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# Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act

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# Draft Guidance for Industry and Food and Drug Administration Staff

***DRAFT GUIDANCE***

**This draft guidance document is being distributed for comment purposes only.**

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For questions about this document regarding CDRH-regulated devices, contact CDRHManufacturerShortage@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.



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# Preface

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Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 21003 and complete title of the guidance in the request.

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# Draft Guidance for Industry and Food and Drug Administration Staff

***This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

The Food and Drug Administration (FDA or Agency) is issuing this guidance to implement section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356j), as added by section 3121 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as it relates to notifying FDA of a permanent discontinuance or interruption in the manufacturing of a device that is likely to lead to a meaningful disruption in the supply of that device during or in advance of a public health emergency.

FDA plays a critical role in protecting the United States from threats, such as emerging infectious diseases, and other public health emergencies. Section 506J of the FD&C Act requires manufacturers to notify FDA, during or in advance of a public health emergency, 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.[1] This guidance is intended to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products that will help prevent or mitigate shortages of such devices. This guidance also recommends that manufacturers voluntarily provide additional details to better ensure FDA has the specific

[1] *See* section 506J(a) of the FD&C Act.

information it needs to help prevent or mitigate shortages during or in advance of a public health emergency.

FDA is issuing this guidance to assist stakeholders in the Agency's implementation of section 506J of the FD&C Act outside of the COVID-19 public health emergency, and will serve as the baseline for information about notifications under section 506J of the FD&C Act during or in advance of any public health emergency. This draft guidance is not intended to supersede the COVID-19 Public Health Emergency Guidance, "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"[2], which will be withdrawn at the end of the COVID-19 Public Health Emergency. Should this guidance be finalized before the COVID-19 public health emergency declaration expires or is terminated, the COVID-19 Public Health Emergency Guidance will be applicable for 506J related issues with respect to COVID-19.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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

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 the FDA with new authorities intended to help prevent or mitigate medical device shortages[3] "during, or in advance of, a public health emergency declared by the Secretary under section 319 of the Public Health Service (PHS) Act."[4]

Under section 506J(a) of the FD&C Act, manufacturers of certain devices,[5] as described in more detail in Section III of this guidance, are required 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 or in advance of a declared public health emergency.[6]

[2] *See* FDA guidance on "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 (Revised)" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc.

[3] "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.

[4] *See* section 506J(a) of the FD&C Act.

[5] *See* section 506J(a) and (b) of the FD&C Act.

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

If a manufacturer fails to submit the information required under section 506J(a) in accordance with the timing set forth in section 506J(b) of the FD&C Act, section 506J(e) of the FD&C Act requires FDA to issue a letter informing them of such failure.[7] In addition, under section 506J(f) of the FD&C Act, if FDA concludes that there is, or is likely to be, a shortage of a device, then inspections as well as review of submissions may be prioritized and expedited to help mitigate or prevent shortages. Section 506J(g) of the FD&C Act also requires FDA to establish and maintain a publicly available, up-to-date list of the devices determined to be in shortage.

FDA is issuing this guidance to clarify and make recommendations regarding who should notify FDA, what information to include in the notification, and how to notify FDA, during or in advance of a public health emergency, regardless of the type of public health emergency. During a specific public health emergency, FDA may issue additional supplemental information to this guidance, through supplemental guidance, FDA's website, or other communications, to assist manufacturers in providing a notification under section 506J of the FD&C Act (hereafter referred to as a "506J notification").

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

## A. Who Must Notify

Under section 506J(a)(1) – (2) of the FD&C Act, manufacturers of the following devices must submit notifications of a permanent discontinuance or an interruption in manufacturing that is likely to lead in a meaningful supply disruption of that device:

- 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;[8] or
- Devices for which FDA determines information on potential meaningful supply disruptions is needed during, or in advance of, a public health emergency.[9]

During or in advance[10] of a public health emergency, FDA may recommend to manufacturers devices or device types we consider to be critical to public health during that public health emergency under section 506J(a)(1) of the FD&C Act. For example, during the COVID-19 pandemic, FDA created a table of device types and corresponding product codes identifying devices that FDA believes to be critical to the public health during a public health emergency under section 506J(a)(1) of the FD&C Act, which manufacturers should consider to determine whether they are required to notify FDA.[11] During or in advance of other public health

[7] *See* section 506J(e) of the FD&C Act.
[8] *See* section 506J(a)(1) of the FD&C Act.
[9] *See* section 506J(a)(2) of the FD&C Act.
[10] *Refer* to Section III.B.(2) "During or in advance of a public health emergency" of this guidance for more information.
[11] *See* FDA website on "Medical Device Types to Help Determine Section 506J Notification Obligations" available at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-types-help-determine-section-506j-notification-obligations.

emergencies, FDA may take a similar approach, or other approaches, as appropriate. FDA may also identify devices or device types for which we have determined that information on meaningful supply disruptions is needed under section 506J(a)(2) of the FD&C Act. Manufacturers of devices that FDA has identified under section 506J(a)(1) – (2) should consider whether there is a permanent discontinuance or interruption in manufacturing and submit appropriate notifications to FDA.

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 506J notification. Manufacturers of devices should use the term "device" as defined in section 201(h) of the FD&C Act.

Section 506J of the FD&C Act requires manufacturers of devices that are critical to public health during a public health emergency, or for which FDA determines information on potentially meaningful supply disruptions is needed during a public health emergency, to notify FDA of an interruption or permanent discontinuance in manufacturing of such devices. If manufacturers are unsure of whether they are required to notify, FDA recommends that manufacturers evaluate the following circumstances to determine whether they manufacture devices for which a notification is required during or in advance of a public health emergency:

- Whether the device (with or without accessories) is life-supporting, life-sustaining, or intended for use in emergency medical care (examples could include extracorporeal life support, hemodialysis equipment, and automated external defibrillators);
- Whether the device (with or without accessories) is intended for use during surgery (examples could include cardiopulmonary bypass oxygenators, and infusion pumps and tubing);
- Whether the device (with or without accessories and/or testing supplies) is used to diagnose, cure, treat, mitigate, or prevent a disease that is related to a pandemic or other public health emergency (examples could include specific supplies from diagnostic and serological specimen collection kits, pulse oximeters, and cardiac and other monitoring equipment); or
- Whether the device (with or without accessories) would be in higher-than-typical demand during the response to a pandemic or other public health emergency compared to a similar period of time (examples could include personal protective equipment and personal oxygen concentrators).

If a manufacturer is not certain whether to notify FDA about a particular device or interruption, we recommend the manufacturer contact the Agency at CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER.

## B. When to Notify

Manufacturers must submit a notification at least six months in advance of a permanent discontinuance 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.[12] If that timeframe is not possible, notification should be done "as soon as is practicable."[13]

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 an interruption in manufacturing occurs, or no later than 7 calendar days after the manufacturer decides to permanently discontinue the device, as applicable. In FDA's experience, even if it is not possible for an applicant to notify the Agency before a permanent discontinuance or an interruption that is likely to lead to a meaningful disruption in supply of the device, it should generally be possible for the applicant to provide notice within a day or two, and it should always be possible for the applicant to notify the Agency no later than 7 calendar days after the permanent discontinuance or meaningful interruption occurs. With sufficient notice, FDA can work with the manufacturer and other stakeholders to potentially prevent and mitigate shortages, helping prevent negative impacts to patients and healthcare personnel.

If the circumstances giving rise to a manufacturer's 506J notification change after notifying FDA, the manufacturer should notify FDA of this change in status. For example, if the situation that caused an interruption in manufacturing has resolved, or the manufacturer has changed the date on which the discontinuance will take effect, the manufacturer should notify FDA of this information.

After the initial 506J notification of an interruption in manufacturing, FDA recommends that manufacturers provide updates every two weeks unless otherwise indicated based on the nature of 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. FDA may contact manufacturers that have not submitted updates and request that the manufacturer provide the most current information on the situation.

FDA welcomes any information that manufacturers wish to provide voluntarily at any time to help understand the status of the supply chain and help protect the public health.

[12] *See* section 506J(b)(1) of the FD&C Act.
[13] *See* section 506J(b)(2) of the FD&C Act.

### (1) Permanent discontinuances, interruptions in manufacturing and meaningful disruptions in supply

For purposes of this guidance, FDA interprets a "permanent discontinuance" to mean when the manufacturer ceases manufacturing and distributing a product indefinitely for business or other reasons.[14]

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 an increase in demand due to the current or potential public health emergency. Manufacturers experiencing an increase in demand of a device relating to a response in a public health emergency (e.g., for the detection, treatment, or prevention of a disease relating to a pandemic, Chemical, Biological, Radiological, Nuclear, or high yield Explosive (CBRNE) event, or natural disaster) should notify FDA of this interruption. Manufacturers experiencing normal variations in product demand generally should not submit a notification. Similarly, manufacturers experiencing an increase in demand for a device due to a temporary market response (e.g., demand for a newer version or model) generally should not submit a notification.

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;"[15]
- "[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."[16] 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

[14] Section 506J makes clear that manufacturers are not required to notify of permanent discontinuances that occur "as a result of an approved modification of the device." *See* section 506J(a) ("A manufacturer of a device…shall…notify… of a permanent discontinuance in the manufacture of the device (*except for discontinuances as a result of an approved modification of the device*)…) (emphasis added).

[15] *See* section 506J(i)(1)(B) of the FD&C Act.

[16] *See* section 506J(i)(1)(C) of the FD&C Act.

procedure or diagnostic test."[17] 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, the manufacturer should notify FDA.

Permanent discontinuances are required to be reported within the timeframe prescribed by section 506J(b) of the FD&C Act through the process explained in Section III.D. of this guidance. If a manufacturer is considering taking an action that may lead to a meaningful disruption in the supply of a device (e.g., transfer of ownership, or holding production to investigate a quality issue), 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 government entity to take an action that diverts supply from the originally intended customer, FDA requests that the manufacturer notify FDA using the process explained in Section III.D. of this guidance.

### (2) During or in advance of a public health emergency

For purposes of this guidance, FDA interprets "during . . . a public health emergency" to mean the time period when the Health and Human Services (HHS) Secretary declares a public health emergency under section 319 of the PHS Act, and includes any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the PHS Act (42 U.S.C. 247d(a)(2)).

For purposes of this guidance, FDA interprets "in advance of a public health emergency" to mean the time period before the Secretary may determine that a disease or disorder presents a public health emergency or that a public health emergency including significant outbreaks of infectious diseases or bioterrorist attacks otherwise exists. If certain conditions exist prior to the occurrence of an outbreak or natural disaster that signal the potential for such event to occur and that may lead to the declaration of a public health emergency, FDA considers such conditions to be "in advance of a public health emergency." When FDA becomes aware of such conditions that are in advance of a public health emergency, the Agency may conduct outreach to or otherwise notify manufacturers to alert them of the situation and the applicability of section 506J of the FD&C Act.

Manufacturers should notify FDA of a potential discontinuance or interruption if any of the following occur prior to a public health emergency being declared (note that this list is not intended to be exhaustive):

- HHS activates the National Disaster Medical System or deploys the Strategic National Stockpile without yet determining a public health emergency under section 319 of the PHS Act;

[17] *See* section 506J(i)(1)(D) of the FD&C Act.

- HHS authorizes assistance for research, investigations, demonstration, and studies into the causes, diagnosis, treatment, control, and prevention of a physical or mental disease under section 301 of the PHS Act;
- HHS authorizes assistance in the prevention and suppression of communicable diseases under section 311 of the PHS Act;
- HHS authorizes FDA to issue an Emergency Use Authorization (EUA) for a drug, biological product, or device intended for use in an actual or potential emergency ("emergency use;" under section 564 of the FD&C Act);
- HHS accesses the Public Health Emergency Fund and/or has enabled the Centers for Disease Control and Prevention Director to access the Infectious Diseases Rapid Response Reserve Fund prior to declaring a public health emergency;
- HHS determines that a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency for purposes of waiving the Paperwork Reduction Act under section 319(f) of the PHS Act;
- Other Federal or State agencies determine that there is an actual or significant potential for a domestic emergency involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent(s); or
- Other Federal or State agencies determine that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces with a biological, chemical, radiological, or nuclear agent or agents.

In addition, because of the potential for a CBRNE event or widespread treatment-resistant outbreaks (e.g., methicillin-resistant Staphylococcus aureus (MRSA) outbreak) leading to a public health emergency, FDA recommends that manufacturers submit a notification with respect to a CBRNE event to enable FDA to work more effectively with manufacturers and entities to prevent or limit any negative impact on patients or healthcare providers.

A public health emergency may be identified in a specific geographical area that has the potential to impact a larger geographical area. Due to the vulnerability of the medical device supply chain, a localized interruption in the supply or demand of a product may have an impact on the national availability of a product. Manufacturers experiencing an interruption during a public health emergency related to a localized event that has the potential to lead to a meaningful disruption of the supply of the device in the United States should notify the Agency under section 506J of the FD&C Act.

If a manufacturer is not certain whether to notify FDA, we recommend the manufacturer contact the Agency at CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER.

## C. What Information To Include in 506J Notifications

Per section 506J(a) of the FD&C Act,[18] manufacturers of the devices identified in Section III.A. of this guidance must submit notifications of:

[18] *See* section 506J(a) of the FD&C Act.

- "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 506J notification, in addition to the information described in section 506J(a) of the FD&C Act, 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 506J notification has been submitted.

It is important to note that manufacturers do not need to have all of the information before submitting a 506J notification; 506J 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 506J notification as soon as is practicable and additional information as it becomes available. If manufacturers do not notify FDA within the timelines specified in section 506J(b), FDA requests that manufacturers explain why such timeline was not possible.

FDA recommends that manufacturers submit additional information that could inform the Agency of current supply chain pressures, including indications of:

- Manufacturing pressures (e.g., labor shortages, delays in raw material supply, temporary plant closures, packaging or sterilization concerns, other unforeseen circumstances that prevent fulfillment);
- Distribution pressures (e.g., shipping/transportation challenges, export/import challenges, procurement issues);
- Increased or projected increased demand (e.g., backorder, allocation, low fulfillment rates);
- Potential broader/connected interruptions (e.g., reliance on critical suppliers who are experiencing supply chain interruptions); and
- Actions or circumstances affecting software-enabled devices that may disrupt healthcare operations (e.g., device cybersecurity vulnerabilities or exploits).

FDA also recommends that manufacturers submit information that could help the Agency better assess the overall state of the market and help inform potential mitigations, including:

- Potential prevention or mitigation strategies, including stakeholder and customer communications; and
- Inventory and production capacity, including potential expansion capabilities (e.g., estimated market share, historic and current production capacity, maximum production volume).

This additional voluntary information is intended to enable us to work more effectively with other agencies and supply chain partners to prevent or mitigate any negative impact on patients or healthcare providers. FDA may on occasion request specific additional information depending on the type of public health emergency. In addition, to inform possible mitigation efforts, FDA may follow up with manufacturers or conduct targeted outreach where an interruption is cross-cutting or may have the potential to impact users.

Appendix A of this guidance provides an example of the information that FDA recommends be included in a 506J notification and examples of reasons for the discontinuance or interruption, as well as the other voluntary information described above.

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.[19]

## D. How to Notify

FDA's website[20] contains information about submitting 506J notifications to CDRH. If you have questions, you can contact CDRH at CDRHManufacturerShortage@fda.hhs.gov and include "Question" in the subject line of the email. To notify CBER or ask questions about CBER-regulated devices, you can contact the CBER at cbershortage@fda.hhs.gov and include "Question" in the subject line of the email.

## E. Failure to Notify

If a manufacturer fails to provide notification of a permanent discontinuance or an interruption in manufacturing as required by section 506J(a) of the FD&C Act and in accordance with the timelines set forth in section 506J(b) of the FD&C Act, FDA will issue a letter to that manufacturer informing the manufacturer of such failure.[21] The manufacturer must respond to FDA's letter not later than 30 calendar days after issuance of FDA's letter, setting forth the basis for noncompliance and providing the required information on the discontinuance or interruption per section 506J(a) of the FD&C Act.[22] Not later than 45 calendar days of issuance of the letter to the manufacturer, FDA will make that letter and any response received available to the public on FDA's website with appropriate redactions to protect trade secrets or confidential commercial information.[23] However, FDA will not post the letter and response if the Agency determines that the letter was issued in error or, after review of the manufacturer's response, that the manufacturer had a reasonable basis for not notifying FDA as required.[24]

[19] *See* section 506J(d) of the FD&C Act.
[20] *See* FDA website on "Contact the FDA About a Medical Device Supply Chain Issue," available at https://www.fda.gov/medical-devices/medical-device-safety/contact-fda-about-medical-device-supply-chain-issue.
[21] *See* section 506J(e)(1) of the FD&C Act.
[22] *See* section 506J(e)(2) of the FD&C Act.
[23] *See* section 506J(e)(3) of the FD&C Act.
[24] *See* section 506J(e)(3) of the FD&C Act.

# IV. FDA's Determination That a Device Is In Shortage

"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."[25]

In determining whether a medical device is in shortage, FDA considers factors such as the relevant information and data available to the Agency, including indications of supply disruptions received through 506J notifications and voluntary manufacturer notifications.

The analysis of information related to potential device shortages informs FDA's work related to other measures FDA uses to help address the public health emergency, including issuance of EUAs for products that play an important role in meeting demand.[26] The analysis of information related to potential device shortages also informs FDA's consideration of additional mechanisms for addressing device supply availability, including use of enforcement discretion, expediting inspections or premarket reviews, and working with other federal partners.

## A. How FDA Determines What Devices Are In Shortage

FDA carefully reviews each 506J notification we receive, and uses this information, along with additional information on the supply and demand of the device, to determine whether a device is in shortage. The other information FDA reviews in making shortage determinations includes, but is not limited to:

- Indications of supply disruptions (e.g., 506J notifications and voluntary manufacturer information);
- Indications of distribution pressures (e.g., from distributors and group purchasing organizations);
- Indications of demand or projected demand, such as availability issues reported from users (e.g., patients, healthcare providers, hospitals and healthcare facilities, nursing homes, and associations representing these groups);
- International factors (e.g., export restriction); and
- Certain actions taken to prevent or mitigate shortages including, but not limited to, actions taken by manufacturers, FDA, or other stakeholders.

In determining whether a medical device is in shortage, FDA considers the entirety of relevant and reliable information and data available to the Agency at the time of a decision.

## B. FDA's List of Devices Determined to Be In Shortage

Section 506J(g) of the FD&C Act requires the establishment and maintenance of an up-to-date list of medical devices that have been determined to be in shortage. This list also identifies medical devices for which there has been notification that manufacturing has been permanently

[25] *See* section 506J(i)(2) of the FD&C Act.

[26] During a public health emergency, certain products may only be available under an EUA, which requires, among other things, that there be no adequate, approved, and available alternatives. See section 564(c) of the FD&C Act.

discontinued ("a discontinuance"). FDA's website[27] contains a list that fulfills this statutory obligation and will reflect the categories of devices FDA has determined to be in shortage. The list will be maintained and updated as information relating to a shortage evolves. FDA publishes this device shortages list to provide transparency to the American public, particularly those who use and/or purchase medical devices.

As outlined by section 506J(g)(2) of the FD&C Act, this list includes the category or name of the device in shortage, the name of each manufacturer, the reason for the shortage, and the estimated shortage duration. The basis for the interruption identified on the list is determined by FDA considering the following factors and categories:

- Requirements related to complying with good manufacturing practices (see section 506J(g)(2)(C)(i));
- Regulatory delay (see section 506J(g)(2)(C)(ii));
- Shortage or discontinuance of a component, part, or accessory of the device (see section 506J(g)(2)(C)(iii))
- Discontinuance of the manufacture of the device (see section 506J(g)(2)(C)(iv));
- Delay in shipping of the device (see section 506J(g)(2)(C)(v));
- Delay in sterilization of the device (see section 506J(g)(2)(C)(vi));
- Increase in demand for the device (see section 506J(g)(2)(C)(vii)); and/or
- Facility closure (see section 506J(g)(2)(C)(viii)).

As appropriate, FDA intends to work with manufacturers to ensure the accuracy and appropriateness of information before posting publicly on its website. FDA may elect not to make information collected under section 506J publicly available if the Agency determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the device to patients).[28]

## C. Expedited Inspections and Reviews

If FDA concludes, based on 506J notifications and/or any other relevant information, that there is, or is likely to be, a shortage of a device, the Agency will, as appropriate:

- "prioritize and expedite the review of a submission under section 513(f)(2), 515, review notification under section 510(k), or 520(m) for a device that could help mitigate or prevent such shortage; or"
- "prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent such shortage."[29]

When prioritizing such work, FDA considers 506J notifications as well as other information related to potential device shortages, including the information FDA reviews in making a shortage determination, described in more detail in Section IV.A. of this document.

[27] *See* https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency.
[28] *See* section 506J(g)(3)(C) of the FD&C Act.
[29] *See* section 506J(f) of the FD&C Act.

# Appendix A. Example 506J Notification

*Note: This example is intended to illustrate the information that could be included in a notification pursuant to section 506J of the FD&C Act. For different types of public health emergencies, FDA may provide an appendix with specific inquiries relating to that public health emergency.*

**Section 1: Type of 506J notification**

☐ Initial 506J notification
☐ Update to previous 506J notification

**Section 2: Identifier information**

- Are you submitting on behalf of another party?
- Submitter's contact information (First Name, Last Name, Email Address, Phone)
- 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

☐ 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 of the manufacture of the device
☐ Delay in shipping of the device (e.g., transportation challenges)
☐ Delay in sterilization of the device
☐ Increase in demand for the device
☐ Facility closure
☐ Device is currently in shortage (i.e., demand currently exceeds supply)
☐ Device is expected to be in shortage (i.e., projected demand exceeds projected supply)
☐ Device on backorder (i.e., temporarily out of stock)
☐ Device on allocation (i.e., limiting the quantity distributed to customers to extend the life of the existing supply)
☐ Device on export or import restrictions (e.g., another country is not allowing this device to be exported from their country)
☐ 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.* |

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*In addition to the information in Sections 1-4, it would be helpful to FDA, during a 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: Manufacturing specific inquiries**

- Has the current situation 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

*Additional details of issue(s).*

- Do you rely on any critical suppliers that might be affected by the public health emergency?

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

*Description of how reliance on critical suppliers affected by the public health emergency 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.* |

- 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 (for this FEI and product code)**

| Device descriptor | Estimated US market share (%) | Average historic production volume [# / mo] | Average historic US distribution [# / mo] | Current production volume [# / mo] | Current US distribution [# / mo] | Max production volume [# / mo] |
|---|---|---|---|---|---|---|
| *e.g., Generic Device* | *e.g., 10%* | *e.g., 300* | *e.g., 250* | *e.g., 100* | *e.g., 100* | *e.g., 500* |
| | | | | | | |
| | | | | | | |
| | | | | | | |