collection will primarily be medical device manufacturers and businesses.

FDA form 3514 was developed to assist respondents in organizing 510(k) data for submission to FDA. This form also assists respondents in organizing and submitting data for other FDA medical device programs such as premarket approval applications, investigational device exemptions, and humanitarian device exemptions.

In the **Federal Register** of April 30, 2001 (66 FR 21398), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Form No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.81 and 807.87 (part 807, subpart E)		4,000	1	4,000	80	320,000
	FDA 3514	2,000	1	2,000	.5	1,000
Total						321,000

[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	No. of recordkeepers	Annual frequency of 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 of this document. The total burden for using voluntary FDA form 3514 is estimated to be approximately 1,000 hours and has been included in this information collection. Once this information collection has been approved, the burden for FDA form 3514 will be reported and approved in each of the following OMB information collections: 0910–0078, investigational device exemption reports and records; 0910–0231, premarket approval of medical devices; and 0910–0332, medical devices, humanitarian devices.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17977 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0359]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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) 2002. 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 September 17, 2001.

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

FOR FURTHER INFORMATION CONTACT: Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS–666), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–5290, e-mail: DCarring@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 9, 2001, CFSAN released a document entitled ''2001 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's Web page (www.cfsan.fda.gov), constitutes the Center's priority workplan for FY 2001, i.e., October 1, 2000, through September 30, 2001. (Copies are also available from the contact person listed above.) The 2001 workplan is based on input we received from our stakeholders (see 65 FR 39415, June 26, 2000), 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?''

The paramount theme for the FY 2001 workplan has been program continuity. We continue to place our highest emphasis on the food safety initiative, food additives, dietary supplements,

and food biotechnology. Outside of these priorities, the workplan identifies 10 other program areas and cross-cutting areas that need emphasis: (1) Nutrition, health claims and labeling; (2) chemical contaminants, pesticides and other hazards; (3) cosmetics; (4) preparing to move CFSAN offices and laboratories to a new facility in College Park, MD; (5) enhancing the science base; (6) international activities; (7) emerging areas (e.g., food allergens); (8) enhancing regulatory processes; (9) focused economic-based regulations; and (10) management initiatives.

The FY 2001 workplan contains two lists of activities in most major sections of the document—the ''A'' list and the ''B'' list. Our goal is to fully complete at least 90 percent of the ''A'' list activities. Activities on the ''B'' list are those we plan to make progress on, but may not complete before the end of the fiscal year. A new feature of the FY 2001 workplan has been ''B'' list items with an asterisk. These are the highest priority ''B'' list activities, most of which are 2-year projects that we are positioning to be on the ''A'' list the following year.

CFSAN intends to issue a progress report shortly on what program priority activities already have been completed to date in FY 2001.

CFSAN has responsibility for many important ongoing activities that are not identified in the workplan. For example, the Center's base programs in data collection, research, and enforcement are important and are ongoing. Rather, the workplan addresses primarily those initiatives representing something new or different that we need to address in 2001, as well as priority initiatives that are being continued from the 2000 workplan. In addition, the workplan does not address the myriad of unanticipated issues that often require a substantial investment of CFSAN resources (e.g., response to outbreaks of foodborne illness).

II. 2002 CFSAN Program Priorities

FDA is requesting comments concerning the establishment of program priorities in CFSAN for FY 2002. The input will be used to develop CFSAN's 2002 workplan. The workplan will set forth the Center's program priorities for October 1, 2001, through September 30, 2002. FDA intends to make the 2002 workplan available in the fall of 2001.

The format of the 2002 workplan will be similar to last year's workplan. FDA expects there will be considerable continuity and follow-through between the 2001 and 2002 workplans. For example, major documents published in early 2001 for public comment (e.g., biotechnology proposal; draft *Listeria* risk assessment) would likely be high priority for completion of final documents in FY 2002. Moreover, a number of goals inherently require a multi-year effort. For example, the Food Allergen Compliance Policy Guide issued in 2001 will need inspectional followup in 2002. FDA requests comments on other broad program areas that should continue to be a priority in FY 2002, or new areas that need to be initiated.

In addition, as noted above, the 2001 workplan highlights certain ''B'' list activities with an asterisk. Many of these are 2-year projects that we are positioning to be candidates for the ''A'' list next year. FDA requests comments on which ''*B'' and regular ''B'' list activities (i.e., those not designated with an asterisk) should be elevated to the ''A'' list for completion in 2002. Finally, as noted, FDA requests comments on new program areas or activities that should be added as a high priority for FY 2002.

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this notice by September 17, 2001. Two copies of any comments are to be submitted, except that individuals may submit one 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 office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17919 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 9, 2001, from 8:30 a.m. to 5 p.m., and on August 10, 2001, from 8:30 a.m. to 3 p.m.

Location: National Institutes of Health, Jack Masur Auditorium, Bldg. 10, 9000 Rockville Pike, Bethesda, MD.

Contact: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419–259–6211, or Jaime Henriquez, 301–827–6803, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 9, 2001, in the morning, the committee will discuss new drug application (NDA) 21–272, Remodulin® (treprostinil sodium injection), United Therapeutics Corp., for the treatment of pulmonary hypertension. On August 9, 2001, in the afternoon, the committee will discuss NDA 21–321, Extraneal® (7.5 percent icodextrin) peritoneal dialysis solution, Baxter Healthcare Corp. On August 10, 2001, in the morning, the committee will discuss NDA 21–290, Tracleer® (bosentan tablets), Actelion, Ltd., for the treatment of pulmonary hypertension.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 2, 2001. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. on each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 2, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–17921 Filed 7–17–01; 8:45 am]

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