PET PRODUCT AVAILABILITY: DRUG SHORTAGE MITIGATION AND PREVENTION EFFORTS

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Drug Shortage Mission

- Our mission is to prevent, mitigate and alleviate drug shortages
- Patient and practitioner access to life-saving medication is our #1 priority
- Drug Shortage Staff works with professional organizations, patient groups, clinicians and other stakeholders (E.g. DOE, NNSA, ACR)

Brief History
- Part of FDA’s Center for Drug Evaluation & Research (CDER)
- Drug Shortage Program began in 1999
- 2011- President Obama signed Executive Order 13588-Reducing Prescription Drug Shortages
- 2012-Requirements to Industry For Early Notifications Under Section 506C of the FD&C Act
- CDER Drug Shortage Program (DSP) changed to Drug Shortage Staff (DSS) in 2012
- Moved under the CDER Office of the Center Director in 2014
- Additional drug shortage staff in other Centers (e.g. CBER, CDRH)
- Coronavirus Aid, Relief, and Economic Security Act (CARES Act) 2020
**FDA Drug Shortage Staff (DSS)**

**Drug Shortage Staff**: The program office that is designated by FDA to oversee and facilitate the resolution of all drug shortage situations

DSS serves to support FDA’s mission of ensuring that safe and effective drugs are available to patients

- Facilitate temporary and long-term strategies to address shortages
- Coordinate for timely and comprehensive risk/benefit decisions
- Distribute information (web posting, professional organizations, e.g. ASHP)

**Often working across suppliers, facilities, and issues - multiple moving parts, urgency**

→ Maintain availability while minimizing risk to patients

**FDA Drug Shortage Staff - Key Communications**

- International Authorities
- Other U.S. Agencies
- Importation Information
- Shortage Information
- Pharmacists
- Patients
- Providers
- Researchers
- Manufacturers
- Notification of supply disruption; mitigation strategies and product information
- [Other FDA Offices]
Important Definitions

**Drug Shortage or Shortage:** A period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (21 CFR 314.81). DSS determines if a shortage concern exists, and what FDA action if any is needed. DSS is designated to oversee and facilitate the resolution of all drug shortage situations.

In general, the Agency focuses on shortages of products that have a significant effect on public health:

- **Life Supporting or Life Sustaining**
  A drug product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life (21 CFR 314.81).

- **Debilitating Disease or Condition**
  A drug product intended for use in the prevention or treatment of a disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning (21 CFR 314.81). Equivalent to serious disease or condition (80 FR 38915).

- Including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.

Manufacturers are required to notify the FDA of a permanent discontinuance in the manufacture of a covered drug or an interruption of the manufacture of a covered drug that is likely to lead to a meaningful disruption in the supply of the drug in the United States

- “At least 6 months in advance of the date of the permanent discontinuance or interruption in manufacturing; or, if 6 months’ advance notice is not possible no later than 5 business days after the...permanent discontinuance or interruption in manufacturing occurs*

- Not limited to medically necessary products

- Regardless of market share, or number of companies marketing, or wholesaler volumes

- **Notification is not required for radiopharmaceutical drug products.**
Manufacturers Report on Potential Impact to Supply

At the time of any change in manufacturing that may lead to a reduction in supply of a product*, e.g.:

- Plans for upgrade or remediation
- Manufacturing issues
  - Environmental concerns
  - Equipment failures
- Container closure issues
  - Changing stopper or vial suppliers

*Note, product refers to a specific strength, dosage form, and route of administration

The Agency’s Approach to Prevention and Mitigation

Early notification is key!!

- Prioritize products that are medically necessary
- Risk/Benefit of the drug in question
- Maintain availability while minimizing risk to patients
- Work with firms to address problems
  - We can advise, assist, and expedite inspections and reviews,
  - The manufacturer must fix the problem
- Drug shortages cannot always be prevented
  - Unanticipated events occur
    - Manufacturing breakdown or
    - Natural disaster (Hurricanes & Floods)
  - If systemic issues are present, the facility may have to close to repair
FDA Toolbox

- Proactive outreach through CDER NextGen Drug Shortage Emergency Event Portal
- Communicate possible shortage concerns on a product or material issue
- Regulatory Discretion:
  - Manufacture of medically necessary products during remediation
  - Use of additional safety controls
    - Special instructions for safe use
    - Filters with injectable products to remove particulate concerns
    - Extra testing at production facility
    - 3rd party oversight of production
- Expedited review of company proposals
  - New manufacturing sites,
  - New material source(s),
  - Changes in specifications, etc.

Impact of Early Notifications to the FDA

- Ongoing dialogue/work with industry - high numbers of prevented shortages continue
- Depending on the precipitating events, some drug shortages can endure for months to years. (Ex: Plant remediations and agency approvals)
Current Challenges: New Shortages and Persistent Shortages

- Shortages peaked in 2011 at 251 and continued to decline through 2016. Shortages rose again in 2017 and 2018 due in part to the 2017 hurricane impact as well as ongoing problems with manufacturers. With last year’s tripledemic, we ended 2022 with 48 new shortages.
- Depending on the precipitating events, some drug shortages can endure for months to years. (Ex: Plant remediations)

Total New US Drug Shortages Per Year

Role of Industry to Help Prevent and Mitigate Drug Shortages

- Understand the frailties in their supply chain
- Communicate early about potential shortages
- Provide short term and long-term plans for preventing and addressing shortages while maintaining and improving quality
- Work with FDA to minimize shutdowns or slowdowns that will lead to shortages
- Provide shortage information for posting on FDA website when a shortage is unavoidable
Enduring Solutions: What’s Still Needed?

- Companies need to have **Risk Management Plans** in place - build better inventories of essential materials and components, have a backup plan for when things fail or demand increases
- **Redundancy in manufacturing** and suppliers - encouraging industry to have alternative sources, components and supplies at the ready for critical drugs
- Communication is key
  - Guidance to Industry issued April 2023 requesting notifications on increased demand in addition to supply disruptions
  - Ongoing Collaboration - Industry, Outside Stakeholders

Contacts:

Current shortage information updated daily at: [https://www.accessdata.fda.gov/scripts/drugs/shortages/default.cfm](https://www.accessdata.fda.gov/scripts/drugs/shortages/default.cfm)

To contact DSS:
Email: drugshortages@fda.hhs.gov


Drug Shortage Mobile APP
Thank You

Questions?