FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency – Immediately In Effect Guidance

Linda Ricci and Katie O'Callaghan

Office of Strategic Partnership and Technology Innovation (OST)

Division of All Hazards Response, Science and Strategic Partnerships (DARSS)

Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

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Agenda

- Background: CDRH's role in COVID-19 public health emergency
- New immediately in effect Guidance: Manufacturer notifications under Section 506J of the FD&C Act during the COVID-19 public health emergency
- Q&A

CDRH plays a critical role during COVID-19 Public Health Emergency

- COVID-19 pandemic triggered unprecedented increased demand for some devices, as well as significant disruptions to global medical device manufacturing and supply chain operations for some devices.

- The FDA has taken many actions to help ensure that patients and health care providers have timely and continued access to high-quality medical devices to respond effectively to the COVID-19 pandemic.

CDRH works collaboratively to prevent and mitigate medical device shortages

- Manufacturers
- Health care sector
- Professional societies
- Patient organizations
- International regulatory partners
- U.S. government
- Foreign governments
- Public health entities
- Supply chain entities
- Researchers / innovators

The CARES Act and Section 506J of the FD&C Act

- 506J requires manufacturers to notify FDA of:
  - a permanent discontinuance in the manufacture of certain devices, or
  - an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States
- This information will help prevent or mitigate shortages during the COVID-19 public health emergency.

FDA Issues Guidance to Help Manufacturers Understand 506J Notification Obligations

- **This immediately in effect guidance:**
  - Implements Section 506J of the Act during the COVID-19 public health emergency
  - Assists manufacturers in providing the FDA timely, informative notifications about changes in the production of certain medical device products
  - Includes recommendations about who must notify the FDA, what information to include in the notification, and how to notify the FDA for the duration of the COVID-19 public health emergency
  - Is immediately in effect and is intended to remain in effect only for the duration of the public health emergency related to COVID-19.

Who must notify?

- Section 506J(a)(1)-(2) requires manufacturers of devices:
  - that are critical to public health during a public health emergency, or
  - for which the FDA determines information on potential meaningful supply disruptions is needed during or in advance of a public health emergency

  to notify the FDA of an interruption or permanent discontinuance in manufacturing of such devices.

Who must notify?

- In determining whether this requirement applies, the FDA recommends medical device manufacturers evaluate the following circumstances – whether the device or accessories are:
  - **life-supporting, life-sustaining,** or intended for use in **emergency medical care**;
  - intended for use **during surgery**;
  - used to **diagnose, cure, treat, mitigate, or prevent COVID-19**; or
  - would be in **higher-than-typical demand during the response to COVID-19 pandemic** compared to a similar period of time.

Are the section 506J notification requirements applicable to me?

Subject to 506J Notification Requirements

- If a manufacturer makes a device described in section 506J(a)(1)-(2) and holds a marketing authorization from FDA, or is listed under section 510(j) of the FD&C Act, that device is subject to a notification to the FDA pursuant to section 506J.

Not subject to 506J Notification Requirements

- Manufacturers of devices that are required to submit a premarket notification under section 510(k) of the FD&C Act to FDA and obtain FDA clearance prior to marketing the devices in the United States, but have not received such clearance and are distributing the device in light of an FDA guidance on enforcement discretion during the COVID-19 public health emergency, are **not** subject to the notification requirements of section 506J.

When must the FDA be notified?

- Device manufacturers must notify the FDA at least six months before the date of the discontinuance or interruption or, if that is not possible, as soon as is practicable.
  - During the COVID-19 pandemic, the FDA considers "as soon as is practicable" to mean notification should be provided no later than 7 calendar days after the discontinuance or interruption in manufacturing occurs.
- After the initial notification, the FDA recommends updates every two weeks, including the expected timeline for recovery, until the shortage risk has been resolved. This ensures the FDA can act on the most current information.

What information to include:

- Section IV of the guidance includes an example of the recommended information to include.
  - Reason(s) for discontinuance or interruption in manufacturing
  - Identifying information
  - Additional information

- Any information provided to the FDA that is trade secret or confidential information will be treated as such, consistent with 5 U.S.C. 552(b)(4), 18 U.S.C. 1905 and other applicable laws.

Where to send notification:

- Medical device manufacturers should submit notifications of discontinuance, disruptions, or shortages to CDRHManufacturerShortage@fda.hhs.gov. Please include "Notification" in the subject line.

Summary

- Section 506J of the FD&C Act requires manufacturers of certain devices to notify the FDA of an interruption or permanent discontinuance in manufacturing of such devices.
- The FDA issued immediately in effect guidance to implement and clarify during the COVID-19 public health emergency.
- Manufacturer notifications contribute critical information to help the FDA assess, prevent, and mitigate shortages during the COVID-19 public health emergency.

Q&A Note

- We are unable to answer questions about specific devices during this webinar, but we recommend that you reach out to CDRHManufacturerShortage@fda.hhs.gov, and we are happy to help you determine whether a notification is required.
- Please begin the email subject line with the word "Question" to help expedite our response.

Q&A

- **Q: I manufacture a 510(k) cleared ventilator accessory. Am I required to notify?**
- Yes, if you make a device described in section 506J(a)(1)-(2) that has marketing authorization from the FDA, or is listed under section 510(j) of the FD&C Act, that device is subject to a notification to the FDA pursuant to section 506J.

Q&A

- **Q: I manufacture surgical gowns listed pursuant to section 510(j) of the FD&C Act. Am I required to notify?**
- Yes, if you make a device described in section 506J(a)(1)-(2) that has marketing authorization from the FDA, or is listed under section 510(j) of the FD&C Act, that device is subject to a notification to the FDA pursuant to section 506J.

Q&A

- **Q: I am manufacturing devices in light of a COVID-19 immediately in effect guidance. Am I required to notify?**
- Manufacturers of devices that are required to submit a premarket notification under section 510(k) of the FD&C Act to the FDA and obtain the FDA clearance prior to marketing the devices in the United States, but have not received such clearance and are distributing the device in light of an the FDA guidance on enforcement discretion during the COVID-19 public health emergency, are **not** subject to the notification requirements of section 506J.

Questions?

CDRHManufacturerShortage@fda.hhs.gov.

Please include “Question” in the subject line

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Under Heading: Post-market Activities; Subheading: General Policy

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