

Emergency Shortages Data Collection
OMB No. 0910-0491
SUPPORTING STATEMENT

Terms of Clearance: None.

A. JUSTIFICATION

The Food and Drug Administration (FDA) is requesting an approval of the information collection requirements for a Shortages Data Collection System. This reinstatement request was initiated in response to an ICR that expired on 08/31/2015.

1. Circumstances Making the Collection of Information Necessary

Under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)), the FDA Commissioner is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA (<https://legcounsel.house.gov/Comps/Federal%20Food,%20Drug,%20And%20Cosmetic%20Act.pdf>).

Subsequent to the events of September 11, 2001, and as part of broader counter-terrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable the Center to anticipate and respond to medical device shortages that might arise in the context of emergencies¹ or regulatory actions. In particular, CDRH has identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans, mitigation plans, and raw material or other supply constraints for essential medical devices that would be vulnerable to shortages in an emergency or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, support real-time decision making by the U.S. Department of Health and Human Services (HHS) during actual emergencies or emergency preparedness exercises, and mitigate or prevent harm to the public health.

CDRH will collect these data from manufacturers on a regular basis, and access to the collected data will be limited to staff engaged in the public health response to a shortage and who have a need to know. The scope of the collection will also be limited only to essential medical devices. The following are examples of factors CDRH considers to determine essential medical devices:

- Devices that are used to diagnose, treat, or prevent a serious disease or medical condition;

¹ An emergency is an urgent need for health care [medical] services to respond to a natural or man-made disaster, significant outbreak of an infectious disease, bioterrorist attack or other significant or catastrophic event, and demands decision making and follow-up in terms of extra-ordinary measures. An emergency may involve the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, our Nation's food supply, cosmetics, products that emit radiation, and tobacco products that **call for immediate actions** by FDA staff. Note this definition was taken from FDA Emergency Operations Plan, August 2010
<http://www.fda.gov/downloads/EmergencyPreparedness/EmergencyPreparedness/UCM230973.pdf>

- Devices for which no satisfactory alternative devices, drugs, or therapies are available;
- Devices used as a tool (e.g. core medical equipment) for life-sustaining conditions or patient care;
- Devices commonly used with vulnerable patient populations (e.g. pediatrics);
- Devices that are part of a system and if it/they were not available, healthcare facilities would be required to switch to a completely different system;
- Devices where the manufacturer is the sole manufacturer; and/or
- Devices are used on pediatric and/or maternal patient populations.

The data collection process will consist of telephone calls/emails to firms who have been identified as producing an essential medical device. In this initial outreach, the intent and goals of the data collection effort will be described, and the specific data request made. Data will be collected using least burdensome methods (paper or phone-based survey) and in a structured manner to answer specific questions about domestic inventory, manufacturing capabilities, distribution plans, mitigation plans, and raw material or other supply constraints. After the initial outreach, we will request updates to the information on a quarterly basis to keep the data current and accurate. Additional ad hoc 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.

2. Purpose and Use of the Information Collection

This information collection allows the Agency not only to respond quickly to medical device shortages that might arise from regulatory action or in the aftermath of an emergency, such as a natural disaster, but also to successfully anticipate, and prevent medical device shortages, and/or mitigate actual medical device shortages, in a much more *proactive* manner. The information will be used to populate and maintain a data collection and management system internal to CDRH that can be accessed immediately and used to inform HHS's decisions regarding shortage management. Contributions to the database will be voluntary. Data will be collected using least burdensome methods.

3. Use of Improved Information Technology and Burden Reduction

Essential device manufacturers will be contacted initially via telephone/email and asked to identify appropriate points of contact to be used during an emergency, the manufacturing locations for the essential devices they manufacture the firm's routine and surge production capacity, any raw material, supplier, and subcomponent constraints, and any other information as appropriate to aid the Center's public health response. In order to provide context for the outreach, CDRH staff will articulate that the data collection effort is intended to limit the potential for disruption in healthcare processes and/or threats to the public health resulting from regulatory action or in the event of an emergency such as a natural or man-made disaster. CDRH will also emphasize that data collected will be considered confidential corporate information and not disclosed outside of CDRH.

4. Efforts to Identify Duplication and Use of Similar Information

Within the Federal system, there are several other groups who conduct some type of data collection related to medical products. For example, the Strategic National Stockpile and the National Acquisition Center have their own data collection systems for pre-procurement analysis. Also, the Biomedical Advanced Research and Development Authority (BARDA) conducts *ad hoc* inquiries to manufacturers of a limited number of medical devices and drugs, and there may be some overlap with these efforts. To limit the potential for duplication, a CDRH staff member will coordinate with other identified Federal entities as needed either directly or through co-participation in working groups and committees. Where data are already available that meet CDRH's needs, it will be obtained from these other groups and not from manufacturers.

5. Impact on Small Businesses or Other Small Entities

The data collected is focused on manufacturers whose devices meet the criteria for inclusion in the shortages database by virtue of their "essential" designation, as described in section 1 of this document. Sometimes this may impact small businesses. However, participation in the medical device shortage data collection process is voluntary, and therefore firms may opt out if participation is felt to be too burdensome. FDA will make every effort to reduce the burden of participation as much as possible, by using the procedures described in this document.

6. Consequences of Collecting the Information Less Frequently

As manufacturers are increasingly adopting just-in-time production methods, FDA expects that device production volumes will change rapidly in response to market demands. Shortage information therefore must be as up-to-date as possible, and must accurately reflect the state of the market at the time a shortage appears or is likely to appear. These data will be leveraged for preparedness and response, including decision making and planning in the context of a disaster/emergency, an official emergency-preparedness exercise, or an actual or potential public health risk posed by non-disaster-related device shortage.

Therefore, to keep information current, CDRH anticipates updating the data records 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 Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of December 28, 2018 (83 FR 67298). No comments were received.

FDA routinely consults with the Centers for Disease Control and Prevention's (CDC's) Strategic National Stockpile program regarding shortages issues. Also, as described above CDRH intends to consult regularly with outside Agencies who possess information relevant to this database.

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

This ICR collects personally identifiable information (PII) or information of a personal nature. PII collected is name, phone number, email address, fax number, and address. 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).

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 routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

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/fdact/fdact3.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

FDA estimates the burden of this collection of information as follows:

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent per year	Total Annual Responses	Average Burden per Response (hours)	Total Hours Required per Year
Shortages data collection	260	4	1,040	0.5	520

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

FDA bases these estimates on past experience with direct contact with the medical device manufacturers, and anticipated changes in the medical device manufacturing patterns for the specific devices that may be monitored. FDA estimates that there are approximately 260 manufacturers whose devices meet the “essential” inclusion determination (discussed in section 1 of this document). They would be contacted by telephone and then by electronic mail quarterly to either obtain primary data or to verify/validate updated data (although additional outreach electronically or by phone may be undertaken as needed).

From the manufacturer’s point of view, the data being requested represent common data elements that manufacturers monitor and track as part of routine business operations and therefore readily available. It is anticipated that for most manufacturers the estimated time to fulfill CDRH’s data request will not exceed 30 minutes per request, or 2 hours per year.

12b. Annualized Cost Burden Estimate

We estimate the annual cost burden to be approximately \$53,160. This is based on the estimated total annual burden hours and the May 2017 Bureau of Labor Statistics (<https://www.bls.gov/oes/current/oes113051.htm>) median hourly wage of \$53.16 for the profession of ‘Industrial production managers’ (SOC Code Number 11-3051).

Type of Respondent	Total Burden Hours per Year	Hourly Wage Rate	Total Respondent Costs per Year
Industrial production managers	520	\$53.16	\$27,643

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 3 full time equivalent employees (FTEs). The fully loaded cost of an FDA Center for Devices and Radiological Health FTE in 2018 is \$270,305. Therefore, the annualized cost to FDA is estimated to be \$810,915.

15. Explanation for Program Changes or Adjustments

This information collection is a reinstatement with changes. There is an increase of 390 hours in the total estimated burden compared with that identified in the ICR previously approved by OMB. This increase reflects changes in market demands; in which, manufacturers are increasingly adopting just-in-time production methods. This change is an adjustment.

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

FDA is not seeking an exemption from displaying the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.