Proposed Project

Performance Evaluation Program for Rapid HIV Testing—New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC).

To support our mission of improving public health and preventing disease through continuously improving laboratory practices, the Model Performance Evaluation Program (MPEP), Division of Laboratory Systems, Public Health Practice Program Office, Centers for Disease Control and Prevention intends to provide a new HIV rapid testing performance evaluation program (HIV Rapid Testing MPEP). This program will offer external performance evaluation (PE) for rapid tests such as the OraQuick® Rapid HIV–1 Antibody Test, recently approved as a waived test by the U.S. Food and Drug Administration, and for other licensed tests such as the Abbott-Murex SUDS® HIV–1 Test. Participation in PE programs is expected to lead to improved HIV testing performance because participants have the opportunity to identify areas for improvement in testing practices. This program will help to ensure accurate testing as a basis for development of HIV prevention and intervention strategies.

This external quality assessment program will be made available at *no cost* (for receipt of sample panels) to sites performing rapid testing for HIV antibodies. This program will offer laboratories/testing sites an opportunity for:

(1) Assuring that the laboratories/testing sites are providing accurate tests through external quality assessment.

(2) Improving testing quality through self-evaluation in a non-regulatory environment.

(3) Testing well characterized samples from a source outside the test kit manufacturer.

(4) Discovering potential testing problems so that laboratories/testing sites can adjust procedures to eliminate them.

(5) Comparing individual laboratory/testing site results to others at a national and international level, and consulting with CDC staff to discuss testing issues.

Participants in the MPEP HIV Rapid Testing program will be required to complete a laboratory practices questionnaire survey annually. In addition, participants will be required to submit results twice/year after testing mailed performance evaluation samples. The estimated annualized cost to respondents is $2,625.00.

Forms	Number of respondents	Frequency of responses	Average burden/response (in hours)	Total burden (in hours)
HIV Rapid Testing Questionnaire	300	1	15/60	75
HIV Rapid Testing Results Booklet	300	2	10/60	100
Total				175

Dated: February 27, 2003.

Thomas Bartenfeld,

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

[FR Doc. 03–5120 Filed 3–4–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic 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: Dermatologic and Ophthalmic 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 March 17, 2003, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: topperk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–414, VITRASE (hyaluronidase for intravitreal injection), ISTA Pharmaceuticals, for the treatment of vitreous hemorrhage. The background material for this meeting will be posted on the Internet when available or 1 working day before the meeting at http://www.fda.ohrms/dockets/ac/menu.htm.

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 March 10, 2003. 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 March 10, 2003, 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.

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 Kimberly Littleton Topper at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the March 17, 2003, Dermatologic and Ophthalmic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Dermatologic and Ophthalmic Drugs Advisory Committee

were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–5074 Filed 3–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dietary Supplement Subcommittee of the Food 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: Dietary Supplement Subcommittee of the Food 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 March 25, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn (Ballrooms A and B), 10000 Baltimore Ave., College Park, MD, 301–345–6700.

Contact Person: Constance J. Hardy, Center for Food Safety and Applied Nutrition (HFS–811), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1433, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: To be a dietary supplement as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(ff)), a product must contain at least one ''dietary ingredient.'' Section 201(ff)(1) of the act lists those substances that are considered ''dietary ingredients.'' Among other things, the term ''dietary ingredient'' includes a metabolite of any other dietary ingredient defined in section 201(ff)(1) of the act. The statute is ambiguous, however, as to what substances are, or are not, metabolites of other substances. The practical result of this ambiguity is that it is often difficult to determine whether a particular substance meets the dietary ingredient definition and, therefore, whether products containing the substance can be marketed as dietary supplements. The purpose of this meeting is to explore whether there are recognized scientific principles that would facilitate reaching a conclusion as to whether a particular substance is a ''metabolite'' of another substance that is a ''dietary ingredient'' defined in the act and, therefore, is itself a dietary ingredient within the scope of section 201(ff)(1) of the act. The background material for this meeting will be posted on the Internet when available or 1-working day before the meeting at http://www.cfsan.fda.gov/~lrd/vidtel.html.

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 March 17, 2003. Oral presentations from the public will be scheduled on March 25, 2003, between approximately 11 a.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 20, 2003, 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.

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 Constance J. Hardy at least 7 days in advance of the meeting.

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

Dated: February 27, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–5073 Filed 3–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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). The meeting will be open 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 March 18, 2003, from 10:30 a.m. to 12:45 p.m.

Location: Food and Drug Administration, 5515 Security Lane, conference room A on the 11th floor, suite 1113, Rockville, MD. This meeting will be held by a telephone conference call. The public is welcome to attend the open portion of the meeting at the location in the first sentence of this paragraph. A speaker phone will be provided at the specified location.

Contact Person: Jody G. Sachs or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–71), 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review and discuss the selection of strains to be included in the influenza virus vaccine for the 2003–2004 season.

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 March 12, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. to 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 12, 2003, 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