

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 essential medical devices that would be vulnerable to shortages in specific disaster/emergency situations, or following specific regulatory actions, the respondent universe is limited to those manufacturers producing essential medical devices. 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 the factors CDRH considers in determining essential medical devices, based on information that the manufacturer submits during the annual registration process), we estimate that approximately 300 registered entities currently meet these inclusion criteria. Because manufacturers enter and leave the market, existing manufacturers merge with other manufacturers, and because manufacturer 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 $\geq 75\%$ 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 Manufacture Essential Devices	Anticipated Response Rate
Medical device manufacturers	~300	$\geq 75\%$

2. Procedures for the Collection of Information

The CDRH Registration and Listing database will be queried every 6 months to generate a list of candidate manufacturers. Criteria for participation/inclusion in this data collection effort are:

- Currently registered with FDA/CDRH
- Currently manufacturing:
 - o Devices that are used to diagnose, treat, or prevent a serious disease or medical condition;
 - o Devices for which no satisfactory alternative devices, drugs, or therapies are available;
 - o Devices used as a tool (e.g. core medical equipment) for life-sustaining conditions or patient care;

- o Devices commonly used with vulnerable patient populations (e.g. pediatrics);
- o 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; and
- o Devices where the manufacturer is the sole manufacturer.

Using the official correspondence contact information provided by the manufacturer during the annual registration and listing process, CDRH shortages staff will initially contact the manufacturer via telephone, at which time the rationale and goals of the program will be explained. If the respondent agrees to participate further, the CDRH caller will pose questions to them. The following represents the content of the 5 questions that will be asked. CDRH shortages staff will forward written documentation of the request to the manufacturer via electronic mail within 24 hours, creating an electronic record of the interaction.

1. What contact name(s), address, phone number, FAX number, and e-mail address can CDRH use to contact you during an emergency?
2. What is the current production capacity and additional surge (i.e., maximum) capacity at the production location, and time required to attain surge capacity for these devices?
3. How long would it take to reach maximal production capacity?
4. What, if any, critical raw material, subcomponent, or contractor dependencies or constraints do these devices have?
5. Do you have any contingency plans in place to provide continued manufacturing of your device should any of your critical suppliers or manufacturing processes become unavailable?

Because the data/information provided by the respondents have 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 (vs. precise) data, their 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 the initial call, one or more additional follow-up calls and/or electronic mail correspondences may be required to verify/validate data sent from the manufacturer, confirm receipt and/or request additional details.

After initial data submissions, CDRH shortages staff will contact respondents every 4 months via electronic mail requesting updates or revisions. They may respond simply that there have been no changes, or provide CDRH with targeted responses where there have been changes.

This mode of communication and timing is a reasonable compromise between the need for CDRH to have the most up-to-date information and the least burdensome imposition on the manufacturer's resources. If a manufacturer were to provide evidence to CDRH of a more stable manufacturing cycle (i.e., the quantity of devices, manufacturing sites, raw material sources, etc. do not change over longer periods of time), then 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, the contacted manufacturers will be given a clear and concise explanation of the rationale for, and goals of, the shortages program. All questions will be answered to the best of CDRH's ability. The manufacturer will be given as much time as they require to discuss CDRH's request internally before committing to participate in data gathering.

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 or emergency, we believe that a clear explanation of the intention to protect the public health, along with an avoidance of any pressure to respond, will enhance voluntary participation. Because the initial contact will be via telephone, and is made by members of the Shortages Team, which includes a senior Medical Officer, we believe that there will be a relatively low rate of non-response. Because of their clinical expertise, the Shortage Team Medical Officer can provide any needed 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. Finally, if additional time for consideration is requested, the same team member will remain the primary CDRH point of contact with the manufacturer; this will help provide continuity and identify a "friendly face" for future questions or concerns.

4. Test of Procedures or Methods to be Undertaken

The current procedure for data collection was operationally validated at 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

As described above, no statistical testing procedures will be applied to the data; this is not applicable.