Date: November 16, 2020

To: Julie Wise, Office of Management and Budget

From: Ellen J. Flannery, Deputy Center Director for Policy, Center for Devices and Radiological Health, U.S. Food and Drug Administration

SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package for the Revision of OMB Control No. 0910-0491 to Add Notifications Under Section 506J of the FD&C Act

Request for Emergency Clearance

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020. Section 3121 of the CARES Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 506J to the FD&C Act. Section 506J provides FDA with new authorities intended to help prevent or mitigate medical device shortages[1] by requiring medical device manufacturers to inform FDA about changes in device manufacturing that could potentially lead to a device shortage. Apprised with that information, section 506J authorizes FDA to take several actions that may help to mitigate or avoid supply disruptions.

Section 506J requires manufacturers to notify FDA about certain information "during, or in advance of, a public health emergency declared by the Secretary [of the Department of Health and Human Services] under section 319 of the Public Health Service (PHS) Act."[2] Section 506J requires FDA to take action based on that information, including (1) publicly posting a list of devices it determines to be in shortage, (2) publicly posting the reasons for the shortage,[3] and (3) issuing letters to manufacturers that fail to comply with the notification requirements of section 506J.[4]

While FDA does have a waiver in place for certain collections during COVID-19, and while this waiver applies to guidance documents that relate to the COVID-19 pandemic public health emergency (PHE) response, recent discussions have raised questions regarding the waiver's applicability to part of the collection in this guidance. Specifically, it was recently brought to our attention that the PRA waiver may not cover the mandatory collections under section 506J of the FD&C Act, but the waiver does cover voluntary collections related to section 506J.

FDA's Center for Devices and Radiological Health (CDRH) is requesting use of the emergency clearance process under 44 U.S.C. 3507(j) and 5 CFR 1320.13 to immediately approve revision of OMB Control No. 0910-0491 to add the information collection required by section 506J of the FD&C Act (added by section 3121 of the CARES Act) to OMB control number 0910-0491. Pursuant to 5 CFR 1320.13(a)(1) and (2)(i), as set forth more fully below, CDRH has determined that:

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[1] "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.

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

[3] *See* Section 506J(g) of the FD&C Act.

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

(1) The revision of the collection of information is needed prior to the expiration of normal clearance time periods and is essential to the mission of the FDA; and

(2) The FDA cannot reasonably comply with normal clearance procedures because public harm is reasonably likely to result if normal clearance procedures are followed.

We also note that FDA has interacted with interested members of the public and has taken steps to create guidance and processes that will minimize the burden of the collection of information.

Background:

The CARES Act

On March 27, 2020, the CARES Act was signed into law. Section 3121 of the CARES Act adds section 506J to the FD&C Act. Section 506J of the FD&C Act requires manufacturers of certain devices[5] 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, and the reason for such discontinuance or interruption.[6] Congress did not provide either a different effective date or implementation period for this new authority.

When the CARES Act was enacted, the Secretary of the Department of Health and Human Services (HHS) had already declared a public health emergency,[7] making manufacturers immediately obligated to submit, and FDA obligated to receive, such notifications.

Section 506J of the FD&C Act requires manufacturers to notify FDA of a discontinuance or interruption in manufacturing, which is likely to lead to a meaningful disruption in the U.S. device supply. In response to inquiries from stakeholders, including medical device-related trade associations, about when a manufacturer is required to submit a notification to the Agency, and to help industry understand its new and immediate obligations, FDA issued a guidance on May 5, 2020, 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) – Immediately in Effect Guidance for Industry and Food and Drug Administration Staff (guidance).[8] This guidance is intended to clarify and make recommendations regarding when manufacturers must notify FDA about supply disruptions, who must notify FDA, what

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[5] Under section 506J of the FD&C Act, manufacturers of the following devices must notify FDA of an interruption or permanent discontinuance in manufacturing:

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

See section 506J(a)(1),(2) of the FD&C Act.

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

[7] There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. See Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (originally issued on Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

information manufacturers should include in the notification, and how manufacturers should update FDA after the initial notification and during the duration of the COVID-19 public health emergency.

To further assist manufacturers in providing these notifications, FDA updated its guidance in June to provide recommendations to help manufacturers make such determinations, including by providing a list of device types that FDA recommends manufacturers consider in determining whether a notification under section 506J of the FD&C Act is required during the COVID-19 pandemic.[9] FDA is also currently considering detailed feedback received individually and to the docket, including from trade associations and medical device manufacturers, regarding implementing section 506J of the FD&C Act, including consideration of a web portal for manufacturers to more easily submit the required notifications.

Need for Emergency Clearance:

FDA Needs Emergency Clearance Because Public Harm is Reasonably Likely to Result if Normal Clearance Procedures are Followed

Receiving the information contained in manufacturers' notifications during the COVID-19 Public Health Emergency (PHE) is critical to FDA to help protect the public health and to work to mitigate and prevent medical device shortages. These notifications provide critical information that FDA uses to help analyze whether there may be a shortage or interruption, and to inform the public of such shortages, as required by section 506J(g) of the FD&C Act. Without these notifications, FDA will not be able to utilize manufacturing data to provide the public with the most up-to-date, accurate information to help prevent or mitigate medical device shortages during the COVID-19 PHE.

In addition, without emergency clearance, FDA will be unable to ensure that manufacturers comply with the notification requirements. Section 506J(e) requires that, 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.[10] If emergency clearance is not granted for the collection of notifications under section 506J of the FD&C Act, we anticipate that FDA's ability to ensure compliance with the notification requirements will be impacted because we will not have clearance to collect the important information needed to help mitigate or prevent medical device shortages during the COVID-19 PHE.

FDA believes up-to-date device shortage information is imperative to health system and other stakeholders' pandemic preparation and response. Given the continued duration of the PHE and

[8] The guidance was updated in June 2020 to provide additional information to aid manufacturers in submitting their notifications.

[9] This list of device types and corresponding product codes identifies devices that FDA believes are critical to the public health during the COVID-19 pandemic under section 506J(a)(1). However, FDA may make additional device type determinations under section 506J(a)(2) and update this list with respect to device type recommendations under section 506(J)(a)(1) as this public health emergency evolves and if FDA learns new information.

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

the ongoing supply availability concerns, we believe that healthcare organizations may attempt to stock up on devices in shortage out of concern that they will face ongoing challenges to getting these devices based on incomplete information. In addition, hospitals may attempt to overprepare in case they are faced with surges in patient admissions, as has been seen in a wide variety of locations within the U.S., which could lead to other hospitals not having access to the devices that they need. These are just a few potential adverse consequences that could impact public health if device shortage information is not readily accessible to the public during a PHE. We also anticipate that health systems could be unnecessarily spending time, effort, and resources to reach out to manufacturers that are nonetheless unable to satisfy health systems' supply needs if FDA does not receive notifications and provide timely determinations of shortages to the public.

Based on current registration and listing data,[11] we estimate that as many as 8,365 manufacturers of the device types that FDA believes are critical to the public health during the COVID-19 pandemic will need to consider whether they are required to notify FDA under section 506J of the FD&C Act. We believe that the burden of this determination by the manufacturer—as well as the provision of required information under section 506J of the FD&C Act[12] and additional, voluntary information as recommended in the guidance[13]—is minimal and such information is readily available to manufacturers of the applicable devices. Therefore, we estimate the hour burden of this information collection to be 15 minutes or less per determination and notification.

Accordingly, FDA is requesting that OMB allow use of its emergency clearance process to immediately approve the revision of OMB Control No. 0910-0491, to include the collection of information required by section 506J of the FD&C Act (added by section 3121 of the CARES Act).

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[11] Registration and listing data collection is approved under OMB Control No. 0910-0625.

[12] Section 506J(a) of the FD&C Act requires manufacturers of certain devices (*see supra* Footnote 5) to provide notification "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, and the reasons for such discontinuance or interruption.

[13] While we have incorporated the voluntary recommendations of the guidance, regarding the content and manner of submission of the notifications, in this total hour-burden estimate (15 minutes per notification), we note that this voluntary collection of information has been granted a waiver from the requirements of the PRA (PRA waiver) by the Secretary of HHS effective March 19, 2020, under section 319(f) of the PHS Act. The PRA waiver is anticipated to remain in effect throughout the time period of the immediate investigation of and response to the emergency declared pursuant to section 319(a) of the PHS Act, and for a reasonable length of time for immediate post response review regarding the PHE. The PRA waiver can be found on the HHS website at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.