

**Proposed Project**

Performance Evaluation Program for Rapid HIV Testing—New—Public Health Practice Program Office (PHPPPO), 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.*

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## 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