

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Certifier N. Hawkins

[Docket No. 02N-0077]

**Agency Information Collection Activities; Submission for OMB Review;
Comment Request; Emergency Medical Device Shortage Program Survey**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Fax written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202-395-6974, or electronically mail comments to sshapiro@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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Emergency Medical Device Shortage Program Survey (OMB Control Number 0910-0491)—Reinstatement

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively FDA's mission. Section 510 of the act (21 U.S.C. 360) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with FDA. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. These sections of the act enable FDA to enhance consumer protection from risks associated with medical devices usage that are not foreseen or apparent during the premarket notification and review process.

Subsequent to the events of September 11, 2001, FDA began planning for handling device-related issues related to counterterrorism. One of the activities related to planning for addressing terrorism-related medical device shortages is that FDA, working with medical experts and medical device industry organizations, developed a medical device formulary that identifies which medical devices would be needed in responding to terrorist incidents. The National Pharmaceutical Stockpile Program managed by the Centers for Disease Control appears to have not given adequate consideration to medical devices.

Therefore, FDA has developed a plan to ensure adequate availability of medical devices in case of terrorist incidents.

Most particularly, consumable supplies or disposable devices are supplied through large regional distributors. Adequate supplies should be available through these existing commercial supply chains. Problems in supplying these items will be due to logistics. In an emergency, FDA plans to ensure adequate availability of these types of devices by working with industry/distributor organizations. These organizations have actively pursued working relationships with appropriate government agencies to facilitate adequate response in emergency situations.

However, there are more sophisticated or specialized devices, for example, ventilators, defibrillators, and portable x-ray machines are sold directly by the manufacturer but are not sold through independent distributors. For these devices, FDA plans to maintain a database of device manufacturers so that specific contact information can be supplied to emergency response personnel as needed. FDA has identified 17 of these devices and has identified 205 manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

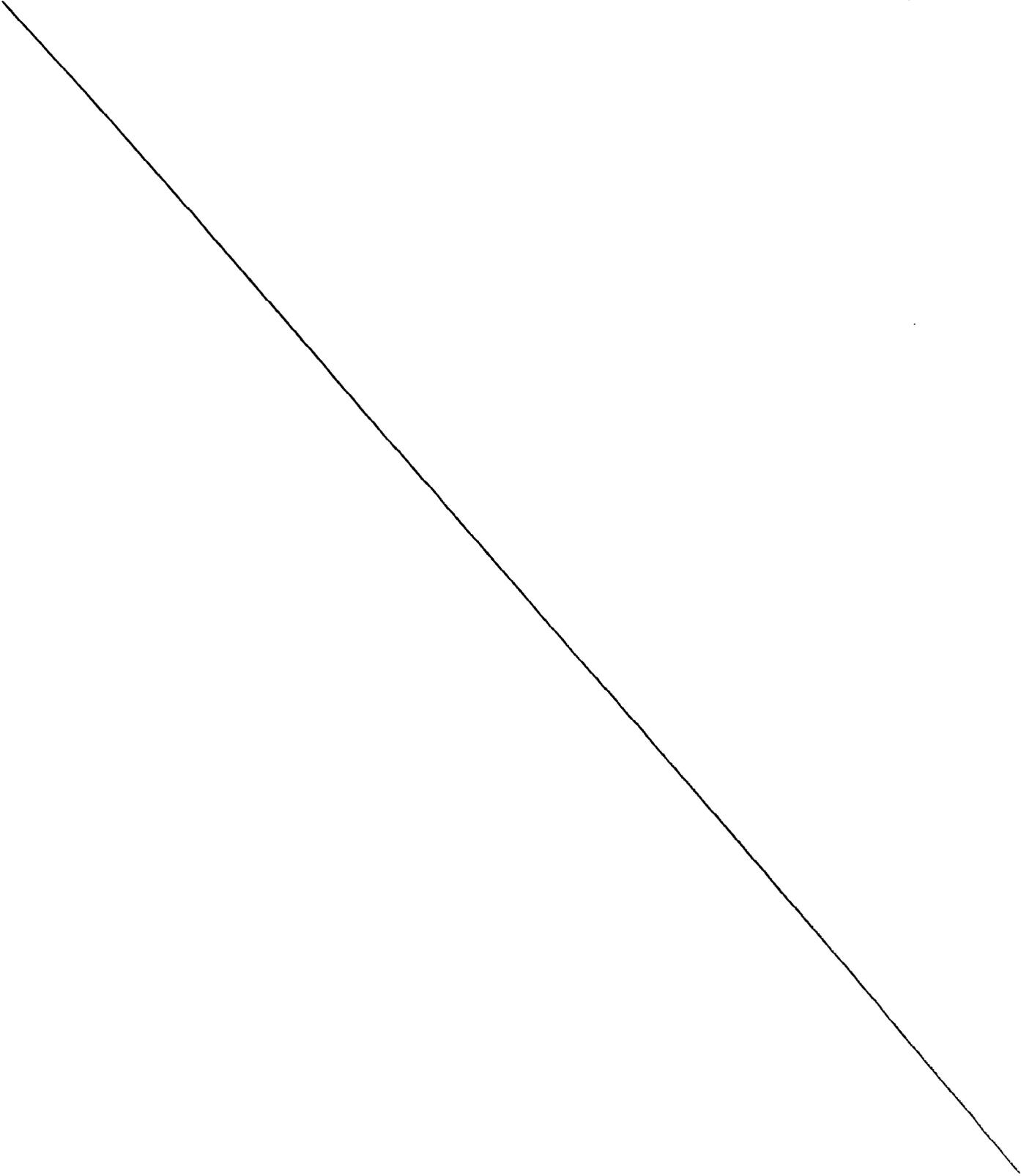
	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Telephone Survey	250	1	250	.5	125

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

FDA has based these estimates on conversations with industry and trade association representatives and from internal FDA experience and estimates.

The total number of medical device manufacturers regulated by FDA is estimated to be 70,000. Because most of the medical devices which might be needed in a terrorist attack are available through regular commercial channels,

FDA focused this collection of information on the 250 manufacturers who manufacture 17 medical devices. Therefore, FDA estimates that approximately



150 manufacturers would be contacted in a 1-year period. It is also estimated from FDA experience that the survey will take approximately 20 to 30 minutes to complete over the telephone.

Dated: 3-7-03
March 7, 2003.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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