DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 22 and 23, 2010, from 8 a.m. to 4:30 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, 3501 University Boulevard East, Adelphi, MD. The conference center telephone number is 301–985–7300.

Contact Person: Kristine T. Khuc, c/o Melanie Whelan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993–0002, FAX: 301–847–8737, to reach by telephone before June 8, 2010, please call 301–827–7001; to reach by telephone after June 8, 2010, please call 301 796–9001, e-mail: *Kristine.khuc@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512529 and 3014512535. 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 committees will discuss Risk Evaluation and Mitigation Strategies (REMS) for extended-release and long-acting opioid analgesics. As a part of the materials for the meeting, FDA anticipates presenting a proposal for a class-wide opioid REMS and will solicit feedback from the advisory committees and public on the components of that proposal. The need for adequate pain control is an element of good medical practice. In this context, some persons suffering from pain need access to potent opioid drug products; however, inappropriate prescribing, addiction, and death due to prescription opioid abuse and misuse have been increasing over the last decade.

FDA intends to make background material available to the public no later than 2 business days before the meeting. For this particular meeting, FDA anticipates that the briefing materials will not contain information that, under certain circumstances, could be considered exempt from public disclosure under the Freedom of Information Act. Therefore, FDA anticipates making the briefing materials available on our Web site no later than 2 weeks before the day the advisory committee meeting is scheduled to occur. 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 July 8, 2010. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. on July 23, 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 June 29, 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 July 2, 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 Kristine T. Khuc 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: June 2, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–13535 Filed 6–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Endocrinologic and Metabolic 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). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic 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 July 15, 2010, from 8 a.m. to 5 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: Paul Tran, c/o Melanie Whelan, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993–0002, FAX: 301–847–8737, to reach by telephone before June 8, 2010, please call 301–827–7001; to reach by telephone after June 8, 2010, please call 301–796–9001, e-mail: *Paul.Tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. 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: On July 15, 2010, the committee will discuss the safety and efficacy of new drug application (NDA) 22–580, proposed tradename QNEXA (phentermine/topiramate) Controlled Release Capsules, by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index of 30 kilograms (kg) per square meter, or a body mass index equal to or greater than 27 kg per square meter if accompanied by weight-related co-morbidities.

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 30, 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 June 22, 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 June 23, 2010.

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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: June 2, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–13534 Filed 6–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13, 2010, from 8 a.m. to 6 p.m. and on July 14, 2010, from 8 a.m. to 5 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: Paul Tran, c/o Melanie Whelan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993–0002, FAX: 301–847–8737, to reach by telephone before June 8, 2010, please call 301–827–7001; to reach by telephone after June 8, 2010, please call 301–796–9001, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512536 and 3014512535. 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: On both days, the committees will focus primarily on the cardiovascular safety of AVANDIA (rosiglitazone maleate) Tablets, GlaxoSmithKline, a drug approved for blood glucose control in adults with type 2 diabetes mellitus. Data specific to rosiglitazone to be presented will include results from the Rosiglitazone Evaluated for Cardiac Outcome and Regulation of Glycemia in Diabetes (RECORD) Trial, observational data, health claims data, and a meta-analysis of controlled clinical trials. In addition, the FDA will present its meta-analysis of several trials of ACTOS (pioglitazone hydrochloride) Tablets, Takeda Pharmaceuticals North America, Inc., another thiazolidinedione for the same indication, in response to public documents comparing the safety of rosiglitazone to pioglitazone based on different meta-analyses performed on each of these two drugs.

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