

important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices (§ 10.115(f)(5)). The CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each FY from 2008 to 2012.

To access the list of the guidance documents CDRH is considering for development in 2009, visit the FDA Web Site at <http://www.fda.gov/cdrh/mdufma/guidance/agenda/fy09.html>.

## II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments submitted to this docket may include draft guidance documents that stakeholders have prepared for FDA's consideration.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: September 24, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0038]

### Antiviral 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). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Antiviral 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 October 30, 2008, from 9 a.m. to 1 p.m.

**Location:** Hilton Washington DC/ Silver Spring, The Ballrooms, 1750 Rockville Pike, Rockville, MD, 301-468-1100.

**Contact Person:** Paul Tran, 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, 301-827-6793, FAX: 301-827-6776, e-mail:

[paul.tran@fda.hhs.gov](mailto:paul.tran@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512531. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The meeting will be open to the public from 8 a.m. to 9 a.m., unless public participation does not last that long, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion of current and future advances on antiviral drugs which will include the review of trade secret and/or confidential information.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

**Procedure:** On October 30, 2008, from 8 a.m. to 9 a.m., the meeting is open to the public. 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 on or before October 16, 2008. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before October 7, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 8, 2008.

**Closed Committee Deliberations:** On October 30, 2008, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During this session, the committee will be updated on current and future advances on antiviral drugs.

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 Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: September 19, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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