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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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Guidance for Industry and Food and Drug Administration Staff

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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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Center for Biologics Evaluation and Research

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Preface

Public Comment

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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

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

The Food and Drug Administration (FDA or Agency) is issuing this guidance to address section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by section 3121 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. No. 116-136 (March 2020), 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 (PHE).

FDA plays a critical role in protecting the United States from threats, such as emerging infectious diseases, and other PHEs. Section 506J requires manufacturers to notify FDA, during or in advance of a PHE, 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 devices that will help prevent or mitigate shortages of such devices. This guidance also recommends that manufacturers voluntarily provide additional information to better ensure FDA has the specific information it needs to help prevent or mitigate shortages during or in advance of a PHE.

FDA is issuing this guidance to assist interested parties in the Agency's implementation of section 506J. This guidance serves as the baseline for information about notifications under

[1] *See* section 506J(a).

section 506J (hereafter referred to as "506J notifications") during or in advance of any PHE. If FDA determines it is appropriate, we may issue individual, PHE-specific updates as appendices to this guidance or individual, PHE-specific guidance documents, among other potential options. Such decisions will be made on a case-by-case basis and will be determined by the specific situation and informational need.

In general, FDA's guidance documents 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 guidances 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 of the FD&C Act provides FDA with new authorities intended to help prevent or mitigate medical device shortages[2] "during, or in advance of, a public health emergency declared by the Secretary under section 319 of the Public Health Service (PHS) Act."[3]

On December 29, 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) was signed into law as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (hereafter referred to as the "FY 2023 Omnibus"). Section 2514(c) of the FY 2023 Omnibus directed FDA to issue or revise guidance regarding requirements under section 506J and include a list of each device product code for which a manufacturer of such device is required to notify the Secretary in accordance with section 506J. Additionally, section 2514 of the FY 2023 Omnibus amended section 506J to add section 506J(h), "Additional Notifications" and directed FDA to issue guidance "to facilitate voluntary notifications." To address these additional statutory directives, FDA has finalized Section III.B ("506J Device List") and Section IV ("Additional Notifications") of this guidance after considering public comments received during the comment period for the draft guidance "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications."

Under section 506J(a), manufacturers of certain devices,[4] 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 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" during or in advance of a declared PHE.[5] Section 506J(a) also requires manufacturers to inform FDA of "the reasons for such discontinuance or interruption."

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[2] "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(j)(2).
[3] *See* section 506J(a).
[4] *See* section 506J(a) and (b).
[5] *See* section 506J(a).

If a manufacturer fails to submit the information required under section 506J(a) in accordance with the timing set forth in section 506J(b), FDA is directed to issue a letter informing them of such failure (see Section III.F).[6] In addition, under section 506J(f), if FDA concludes that there is, or is likely to be, a shortage of a device, the Agency will prioritize and expedite inspections and premarket review, as appropriate, to help mitigate or prevent the shortage (see Section III.D.3). Section 506J(g) also requires FDA to establish and maintain a publicly available, up-to-date list of the devices that have been determined to be in shortage (see Section V.B).

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

Under section 506J, during or in advance of a PHE, manufacturers are required to submit notifications for devices that are critical to public health.[7] Specifically, section 506J(a) of the FD&C Act requires manufacturers to notify FDA of permanent discontinuances or interruptions in the manufacture of a device that are likely to lead to a meaningful disruption in the supply of that device in the United States. Notifications are not limited, under section 506J, to devices used to diagnose, cure, treat, mitigate, or prevent a specific PHE.

This section provides additional clarification on who is required to notify FDA, when such notifications are required pursuant to section 506J, what information FDA expects manufacturers to include in such notifications, and how to submit notifications. If a manufacturer has questions regarding 506J notifications, the manufacturer should contact the Agency at CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER, and include "Question" in the subject line of the email. A manufacturer may still submit a 506J notification even if they have questions.

A. Who Must Notify

For purposes of this guidance, FDA interprets the term "manufacturer" to mean the entity that holds the device marketing authorization (e.g., 510(k)), or, if a 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) that has marketing authorization from FDA, or is listed under section 510(j), that device is subject to section 506J and the manufacturer is required to submit a 506J notification.

If a manufacturer, as defined above, relies on a contract manufacturer or others in the production process, the manufacturer is responsible for ensuring the contract manufacturers, supply chain partners, or other entities provide them with sufficient notice and information to fulfill their notification obligations under section 506J.

Under section 506J, manufacturers of the following devices must submit notifications of a permanent discontinuance or an interruption in manufacturing "that is reasonably likely to lead

[6] *See* section 506J(e).
[7] *See* section 506J(a).

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":[8]

- Devices that are critical to public health during a PHE, including those that are life-supporting, life-sustaining,[9] or intended for use in emergency medical care or during surgery;[10] or
- Devices for which FDA determines information on potential meaningful supply disruptions is needed during, or in advance of, a PHE.[11]

FDA has developed a list of devices, by FDA product code ("product code"), for which a manufacturer of such devices is required to notify FDA in accordance with section 506J (hereafter referred to as the "506J Device List") in Section III.B, below.

For purposes of this guidance, the term "device" means a device as defined in section 201(h) of the FD&C Act that is intended for human use and that is subject to section 506J.

B. 506J Device List

Section 2514(c) of the FY 2023 Omnibus directs FDA to issue guidance on the requirements under section 506J of the FD&C Act and to include "a list of each device product code for which a manufacturer of such device is required to notify the Secretary in accordance with section 506J"[12] (the "506J Device List"). Thus, manufacturers of a device on the 506J Device List must notify FDA in accordance with section 506J for each such device.

FDA has developed a list of devices, by product code, according to the criteria set forth in section 506J(a), as discussed in Section III.A. FDA solicited public comments on the draft 506J Device List[13] in addition to receiving recommendations from the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee for the FDA (hereafter referred to as the "Panel").[14] FDA subject matter experts (including product reviewers, device experts, and clinical experts) reviewed and considered the public comments and the Panel recommendations during the finalization of the 506J Device List.

Separately, in response to Executive Order 14001 ("EO 14001"), A Sustainable Public Health Supply Chain, signed on January 21, 2021, FDA led an interagency effort (including FDA,

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[8] *See* section 506J(a) and (j)(1)(A).
[9] 21 CFR 860.3 defines a life-supporting or life-sustaining device as "a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life."
[10] *See* section 506J(a)(1).
[11] *See* section 506J(a)(2).
[12] *See* section 2514(c) of the FY 2023 Omnibus.
[13] FDA solicited comments on the draft 506J Device List according to the level 1 guidance procedures; *see* 21 CFR 10.115(g)(1).
[14] On February 6, 2024, the Panel met to discuss and make recommendations on medical device supply chain resiliency and shortage issues, including the proposed 506J Device List. For more information on the Panel's recommendations, see February 6, 2024: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting Announcement.

Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention, Administration for Strategic Preparedness and Response, United States Department of Veterans Affairs) in collaboration with healthcare providers and industry representatives within the device ecosystem, to develop a critical medical device list (CMDL). The CMDL was developed in response to EO 14001 to provide a comprehensive list of critical medical devices necessary for promoting public health and strengthening healthcare and the public health critical infrastructure. The CMDL, developed by device type, is intended for use by a broad set of interested parties to include clinicians; hospital systems; group purchasing organizations (GPOs); medical device industry; and state, local, territorial, and tribal governments. There is some overlap between the 506J Device List and CMDL given the commonality of identifying medical devices critical to public health. However, the CMDL is broader in scope than the 506J Device List, and the criteria for determining devices that were included on the CMDL and 506J Device List differ.

FDA leveraged the information and perspectives shared during the collaborative efforts to develop the CMDL, lessons learned during previous PHEs and other events that have led to shortages of critical medical devices, and all of the information described above, including the public comments and Panel recommendations, to develop the 506J Device List.

FDA's website, "506J Device List," hosts the 506J Device List. Per section 2514(c) of the FY2023 Omnibus, manufacturers of devices that FDA has identified by product code on this 506J Device List are required to submit 506J notifications when statutory conditions are met (see Section III.C for more information on when to notify FDA).[15]

FDA expects that the 506J Device List will evolve over time and FDA intends to periodically reevaluate the list, as appropriate, according to the criteria set forth in section 506J(a). For example, FDA may add or remove product codes during or in advance of a new PHE. Any revisions to the 506J Device List will follow FDA's good guidance practices[16] and FDA intends to publicize the revisions to the public through CDRH's communication processes. If an interested party has questions or comments regarding the 506J Device List, the interested party should contact the Agency at DeviceShortages@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER and include "506J Device List Inquiry" in the subject line of the email.

(1) Devices FDA has determined are "critical to public health during a public health emergency" under Section 506J(a)(1)

The 506J Device List contains those devices FDA has determined are "critical to public health during a public health emergency" within the meaning of section 506J(a)(1). FDA focused on those devices that are critical to public health during a PHE. In determining whether a device is critical to public health during a PHE, FDA considers a number of factors. For various reasons,[17] and consistent with the language of section 506J, FDA considers whether a device is critical to public health during *any* PHE.[18] However, FDA also considers whether there are certain devices

[15] *See* section 506J(a).
[16] *See* 21 CFR 10.115(g)(4).
[17] For example, multiple PHEs may exist at one time.
[18] Some devices, such as personal protective equipment devices, may be critical to public health during any PHE.

that may be critical to *specific* PHEs.[19] For example, FDA's consideration of whether a device is critical to a PHE includes, but is not limited to, the following:

- Whether the device is used to diagnose, treat, monitor, or prevent a serious disease or medical condition; and if the device is "life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery" (section 506J(a)(1)).
- Whether the lack of availability of the device is reasonably likely to cause serious injury or death to patients, healthcare workers, or others if it is not available and there are no suitable alternatives.[20]

These considerations, coupled with FDA's experience in responding to previous supply chain disruptions and shortages and the subsequent continued implementation of section 506J has informed the development of the 506J Device List. The product codes set forth in this list reflect, at this time, the product codes that FDA has determined are critical to public health during a PHE, and for which manufacturers should notify FDA, as appropriate. However, if FDA learns new information, consistent with the factors summarized above, FDA intends to reevaluate the product codes that are critical to public health during a PHE and update the 506J Device List accordingly. As previously stated, any revisions to the 506J Device List will follow FDA's good guidance practices.[21]

(2) Devices for which FDA has determined additional information is needed under Section 506J(a)(2)

During or in advance of a PHE, FDA may also identify, under section 506J(a)(2), devices for which we have determined "that information on potential meaningful supply disruptions" is needed. In making such determinations, FDA's considerations may include, but not be limited to, devices that are specific to a type of illness or event (e.g., respiratory illness; traumatic burns and/or wounds resulting from a disaster).

If FDA determines there are devices for which information on potential meaningful supply disruptions is needed during a specific PHE, FDA intends to add such product codes to the 506J Device List to assist manufacturers in determining whether they must submit a 506J notification to FDA.

C. When to Notify

Section 506J(b)(1) requires manufacturers to 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

[19] Specific PHEs may have certain devices that are critical to that specific PHE. For example, diagnostic tests may be critical to a specific PHE.

[20] For purposes of this guidance, FDA considers a "suitable alternative" to mean an alternate FDA authorized or legally marketed medical device, procedure, drug, or other intervention that could be used to address a medical condition or disease. FDA considered whether there are suitable alternatives during the development of the 506J Device List and intends to continue to factor in this consideration when updating the 506J Device List, as appropriate.

[21] *See* 21 CFR 10.115(g)(4).

States. If that timeframe is not possible, section 506J(b)(2) requires that notification be done "as soon as practicable."

For purposes of this guidance, FDA considers "as soon as practicable" to mean that a manufacturer should notify FDA no later than seven calendar days after an interruption in manufacturing occurs, or no later than seven calendar days after the manufacturer decides to permanently discontinue the device, as applicable. In FDA's experience, even if it is not possible for a manufacturer to notify the Agency before an interruption or a decision to discontinue that is likely to lead to a meaningful disruption in supply of the device, it should generally be possible for the manufacturer to provide notice within one or two calendar days, and in most cases it should be possible for the manufacturer to notify the Agency no later than seven calendar days after the permanent discontinuance or meaningful interruption occurs. With sufficient notice, FDA can work with the manufacturer and other interested parties to potentially prevent and mitigate shortages, reducing the impact on patients and healthcare providers.

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 as soon as practicable, preferably within seven calendar days. 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 four weeks, unless otherwise indicated by FDA, even if the status remains unchanged. FDA does not anticipate recommending manufacturers provide updates more frequently than every four weeks; however, based on the nature of the situation, including the expected timeline for recovery, FDA may recommend updates at less frequent intervals (e.g., every six weeks). For example, early during the Coronavirus Disease 2019 (COVID-19) pandemic,[22] it was helpful for FDA to receive updates every two weeks. However, later in the COVID-19 pandemic, as the pace at which device shortages evolved, we recommended manufacturers provide updates every six weeks. Updates help ensure that FDA is acting on the most current information, therefore, reducing additional outreach and minimizing overall burden to manufacturers. We recommend such updates be submitted until the supply chain disruption has been resolved. If updates have not been submitted, FDA may contact manufacturers and request that the manufacturer provide the most current information about the situation.

FDA welcomes information from manufacturers at any time that may help us better understand supply chain challenges and promote device availability.

[22] In 2019, an outbreak of respiratory disease caused by a novel coronavirus began. 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, the Secretary of Health and Human Services (HHS) issued a declaration of a PHE related to COVID-19 in accordance with section 319 of the PHS Act (hereinafter referred to as "section 319 PHE declaration") and mobilized the Operating Divisions of HHS. In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19. The section 319 PHE declaration related to COVID-19 expired on May 11, 2023.

(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.[23]

For purposes of this guidance, FDA interprets "interruptions in manufacturing" to include those that occur as a result of a more than negligible decrease in manufacturing capability or situations for which a manufacturer's supply cannot meet an increase in demand or projected demand.

- Manufacturers experiencing an increase in demand of a device relating to a response during or in advance of a PHE (e.g., for the detection, treatment, or prevention of a disease relating to a pandemic, Chemical, Biological, Radiological, Nuclear, or Explosive (CBRNE) event, or natural disaster) should notify FDA.
- Manufacturers experiencing a decrease in manufacturing capability (e.g., as a result of a device that is subject to a medical device recall, inability to manufacture a device because of labor constrains, or an inability to obtain raw materials or components necessary to manufacture a device) should also notify FDA.

For purposes of this guidance, we generally do not believe the following instances should be considered "interruptions in manufacturing." 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.
- Normal variations in product demand generally should not submit a notification.

The term "meaningful disruption" is defined in section 506J(j)(1)(A) 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 notifications to FDA 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(j)(1) 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 6 months."[24]
- "[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

[23] Section 506J(a) makes clear that manufacturers are not required to notify FDA of permanent discontinuances that occur "as a result of an approved modification of the device."
[24] *See* section 506J(j)(1)(B).

resume operations in a reasonable period of time."[25] For purposes of this guidance, FDA interprets "resume operations in a reasonable period of time" to mean that the manufacturer is generally able to resume pre-interruption operations and resume distribution of the devices within 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."[26] 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.

Manufacturers are required to notify FDA of permanent discontinuances within the timeframe prescribed by section 506J(b) through the process explained in Section III.E of this guidance. If any of the following situations occur, FDA requests that the manufacturer notify FDA immediately through the process explained in Section III.E of this guidance so that we may work together with the manufacturer to help prevent or mitigate any supply disruptions:

- 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).
- If a manufacturer is ordered by another government entity (e.g., a state government or foreign government entity) to take an action that diverts supply from the originally intended customer in a manner that may lead to a meaningful disruption.

(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 Secretary declares a PHE under section 319 of the PHS Act, including any renewals made by the 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 PHE or that a PHE, including significant outbreaks of infectious disease 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 PHE, FDA considers such conditions to be "in advance of a public health emergency." This would be the case irrespective of whether a PHE is ultimately declared. See Appendix A for more information on when manufacturers should expect 506J notifications to be required.

When FDA becomes aware of such conditions that are in advance of a PHE, the Agency intends to conduct outreach to or otherwise notify manufacturers to alert them of the situation and the

[25] *See* section 506J(j)(1)(C).
[26] *See* section 506J(j)(1)(D).

applicability of section 506J. For example, we may send an email communication and post on our website in advance of an impending natural disaster to make clear that manufacturers should, if their situation requires, submit notifications, as well as highlight any specific devices, or specific geographic areas where manufacturers should be particularly attuned and prepared to submit notifications if their situation requires.

A PHE 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 PHE 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.

Under section 506J, manufacturers are required to submit notifications for devices that are critical to public health, irrespective of whether the devices are related to a specific PHE for which FDA has indicated to be "in advance of," or that has been declared under section 319 of the PHS Act. For more information on the types of devices for which 506J notifications are required, see the 506J Device List in Section III.B.

D. What Information To Include in 506J Notifications

When submitting a 506J notification, it is important that manufacturers include the required information to help enable FDA to understand the supply situation to determine any appropriate and available mitigations. In some instances, the Agency may also request manufacturers to provide additional information to help the Agency's assessment of the supply issue and appropriate, available mitigations. Information from 506J notifications is used by FDA to assess whether a device is in, or potentially facing, a shortage at the time of notification.

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.[27]

(1) Information required by section 506J

Section 506J(a) requires manufacturers of the devices identified in Section III.B of this guidance to submit notifications 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."

[27] *See* section 506J(d).

Section 506J(g) requires FDA to publish a list of devices determined to be in shortage. Under section 506J(g)(2), FDA is required to include specific information on that list.[28] For FDA to carry out its requirements under section 506J(g)(2), manufacturers, in turn, must include the following information in their 506J notifications:

- The category or name of the device that is the subject of the 506J notification;
- The name of the manufacturer submitting the 506J notification; and
- The reason for the 506J notification, selecting from the following categories:[29]
    - Requirements related to complying with good manufacturing practices;
    - Regulatory delay;
    - Shortage or discontinuance of a component or part;
    - Discontinuance in the manufacture of the device;
    - Delay in shipping of the device;
    - Delay in sterilization of the device;
    - Demand increase for the device; and/or
    - Facility closure.
- The estimated duration of the discontinuance or interruption of the device that is the subject of the notification.

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 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.

(2) Additional information to help inform FDA's supply chain analysis

The information in Section III.D.1 is the information needed to enable FDA to meet its statutory obligations under section 506J(g) and to make determinations about potential supply chain disruptions. However, to help FDA appropriately identify the specific device for which the 506J notification has been submitted, FDA requests that manufacturers provide the following information in their 506J notifications:

- Submitter name, email, phone, company name;
- Marketing submission number, if applicable;
- FDA Establishment Identifier (FEI) number;
- Notification type (i.e., initial or update); and

[28] However, section 506J(g)(3)(C) contains a public health exception that allows FDA to not make information collected under section 506J publicly available if we determine "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)."

[29] If none of the categories listed reflect the manufacturer's situation, we recommend the manufacturer provide additional information in the 506J notification describing the reason for the 506J notification.

- FDA product code.

FDA also recommends that manufacturers submit additional information, as described below, that will assist the Agency in determining the potential for, and criticality of, a supply chain disruption. Examples of such additional information may include:

- Unplanned manufacturing challenges (e.g., labor shortages, delays in raw material supply, temporary plant closures, packaging or sterilization concerns, or other unforeseen circumstances that prevent the manufacturer from meeting demand);
- Unplanned distribution challenges (e.g., shipping/transportation delays, export/import challenges, procurement issues);
- Increased or projected increased demand unable to be met by the manufacturer (e.g., backorder,[30] allocation,[31] 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. Examples of such additional information may include:

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

This additional information, while not required, is helpful to FDA in a number of ways. In particular, this information helps enable FDA to work more effectively with other agencies and supply chain partners to prevent or mitigate any negative impact on patients or healthcare providers.

(3) How FDA uses information from 506J notifications

FDA may on occasion request specific additional information depending on the type of PHE. 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 patients.

FDA utilizes the data provided through 506J notifications, in combination with other internal and external data sources, to perform impact assessments that are subsequently used to: (1) determine if a medical device is in shortage or if a shortage is imminent; (2) determine potential impact(s) to patients and healthcare delivery in the United States; and (3) inform on the need for

[30] For purposes of this guidance, FDA interprets "backorder" to mean temporarily out of stock.
[31] For purposes of this guidance, FDA interprets "allocation" to mean the practice of rationing customer orders at times of supply shortage.

implementation of both regulatory and non-regulatory mitigation strategies (e.g., enforcement discretion, expediting premarket review, conservation strategies, and Defense Production Act priority ratings). For example, U.S. government partners (e.g., Administration for Strategic Preparedness and Response; Department of Commerce; Department of Transportation) use FDA impact assessments to inform and determine if and when mitigations should be implemented.

If FDA concludes 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 of a 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."[32]

When considering whether to prioritize and expedite FDA processes, as set forth in section 506J(f), FDA will consider information available to FDA, such as trade secret and confidential commercial information, and whether FDA resources allow for prioritization. In making prioritization determinations, FDA considers 506J notifications as well as other information related to potential device shortages available to the Agency, such as the information FDA reviews in making a shortage determination.

E. How to Notify

FDA's website, "Notify the FDA About a Medical Device Supply Issue," contains the most current information about submitting 506J notifications to FDA as well as a way for manufacturers to electronically submit 506J notifications. We recommend that manufacturers utilize this electronic method to submit both initial notifications and update notifications. Manufacturers submitting a large number of notifications may upload a spreadsheet using the template provided by FDA. Additionally, for manufacturers that do not wish to utilize this method, notifications may be emailed to CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER, and include a subject line beginning with the word "Notification."

F. Failure to Notify

If FDA determines that a manufacturer has failed to provide a notification as required by section 506J(a) and in accordance with the timelines set forth in section 506J(b), FDA is directed to issue a letter informing the manufacturer of such failure.[33] The manufacturer must respond to FDA's letter not later than 30 calendar days after the issuance of FDA's letter, setting forth the basis for noncompliance and providing the required information on the discontinuance or interruption.[34] Not later than 45 calendar days after the issuance of the letter to the manufacturer,

[32] *See* section 506J(f).
[33] *See* section 506J(e)(1).
[34] *See* section 506J(e)(2).

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.[35] 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.[36]

IV. Additional Notifications

Section 2514 of the FY 2023 Omnibus amended section 506J of the FD&C Act to add subsection (h), "Additional Notifications." Section 506J(h) clarifies for interested parties that FDA may receive voluntary notifications pertaining to the permanent discontinuance or interruption in the manufacture of a device at any time, unrelated to the declaration or potential declaration of a PHE.

Under section 506J(h), manufacturers of devices that are "life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery, or any other device the Secretary determines to be critical to the public health" may submit voluntary, additional notifications to FDA "pertaining to a permanent discontinuance in the manufacture of the device (except for any discontinuance 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." FDA's interpretation of who should submit notifications using section 506J(h) is consistent with our interpretation in Section III.A of this guidance.

For purposes of this guidance, FDA interprets section 506J(h) to clarify that FDA may receive additional notifications about medical devices at any time, unrelated to the declaration or potential declaration of a PHE. FDA has always accepted voluntary submissions of information across many topics, including device supply chain matters. Section 506J(h) does not alter FDA's ability or authority to receive voluntary information on supply chain or other matters. 506J notifications are intended to supplement existing collaboration and communication between industry, FDA, and other interested parties, which proved to be essential to help mitigate supply chain disruptions and shortages during the COVID-19 pandemic, for example, as well as when other supply chain disruptions have occurred. For example, early in the COVID-19 pandemic, prior to the enactment of section 506J, FDA solicited and received voluntarily information from manufacturers of critical devices regarding supply chain disruptions and manufacturing capacity. During the COVID-19 pandemic, FDA also received notifications regarding manufacturing interruptions and permanent discontinuances of a wide range of devices, not all of which were critical to public health. FDA further solicited – and received – voluntary information from manufacturers that were not experiencing interruptions in manufacturing. This information is imperative to FDA's ability to help prevent and mitigate shortages. As such, any time a manufacturer of a device is experiencing a permanent discontinuance or interruption in the manufacture of a device, the manufacturer is encouraged to submit a notification to FDA. In Section III.D.2, FDA provided examples of additional information to assist the Agency in

[35] *See* section 506J(e)(3).
[36] *See* section 506J(e)(3).

determining the potential for and criticality of a supply chain disruption. In line with the examples in Section III.D.2, we recommend that manufacturers submit a 506J notification to FDA if they are experiencing any of the following circumstances:

- Unplanned manufacturing challenges (e.g., labor shortages, delays in raw material supply, temporary plant closures, packaging or sterilization concerns, or other unforeseen circumstances that prevent the manufacturer from meeting demand);
- Unplanned distribution challenges (e.g., shipping/transportation delays, export/import challenges, procurement issues);
- Increased or projected increased demand unable to be met by the manufacturer (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 utilizes this information to help inform our analysis of the demand and supply of medical devices. Understanding the availability of such devices and whether or not they are in distribution or on allocation helps inform the Agency's determination of whether there is or could be a shortage.

FDA encourages submission of these additional voluntary notifications to FDA within seven calendar days after an interruption in manufacturing occurs, or no later than seven calendar days after the manufacturer decides to permanently discontinue the device, as applicable. Section III.C provides more information about when to submit notifications to FDA. For these additional notifications, we recommend that manufacturers provide updates to the initial 506J notification when there is a change in status to help ensure that FDA is acting on the most current information.

Section III.D describes what information to include in 506J notifications. 506J notifications may include both information required by section 506J (see Section III.D.1) and additional information to help inform FDA's supply chain analysis (see Section III.D.2). Section III.E provides more information about how to submit notifications. Section III.D provides more information about how the Agency uses information from notifications, including actions FDA may take to help mitigate or prevent a shortage resulting from a discontinuance or interruption in the manufacture of a device for which a notification is received.

V. FDA's Determination That a Device Is In Shortage

Section 506J(j)(2) of the FD&C Act defines "shortage" to mean "a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device." 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.

The analysis of information related to potential device shortages informs other measures FDA uses to help address the PHE, including issuance of Emergency Use Authorizations (EUAs) for products that play an important role in meeting demand.[37] 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 continuously reviews in making shortage determinations includes, but is not limited to:

- Indications of supply disruptions (e.g., 506J notifications and additional manufacturer information);
- Indications of distribution pressures (e.g., from distributors and GPOs);
- Indications of demand or projected demand, such as availability issues reported from users (e.g., patients, healthcare providers, hospitals and healthcare facilities, 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 interested parties (e.g., a manufacturer places product on allocation).

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 Device Shortage List

Section 506J(g) requires the establishment and maintenance of an up-to-date list of medical devices that have been determined to be in shortage. FDA's website, "Medical Device Shortages List," contains a list that fulfills this statutory obligation and will reflect the categories of devices FDA has determined to be in shortage. The list is maintained and updated as information relating to a shortage evolves. This list also identifies medical devices for which there has been notification that manufacturing has been permanently discontinued ("a discontinuance"). In times when 506J notifications are not required, FDA has more limited information about potential disruptions in the domestic supply of critical devices and is more limited in our ability to prevent and mitigate shortages. However, FDA intends to continue to maintain an up-to-date device shortages list to provide transparency to the American public, based on the information available to us.

[37] During a PHE, 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.

As outlined by section 506J(g)(2), 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 reason 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 will 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).[38]

VI. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated 30 minutes. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0491 (To find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).

[38] *See* section 506J(g)(3)(C).

Appendix A. Examples Likely to Be "In Advance of a Public Health Emergency"

The list below, while not exhaustive, contains examples of circumstances likely to be considered "in advance of a public health emergency." This list is intended to help manufacturers of certain devices understand when they may be required to submit 506J notifications in advance of a PHE declaration:

- HHS activates the National Disaster Medical System or deploys the Strategic National Stockpile without yet determining a PHE under section 319 of the PHS 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 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 Director for the Centers for Disease Control and Prevention to access the Infectious Diseases Rapid Response Reserve Fund prior to declaring a PHE;
- HHS determines that a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a PHE for purposes of waiving the PRA under section 319(f) of the PHS Act;
- Other federal, state, or other jurisdictions 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.

If any of these conditions arise, FDA intends to conduct outreach or otherwise notify manufacturers of the situation and the applicability of section 506J of the FD&C Act. 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 PHE, FDA recommends that manufacturers submit a notification with respect to an FDA-communicated 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.