

Contains Nonbinding Recommendations

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

Guidance for Industry and Food and Drug Administration Staff

May 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20032 and complete title of the guidance in the request.

Questions

For questions about this document, contact CDRHManufacturerShortage@fda.hhs.gov.

Table of Contents

I. Introduction	1
II. Background.....	2
III. Policy for Notifying CDRH of an Interruption or Permanent Discontinuance in Manufacturing ..	3
A. Who Must Notify CDRH	3
B. When To Notify FDA	4
C. What Information To Include in Notifications.....	6
D. How To Notify FDA	7
IV. Example Notification.....	7

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

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to implement section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351 et seq.), as added by section 3121 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as it relates to device shortages and potential device shortages occurring during the COVID-19 pandemic, for the duration of the COVID-19 public health emergency.¹

Section 506J of the FD&C Act 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.² This guidance is intended to assist manufacturers in providing FDA timely, informative notifications about changes in the production of certain medical device products that will help the Agency prevent or mitigate

¹ This guidance applies only to devices regulated by the Center for Devices and Radiological Health (CDRH).

² See section 506J(a) of the FD&C Act.

Contains Nonbinding Recommendations

shortages of such devices during the COVID-19 public health emergency. This guidance also recommends that manufacturers voluntarily provide additional details to better ensure FDA has the specific information it needs to help prevent or mitigate shortages during the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.³ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.⁴

On March 27, 2020, the CARES Act was signed into law. Section 3121 of the CARES Act amends the FD&C Act by adding section 506J to the statute. Section 506J provides FDA with new authorities intended to help prevent or mitigate medical device shortages⁵ “during, or in advance of, a public health emergency declared by the Secretary under section 319 of the PHS Act.”⁶ The provision includes requirements for manufacturers of certain devices,⁷ as described in more detail in

³ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

⁴ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

⁵ “Shortage” is defined as “a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device.” See section 506J(i)(2) of the FD&C Act.

⁶ See section 506J(a) of the FD&C Act.

⁷ See section 506J(a) and (b) of the FD&C Act.

Contains Nonbinding Recommendations

section III, to notify FDA “of a permanent discontinuance in the manufacture of the device” or “an interruption in the manufacture of the device that is likely to lead to a meaningful disruption in supply of that device in the United States” during a declared public health emergency.⁸ FDA is issuing this guidance to clarify and make recommendations regarding who must notify FDA, what information to include in the notification, and how to notify FDA, for the duration of the COVID-19 public health emergency.⁹

During the COVID-19 pandemic, FDA has taken many actions¹⁰ 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. These actions include issuing Emergency Use Authorizations (EUAs), as well as guidance documents to provide policies to help expand the availability and capability for various diagnostic, therapeutic, and protective medical devices in high demand during the COVID-19 pandemic. FDA continues to monitor the healthcare landscape and supply chain for resulting shortages, or meaningful disruptions to U.S. supply, of certain medical devices.

III. Policy for Notifying CDRH of an Interruption or Permanent Discontinuance in Manufacturing

A. Who Must Notify CDRH

Under section 506J of the FD&C Act, manufacturers of the following devices must notify FDA 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;¹¹ or
- Devices for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency.¹²

For purposes of this guidance, FDA interprets the term “manufacturer” to mean the entity that holds the medical device marketing submission authorization, 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. If a manufacturer makes a device described in section 506J(a)(1) – (2) that has marketing authorization from FDA, or is listed under section 510(j) of the FD&C Act, that device is subject to a notification to FDA pursuant to section 506J. For example, manufacturers of ventilators or thermometers that have received 510(k) clearance, or of surgical gowns listed pursuant to section 510(j) of the FD&C Act are subject to the notification requirement in section 506J. Manufacturers of devices, such as ventilators or thermometers that are required to submit a premarket notification

⁸ See section 506J(a) of the FD&C Act.

⁹ This guidance applies to reporting under section 506J of the FD&C Act during the COVID-19 public health emergency. Implementation of section 506J of the FD&C Act is ongoing, and the Agency intends to provide more details regarding implementation when they are available.

¹⁰ See <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/medical-devices-and-covid-19-coronavirus-pandemic#response>.

¹¹ See section 506J(a)(1) of the FD&C Act.

¹² See section 506J(a)(2) of the FD&C Act.

Contains Nonbinding Recommendations

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.¹³

Under section 506J of the FD&C Act, manufacturers of devices that are critical to public health during a public health emergency, or for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency, are required to notify FDA of an interruption or permanent discontinuance in manufacturing of such devices. FDA recommends that manufacturers evaluate the following circumstances when determining whether they are required to notify FDA:

- Whether the device (with or without accessories) is life-supporting, life-sustaining, or intended for use in emergency medical care (examples could include ventilator and ventilator tubing, hemodialysis equipment, automated external defibrillator);
- Whether the device (with or without accessories) is intended for use during surgery (examples could include 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 (examples could include 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 (examples could include personal protective equipment).

If a manufacturer is not certain whether to notify FDA about a particular device, we recommend the manufacturer contact the Agency at the mailbox listed in Section III.D of this guidance.

B. When To Notify FDA

Per section 506J(b) of the FD&C Act, manufacturers must notify FDA at least six months in advance of a permanent discontinuance¹⁴ in manufacturing of a device or an interruption in manufacturing of a device that is likely to lead to a meaningful disruption in supply of the device in the United States.¹⁵ If that timeframe is not possible, notification should be done “as soon as is practicable.”¹⁶

For purposes of this guidance, FDA considers “as soon as practicable” to mean that a manufacturer should notify FDA no later than 7 calendar days after the discontinuance or interruption in manufacturing occurs. With sufficient notice, FDA can work with the manufacturer and other

¹³ During the COVID-19 public health emergency, FDA has issued a number of guidances where it has stated that it does not intend to object to modifications to FDA-cleared devices, or to the distribution and use of new devices, without prior submission of a premarket notification pursuant to section 510(k) of the FD&C Act. See <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

¹⁴ FDA interprets a “permanent discontinuance” to be a decision by the manufacturer to cease manufacturing and distributing a product indefinitely for business or other reasons. All such discontinuances are required to be reported within the timeframe prescribed by section 506J(b) of the FD&C Act.

¹⁵ See section 506J(b)(1) of the FD&C Act.

¹⁶ See section 506J(b)(2) of the FD&C Act.

Contains Nonbinding Recommendations

stakeholders to potentially prevent and mitigate shortages, helping prevent negative impacts to patients and healthcare personnel.

The term “meaningful disruption” is defined in section 506J(i)(1)(A) of the FD&C Act as “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.” For purposes of this guidance, we interpret this to mean that a manufacturer should base its reporting on its own capacity, supply, and orders, and should not consider other manufacturers’ or competitors’ capacities or assumed capacities, or what it understands about market demand for the device.

Section 506J(i)(1) of the FD&C Act also provides that the term “meaningful disruption” does not include:

- “[I]nterruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing, so long as the manufacturer expects to resume operations in a short period of time, not to exceed six months;”¹⁷
- “[I]nterruptions in manufacturing of components or raw materials, so long as such interruptions do not result in a shortage of the device, and the manufacturer expects to resume operations in a reasonable period of time.”¹⁸ For purposes of this guidance, FDA believes a “reasonable period of time” would not exceed one month.
- “[I]nterruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than one procedure or diagnostic test.”¹⁹ For devices designed to perform more than one procedure or diagnostic or serological test, manufacturers should provide notification of any interruption that could lead to reduction in any of the procedures or testing capabilities. For example, if a device can be used for five types of procedures, and the manufacturing interruption means only four types of procedures can be performed, this should be reported to FDA.

The COVID-19 pandemic triggered unprecedented increased demand for some medical devices, as well as significant disruptions to global medical device manufacturing and supply chain operations. For purposes of this guidance, FDA interprets “interruptions in manufacturing” to include those that occur as a result of a decrease in manufacturing capability or increased demand.

After the initial notification of an interruption in manufacturing, FDA recommends that manufacturers provide updates every two weeks on the situation, including the expected timeline for recovery, even if the status remains unchanged. These updates are important to ensure that FDA can act on the most current information. We recommend such updates be submitted until the shortage risk has been resolved.

If a 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), FDA requests that the manufacturer notify FDA immediately through the process explained in Section III.D. of this guidance. In addition, if a manufacturer is ordered by another United States

¹⁷ See section 506J(i)(1)(B) of the FD&C Act.

¹⁸ See section 506J(i)(1)(C) of the FD&C Act.

¹⁹ See section 506J(i)(1)(D) of the FD&C Act.

Contains Nonbinding Recommendations

government entity to take an action that diverts supply from the originally intended customer, FDA requests that the manufacturer notify FDA through the electronic mailbox listed in Section III.D. of this guidance.

If a manufacturer is not certain whether to notify FDA, we recommend the manufacturer contact the Agency at the electronic mailbox listed in Section III.D of this guidance.

C. What Information To Include in Notifications

Per section 506J(a) of the FD&C Act,²⁰ manufacturers of the devices identified in Section III.A. of this guidance must notify FDA of:

- “a permanent discontinuance in the manufacture of the device (except for discontinuances as a result of an approved modification of the device);” or
- “an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States;” and
- “the reasons for such discontinuance or interruption.”

When providing a notification pursuant to 506J, in addition to the information described in 506J(a), the manufacturer should also provide FDA with appropriate identifying information, such as marketing submission holder name, marketing submission number (if applicable), manufacturer name (if manufacturer different from marketing submission holder), FDA Establishment Identifier (FEI) number, device name, product code, and contact information. Having this information enables FDA to appropriately identify the specific device for which the notification has been submitted.

In addition, FDA recommends that manufacturers submit other information, as outlined in Section IV of this guidance, that enables us to work more effectively with other manufacturers and entities to prevent or limit any negative impact on patients or healthcare providers during the COVID-19 public health emergency.

Section IV of this guidance provides an example of information that FDA recommends be included in a notification pursuant to section 506J of the FD&C Act and examples of reasons for the discontinuance or interruption, as well as the other information described above.

It is important to note that manufacturers need not have all of the information before submitting a notification; notifications can be updated at any time to include additional information. Therefore, we recommend that manufacturers not delay notifying the Agency until all information is available, but instead recommend that they provide initial notification as soon as is practicable and additional information as it becomes available.

Any information provided to FDA that is trade secret or confidential information will be treated as such, consistent with section 552(b)(4) of title 5, United States Code, section 1905 of title 18, United States Code, and other applicable laws.²¹

²⁰ See section 506J(a) of the FD&C Act.

²¹ See section 506J(d) of the FD&C Act.

Contains Nonbinding Recommendations

D. How To Notify FDA

Notifications should be submitted via email to CDRHManufacturerShortage@fda.hhs.gov.

A single initial notification may include a list of all affected devices and must include the information required by section 506J(a) of the FD&C Act. If an additional device is newly affected, FDA recommends submitting a new notification as opposed to an update to a previous notification.

IV. Example Notification

Note: This example is intended to illustrate the type of information that FDA recommends be included in a notification pursuant to section 506J of the FD&C Act.

Section 1: Type of notification

- Initial notification
- Update to previous notification

Section 2: Identifier information

- Marketing submission holder
- Marketing submission number (as applicable)
- Manufacturer name (if different from marketing submission holder)
- FDA Establishment Identification (FEI) number(s) (where device is manufactured)
- Generic device name
- Product code
- Device trade name
- UDI number

- Yes; UDI numbers provided below

UDI number(s)

- No; model or catalog number(s) provided below

Model or catalog number(s)

- Contact name
- Contact email and phone number

Section 3: Reason(s) for the discontinuance or interruption (*more than one may apply*)

- Requirements related to complying with good manufacturing practices
- Regulatory delay
- Order to divert devices from other U.S. government entities

Contains Nonbinding Recommendations

- Shortage or discontinuance of a component, part or accessory of the device (including specific supplies from diagnostic and serological specimen collection kits or reagents for extraction or PCR amplification or serological testing)
- Discontinuance or disruption of the manufacture of the device
- Delay in shipping of the device (e.g., due to export or import challenges, or transportation challenges)
- Delay in sterilization of the device
- Increase in demand for the device
- Facility closure
- Product is currently in shortage (i.e., demand currently exceeds supply)
- Product is expected to be in shortage (i.e., projected demand exceeds projected supply)
- Product on backorder (i.e., temporarily out of stock)
- Product on allocation (i.e., limiting the quantity distributed to customers to extend the life of the existing supply)
- Product on export restriction
- Longer than usual delay from order to delivery
- Other reasons not listed above; description below.

Description of reason(s) for the discontinuance or interruption.

Section 4: Duration of discontinuance or interruption

Estimated timeframe (i.e., dates) and/or duration (i.e., number of days) of the discontinuance or interruption.

In addition to the information in Sections 1-4, it would be helpful to FDA, during the COVID-19 public health emergency, to receive the following information to help enable FDA to better manage any potential shortages or meaningful disruptions to the device supply chain.

Section 5: COVID-19 pandemic-specific inquiries

- Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)?
 - No
 - Yes; issue(s) described below
 - Labor shortages
 - Lack of protective equipment for employees
 - Shortage or delay in raw material supply
 - Temporary plant closure
 - Shipping/transportation challenges
 - Export/import challenges
 - Other

Contains Nonbinding Recommendations

Additional details of issue(s).

- Do you rely on any critical suppliers that might be affected by the COVID-19 pandemic?

- No
- Yes; impact and supplier(s) below.

Description of how reliance on critical suppliers affected by the COVID-19 pandemic might adversely impact your ability to manufacture device(s). (If you are willing/able), names of your critical supplier(s).

Section 6: Additional information, including possible mitigations

- Is this device manufactured on multiple lines?
 - No
 - Yes
- Is this device manufactured in multiple facilities?
 - No
 - Yes
- How much device inventory do you have?

Current device inventory.

- Have you provided, or will you provide, public information for your stakeholders and patients regarding this actual or potential shortage (e.g., Dear Healthcare Provider (DHCP) Letters, supply or shortage information posted on your website)?
 - No
 - Yes
- Do you have a proposal for FDA to review to expedite availability of your device? What else do you think FDA can do to help prevent or mitigate a supply disruption?
 - No
 - Yes

Proposal to expedite availability of device and/or for FDA to help prevent or mitigate a supply disruption.

Contains Nonbinding Recommendations

- Do you have shortage mitigation plans in place that could be shared with FDA?
 - No
 - Yes; description below

Describe shortage mitigation plans or provide a copy as an attachment.

Section 7: Production Capacity & Market Share

Device descriptor	Estimated US market share (%)	Avg Historic Production Volume [# / mo]	Avg Historic US distribution [# / mo]	Current Prod Volume [# / mo]	Current US distribution [# / mo]	Max Production Volume [# / mo]
<i>e.g., GenericDevice</i>	<i>e.g., 10%</i>	<i>e.g., 300</i>	<i>e.g., 250</i>	<i>e.g., 100</i>	<i>e.g., 100</i>	<i>e.g., 500</i>