

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 BURDEN¹

| 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 |

¹There 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.

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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.

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