To assist in completing the surveys and providing accurate data responses, the hotlines will be using the CDC Federal Telecommunications Service (FTS) 2001 telephone systems; call length data from the Integrated Information Program (IIP), which is a computer interface. The hotlines will also be using the Automated Call Distribution (ACD) program which allows the calls to be distributed to the correct numbers (AIDS or STD) and Symposium software which can assist the hotlines in several areas, including quickly (1) determining what happened to a call that may be in the queue,(2) compiling a geographic distribution table of all calls throughout the United States, including ages of callers,(3) and routing calls to the English, Spanish or TTY service.

For the AIDS and STD integrated English service, the estimated number of persons surveyed for the active survey is 34,520, and the average active survey length is 72 seconds with a yearly burden of 691 hours. It is estimated that passive surveys are completed on 29,420 calls, and the average passive survey length for completion is 179 seconds, with a yearly burden of 1,463 hours.

Active surveys for the Spanish service for the AIDS Hotline are estimated to be about 5,040 calls with an average active survey length of 88 seconds. The average number of passive surveys estimated for the Spanish service is 5,000. All callers are surveyed from the TTY service and one out of three callers are surveyed from the Spanish service. There is no cost to the respondents.

Respondents	Number of respondents	Number of responses/respondents	Avg Burden/response (in hours)	Total burden (in hours)
AIDS Hotline Calls/English	21,760	1	1/60	363
AIDS Hotline Calls/Spanish	5,040	1	2/60	168
AIDS Hotline Calls/TTY	350	1	7/60	40
STD Hotline Calls/English	12,760	1	1/60	212
Totals	39,910			783

Dated: November 15, 2001.

John Moore,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–29050 Filed 11–20–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC Advisory Committee on HIV and STD Prevention.

Times and Dates: 8:30 a.m.–5 p.m., December 13, 2001. 8:30 a.m.–3 p.m., December 14, 2001.

Place: Corporate Square Office Park, Corporate Square Boulevard, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

PURPOSE: This Committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

Matters to be Discussed: Agenda items include issues pertaining to (1) Global AIDS Activities (2)syphilis elimination (3) issues pertaining to HIV and STD Prevention among Men Who Have Sex With Men (MSM).

Agenda items are subject to change as priorities dictate.

Contact Person for more Information: Paulette Ford-Knights, Committee Management Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, Mailstop E–07, Atlanta, Georgia 30333. Telephone 404/639–8008, fax 404/639–3125, *e-mail pbf7@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 15, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–29051 Filed 11–20–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine 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: Veterinary Medicine 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 January 22, 23, and 24, 2002, from 8:30 a.m. to 5 p.m.

Location: The DoubleTree Hotel, Plaza Rooms I and II, 1750 Rockville Pike, Rockville, MD.

Contact: Aleta Sindelar, Center for Veterinary Medicine (CVM) (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4515, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 22, 23 and 24, 2002, the committee will seek recommendations on the issues of import tolerances under the provisions of the Animal Drug Availability Act of

1996, and the antimicrobial drug effects on pathogen load in food-producing animals as pathogen load relates to the preapproval process of new animal drug applications (NADAs). Information concerning the discussion of import tolerances can be found in the August 13, 2001, CVM Update at: http://www.fda.gov/cvm/index/updates/importol.htm and in the **Federal Register** advance notice of proposed rulemaking of August 10, 2001 (66 FR 42167). Information concerning the issues of pathogen load will be made publicly available to the Veterinary Medicine Advisory Committee members and the public in advance of the meeting and posted on the CVM home page at: http://www.fda.gov/cvm. A limited number of paper copies of the background information will be available at the meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on the issues pending before the committee. Written submissions may be made to the contact person by January 4, 2002. Oral presentations from the public will be scheduled between approximately 3 p.m. and 5 p.m. on January 22, and between approximately 8 a.m. and 10 a.m. on January 24, 2002. The time allotted for each presentation may be limited. Those desiring to make oral presentations should notify the contact person before January 4, 2002, 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. You will be notified of your allotted time prior to the meeting. Your entire statement should be submitted for the record.

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

Dated: November 8, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–29003 Filed 11–20–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2405]

''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated November 2001. The guidance document provides guidance to industry on the use of certain types of letters by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) as part of the review of marketing applications for certain drug and biological products. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated August 1999.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT:

Michael Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or

Paul Varki, Center for Drug Evaluation and Research (HFD–7), 5600 Fishers Lane, Rockville, MD 20852–1448, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated November 2001. In a November 1997 letter to Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the Secretary of Health and Human Services (the Secretary) committed FDA to certain user fee performance goals and additional procedures related to the review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1) (PDUFA products)). The guidance document explains how the agency will issue and use information request letters and discipline review letters during the review of PDUFA products. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' dated August 1999 that was announced in the **Federal Register** of August 17, 1999 (64 FR 44741).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on information request letters under PDUFA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document