Types of Drugs FDA Considers for Drug Shortages

FDA prioritizes drugs that are medically necessary. A medically necessary drug is defined as one that is used to treat or prevent a serious disease or medical condition for which there is no alternative drug, or an existing drug that has been determined to be an acceptable substitute. Sea Moro staff has determined to be an acceptable substitute.

Although the agency focuses on medically necessary drugs, FDA also considers non-medically necessary drugs, such as those used for elective surgery or for which a substitute is available. Additionally, FDA takes into account whether a shortage is likely to result in a significant decrease in the availability of a drug to patients.

FDA Can’t Require a Pharmaceutical Company to:  

1. Make a drug, even if it is a medically necessary drug, if the drug is made.
2. Make more of a drug.
3. Change its expiration data to when the drug is distributed.

FDA Responds to Drug Shortages

FDA responds to potential drug shortages and for drug shortages that are causing or are likely to cause serious patient harm or where there is no acceptable substitute drug.

When there are quality or production problems for sterile injectables, including chemotherapy, anesthesia and other acute drugs, FDA will work to find ways to mitigate drug shortages. However, there are a variety of ways, while minimizing the risk to patients.

The Pharmaceutical Industry Can Help Prevent Drug Shortages

FDA works with pharmaceutical companies to address drug shortages. Through the Food and Drug Administration Safety and Innovation Act (FDASIA), pharmaceutical companies are required to notify FDA, when manufacturing interruptions or production changes could lead to a supply disruption or discontinuation.

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