III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) have been approved under OMB Control No. 0910–0032.

IV. Comments

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: July 30, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010–19360 Filed 8–5–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Vaccines and Related Biological 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: Vaccines and Related Biological Products 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 September 21, 2010, from 2 p.m. to approximately 6 p.m.

Location: National Institutes of Health (NIH), Building 29B/Conference Room C. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at http://www.nih.gov/about/visitor/index.htm. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.) Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver’s license, passport, green card, etc. Detailed information about security procedures is located at http://www.nih.gov/about/visitorsecurity.htm. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–433–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency’s Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 21, 2010, the committee will meet in open session to hear updates of the research programs in the Laboratory of Respiratory & Special Pathogens, Division of Bacterial, Parasitic, & Allergic Products; Laboratory of Hepatitis Viruses, and Laboratory of Vector Borne Virus Diseases, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Procedure: On September 21, 2010, from 2 p.m. to approximately 5:10 p.m., the meeting is open to the public.

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 on or before September 15, 2010. Oral presentations from the public will be scheduled between approximately 4:10 p.m. and 5:10 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 9, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session,
FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 10, 2010.

Closed Committee Deliberations: On September 21, 2010, from approximately 5:10 p.m. to approximately 6 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)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.


Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–19383 Filed 8–5–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0386]

Strategic Plan for Consumer Education via Cooperative Agreement (U18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application under a cooperative agreement grant (U18) in fiscal year (FY) 2010 to the Partnership for Food Safety Education (PFSE) located in Washington, DC. This cooperative agreement grant is being provided to facilitate a “Strategic Plan for Consumer Education” to determine future directions for PFSE in carrying out a nationwide food safety education program on safe handling practices to prevent foodborne illness. The goal of the cooperative agreement is to help strengthen PFSE, so that FDA’s goal may be achieved in improving consumer food safety practices and in turn reduce the incidence of foodborne illness.

DATES: Important dates are as follows:

1. The application due date is August 13, 2010.
2. The anticipated start date is September 2010.
3. The opening date is August 6, 2010.
4. The expiration date is August 16, 2010.

FOR FURTHER INFORMATION CONTACT AND ADDITIONAL REQUIREMENTS CONTACT:

Center’s Contact: Danielle Schor, Office of Foods, Food and Drug Administration, WO-Bldg. 1, rm. 3230, Silver Spring, MD 20993, 301–796–5404, email: Danielle.Schor@fda.hhs.gov.

Grants Management Contact: Camille Peake, Division of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2139, Rockville, MD 20857, 301–827–7175, FAX: 301–827–7101, email: Camille.Peake@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm212095.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Description Number RFA–FD–10–015
Catalog of Federal Domestic Assistance Number: 93.103

A. Background

This Federal Register notice is being issued by the Office of Foods within the Office of the Commissioner soliciting a sole source grant application from PFSE for funding in support of strategic planning for consumer education. PFSE, begun in May 1997, is the only organization that unites industry associations, consumer and public health groups, academia and government (the U.S. Department of Agriculture (USDA), the Centers for Disease and Control and Prevention, and the Food and Drug Administration) to educate the public about safe food handling and preparation. In 2009, PFSE had 18 association and non-profit contributing members. PFSE, a non-profit organization, is the creator and steward of the “Fight BAC! Campaign”, a food safety education program developed using scientifically based recommendations and resulting from an extensive consumer research process. In 2007, PFSE joined with USDA to create the “Be Food Safe” platform—designed to bring a new look to the four core safe food handling practices and to bring food safety reminders to places where people shop for food. “Fight BAC! Campaign” materials are fully accessible online and utilized by consumers, teachers, dietitians, public health officials, and extension agents across the nation. FDA is one of several government agencies that has signed a Memorandum of Understanding with PFSE.