infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This study will collect information from Court Improvement Program (CIP) staff to (1) understand data capacity and current use of performance measures and (2) gather feedback from the performance measure pilot process. This will be accomplished using two instruments:

JCAMP CIP Data Capacity Survey

The survey asks CIPs about their current capacity to collect specific data elements from the following six categories of measurement: (1) Legal and judicial context (*e.g.,* court docketing), (2) Practices (*e.g.,* attorney pre-petition legal practice), (3) Short-term outcomes that happen during hearings (*e.g.,* discussion of key issues), (4) Intermediate outcomes that happen during the case (*e.g.,* judicial continuity), (5) Long-term outcomes that happen after case closure (*e.g.,* child safety), and (6) Cross-cutting themes (*e.g.,* equity). The survey asks about capacity broadly and then specifically for a series of subcategories.

JCAMP Pilot Site Debrief Form

The JCAMP Pilot Site Debrief Form is a survey developed to be administered to CIP staff who have assisted with piloting of the performance measures. The survey asks participants about the challenges and successes in collecting pilot data for the measures, their confidence in collecting the data going forward, and suggestions for improving future efforts.

Respondents: Respondents include CIP Administrators and staff.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
JCAMP CIP Data Capacity Survey	106	1	.83	264	88
JCAMP Pilot Debrief Form	24	1	.25	18	6

Estimated Total Annual Burden Hours: 94.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 5106, Public Law 111–320, the Child Abuse Prevention and Treatment Act Reauthorization Act of 2010, and titles IV–B and IV–E of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–00238 Filed 1–10–22; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0053]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States. 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 during or in advance of a public health emergency. FDA is issuing this guidance to implement amendments to the FD&C Act by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as it relates to device shortages and potential device shortages during or in advance of a public health emergency. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 14, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0053 for ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Center for Biologics Evaluation and Research, Office of Communication, Outreach, and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20903. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Brittany Caldwell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5556, Silver Spring, MD 20993–0002, 301–796–5900 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. 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 (21 U.S.C. 356j) provides the Secretary of Health and Human Services with new authorities intended to help prevent or mitigate medical device shortages ''during, or in advance of, a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.''

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 FDA's website or a supplemental guidance, to assist manufacturers in determining whether a notification under section 506J of the FD&C Act (hereafter referred to as a ''506J notification'') is required during a public health emergency.

FDA is issuing this draft guidance to assist stakeholders in the Agency's implementation of section 506J(a) of the FD&C Act outside of the COVID–19 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 506J of the FD&C Act during the COVID–19 Public Health Emergency'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc,* 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 withdrawn, the COVID–19 Public Health Emergency Guidance will be applicable for 506J related issues with respect to COVID–19.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act''. 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.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all

Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 21003 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in section 506J of the FD&C Act have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
506J	Shortages Data Collection	0910–0491

IV. Other Issues for Consideration

The Agency invites comments on the ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' draft guidance, in general, and on the following questions, in particular:

- Section 506J of the FD&C Act requires notifications ''during, or in advance of'' a public health emergency. Does the draft guidance provide sufficient clarity regarding what FDA considers to be ''in advance of a public health emergency''? Is there additional information that you believe would be helpful? If so, what?
- Are there other situations or circumstances that could lead to a situation that could be considered to be ''in advance of a public health emergency''?
- FDA has proposed providing supplemental information during specific public health emergencies, which is intended to contain information specific to that public health emergency to assist manufacturers in providing notifications. Is there specific information that you believe should be conveyed in such supplements?
- Are there circumstances where it is unclear whether you should notify FDA? How could FDA provide clarity?
- Should FDA notify stakeholders when an event is considered to be ''in advance of a public health emergency'', and if so, how should FDA best do so?
- FDA recommends that manufacturers provide updates to notifications 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. Please provide feedback on this proposed frequency.
- How can FDA best disseminate supplemental information during or in advance of a public health emergency to manufacturers and other stakeholders?
- How can FDA keep all stakeholders, including healthcare providers and patients, better informed regarding shortages during or in advance of a public health emergency?
- In the draft guidance document, Appendix A displays an example of supplemental information for an epidemic or pandemic that FDA believes would be helpful to assess the overall state of the market and help inform potential mitigations. What additional information might be helpful for other public health emergencies?

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00321 Filed 1–10–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 10, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0806. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Drug Supply Chain Security Act Implementation

OMB Control Number 0910–0806—Revision

This information collection supports Agency implementation of provisions in section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding the pharmaceutical distribution supply chain. Section 202 of the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54), added sections 581 and 582 to the FD&C Act (21 U.S.C. 360eee and 360eee-1) and governs the tracing of certain pharmaceutical drugs, outlining critical steps for an electronic interoperable system to identify these