



## Notice of upcoming Blood Products Advisory Committee Meeting: Home-use HIV Test

FDA's Center for Biologics Evaluation and Research (CBER) will discuss the design of proposed studies to support the approval of over-the-counter (OTC) home-use human immunodeficiency virus (HIV) test kits as part of a two-day meeting of FDA's Blood Products Advisory Committee. The discussion of proposed studies to support the approval of OTC Home-Use HIV Test Kits will take place on the morning of March 10, 2006, beginning at 8:30 a.m. at the Hilton Hotel, 620 Perry Parkway, Gaithersburg, MD, 20879, 301-977-8900.

There are two types of home-use tests: *collection kits* and *test kits*.

There is currently one FDA approved *home-use collection kit* on the market for HIV testing, where the user collects their own sample, mails it to a laboratory, and gets the result over the phone or in the mail.

*Home-use tests* are designed to be used at home by untrained persons without the help of a healthcare professional. Most home-use tests, such as tests for blood glucose, cholesterol, and pregnancy, are available OTC without a prescription. With a test kit, users collect their own sample, test the sample, and read/interpret their own result.

There are currently no home-use test kits approved for the detection of any infectious agent.

At the meeting, FDA will be seeking the advice of the Committee on proposed studies that would be needed to validate a home-use HIV test kit with regard to test accuracy, test interpretation, and medical follow-up based on the provision of informational material in place of a trained test operator and counselor.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to Donald W. Jehn, or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852. To speak at the open public hearing section of the meeting, please contact Donald W. Jehn, or Pearline K. Muckelvene, at 301-827-0314.

Additional information about the meeting may be obtained from the Federal Register announcement of the meeting at <http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-1075.htm> or through the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516.

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 Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

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

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An archive of past list serve announcements is available on the FDA web site at <http://www.fda.gov/oashi/aids/listserve/archive.html>

This release was provided by the FDA and posted on **AIDSinfo** Web site (<http://AIDSinfo.nih.gov>).