TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	No. of Responses per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
203.31(d)(1) and (d)(2)	2,208	1	2,208	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768
203.39(g)	3,221	1	3,221	8.00	25,768
203.50(a)	0	0	0	0	0
203.50(b)	0	0	0	0	0
203.50(d)	0	0	0	0	0
Total Recordkeeping Burden Hours					409,409

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

Dated: March 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3818 Filed 3–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0426]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notice of Participation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by April 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Notice of Participation—(OMB Control Number 0910–0191)—Extension

Section 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in § 12.85, or, in the case of a hearing before a Public Board of Inquiry (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the pre-hearing conference and commits participation.

The respondents are individuals or households, State or local governments, not for profit institutions, and businesses, or other for profit groups and institutions.

In the **Federal Register** of November 1, 2005 (70 FR 65904), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received. However, it was not related to the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	264	1	264	3	792

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

Dated: March 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3819 Filed 3–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0422]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Shortages Data Collection System (Formerly the Emergency Medical Device Shortage Program Survey)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by April 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Emergency Shortages Data Collection System (Formerly the Emergency Medical Device Shortage Program Survey)—(OMB Control Number 0910–0491)—Extension

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 the mission of FDA. 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. 360(l)) 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 device usage that are not foreseen or apparent during the premarket notification and review process.

Subsequent to the events of September 11, 2001, FDA's Center for Devices and Radiological Health (CDRH) began planning for handling medical device shortage issues associated with counter-terrorism. One of the activities related to the planning was that CDRH would establish a data collection system as a supplemental source for available product. Because of events on September 11, 2001, local and State governments have obtained stockpiles of backup supplies within their jurisdiction to cover an emergency for the first 12 hours following a terrorist attack. The second 12 hours will have additional medical devices supplied by the Centers for Disease Control's Strategic National Stockpile and the National Acquisition Center. However, if additional supplies are needed in the first 12 hours, the Department of Health and Human Services (HHS) will request that FDA provide the number of medical devices readily available to meet demands. HHS has an established transportation and delivery mechanism in place to provide these emergent needs to the local and State authorities.

The Emergency Medical Device Shortage Survey was established in 1992 to collect data to assist FDA in implementing an emergency medical device shortage program that would find resources to supplement the needed supplies. In 2004, CDRH changed the process for the data collection and the name was changed to the Emergency Shortages Data Collection System. Because of the confidentiality aspect of the information, the information is only available to those on FDA's Emergency Shortage Team (EST) and senior management with a need-to-know. The need-to-know personnel include five EST members, the EST leader, the EST data entry technician, and five senior managers.

The Emergency Shortages Data Collection System will be updated every 4 months to keep information current. CDRH learned that medical device manufacturers have a high rate of turnover in personnel and in corporate structures due to mergers with larger companies. In addition, with the constant advances in technology, some of these manufacturers are forced to discontinue product lines or add product lines to their inventory. This new data collection system process will update information on a regular basis ensuring more accurate information in an emergency/disaster.

The process consists of one scripted telephone call to the designated shortage person at the four or five largest manufacturers of specific medical devices that may be needed by first responders in a national emergency. At the current time, the list contains 67 products from 65 manufacturers. If other products or new technology are deemed necessary to add at a later date, then the EST will conduct the appropriate search to find the four or five largest manufacturers of that product line and request the manufacturer's voluntary inclusion into the program.

The Emergency Shortages Data Collection System will only include