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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	1	35	35	5	175
Total	70				15,019

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

Dated: June 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–5805 Filed 6–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0247]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3601 entitled ''Medical Device User Fee Cover Sheet'' which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

DATES: Submit written or electronic comments on the collection of information by August 28, 2006.

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, Office of Management Programs (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 requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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, to determine the amount of the fee required, and to 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 FDA's 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 cover sheet submissions received by FDA in fiscal year 2005. CDRH received 4,436 annual responses that included the following submissions: 43 premarket approval applications (PMAs), 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 submissions: 2 PMAs, 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.

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: June 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–5806 Filed 6–28–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–0359] (formerly 98N–0359)

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2007. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Submit written or electronic comments by August 28, 2006.

ADDRESSES: Submit written comments concerning this document 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Tracy Summers, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20740, e-mail: *tsummers@.fda.hhs.gov*, 301–827–6733.

SUPPLEMENTARY INFORMATION:

I. Background

On May 3, 2006, CFSAN released a document entitled ''FY 2006 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's Web page (*http://www.cfsan.fda.gov*) or from the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document, constitutes the center's priority workplan for FY 2006 (i.e., October 1, 2005, through September 30, 2006). The FY 2006 workplan is based on input we received from our stakeholders (see 70 FR 29328, May 20, 2005), as well as input generated internally. Throughout the priority-setting process, we focused on one central question: ''Where do we do the most good for consumers and the overall public health?'' The FY 2006 workplan was developed in recognition of a diminished budget, including projected reductions and redeployment of resources to achieve funding for priorities outlined in the President's FY 2007 budget.

The FY 2006 workplan is structured differently than previous years. It contains only those activities previously listed as ''A'' list items. Our goal is to fully complete at least 90 percent of the activities listed under sections 1 through 4 of the FY 2006 workplan by the end of the fiscal year, September 30, 2006. The FY 2006 workplan also includes a fifth section entitled ''Priority Ongoing Activities.'' Many of these activities are core functions that we perform on a regular basis and are among our very highest priorities.

II. 2007 CFSAN Program Priorities

FDA is requesting comments on what program priorities CFSAN should consider establishing for FY 2007. The input will be used to develop CFSAN's FY 2007 workplan. The workplan will set forth the center's program priorities for the period of October 1, 2006, through September 30, 2007. FDA intends to make the FY 2007 workplan available in the fall of 2006.

The format of the FY 2007 workplan will be similar to the FY 2006 workplan in that it will be divided into the following five sections:

(1) Ensuring Food Defense,

(2) Ensuring Food Safety,

(3) Improving Nutrition,

(4) Improving Dietary Supplement Safety, and

(5) Ensuring Cosmetic Safety.

While there will likely be continuity and follow-through on many activities between the 2006 and 2007 workplans, the final FY 2007 Congressional Appropriation will unquestionably affect what we will be able to commit to accomplish in FY 2007. Accordingly, FDA requests comments on broad program areas that should continue to be a priority as well as new program areas or activities that should be added as a high priority for FY 2007.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–10241 Filed 6–28–06; 8:45 am]

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