active Ingredient

Under section 506C of the Federal Food, Drug, and Cosmetic Act, manufacturers of certain finished drug products must submit a notification to FDA at least 6 months in advance of a permanent discontinuance in manufacturing of a such product, or a permanent discontinuance in manufacturing of API for such product. However, if 6 months' advance notice is not possible, the notification must be submitted as soon as practicable thereafter. These drugs include those that are life-supporting, life-sustaining, or for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery. The discontinuations listed on FDA's drug shortage database reflect information received from manufacturers and are for informational purposes only.

Withdrawal notifications can be found here: <https://www.federalregister.gov>

Generic Name or Active Ingredient
Acyclovir Ointment
Adalimumab-adaz Injection

Showing 1 to 20 of 129 entries Show 20 entries

# Drug Shortage Database

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Search by Generic Name or Active Ingredient:  **SUBMIT**

SELECT A CATEGORY [CURRENT/RESOLVED SHORTAGES](#) [DISCONTINUATIONS](#) [THERAPEUTIC CATEGORIES](#) **NEW AND UPDATED**

**+** New  
**+** Updated

# Reporting a Drug Shortage

**Drug Shortages**

**Drug Shortages** can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Manufacturers provide FDA most drug shortage information, and the agency works closely with them to prevent or reduce the impact of shortages. When a shortage is listed as current on the Drug Shortage Database, the FDA is aware of the supply situation and is working with the manufacturers on efforts to mitigate the supply disruption. FDA also continue to work with manufacturers on shortage prevention efforts for drugs not yet listed on the Drug Shortage Database.

Content current as of: 03/13/2025  
Regulated Product(s): Drugs

Current and resolved drug shortages and discontinuations. List of extended use dates to assist with drug shortages.

[Search Drug Shortage Database](#) [Search Extended Use Dates](#)

**Drug Shortage Notifications**

For Industry

Industry can notify FDA Drug Shortage Staff of drug and supply shortages via the [CDER Direct NextGen Portal](#).

This portal is intended ONLY for drug manufacturers/applicants. [Industry can notify the FDA Drug Shortage Staff](#) of new discontinuances, GMP issues, increase in product demand, recalls, supply interruptions, or other events. If you have any questions, please contact [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov).

**Drug Shortage Status Information**

Patients, healthcare providers, organizations, and other interested parties may submit information to FDA regarding the status of an existing shortage by emailing [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov).

Public portal for patients, healthcare providers, and organizations to report NEW shortages

When a medication is not available, it can be helpful to make FDA's Drug Shortages staff aware. Usually when a drug is not in stock, it's a temporary, localized issue and more product is on the way. Occasionally local supply issues can be a signal of a future drug shortage.

When FDA receives reports of new local shortages, we contact the manufacturers to confirm if their available supply will meet the national demand for the drug. If a drug is at risk of going into shortage, sometimes this advanced notice helps FDA take early action to prevent or shorten the duration of a shortage.

To use the public portal:

1. First check the [Drug Shortages Database](#) for current shortages to see if FDA is already aware of this shortage. Search by your product's generic name or active ingredient.
2. If the drug is already in the Drug Shortages Database, talk with your health care provider or pharmacist for other treatment options during the shortage. FDA is actively working on resolving that shortage.
3. If the drug is NOT in the Drug Shortages database, send a report to FDA through our new public portal.

[Report New Drug Shortage](#)

# Reporting a Drug Shortage

 U.S. FOOD & DRUG  
ADMINISTRATION

## Drug Shortage Public Notification

<b>Submission</b>	
Attention	<p>* Is the drug shortage you are reporting currently posted on the CDER Drug Shortage Database <a href="#">webpage</a>?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p>
Submitter Information	<p>* Who is submitting the notification?</p> <p><input checked="" type="radio"/> Patient or Caregiver <input type="radio"/> Healthcare Provider <input type="radio"/> Professional Organization</p>
Product Selection	<p><a href="#">+</a> * Add Product Information</p> <p>Note: When adding products, only products with the same active ingredient(s) can be selected for the same notification.</p>
Notification Details	<p>* Contact Information (please submit a valid email address so we can follow up with you if necessary): <input type="text"/></p> <p>* Confirm contact information: <input type="text"/></p> <p>Reason for Notification/Type:</p> <p><input type="checkbox"/> Unable to fill a prescription <input type="checkbox"/> Unable to fill a brand specific prescription <input type="checkbox"/> Other</p> <p>Other information, comments, and concerns prompting your inquiry: <input type="text"/> 0/2000 characters</p>
Need Help?	<p>The <a href="#">Drug Shortage Public Notification Help Center</a> and the <a href="#">NextGen Portal Help Center</a> are available to answer all your related questions.</p> <p><a href="#">Delete</a> <a href="#">Submit</a></p>



# QUESTIONS?



**THANK YOU.**

**ROBERT.KOSKO@FDA.HHS.GOV  
DRUGSHORTAGES@FDA.HHS.GOV**

