

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2010-N-0001]

### Advisory Committee for Reproductive Health Drugs; 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:* Advisory Committee for Reproductive Health Drugs.

*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 June 17, 2010, from 8 a.m. to 4:30 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301-977-8900.

*Contact Person:* Kalyani Bhatt, 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:

*Kalyani.Bhatt@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in 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 Web site and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On June 17, 2010, 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.

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/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*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 on or before June 2, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 May 24, 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 25, 2010.

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 Kalyani Bhatt 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: April 21, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2010-9660 Filed 4-26-10; 8:45 am]

**BILLING CODE 4160-01-S**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2010-N-0001]

### Advisory Committee for Reproductive Health Drugs; 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:* Advisory Committee for Reproductive Health Drugs.

*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 June 18, 2010, from 8 a.m. to 4:30 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301-977-8900.

*Contact Person:* Kalyani Bhatt, 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:

*Kalyani.Bhatt@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in 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 Web site and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On June 18, 2010, the committee will discuss new drug application (NDA) 22-526, flibanserin

100 milligram (mg) tablets, by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed indication of the treatment of hypoactive sexual desire disorder in premenopausal women.

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/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**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 on or before June 3, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 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.

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 Kalyani Bhatt 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: April 12, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2010-9661 Filed 4-26-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council will meet on May 11-12 at SAMHSA, Rockville, Maryland. The meeting is open to the public.

The SAMHSA National Advisory Council was established to advise the Secretary, Department of Health and Human Services (HHS), and the Administrator, SAMHSA, to reduce the impact of substance abuse and mental illnesses in American communities. The Agenda will include a report from the new SAMHSA Administrator and presentations and discussions related to SAMHSA's 10 strategic initiatives that will focus the Agency's work on improving lives and capitalizing on emerging opportunities that advance and protect the Nation's health.

Attendance by the public will be limited to space available. Public comments are welcome. The meeting can also be accessed via webstream. To obtain the call-in numbers and access codes, to submit written or brief oral comments, or to request special accommodations for persons with disabilities, please register on-line at <https://nac.samhsa.gov/Registration/meetingsRegistration.aspx>. You may also communicate with the SAMHSA National Advisory Council Designated Federal Officer, Ms. Toian Vaughn (see contact information below).

Substantive program information and a roster of Council members may be obtained either by accessing the SAMHSA Committee Web site, <https://nac.samhsa.gov/NACcouncil/index.aspx> or by contacting Ms. Vaughn. The transcript for the meeting will be available on the SAMHSA Committee Web site within three weeks after the meeting.

**Committee Name:** SAMHSA National Advisory Council.

**Date/Time/Type:** Tuesday, May 11, 2010, from 9 a.m. to 6 p.m.: OPEN. Wednesday, May 12, 2010, from 9 a.m. to 3 p.m.: OPEN.

**Place:** Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Rd., Sugarloaf and Seneca Conference Rooms, Rockville, Maryland 20857.

**Contact:** Toian Vaughn, M.S.W., Designated Federal Official, SAMHSA National Advisory Council and SAMHSA Committee Management Officer, 1 Choke Cherry Road, Room 8-1089, Rockville, Maryland 20857, Telephone: (240) 276-2307; FAX: (240) 276-2220 and E-mail: [toian.vaughn@samhsa.hhs.gov](mailto:toian.vaughn@samhsa.hhs.gov).

**Toian Vaughn,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 2010-9715 Filed 4-26-10; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA-2010-N-0001]**

#### Tobacco Product Constituents Subcommittee of the Tobacco Products Scientific 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:** Tobacco Product Constituents Subcommittee of the Tobacco Products Scientific 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 June 8, 2010, from 8:30 a.m. to 5 p.m. and on June 9, 2010, from 8 a.m. to 5 p.m.

**Location:** Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301-948-8900.

**Contact Person:** Karen Templeton-Somers, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose Option 4), e-mail:

[TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov) or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732110002. Please call the Information