

and naturally occurring sugars (58 FR 2079 at 2098). FDA listed three reasons for deciding against implementing these recommendations: (1) The body does not make any physiological distinction between added and naturally occurring sugars in foods; (2) for most foods there is no analytical method to differentiate between added and naturally occurring sugars; and (3) the declaration of only added sugars could significantly underrepresent the sugars content of many foods that have a large quantity of naturally occurring sugars. Instead, the final rules required that total sugars be a mandatory component of nutrition labeling (21 CFR 101.9(c)(6)(ii)) (58 FR 2079 at 2176).

In the January 6, 1993, final rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (58 FR 2206), FDA concluded that there was not sufficient basis to establish a DRV for added sugars because there was no conclusive evidence that demonstrated that sugars intake from any source was associated with chronic disease conditions. Additionally, the agency noted the absence of analytical capabilities to distinguish between added sugars and naturally-occurring sugars and the lack of consensus concerning the specific proportion of total carbohydrate that should be attributed to total sugars and complex carbohydrate. In conclusion, FDA did not support the separate establishment of DRV's for added sugars, naturally-occurring sugars, and total sugars (58 FR 2206 at 2221 and 2222).

FDA's food labeling regulations do require that sugars that are used as ingredients in a food product (i.e., that are added) be declared in the ingredient list on the label or labeling of that food (21 CFR 101.4(a)(1)). The listing of the added sugars must be by the common or usual name of the particular sugar and be in descending order of predominance among the other ingredients in the food product.

III. Comments

You may submit written or electronic comments to the Dockets Management Branch (address above), on or before September 25, 2000. Electronic comments may be submitted via the Internet to: www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail to: fdadockets@oc.fda.gov. Groups or organizations must submit two copies of any comments. Individuals may submit one copy of their comments. Identify your written comments by placing the docket number at the top of your comment(s). If you base your comments

on scientific evidence or data, please submit copies of the specific information along with your comments. Any comments submitted will be filed under the docket number identified in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-16066 Filed 6-23-00; 8:45 am]

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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) 2001. 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: Written comments by August 25, 2000.

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. 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: DCarrington@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On February 10, 2000, CFSAN released a document entitled "2000

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 a 9-month period, from January 1, 2000, through September 30, 2000, the end of the fiscal year. Henceforth, to be consistent with the Federal budgetary cycle, the priority-setting process and development of annual workplans will be done on a fiscal year basis. The 2000 workplan is based on input we received from our stakeholders (see 64 FR 47845, September 1, 1999), 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?"

Approximately half of the 2000 workplan consists of activities implementing the President's Food Safety Initiative (FSI). This is consistent with the fact that currently, approximately half the Center's resources are devoted to FSI work (i.e., all activities related to pathogen reduction in food.) Outside of FSI, the workplan identifies five program areas and six cross-cutting areas that need emphasis. The five program areas are: (1) Premarket review of food ingredients; (2) nutrition, health claims, and labeling; (3) dietary supplements; (4) chemical and other contaminants; and (5) cosmetics.

The six cross cutting areas are: (1) Enhancing the science base, (2) international activities, (3) emerging areas such as food biotechnology, (4) enhancing regulatory processes, (5) focused economic-based regulations, and (6) management initiatives.

In keeping with last year's format, the workplan contains two lists of activities in most major sections of the document, i.e., the "A" list and the "B" list. Because we condensed this year's plan to three-fourths of the year (9 months), our goal will be to fully complete at least three-quarters 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. 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 2000. In addition, the workplan does not address the myriad of unanticipated issues which often require a substantial investment of CFSAN resources (e.g., response to outbreaks of foodborne illness).

II. 2001 CFSAN Program Priorities

FDA is requesting comments concerning the establishment of program priorities in CFSAN for FY 2001. The input will be used to develop CFSAN's 2001 workplan. The workplan will set forth the Center's program priorities for October 1, 2000, through September 30, 2001. FDA intends to make the 2001 workplan available in October 2000.

The format of the 2001 workplan will be similar to the 2000 workplan. Moreover, FDA expects there will be considerable continuity between the 2000 and 2001 workplans. For example, a broad program area targeted for enhancement in the 2000 plan is improving the safety of imported food; five specific activities are identified to implement the Imported Foods Action Plan. As the initiative to prevent importation of unsafe food requires a multiyear effort, ensuring the safety of imported food will continue to be a high priority in the 2001 workplan. The same is true for the Egg Safety Action Plan. FDA requests comments on other broad program areas that should continue to be a priority in FY 2001.

In addition, because the 2000 workplan, as noted above, was a condensed (i.e., 9-month) plan, our goal for FY 2000 will be to fully complete at least three-quarters of the "A" list activities. FDA requests comments on those "A" list activities in the 2000 plan that, if not completed, should be carried over to the 2001 workplan. FDA also requests comments on the FY 2000 "B" list activities that should be elevated to the "A" list for completion in FY 2001. Finally, FDA requests comments on new program areas or activities that should be a high priority for FY 2001.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this notice by August 25, 2000. 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: June 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-16067 Filed 6-23-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Imaging 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: Medical Imaging 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 July 10, 2000, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail at PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12540. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss biologic license application (BLA) 99-1407, Leutech™ (Technetium labeled TC99m anti/CD15 antibody injection), Palatin Technologies, Inc., imaging agent as an aid in the diagnosis of equivocal appendicitis.

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 July 3, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 2000, 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: June 19, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-16065 Filed 6-23-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-0282]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Request: Reinstatement, without change, of a previously approved collection; *Title of Information Collection:* Medicare+Choice (M+C) Organization Appeals and Grievance Data Disclosure Requirements and Supporting Regulations in 42 CFR 422.64, 422.111, and 422.560-422.622; *HCFA Form Number:* HCFA-R-0282 (OMB approval #: 0938-0778); *Use:* These information collection pertains to the aggregate number and disposition of grievances and appeals by M+C organizations. Both the Balanced Budget Act (BBA) of 1997 and the Government Performance and Results Act (GPRA) of 1993 establish a need for HCFA to set and monitor performance standards in the area of appeals. The purpose is to hold M+C organizations accountable to regulators and consumers, as well as promote informed choice; *Frequency:* Semi-annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 268; *Total Annual*