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

B. Statistical Methods (used for collection of information employing statistical methods)

1. Respondent Universe and Sampling Methods

Because the goals of this program are 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, the respondent universe is limited to those manufacturers meeting these criteria. The CDRH Registration and Listing database has been queried on a regular basis to generate a list of candidate manufacturers (i.e., believed to meet inclusion criteria, based on information that the manufacturer submits during the annual registration process), we estimate that approximately 125 registered entities currently meet these inclusion criteria. Because new manufacturers enter the market on a continuous basis, and because manufacturing entities may withdraw products and product lines, this number is subject to change. Given the low number of candidate respondents and because of the need to be comprehensive in the data acquisition, all candidate respondents will be contacted and invited to participate. We anticipate a response rate in ≥ 75% based on prior years' activities. However, unlike typical surveys, the information acquired will not be used for inferential purposes or hypothesis testing, and therefore will not be subjected to a statistical test procedure.

Type of Respondents	Approximate No. of Respondents That Meet the Inclusion Criteria	Anticipated Response Rate
Medical device manufacturers	125	≥ 75 %

2. Procedures for the Collection of Information

CDRH Registration and Listing database will be queried on a regular basis to generate a list of candidate manufacturers. Criteria for participation/inclusion in this data collection effort are:

- Currently registered with FDA/CDRH
- Actively manufacturing one or more medical devices that would be in high demand, or that would be vulnerable to shortages in specific disaster/emergency situations

Using the official correspondence contact information provided by the manufacture during the annual registration and listing process, the manufacturer initially will be contacted via telephone, at which time the rationale and goals of the program will be explained. If the respondent volunteers to participate further, the caller will provide them with 4 questions/statements to which a response will be requested. The following represents the content of the 4 questions that will be 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?

If the respondent requests a written documentation of the request, one will be forwarded via electronic mail, reiterating the rationale and goals of the program, and the 4 questions that are being asked. Because the data/information provided by the respondents has the potential to impact public health preparedness, we ask that the respondents provide data that are as accurate and up-to-date as possible. If the respondent prefers to provide estimates, or provide range data (vs. precise data), responses will be annotated in the database to reflect this level of precision. If the respondent prefers to provide data for only a subset of questions, the database will be annotated to reflect the incompleteness of the dataset. After initial data submissions, respondents will be contacted by CDRH via electronic mail requesting updates or revisions. This mode of communication is less burdensome and enables manufacturers to provide any necessary updates at their convenience.

Because the manufacturing cycle of medical devices is dynamic and subject to change on a quarterly basis, we feel that data collection for certain device classes may need to occur as frequently as every 4 months. If a manufacturer provides evidence for a more stable manufacturing cycle (i.e., the quantity of devices, manufacturing sites, raw material sources, etc. do not change), data collection *for this manufacturer/device pairing* may be conducted at less frequent intervals.

3. Methods to Maximize Response Rates and Deal with Non-response

In an effort to maximize response rates, respondents will be given a clear and concise explanation of the rationale for, and goals of the program. Because the data collection effort is intended to limit the potential for disruption in healthcare processes and/or threats to the public health in the event of a natural or man-made disaster, we believe that a clear explanation of this intention will enhance voluntary participation. Because the initial contact is via telephone, and is made by a senior staff member at CDRH (i.e., at the level of Medical Officer), we believe that there will be a relatively low rate of non-response. Moreover, because of their clinical expertise, the Medical Officer performing the initial contact can provide real-time clarification (i.e., with respect to granularity of data) and perform first-pass validation of the data and/or source of the data to be provided.

4. Test of Procedures or Methods to be Undertaken

The current procedure for data collection has been operationally validated since the program's inception. We do not anticipate a need for significant changes in the procedure at this time.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Because no statistical testing procedures will be applied to the data, this is not applicable.