

Name of Committees:
Nonprescription Drugs Advisory Committee and the Pediatric 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 May 17, 2011, from 8 a.m. to 5 p.m. and on May 18, 2011, from 8 a.m. to 12 noon.

ADDRESSES: FDA is opening a docket for public comment on this meeting. The docket number is FDA-2011-N-0002. The docket will open for public comment on *March 9, 2011*. The docket will close on June 30, 2011. Interested persons may submit electronic or written comments regarding this meeting. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Submit a single copy of electronic comments or a paper copy 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 meeting notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments received on or before May 3, 2011, will be provided to the committee before the meeting.

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 May 17 and 18, 2011, the committees will review pertinent pharmacokinetic (how drugs are absorbed, distributed, used, and eliminated by the body), safety and efficacy data, and discuss whether new dosing information for oral over-the-counter (OTC) drug products containing acetaminophen should be added to the label for children less than 2 years of age. In addition, the committees will consider adding a weight-based dosing regimen to the existing age-based dosing regimen for children 2 to 12 years of age. Dosing for children 12 years of age and older will not be discussed. Lastly, the committees will discuss ways that administration by caregivers can be improved so that medication errors can be minimized.

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. All electronic and written submissions submitted to the Docket (*see* the **ADDRESSES** section of this document) on or before May 3, 2011, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 3 p.m. and 5 p.m. on May 17, 2011. 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 April 25, 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 April 26, 2011.

FDA will work with sponsors of acetaminophen products who wish to make presentations to ensure that adequate time, separate from the 3 p.m. to 5 p.m. time slots for the general open public hearing, is provided. Sponsors interested in making formal presentations to the committees should notify the contact person on or before April 25, 2011. Sponsors with common interest are urged to coordinate their oral presentations.

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/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: March 3, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2011-5284 Filed 3-8-11; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Neurological Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of February 7, 2011 (76 FR 6625). The amendment is being

made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Olga I. Claudio, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, 301-796-7608, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 7, 2011, FDA announced that a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee would be held on March 17 and 18, 2011. On page 6625, in the second column, in the last paragraph, in the first and second sentences, the "for the NovoTTF-100A Treatment Kit, sponsored by Hogan Lovells US LLP for NovoCure, Ltd. The NovoTTF-100A Treatment Kit" portion of the document is changed to read as follows: "for the NovoTTF-100A System, sponsored by NovoCure, Ltd. The NovoTTF-100A System".

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5285 Filed 3-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2010-E-0483 and FDA-2010-E-0484]

Determination of Regulatory Review Period for Purposes of Patent Extension; AMPYRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AMPYRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>.

Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these Acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product AMPYRA (dalfampridine). AMPYRA is indicated to improve walking in patients with multiple sclerosis. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for AMPYRA (U.S. Patent Nos. 5,370,879 and 5,540,938) from Elan Pharma International Ltd., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term

restoration. In a letter dated September 30, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AMPYRA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for AMPYRA is 9,845 days. Of this time, 9,569 days occurred during the testing phase of the regulatory review period, while 276 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* February 10, 1983. The applicant claims January 1, 1980, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was initially placed on clinical hold. The applicant was informed that the investigational studies were allowed to proceed on February 10, 1983, the effective date of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 22, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for AMPYRA (NDA 22-250) was submitted on April 22, 2009.

3. *The date the application was approved:* January 22, 2010. FDA has verified the applicant's claim that NDA 22-250 was approved on January 22, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,827 and 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments and ask for a redetermination by May 9, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 5, 2011. To meet its burden, the petition must contain sufficient facts