

Upcoming Advisory Committee Meeting

The Food and Drug Administration (FDA) will hold a public meeting of its Antiviral Drugs Advisory Committee on October 19 and 20, 2006, to discuss design issues in the development of products for treatment of chronic Hepatitis C, including co-infection with HIV.

The meeting will be held on October 19, 2006, from 8 a.m. to 4 p.m. and on October 20, 2006, from 8 a.m. to 4 p.m. at the Hilton Washington DC/Silver Spring, 8727 Colesville Rd., Silver Spring, MD, 20910 in The Ballrooms. Please note that meeting will be closed to the public on October 20 from 1 p.m. to 4 p.m., to permit discussion and review of trade secret and/or confidential information.

On both days, the committee will discuss clinical trial design issues in the development of products for the treatment of chronic hepatitis C infection. This meeting is being convened in response to the growing number of products in development for this indication. The primary objectives for committee deliberations are to discuss issues related to the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up. As noted above, on October 20, 2006, the meeting will be open to the public from 8 a.m. to 12 noon, unless public participation does not last that long, and closed to the public from 1 - 4 p.m.

Background material will become available no later than 1 business day before the meeting and will be posted on FDA's Web site at <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year "2006" and scroll down to the Antiviral Drugs Advisory Committee meeting.)

Interested parties may submit comments electronically on line at <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/dockets/ecomments>. Select "2006N-0219--Clinical Trial" and follow the prompts to submit your statement.

Written comments may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on October 5, 2006.

All comments received will be posted without change, including any personal information provided. Comments received on or before October 5, 2006, will be provided to committee members before the meeting.

Oral presentations from the public (the open public hearing section of the meeting) will be scheduled between approximately 1 p.m. and 2 p.m. on October 19, 2006. Time allotted for each presentation may be limited depending on the number of requests to speak. Those desiring to make formal oral presentations should notify the contact person (below) on or before October 5, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the name(s) and contact information of the proposed speaker(s), and an indication of the approximate time requested to make their presentation.

Contact Person: Cicely Reese, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: cicely.reese@fda.hhs.gov

For up-to-date information about the meeting, please use the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and enter code no. 3014512531.

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 Cicely Reese at least 7 days in advance of the meeting.

No registration is necessary.

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

If you need hotel accommodations or directions, please contact the hotel directly at 301-589-5200.

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Food and Drug Administration

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>).