OMB No. 0910-0491
Exp. Date:

EMERGENCY SHORTAGES DATA COLLECTION SYSTEM QUESTIONS

PUBLIC Disclosure Burden Statement

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Exhibit 1:
Telephone script to be used at time of initial contact:

"Hello, my name is ___ and I am a member of the emergency preparedness team at the FDA's Center for Devices and Radiological Health. We are calling to request your participation in a data request that we believe will significantly support emergency preparedness activities in the healthcare and public health sector. Your company's participation is voluntary, we hope that you will consider participating.

By way of background, several years ago, the FDA/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. 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.

Based on our records, your company currently manufacturers one or more devices that meet the criteria of being in high demand, or vulnerable to shortages during a specific disaster/emergency situation. To help us with this initiative, we would need you to answer the following four question:

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 you would like, I can forward this request to you via electronic mail."