

Dated: January 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-1270 Filed 1-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Peripheral and Central Nervous System 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: Peripheral and Central Nervous System 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 March 10, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: diem.ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 March 10, 2011, the committee will discuss, in general, the use of historical-controlled trials for the

approval of anticonvulsant monotherapy for seizures of partial origin for antiepileptic drug products that are already approved for adjunctive therapy. The committee will also discuss how this may specifically apply to the approval of the supplemental new drug application 022115/S-011, LAMICTAL XR (lamotrigine extended-release tablets), sponsored by SmithKline Beecham Corp. d/b/a GlaxoSmithKline, for monotherapy in patients 13 years of age and older with partial seizures who are receiving therapy with a single antiepileptic drug.

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 February 24, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making 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 February 15, 2011. 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 February 16, 2011.

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 Diem-Kieu Ngo 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/ucm11462.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: January 18, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-1264 Filed 1-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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 Pharmaceutical Science and Clinical Pharmacology.

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 March 2, 2011, from 7:15 a.m. to 3 p.m.

Location: Hyatt Regency Dallas at Reunion, Landmark Ballroom, 300 Reunion Blvd., Dallas, TX 75207. The hotel phone number is 214-651-1234.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8540, e-mail: yvette.waples@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow prompts to the desired center or product area. 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 committee will discuss innovative approaches to the development of drugs for orphan and rare diseases to support decisions such as dose and trial design selection. FDA will seek input and comment on how to optimally utilize mechanistic biomarkers and apply clinical pharmacology tools, such as pharmacogenetics and modeling and simulation, to facilitate efficient and informative drug development and regulatory review. FDA will present and seek input from the committee on how lessons learned from other applications of clinical pharmacology tools in pediatrics and oncology can be applied to orphan and rare disease drugs. The committee will be asked to comment on the current status and future direction for clinical pharmacology studies (e.g., dose-response, drug-drug interactions, pharmacokinetics in patients with renal or hepatic impairment) as they pertain to drug development for orphan and rare diseases.

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 February 15, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making 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 February 7, 2011. 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 February 8, 2011.

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 Yvette Waples, 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: January 18, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-1223 Filed 1-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Council on Blood Stem Cell Transplantation.

Date and Time: February 4, 2011, from 3 p.m. to 5 p.m. EST.

ACTION: Notice of Advisory Council on Blood Stem Cell Transplantation (ACBSCT) Meeting to be Held by Conference Call.

SUMMARY: The ACBSCT will be conducting a conference call to discuss:

- (1) Final language of recommendations from November 15, 2010, Council meeting; and
- (2) Interim Report to Congress.

DATES: The conference call will be held on February 4, 2011, at 3 p.m. to 5 p.m. EST. Participants must dial: (800) 988-9536 and enter the corresponding pass code 2741198. Patricia A. Stroup, MBA, MPA, is the call leader. Participants should call no later than 2:50 p.m. EST in order for the logistics to be set up. Participants are asked to register for the conference by contacting Passy Tongele at (301) 443-0437 or e-mail ptongele@hrsa.gov. The registration deadline is February 2, 2011. The Department will try to accommodate those wishing to participate in the call.

Any member of the public can submit written materials that will be distributed to Council members prior to the conference call. Parties wishing to submit written comments should ensure that the comments are received no later than February 2, 2011, for consideration. Comments should be submitted to Passy Tongele, Healthcare

Systems Bureau, HRSA, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-0437; fax (301) 594-6095; or e-mail to ptongele@hrsa.gov.

Members of the public can present oral comments during the conference call during the public comment period. If a member of the public wishes to speak, the Department should be notified at the time the participant registers. Others members of the public will be allocated time if time permits.

FOR FURTHER INFORMATION CONTACT:

Patricia A. Stroup, MBA, MPA, Executive Secretary, ACBSCT, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-1127; fax (301) 594-6095; or e-mail to pstroup@hrsa.gov.

SUPPLEMENTARY INFORMATION: The purpose of this call is to hear discussion from the ACBSCT members on the final language of the eight recommendations approved at the November 15, 2010, Council meeting and to discuss the Interim Report to Congress. Public Law 111-264 states that “* * * the Secretary of Health and Human Services * * * in consultation with the Advisory Council * * * shall submit to Congress an interim report not later than 180 days after the date of enactment of this Act describing (A) the methods to distribute Federal funds to cord blood banks used at the time of submission of the report; (B) how cord blood banks contract with collection sites for the collection of cord blood units; and (C) recommendations for improving the methods to distribute Federal funds described in subparagraph (A) in order to encourage the efficient collection of high-quality and diverse cord blood units.”

Dated: January 14, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011-1266 Filed 1-20-11; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA. The