TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Meeting Requests and Information Packages	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	774	2.20	1,705	18	30,690
CBER	120	1.65	198	18	3,564
Total					34,254
Grand Total					59,224

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

Dated: March 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5536 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0635]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Shortages Data Collection System (formerly ''Emergency Medical Device Shortages 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 15, 2009.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0491. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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 ''Emergency Medical Device Shortages Program Survey'')—(Federal Food, Drug, and Cosmetic Act, Section 903 (d)(2) (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 FDA Commissioner is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Subsequent to the events of September 11, 2001, and as part of broader counter-terrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable the Center to anticipate and respond to medical device shortages that might arise in the context of federally-declared disasters/emergencies or regulatory actions. In particular, 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, and/or would be vulnerable to shortages in specific disaster/emergency situations, or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, and support real-time decision making by the Department of Health and Human Services during actual emergencies or emergency preparedness exercises.

''The Emergency Medical Device Shortage Program Survey'' was developed in 2002 to support the acquisition of such data from medical device manufacturers. In 2004, CDRH changed the process for the data collection, and the electronic database in which the data were stored and was formally renamed the ''Emergency Shortages Data Collection System'' (ESDCS). Recognizing that some of the data collected may be commercially confidential, access to ESDCS is restricted to members of the FDA Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to 5 senior managers. Further, the data are used by this defined group only for decision making and planning in the context of a federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by nondisaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices being tracked in the emergency shortages data collection system. In this initial call, the intent and goals of the data collection effort are described, and the specific data request is made. After the initial call, one or more additional follow-up calls and/or electronic mail correspondence may be required to verify/validate data sent from the manufacturer, confirm receipt and/or request additional detail. Although the regulatory officer is the agent who is initially contacted, they may designate an alternate representative within their organization to correspond subsequently with the CDRH EST member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities and raw material/subcomponent sourcing, it is necessary to update the data in the ESDCS at regular intervals. This is done on a weekly basis, but efforts are made to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The ESDCS will only include those medical devices for which there will likely be high demand during a specific

emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

In the **Federal Register** of December 19, 2008 (73 FR 77718), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
903(d)(2)	125	3	375	0.5	188

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

FDA based the burden estimates in Table 1 on past experience with direct contact with the medical device manufacturers, and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year to either obtain primary data or to verify/validate data. Because the data being requested represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: March 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5545 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0051]

Draft Guidance for Industry and Food and Drug Administration; User Fees and Refunds for Premarket Approval Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''User Fees and Refunds for Premarket Approval Applications'' (PMAs). The purpose of this draft guidance document is to outline the types of PMAs subject to user fees, including supplements and other submissions, as well as those that do not have an associated user fee. The draft guidance also identifies industry and FDA actions on these submissions that may result in a refund of the fee.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 15, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''User Fees and Refunds for Premarket Approval Applications,'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 5515 Security Lane, rm. 130, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amends the Federal Food, Drug, and Cosmetic Act (the act) to provide FDA new responsibilities and resources associated with the collection and refund of user fees. The primary difference between this draft guidance and the November 24, 2003, version now in effect is the addition of user fee and user fee refund information for 30-day notices and periodic reports. Additionally, the draft guidance discusses the modified user fee refund provisions for modular PMAs. If finalized, this draft guidance will supersede the 2003 guidance.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on user fees and refunds for premarket approval applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''User Fees and Refunds for Premarket Approval Applications,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1681) to identify the guidance you are requesting.