

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 RAPLON (Rapacuronium Bromide). RAPLON is indicated as an adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgical procedures. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for RAPLON (U.S. Patent No. 5,418,226) from Akzo Nobel N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of RAPLON represented the first permitted commercial marketing or use of the product. Shortly 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 RAPLON is 1,724 days. Of this time, 1,304 days occurred during the testing phase of the regulatory review period, while 420 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 act) (21 U.S.C. 355(i)) became effective:* November 30, 1994. The applicant claims October 31, 1994, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was November 30, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 25, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for RAPLON (NDA 20-984) was initially submitted on June 25, 1998.

3. *The date the application was approved:* August 18, 1999. FDA has verified the applicant's claim that NDA 20-984 was approved on August 18, 1999.

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 application for patent extension, this applicant seeks 126 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**) written or electronic comments and ask for a redetermination by August 6, 2007. 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 December 3, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E7-10853 Filed 6-5-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0215]

#### 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 30, 2007, from 8 a.m. to 5 p.m.

*Addresses:* Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2007N-0215—Thiazolidinedione" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on July 23, 2007. All comments will be posted without change, including any personal information provided. Comments received on or before July 23, 2007, will be provided to the committee before the meeting.

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

*Contact Person:* Cathy A. Miller, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1099), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [Cathy.Miller1@fda.hhs.gov](mailto:Cathy.Miller1@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:* The Endocrinologic and Metabolic Drugs and the Drug Safety and Risk Management Advisory Committees will meet in joint session to discuss the cardiovascular ischemic/thrombotic risks of the thiazolidinediones, with focus on rosiglitazone, as presented by FDA and GlaxoSmithKline.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and 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 6, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2:30 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 28, 2007. 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 29, 2007.

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 John Luttman, 301-827-7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 31, 2007.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E7-10850 Filed 6-5-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel, Comparative Medicine SEP.

*Date:* June 12, 2007.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mohan Viswanathan, PhD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6705 Democracy Blvd., 1 Democracy Plaza, Room 1084, MSC 4874, Bethesda, MD 20892-4874, 301-435-0829, [viswanathanm@ncrr.nih.gov](mailto:viswanathanm@ncrr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure; 93.306, 93.333, National Institutes of Health, HHS)

Dated: May 30, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-2794 Filed 6-5-07; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel, T-SEP.

*Date:* June 26, 2007.

*Time:* 10 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Room 1068, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* John R. Glowa, PhD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1078, MSC 4874, Bethesda, MD 20892-4874, 301-435-0807, [glowaj@mail.nih.gov](mailto:glowaj@mail.nih.gov).

*Name of Committee:* National Center for Research Resources Special Emphasis Panel, CR-SEP.

*Date:* July 10, 2007.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* John R. Glowa, PhD, Scientific Review Administrator, National Institutes of Health, NCRR/ or 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1078-MSC 4874, Bethesda, MD 20892-4874, 301-435-0807, [glowaj@mail.nih.gov](mailto:glowaj@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389 Research Infrastructure,