SUPPORTING STATEMENT
FOR
EMERGENCY SHORTAGES DATA COLLECTION SYSTEM
OMB No. 0910-0491

A. JUSTIFICATION

The Food and Drug Administration (FDA) is requesting an approval of the information collection requirements for the Emergency Shortages Data Collection System.

1. Circumstances Making the Collection of Information Necessary

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the 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 (**http://www.fda.gov/opacom/laws/fdcact/fdcact9.htm**).

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 Federally-declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans and raw material constraints for medical devices that would be in high demand, or that would be vulnerable to shortages in specific disaster/emergency situations, or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, and support real-time decision making by US Department of Health and Human Services (HHS) during actual emergencies or emergency preparedness exercises.

The Emergency Medical Device Shortage Survey was developed in 2002 to support the acquisition of such data from medical device manufacturers. In 2004, CDRH changed the process for the data collection, and the electronic database in which the data were stored was formally named the Emergency Shortages Data Collection System. Recognizing that some of the data collected may be commercially confidential, access to the Emergency Shortages Data Collection System is restricted to members of the FDA/CDRH Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to 5 senior managers. Further, the data are used by this defined group only for decision making and planning in the context of a Federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices being tracked in the Emergency Shortages Data Collection System. In this initial call, the intent and goals of the data collection effort are described, and the specific data request is made. After the initial call, one or more additional follow-up calls and/or electronic mail correspondence may be required to verify/validate data sent from the manufacturer,

confirm receipt and/or request additional detail. Although the regulatory officer is the agent who is initially contacted, they may designate an alternate representative within their organization to correspond subsequently with the CDRH Emergency Shortages Team member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particular with respect to specific product lines, manufacturing capabilities and raw material/subcomponent sourcing, it is necessary to update the data in the Emergency Shortages Data Collection System at regular intervals. This is done on a weekly basis, but efforts are made to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The Emergency Shortages Data Collection System will only include those medical devices for which there will likely be high demand during a specific emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture, or loss of one or more of these manufacturers would create a shortage.

2. Purpose and Use of the Information

This collection of information allows the Agency to respond quickly to medical device shortages that might arise in the aftermath of a biological, chemical, or radiological exposure following a terrorist attack or for a natural disaster such as a hurricane or earth quake.

3. Use of Information Technology and Burden Reduction

Members of the Emergency Shortages Team (EST) completed the initial telephone contact with medical device manufacturers early in 2005. The telephone request consisted of an explanation of the rationale and goals of the program, and 4 questions/statements to which a response was requested. The following represents the content of the 4 questions that were asked:

1. What is the manufacturer's contact name(s), address, phone number, FAX number, and e-mail address for use by CDRH during an emergency?
2. What are the names and location(s) of manufacture for device(s) that would be in demand during a natural/man-made disaster (primarily focus on personal protective equipment, airway support/ventilation devices, intravenous infusion devices and drug delivery devices)?
3. What is the current production capacity and additional surge capacity for these devices?
4. What, if any, raw material or subcomponent dependencies or constraints do these devices have?

An electronic mail request from CDRH to update the information every 4 months is less burdensome and enables manufacturers to update medical device shortage information at any hour or in any country while they are on travel or in any US time zone.

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 relatd to medical materiel. The Strategic National Stockpile and the National Acquisition Center have their own

data collection systems for the purposes of pre-procurement analysis. 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. To limit the potential for duplication, at least one member of the Emergency Shortages Team routinely coordinates with these other Federal entities either directly or through co-participation in working groups and committees.

If supplies are needed within the first 12 hours of an event, the Local and State supplies of medical devices will be used. If Local and State supplies are depleted and additional supplies are needed, with the aid of this data collection system, FDA/CDRH can supply resources where those additional supplies may be acquired.

5. Impact on Small Business or Other Small Entities

Participation in the emergency medical device shortage program is voluntary. The designated agent from the FDA/CDRH's Emergency Shortage Team will maintain and update the information as stated previously. The data collection includes a limited supply of medical devices and only the 4 or 5 largest manufacturers of those specific devices will be contacted. There is potentially no impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

To keep information current, it will be requested via electronic mail every 4 months. Shortages information is included in every national and FDA emergency exercise to check for readiness. This information must be kept current.

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

This regulation is consistent with principles in 5 CFR 1320.5.

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

Notice has been published in the Federal Register on December 19, 2008, (73 FR 77718) soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d) (E). No comments on the information collection were received during this period.

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 Respondent

Recognizing that some of the information collected may be commercially confidential, it will be subject to protections outlined in the Food and Drug Cosmetic Act (the Act) SEC. 301. [21 USC §331] Prohibited acts section (j) which, among other things, prohibits employees of the FDA from revealing trade secrets (**http://www.fda.gov/opacom/laws/fdcact/fdcact3.htm**). 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, access to the content of the Emergency Shortages Data Collection System is restricted to members of the FDA Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to 5 senior managers. The data, moreover, are used by this defined group only for decision making and planning in the context of a Federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage.

11. Justification for Sensitive Questions.

The information required in a premarket approval or premarket supplement application does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

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

Table 1. --Estimated Annual Reporting Burden[1]

FD&C Act Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
903(d)(2)	125	3	375	.5	188

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

FDA based 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 are being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year to either obtain primary data or to verify/validate data. Because the data being requested represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Cost to Respondents: The annual cost burden needed for the respondent to answer the electronic mail request three times annually for 0.5 hours is expected to be approximately $50/hour or a total of $75.00

($25x3) per medical device manufacturer. This is based on 2008 Bureau of Labor Statistics median hourly wage of $44.96 for the year 2008 for the profession of 'Industrial production managers' (SOC Code Number 11-3051) in the 'medical equipment and supplies manufacturing industry' (2007 NAICS code 3391), and adjusted for inflation.

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

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 the Emergency Shortages Data Collection System will require approximately 0.6 full time equivalent employee (FTE). This is based on estimated contact time, data verification/normalization, data input, data analysis and maintenance activities that would need to be performed on the database, itself. The tasks require that an individual have some clinical experience, as well as some experience with data management, and may require that the FTE is a the level and experience of a Medical Officer. An average Full Time Equivalent employee (FTE) in the position of Medical Officer is projected to earn a base salary of $127,604 per year (GS Grade 15 Step 10). The estimated cost of an FDA employee's involvement with this collection, therefore, is estimated to be $76,562 (which is 0.6 times $127,604).

15. Explanation for Program Changes or Adjustments

Since its inception, the range and breadth of medical devices that are now tracked under this program has expanded considerably. For this reason, while the burden hours to any individual respondent has remained stable, the total burden hours has increased due to an increase in the number of respondents. The expertise required for program activities (data verification/normalization, data input, data analysis and maintenance activities that would need to be performed on the database, itself) has also increased. Such activities can no longer be reliably carried out by a technician, and instead, require specific clinical expertise. For this reason, the annualized cost to the Federal Government may increase slightly as the type of FTE required to carry out these activities has changed.

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 of display of effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.