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FDA Issues Temporary Guidance on New CARES Act Provision Requiring Certain Device Notifications to CDRH

May 14, 2020

Food, Drugs, and Devices

The recently-enacted Coronavirus Aid, Relief, and Economic Security Act (CARES Act) added new section 506J to the Federal Food, Drug, and Cosmetic Act (FDCA). This section requires manufacturers of certain devices to notify FDA of an interruption or permanent discontinuance in manufacturing during, or in advance of, a declared public health emergency. On May 6, FDA's Center for Devices and Radiological Health (CDRH) issued a direct-to-final guidance document addressing: (1) who must notify CDRH, (2) devices for which CDRH requires notification, (3) when to notify CDRH, (4) what information to include in the notification, and (5) how to notify CDRH. This guidance is intended to remain in effect only for the duration of the COVID-19 public health emergency.

(1) Who must notify CDRH?

"Manufacturers" of certain devices must notify CDRH of an interruption or permanent discontinuance in manufacturing. FDA interprets "manufacturer" to be "the entity that holds the medical device marketing submission authorization [(e.g., PMA, de novo, 510(k)] or, if a medical device marketing submission is not required, the entity responsible for listing the medical device under section 510(j) of the FD&C Act." Manufacturers of devices that would typically require marketing authorization from FDA, but are distributed under FDA's exercise of enforcement discretion during the COVID-19 public health emergency, are **not** required to notify CDRH under section 506J.

(2) For which devices does CDRH require notification?

Manufacturers of the following devices must notify CDRH of an interruption or permanent discontinuance in manufacturing:

- Devices that are critical to public health during a public health emergency, including those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or

- Devices for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency.[1]

In determining whether a manufacturer is required to notify CDRH about a particular device, FDA recommends that manufacturers evaluate a number of criteria, although standing alone, FDA does not describe them as necessarily determinative:

- Whether the device (with or without accessories) is life-supporting, life-sustaining, or intended for use in emergency medical care (e.g., ventilator and ventilator tubing, hemodialysis equipment, automated external defibrillator);
- Whether the device (with or without accessories) is intended for use during surgery (e.g., cardiopulmonary bypass oxygenators, infusion pumps and tubing);
- Whether the device (with or without accessories and/or testing supplies) is used to diagnose, cure, treat, mitigate or prevent COVID-19 (e.g., specific supplies from diagnostic and serological specimen collection kits, reagents for extraction or PCR amplification or serological testing, pulse oximeters, cardiac and other monitoring equipment); or
- Whether the device (with or without accessories) would be in higher-than-typical demand during the response to COVID-19 pandemic compared to a similar period of time (e.g., personal protective equipment).

(3) When must a manufacturer notify CDRH?

Manufacturers must notify CDRH:

- At least six months in advance of a "**permanent discontinuance**" in the manufacture of the device;
- At least six months in advance of an "**interruption of the manufacture**" of a device that is likely to lead to a "**meaningful disruption**" in the U.S. supply of that device (FDA also recommends updates every two weeks until the shortage risk has been resolved); or
- If the six-month-advance timeframe is not possible, manufacturers must notify CDRH "as soon as practicable," which FDA has interpreted to mean "no later than 7 calendar days after the discontinuance or interruption in manufacturing occurs."

"**Permanent discontinuance**" is interpreted to mean "a decision by the manufacturer to cease manufacturing and distributing a product indefinitely for business or other reasons."

FDA broadly interprets an "**interruption in manufacturing**" as an interruption that occurs "as a result of a decrease in manufacturing capability or increased demand." Interruptions in manufacturing must be reported if they are likely to result in a "**meaningful disruption**," which is "a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product." It is significant that FDA interprets an

[1] *See* FDCA § 506J(a). Section 506J(a)(2) states that notification is required for devices for which FDA determines information is needed "during, *or in advance of*, a public health emergency" (emphasis added). The "in advance of" language is omitted in this guidance, possibly because the COVID-19 public health emergency has already been declared by the HHS Secretary. The "in advance of" statutory language might become relevant for any future public health emergencies.

"interruption in manufacturing" to include instances of **increased demand**, even if a manufacturer's production remains the same; this is in contrast to the drug notification provisions where FDA states that increases in demand do not trigger mandatory reporting to FDA, but encourages voluntary reporting in such instances.[2]

The guidance further enumerates what is *not* a meaningful disruption, including certain short-term interruptions due to routine maintenance, certain short-term interruptions in component/raw material manufacturing, and interruptions that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform multiple procedures or diagnostic tests.

Although not a "permanent discontinuance" or an "interruption in manufacturing," the guidance requests that manufacturers voluntarily notify FDA in the following two scenarios:

- If the manufacturer is considering taking an action that may lead to a meaningful disruption in the supply of a device (e.g., holding production to investigate a quality issue or transfer of ownership); and
- If the manufacturer is ordered by another United States government entity to take an action that diverts supply from the originally intended customer.

Finally, as with its drug shortage notification guidance, FDA requests that manufacturers voluntarily report additional information that would help FDA better prevent or mitigate device shortages during the public health emergency.

(4) What information should be included in the notifications?

A notification should include information identifying the subject device, as well as the reasons for the discontinuance or interruption. FDA also recommends that manufacturers include information related to: the duration of the discontinuance or interruption, COVID-19 pandemic-specific inquires, possible mitigations, and production capacity & market share.

The guidance includes a template example intended to illustrate the type of information FDA recommends be included in the notification.

(5) How should manufacturers notify CDRH?

Notifications should be submitted via email to CDRHManufacturerShortage@fda.hhs.gov. FDA also encourages manufacturers to submit questions to this mailbox.

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[2] *See* FDA Guidance, *Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act* at 8 (Mar. 2020) (requesting manufacturers notify FDA for covered products "even in the absence of an interruption in manufacturing, for example, when there is a sudden, unexpected spike in demand" even though "manufacturers are not required to report this type of situation to FDA").

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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