reprocessors of SUDs, and initial importers of devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form FDA Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807, subpart E (807.81 and 807.87/510(k))		3,700	1	3,700	80	296,000
	3514	2,000	1	2,000	0.5	1,000
	3654	150	1	150	1	150
Totals						297,150

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Form FDA Number	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93		2,000	10	20,000	0.5	10,000
Total						10,000

[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 review of the documents listed in tables 1 and 2.

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18553 Filed 11–2–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0247]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Medical Device User Fee Cover Sheet

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 December 4, 2006.

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.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Medical Device User Fee Cover Sheet; Form FDA 3601 (OMB Control Number 0910–0511)—Extension

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, determine the amount of the fee required, and account for and track user fees. The form provides a cross-reference of the fees submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

According to the FDA database system, there are an estimated 4,600 manufacturers of products subject to MDUFMA. However, not all manufacturers will have any cover sheet submissions in a given year and some may have multiple cover sheet submissions. The total number of annual responses is based on the number of coversheet submissions received by FDA in fiscal year (FY) 2005. CDRH received 4,436 annual responses that included the following: 43 premarket approval applications, 4,071 premarket notifications, 22 modular premarket applications, 1 product development protocol, 1 premarket report, 15 panel track supplements, 174 real-time supplements, and 109 180-day supplements. CBER received 106 annual responses that included the following: 2 premarket approval applications, 16 biologics license applications, 84 premarket notifications, 1 modular premarket application, 2 180-day supplements, and 1 real-time supplement. The number of received

annual responses in FY 2005 included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of June 29, 2006 (71 FR 37082), FDA published a 60-day notice soliciting comments on the proposed collection of information. In response to that notice, one comment was received regarding the MDUFMA cover sheet. FDA responded as follows ''The current layout of the online form is to ensure information and questions presented on the Web site are easy to read for all users. When this system was constructed, the Food and Drug Administration was limited to the format and the layout of questions and answers. FDA took an already approved form and created an interactive system that determines the payments of requested applications based on the answers to the questions. The questions are sequential. After completing the first question, the system decides and chooses the next question for the customers. This **Federal Register** notice renews the current construction. Careful consideration during the next review will be given and FDA will certainly consider the commenter's suggestion of saving screen refresh time.''

As noted previously, FDA will be glad to take under consideration the commenter's template and the ability to download the form, when the next update or review is initiated. You can, however, retrieve an existing cover sheet by logging into the system, and clicking on the name of the cover sheet. The retrieved form is a photo shot html format. Thus, no changes can be made directly onto the form. To print the cover sheet, please select ''Print Cover Sheet'' on the bottom of the form. Currently, the printed cover sheet contains all information on one page. Again, FDA will be glad to consider this request during the next review. The current cover sheet is designed to contain all information on one page. By creating more room on the left margin, the form may extend to two pages.

Having instructions 1 through 6 on the cover sheet seems redundant. However, at the time, when creating the interactive system, FDA took into consideration that once a cover sheet is completed and ready to mail, all information would be displayed on the same page. Instructions 1 through 6 are very important information for all customers to follow in order to expedite the application review process. The instructions printed on the cover sheet provide easy access for all customers to learn about them, especially for new users. FDA will continue to use the current form. For other questions regarding submitted cover sheets, please contact the User Fee Hotline at 301–827–9539, or e-mail the User Fee Financial Support Team at *userfees@fda.gov*.

The most likely respondents would be medical device manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3601	4,600	1	4,600	0.30	1,380
Total					1,380

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

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18557 Filed 11–2–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0427]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Submit written or electronic comments on the collection of information by January 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this