Resilient Supply Chain Program (RSCP)

U.S. FOOD & DRUG ADMINISTRATION

506J FACT SHEET

How CDRH Uses 506J Notifications and Other Information

The FDA CDRH Resilient Supply Chain Program (RSCP) uses information provided by stakeholders about supply chain disruptions to assess potential shortages of medical devices and inform actions to prevent or mitigate impacts to patients and providers.

Under section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act), manufacturers are required to notify the FDA during, or in advance of, a public health emergency (PHE), of a permanent discontinuance or interruption in the manufacturing of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States. The FDA also encourages device manufacturers to submit 506J notifications on a voluntary basis to help the FDA proactively identify and mitigate potential shortages before they occur.

The FDA developed the proposed 506J Device List according to the criteria in section 506J(a) of the FD&C Act to assist manufacturers in providing timely notifications to the FDA. When finalized, the 506J Device List will serve as the list of devices for which a manufacturer would be required to notify the FDA of a discontinuance or interruption in manufacturing during or in advance of a PHE under section 506J.

When information about a potential shortage is received via 506J or other means, RSCP analyzes the information and conducts a patient impact assessment to inform potential mitigations, including but not limited to:

Regulatory Mitigation Strategies:

- Expedited premarket review
- Emergency Use Authorizations (EUAs)
- Enforcement Discretion
- Device-specific Guidance
- Letters to Healthcare Providers (LHCP)

Non-Regulatory Mitigation Strategies:

- Actions by other US Government partners, including:
  - Transportation prioritization
  - Defense Production Act (DPA) priority ratings and priority request letters
  - Clearance through Customs and Border Protection (CBP)

EXAMPLE: Saline Flush Syringes (March 2022)

Background:

A manufacturer notified the FDA of a recall and discontinuance, significantly disrupting the availability of saline flush syringes.

Key Actions Taken by the FDA:

- Issued communications to recommend conservation strategies and alternatives
- Used enforcement discretion and expedited reviews to support device availability

Impact:

These actions significantly increased the availability of saline flush syringes, reducing the impacts to patients and providers.

EXAMPLE: Resin Shortages (February 2021)

Background:

Winter Storm Uri shut down the oil and gas industry along the Gulf Coast, causing a shortage of resins used for thousands of medical devices.

Manufacturers notified the FDA of potential interruptions in manufacturing due to resin shortages.

Key Actions Taken by the FDA:

- Implemented regulatory mitigations
- Conducted a patient impact assessment and shared with HHS ASPR to inform the use of priority ratings and priority request letters

Impact:

Prevented shortages of critical devices (e.g., COVID-19 tests, blood collection tubes, syringes) needed in delivery of healthcare.

U.S. FOOD & DRUG ADMINISTRATION

Frequently Asked Questions (FAQs)

When should stakeholders submit shortage notifications to the FDA?

The earlier RSCP is aware of a potential supply chain disruption or shortage, the sooner the FDA can take action to prevent shortages and minimize impacts to patients and providers.

What happens after a 506J notification (or other information) is submitted?

RSCP analyzes available supply chain data to determine if there is a shortage, assess the impact, and identify potential mitigations.

If additional information is required, RSCP will reach out to stakeholders (e.g., manufacturers, distributors, and healthcare providers) to gather additional information. With the information provided, RSCP can determine impacts and inform implementation of regulatory and non-regulatory mitigations.

How does the information submitted help to prevent a shortage?

Information submitted via 506J notifications and other sources is critical to prevent and mitigate shortages.

RSCP uses the information to develop a patient impact assessment which informs both regulatory (e.g., enforcement discretion, EUAs, expedited 510(k)s, conservation strategies, etc.) and non-regulatory mitigation strategies (e.g., priority ratings under the Defense Production Act) with other U.S. government partners.

How to Notify RSCP of a Potential Shortage

- **Device Manufacturers:** Submit a 506J Notification, either voluntarily or when required during, or in advance of, a public health emergency (PHE).
- **Other Stakeholders (GPOs, distributors, healthcare providers, etc.):** Email details of the potential shortage to RSCP at deviceshortages@fda.hhs.gov.

DID YOU KNOW?

FDA & Other US Government Actions

The FDA can take many regulatory actions to prevent or mitigate shortages. For example, the RSCP informs regulatory mitigations to include but not limited to expediting 510(k) reviews and inspections, emergency use authorizations (EUAs), enforcement discretion, and letters to healthcare providers. The FDA also works with other US Government partners to inform prioritization of raw materials and components for medical devices when supply chain disruptions occur. For example, although the FDA does not have delegated authorities under the Defense Production Act (DPA), the FDA worked with the Department of Commerce and the HHS Administration for Strategic Preparedness and Response (ASPR) to inform the use of DPA priority ratings during the COVID-19 PHE.

The earlier RSCP is notified of a potential shortage, the sooner the FDA can take action to prevent or mitigate medical device shortages. Information submitted to the FDA using 506J notifications and other methods is a critical first step to building resiliency in the medical device supply chain and preventing impacts to patients and providers.

Want to learn more about the FDA's role in medical device shortages?

Visit RSCP on fda.gov