FDA U.S. FOOD & DRUG ADMINISTRATION

Acquisitions / Licensing and Mergers – Regulatory Requirements and Strategies: Drug Shortage Considerations

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REQUIREMENTS TO INDUSTRY FOR EARLY NOTIFICATIONS: UNDER SECTION 506C OF THE FD&C ACT (2012)

Manufacturers are required to notify the FDA of "a change in production that is reasonably likely to lead to a reduction in the supply" of a covered drug in the United States

- "At least 6 months in advance of…but in no case later than 5 business days after the…interruption in manufacturing occurs"
- Not limited to medically necessary products
- Regardless of market share, or number of companies marketing, or wholesaler volumes

One Hundred Twelfth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and twelve

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Administration Safety and Innovation Act".

TITLE X—DRUG SHORTAGES

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 plant upgrade or remediation or closure**
- **Manufacturing issues**
- **Product quality issues**
- **Distribution changes**

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

FDA requests manufacturers notify FDA ahead of any potential impact if known, not as, or after, they are unable to fill orders or unable to meet expected demand

Considerations During Mergers and Acquisitions

- **Understand product portfolio, market position and possible overlap. Is your product now sole source ?**
- **Do both organizations have established communication channels with the Drug Shortage Staff ? Transitioning when appropriate.**
- **Are there existing shortages or shortage prevention efforts on going ?**
- **Risk management plan impact ?**

CONTACTS

Current shortage information updated daily at:
https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

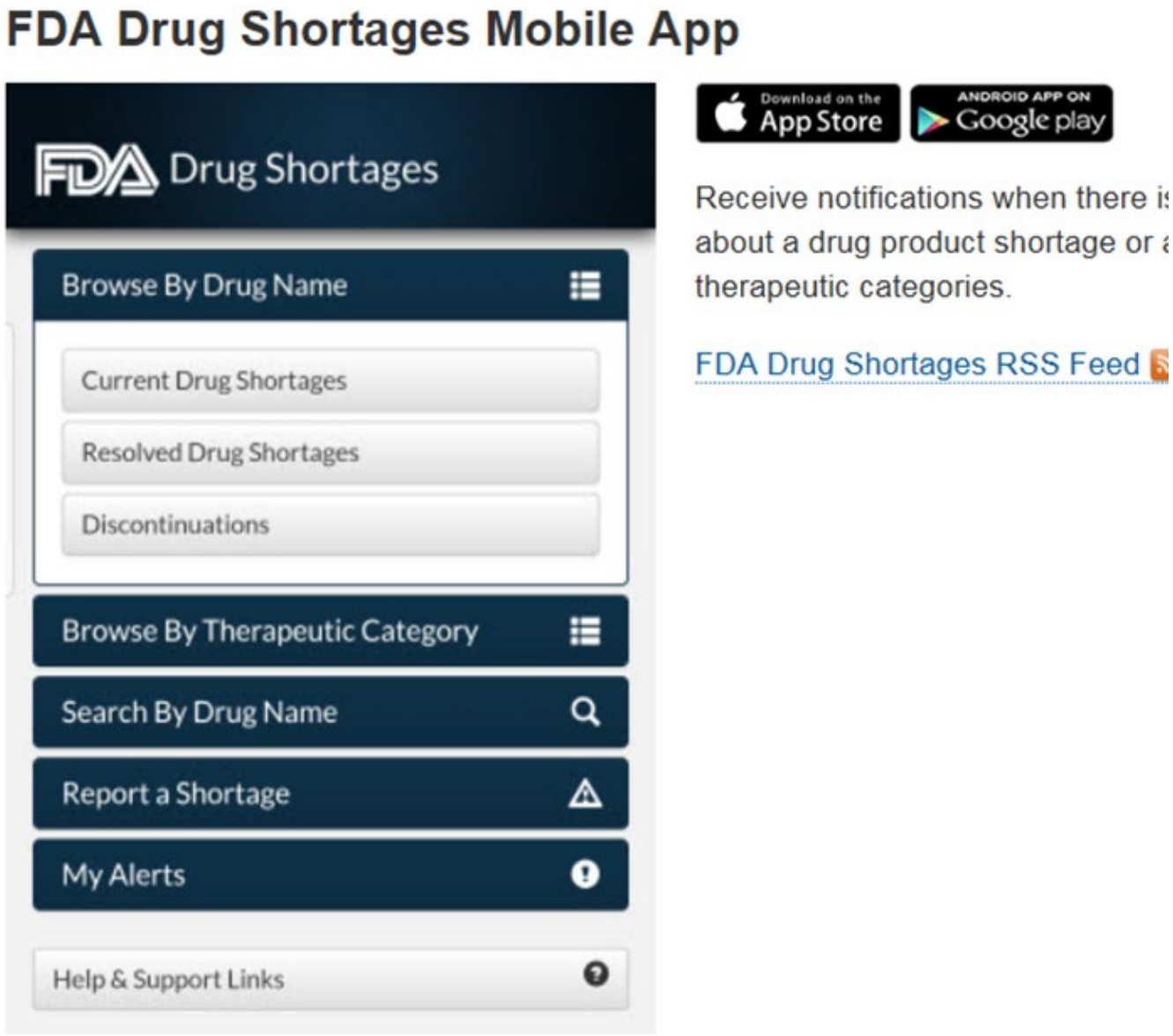
Industry can notify FDA Drug Shortage Staff via CDER Direct NextGen Portal.

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.

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

FDA Drug Shortages Homepage:
https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

Drug Shortage Mobile APP



THANK YOU