United States Food and Drug Administration

Shortages Data Collection

OMB Control No. 0910-0491

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), along with provisions of the Public Health Service Act (PHS Act), with regard to medical device shortages.

Under section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. After the events of September 11, 2001, and as part of broader counterterrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of federally declared disasters/emergencies or regulatory actions. This voluntary data collection process consists of outreach to firms who have been identified as producing or distributing medical devices that may be considered essential to the response effort. Additional follow-up correspondence may occasionally be needed to verify/validate data, confirm receipt of follow-up correspondence(s), and/or request additional details to further inform FDA's public health response.

Enacted on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) added section 506J to the FD&C Act. Section 506J of the FD&C Act requires manufacturers of certain devices 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. Section 506J sets forth content and timing requirements and provides for FDA action on information, including (1) publicly posting a list of devices it determines to be in shortage, (2) publicly posting the reasons for the shortage, and (3) issuing letters to manufacturers that fail to comply with the notification requirements of section 506J.

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. 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 FDA in accordance with

section 506J. Section 2514 the FY 2023 Omnibus amended section 506J to add section 506J(h), "Additional Notifications" and directed FDA to issue guidance "to facilitate voluntary notifications."

In the Federal Register of November 17, 2023 (88 FR 80310),[1] FDA announced the availability of the final guidance entitled "Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act" and the draft guidance entitled "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications."

The final guidance, "Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act" (hereafter referred to as the "506J Guidance") assists stakeholders in the Agency's implementation of section 506J. This guidance serves as the baseline for information about notifications under section 506J during or in advance of any PHE. FDA provides additional clarification on who is required to notify FDA, when such notifications are required, what information FDA expects manufacturers to include in such notifications, and how to submit notifications. Additionally, FDA describes how FDA determines that a device is in shortage and additional actions FDA may take to help prevent or mitigate a potential device shortage.

In the draft guidance "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications," FDA proposes updates to the 506J Guidance. Specifically, FDA has developed a list of devices, by FDA 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"). The 506J Device List is based on the requirements under section 506J(a). In section 2514 of the FY 2023 Omnibus, Congress directed FDA to issue guidance on the requirements under section 506J 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." Thus, manufacturers of a device on the 506J Device List must notify FDA in accordance with 506J for each such device. For more information, see the 506J Device List web page, available at https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list. Additionally, consistent with section 506J(h), FDA is proposing to clarify for stakeholders that manufacturers may submit, and FDA may receive, voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

2. Purpose and Use of the Information Collection

We use the information to help mitigate potential and actual medical device shortages. We also use the information as prescribed in section 506J regarding the public posting of device shortage information.

3. Use of Improved Information Technology and Burden Reduction

[1] **https://www.federalregister.gov/documents/2023/11/17/2023-25458/notifying-the-food-and-drug-administration-of-a-permanent-discontinuance-or-interruption-in**

We utilize electronic means to implement the information collection, seeking least burdensome ways to gather and receive necessary data. Respondents may notify FDA about an interruption or permanent discontinuance in device manufacturing (506J notification) on our website at https://fda-cdrh.my.salesforce-sites.com/shortages/.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Although some respondents to the information collection may be small businesses, FDA utilizes the least burdensome means to gather information.

6. Consequences of Collecting the Information Less Frequently

The timing of mandatory information collection is consistent with statutory requirements. Voluntary information collection is conducted quarterly (every 3 months), or upon a significant change in a manufacturer's ability to produce and/or market an essential device. The consequence of collecting this information less frequently is that CDRH's ability to make the correct decision or to disseminate the correct information to the public may be compromised, hampering its mission to protect the public health.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of November 28, 2023 (88 FR 83134). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Section 506J Template (webform) (available online: https://fda-cdrh.my.salesforce-sites.com/shortages) is

name, phone number, email address, fax number, and address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. The data will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Shortages outreach data collection	1,000	4	4,000	1	4,000
Information collection under Section 506J	8,400	1	8,400	0.25	2,100
Additional voluntary collections related to 506J	8,400	1	8,400	0.25	2,100
TOTAL			20,800		8,200

I. Shortages Outreach Data Collection

Our estimate is based on our recent experience with the collection and informal direct contact with respondents. We estimate up to 1,000 manufacturers, distributors, healthcare systems, healthcare providers, group purchasing organizations, and sterilizers for which there may be targeted outreach because their devices may be essential to the response effort. This targeted outreach will be conducted periodically to either obtain primary data or to verify/validate updated data (although additional outreach may be undertaken as needed). The data being requested represent common data elements that respondents monitor and track as part of routine business operations and, therefore, are readily available. It is anticipated that for most respondents, the estimated time to fulfill CDRH's data request will not exceed 1 hour per request, or 4 hours per year.

II. Information Collection Under Section 506J of the FD&C Act and Related Voluntary Collections

Based on current registration and listing data (approved under OMB control number 0910-0625), we estimate the number of respondents that will submit a notification under section 506J of the FD&C Act to be approximately 20 percent of currently registered manufacturers. Data from our Registration & Listing system indicates that there are approximately 42,000 unique FDA Establishment Identification registered manufacturers. Therefore, we estimate 8,400 respondents per year. We believe that the burden as well as the provision of required information under section 506J of the FD&C Act--as well as additional voluntary information related to the determination (including additional issues that may impact the availability of the device, such as information about critical suppliers, potential mitigations, production capacity and market share, and notification updates)--is minimal and such information is readily available to respondents. Therefore, we estimate the burden of this information collection to be 15 minutes or less per determination and notification.

12b. Annualized Cost Burden Estimate

We calculate an estimated annual cost of $476,666 by multiplying the estimated total annual burden hours (8,200) by a median hourly wage of $58.13 (using Bureau of Labor Statistics Data) for the profession of '*Industrial production managers*' (SOC Code Number 11-3051).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industrial production managers	8,200	$58.13	476,666

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The activities and ongoing support for shortage data collection, including contact time, data verification/normalization, data input, data analysis, and database maintenance activities, involve approximately 5 full time equivalent employees (FTEs), though this number may increase during public health emergency events. Based on an internal cost model, we assume a fully-loaded cost of $297,561 per position. We therefore calculate an annualized cost of $1,487,805 to FDA.

15. Explanation for Program Changes or Adjustments

We have updated the Number of Respondents and Average Burden per Response for the Shortages Outreach Data Collection element based on our recent experience with the information collection and informal direct contact with respondents. The updates result in an adjustment of an additional 3,000 hours and 2,000 responses annually.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to **www.reginfo.gov** to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.