U.S. Food and Drug Administration

Advisory Committees

June 17, 2010: Reproductive Health Drugs Advisory Committee Meeting Announcement

Center	Date	Time	Location
CDER	June 17, 2010	8:00 a.m. to 4:30 p.m.	Hilton Washington DC North/Gaithersburg The Ballrooms 620 Perry Parkway Gaithersburg, Maryland

Agenda

The committee will discuss new drug application (NDA) 22-474, ulipristal acetate tablets, 30 milligrams (mg), by Laboratoire HRA Pharma. Ulipristal is an emergency contraceptive for the proposed indication of the prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure.

Meeting Materials

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.

- 2010 Meeting Materials, Reproductive Health Drugs Advisory Committee [1]

Public Participation Information

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 June 3, 2010.
- Oral presentations from the public will be scheduled between approximately 1:00 PM-2:00 PM June 17, 2010. 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 May 25, 2010.

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 May 26, 2010.

Contact Information

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  (301-443-0572 in the Washington DC area)
  Code: 3014512537
  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 Website and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

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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 disabilitie or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at (301) 827-7001 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 Public Conduct During FDA Advisory Committee Meetings [2] 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).

Links on this page:

1. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm210869.htm

2. http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm