

UNITED STATES FOOD & DRUG ADMINISTRATION

Shortages Data Collection

OMB Control No. 0910-0491 – Revision

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, our 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.

Under section 319(f) of the PHS Act, added by the 21st Century Cures Act, the Secretary issued the immediately-in-effect guidance entitled, “*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 November 2020) to implement section 506J of the FD&C Act, as it relates to device shortages and potential device shortages occurring during the COVID-19 pandemic, for the duration of the COVID-19 public health emergency. The guidance discusses additional voluntary information

collection manufacturers could provide to FDA, including additional information about device manufacturing and supply, and updates to initial notifications.

Having previously requested emergency review and approval of the revised information collection, we are now requesting continued approval, as discussed in this supporting statement.

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 publicly posting device shortage information.

3. Use of Improved Information Technology and Burden Reduction

We utilize electronic means to implement the information collection, seeking least burdensome ways to gather and receive necessary data.

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 consequences 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), we published a 60-day notice for public comment in the Federal Register of February 23, 2021 (86 FR 10972). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected. We have minimized personally identifiable information (PII) collected to protect the privacy of individuals. The information collection includes PII pertaining to name, phone number, email address, fax number, and address and 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). We have 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 routinely retrieve records from the information collected.

Recognizing that some of the information collected may be commercially confidential, it will be subject to protections outlined in section 301(j) of the FD&C Act (21 U.S.C. 331(j)), which, among other things, prohibits employees of the FDA from revealing trade secrets (<http://www.fda.gov/opacom/laws/fdcact/fdcact3.htm>). Before sharing information from this data collection with other federal agencies, verification of appropriate sharing agreements will be made. Also, the information is subject to the exemption under the Freedom of Information Act (FOI) requirements with the applicable limitations on exemptions disclosure for Federal, State, and local governments.

To further assure commercial confidentiality, data access is restricted to CDRH staff engaged in the public health response to a shortage with a need to know. This named group, typically fewer than 10 people, is permitted to use the data only for decision making and planning in the context of a shortage or potential shortage, an official emergency-preparedness exercise, or an actual or potential public health risk posed by non-disaster-related device shortage.

11. Justification for Sensitive Questions

This information collection does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Shortages data collection	500	4	2,000	0.5	1,000
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			18,800		5,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

I. Shortages Data Collection

Our estimate is based on our experience with the collection and informal direct contact with respondents. We estimate up to 500 manufacturers and distributors for which there may be targeted outreach because their devices may be essential to the response effort. This targeted outreach will be conducted quarterly to either obtain primary data or to verify/validate updated data (although additional outreach may be undertaken as needed). From the manufacturer and distributor's point of view, the data being requested represent common data elements that they monitor and track as part of routine business operations and therefore are readily available. It is anticipated that for most manufacturers and distributors, the estimated time to fulfill CDRH's data request will not exceed 30 minutes per request, or 2 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 manufacturers of the applicable devices. 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 \$263,692 by multiplying the estimated total annual burden hours (5,200) by a median hourly wage of \$50.71 (using Bureau of Labor Statistics Data) for the profession of ‘*Industrial production managers*’ (SOC Code Number 11-3051).

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. The fully loaded cost of an FDA Center for Devices and Radiological Health FTE in 2020 is \$278,602. We therefore calculate an annualized cost of \$1,393,010 to FDA.

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments. We have revised the information collection to include voluntary collection elements and provisions related to the CARES Act. This results in an adjustment of an additional 2,719 hours and 9,655 responses annually.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.