| Form | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| CBER: | | | | | |
| Form FDA 3500 | 804 | 1 | 804 | 0.5 | 402 |
| Form FDA 3500A | 63 | 158.5 | 9,988 | 1.0 | 9,988 |
| CDER: | | | | | |
| Form FDA 3500 | 14,875 | 1 | 14,875 | 0.5 | 7,438 |
| Form FDA 3500A | 500 | 375 | 187,522 | 1.0 | 187,522 |
| CDRH: | | | | | |
| Form FDA 3500 | 2,807 | 1 | 2,807 | 0.5 | 1,404 |
| Form FDA 3500A | 39,889 | 2.05 | 81,928 | 1.0 | 81,928 |
| CFSAN: | | | | | |
| Form FDA 3500 | 646 | 1 | 646 | 0.5 | 323 |
| Form FDA 3500A | 0 | 0 | 0 | 1.0 | 0 |
| Total Hours | | | | | 289,005 |
| Form FDA 3500 | | | | | 9,567 |
| Form FDA 3500A | | | | | 279,438 |

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

Note: CBER = Center for Biologics Evaluation and Research; CDER = Center for Drug Evaluation and Research; CDRH = Center for Devices and Radiological Health; CFSAN = Center for Food Safety and Applied Nutrition. Form FDA 3500 is for voluntary reporting; Form FDA 3500A is for mandatory reporting.

As more medical products are approved by FDA and marketed, FDA expects that more reports will be submitted. The figures in the table are based on the average number of reports received in FY 1996, adjusted for the anticipated annual increase in reports. The anticipated annual increase in reports is based on the average annual increase from 1993 to 1996. There are zeroes in the CFSAN row for Form FDA 3500A because mandatory reporting using Form FDA 3500A is not applicable to foods.

Dated: May 28, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–14721 Filed 6–2–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Blood Products 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). At least one portion of the meeting will be closed to the public.

*Name of Committee*: Blood Products Advisory Committee.

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

*Date and Time*: The meeting will be held on June 18, 1998, 8 a.m. to 5:30 p.m., and on June 19, 1998, 8 a.m. to 3 p.m.

*Location*: Doubletree Hotel, Plazas I and II, 1750 Rockville Pike, Rockville, MD.

*Contact Person*: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On June 18, 1998, the committee will: (1) Hear updates on hepatitis C recipient notification and partner deferral of xenotransplantation recipients; (2) discuss information provided on the Blood Action Plan, Immune Globulin Intravenous supply issues, and Plasma Inventory Hold; and (3) discuss and make recommendations on standard testing for human immunodeficiency virus (HIV) variants. On June 19, 1998, the committee will: (1) Discuss and make recommendations on the review of clinical trial design for Alpha-1-Proteinase Inhibitor; and (2) review and discuss the draft report on the intramural site visit of the Laboratories of Hemostasis and Cellular Hematology, Division of Hematology, and the Laboratories of Hepatitis and Molecular Virology, Division of Transfusion Transmitted Diseases.

*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 June 9, 1998. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. on June 18, 1998, and between 10:45 a.m. and 11:15 a.m. on June 19, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 9, 1998, 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.

*Closed Committee Deliberations*: On June 18, 1998, from 3 p.m. to 3:30 p.m., and on June 19, 1998, from 10:15 a.m. to 10:45 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to discuss increased sensitivity of manufacturers' tests for HIV variants and review of clinical trial design for Alpha-1-Proteinase Inhibitor. On June 19, 1998, from 2 p.m. to 3 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to discuss the draft report of the intramural site visit.

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

Dated: May 28, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–14760 Filed 6–2–98; 8:45 am]

**BILLING CODE 4160–01–F**

## 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; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to solicit input on program priorities in the Center for Food Safety and Applied Nutrition (CFSAN). CFSAN is currently conducting a comprehensive review of its programs to set priorities and establish work product expectations. This meeting is intended to give the public an opportunity to provide input into the priority-setting process.

*Date and Time*: The meeting will be held on June 24 and 25, 1998, 10 a.m. to 5 p.m.

*Location*: The meeting will be held in the auditorium at the Cohen Bldg., 330 Independence Ave. SW., Washington, DC.

*Contact*: Tracy S. Summers, Center for Food Safety and Applied Nutrition (HFS–1), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4850, FAX 202–205–5025, e-mail tsummers@bangate.fda.gov.

*Registration and Requests for Oral Presentations*: Send registration information (name, title, firm name, address, telephone, and fax number) and requests to make oral presentations to the contact person by June 15, 1998. Written comments should be identified with the docket number found in brackets in the heading of this document and should be submitted by July 15, 1998, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:** FDA's CFSAN is conducting a comprehensive review of all its programs to set priorities and establish reasonable work product expectations. Although implementation of the President's Food Safety Initiative (FSI) is clearly CFSAN's top priority, CFSAN has responsibility for many other important programs as well. (The Presidential initiative is aimed at reducing foodborne microbial illness by strengthening food safety practices and policies.) This meeting is intended to provide the public with an opportunity to provide input into the priority-setting process. This meeting will also serve as one of many activities undertaken by the agency to solicit input in accordance with section 406(b) of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (Pub. L. 105–115) (codified at 21 U.S.C. 393(f)). Section 406 of FDAMA requires that FDA, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, develop and publish in the **Federal Register** a plan for meeting all statutory obligations of the Federal Food, Drug, and Cosmetic Act.

By way of example, in CFSAN's regulations program, work priorities are being assigned as follows: (1) The highest priority will be those regulations that enhance consumer safety, such as those issued to carry out the President's FSI; (2) those regulations that are mandated by statute; (3) health-related product labeling regulations; (4) regulations that will improve efficiency of operations; and (5) those additional regulations that have a major positive impact. The agency is interested in comments regarding the use of these criteria for setting priorities in CFSAN's other program areas. To facilitate comments on this issue, the appendix to this notice contains a list of major activities undertaken by FDA to ensure that foods are safe, wholesome, sanitary, and properly labeled, and that cosmetics are safe and properly labeled. Specific activities are listed in one of six general categories: Application review, injury reporting, product safety assurance, research, outreach, and enforcement.

The agency is most interested at this time in receiving comments regarding program priorities outside of FSI, as other venues are available for interested persons to provide input regarding implementation of FSI across the Federal Government. (Information regarding public meetings on the implementation of FSI can be obtained by contacting Camille E. Brewer at 202–260–1784.) Moreover, because many FSI-related activities require that FDA collaborate with one or more of the other Federal agencies that have primary responsibility for food safety (e.g., the Centers for Disease Control and Prevention in the Department of Health and Human Services; the Food Safety and Inspection Service, the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service in the Department of Agriculture; and the Environmental Protection Agency), comments on priorities in the FSI program at the meeting should be limited to those activities for which FDA has sole responsibility.

To help focus comments, FDA requests that oral and/or written input regarding CFSAN program priorities address the following questions:

1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

2. Beyond implementation of FSI, which program areas and/or activities do you believe should be top priorities for CFSAN, and why?

3. The criteria being used to set priorities for CFSAN's regulations are described above. Should these same criteria be used to set priorities for work in CFSAN's other program areas? If not, what criteria should be used?

4. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

5. Because so much of our nation's food supply is either imported or exported, international activities, such as Codex, appear to be growing in importance. What level of priority do you believe should be given in CFSAN to international activities? Please identify specific activities in your answer.

6. Finally, while not a public health issue, economic fraud affects both the industry and consumers. What level of priority do you believe should be given to addressing issues of economic fraud in the food supply?

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after each meeting at a cost of 10 cents per page. The transcript of the meeting will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Persons requiring a sign language interpreter or other special