DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E–0252]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYCAMINE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 MYCAMINE (micafungin sodium). MYCAMINE is indicated for treatement of patients with esophageal candidiasis and prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MYCAMINE (U.S. Patent No. 5,376,634) from Astellas Pharma, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MYCAMINE 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 MYCAMINE is 2,546 days. Of this time, 2,221 days occurred during the testing phase of the regulatory review period, while 325 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: March 29, 1998. The applicant claims June 30, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 29, 1998, 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 of the act*: April 26, 2004. The applicant claims April 23, 2004, as the date the new drug application (NDA) for MYCAMINE (NDA 21–754) was initially submitted. However, FDA records indicate that NDA 21–754 was submitted on April 26, 2004.

3. *The date the application was approved*: March 16, 2005. FDA has verified the applicant's claim that NDA 21–754 was approved on March 16, 2005.

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 476 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 May 22, 2006. 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 19, 2006. 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: February 13, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–4165 Filed 3–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Dates and Times: April 6, 2006, 3 p.m.–5:30 p.m. April 7, 2006, 8:30 a.m.–4 p.m.

Place: DoubleTree Hotel and Executive Center, 1750 Rockville Pike, Rockville, Maryland 20852.

Status: The meeting will be open to the public.

Agenda: Agency and Bureau administrative updates will be provided. The purpose of the meeting will be to address issues related to the status of the nursing workforce. A representative from the Bureau of Health Professions will present an overview of the preliminary findings from the 2004 National Sample Survey of Registered Nurses. In addition, representatives from the Bureau of Labor Statistics will present data on registered nurses employment projections from 2004 to 2014. During this meeting, Council workgroups will deliberate on content presented and formulate recommendations to the Secretary of Health and Human Services and the Congress on nursing workforce issues based on the latest data and trends. This meeting will form the basis for NACNEP's mandated Sixth Annual Report.

FOR FURTHER INFORMATION CONTACT: Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Ms. Donna English, M.P.H., R.N., Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9–35, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–5688.

Dated: March 16, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–4166 Filed 3–22–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Subcommittee D—Clinical Studies, April 9, 2006, 6 p.m. to April 10, 2006, 5 p.m., Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814 which was published in the **Federal Register** on March 9, 2006, 71 FR 12202.

The meeting is amended to change the meeting location from Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814 to Marriott Bethesda North Hotel Conference Ctr, 5701 Marinelli Rd., N. Bethesda, MD 20852. The meeting is closed to the public.

March 17, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–2817 Filed 3–22–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Academic/Teacher Award (K07s).

Date: March 21, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: William J. Johnson, PhD., Scientific Review Administrator, Review Branch, Division of Extramural Affairs, NIH/NHLBI, 6701 Rockledge Drive, Bethesda, MD 20892–7924, 301–435–0317, *johnsonw@nhlbi.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.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, The Career Enhancement Award (K18s).

Date: April 4, 2006.

Time: 1:30 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Keith A. Mintzer, PhD., Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892–7924, (301) 435–0280, *mintzerk@nhlbi.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. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 16, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–2821 Filed 3–22–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, March 31, 2006, 3 p.m. to March 31, 2006, 4 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which is published in the **Federal Register** on March 14, 2006, 71 FR 13131.

This meeting has been changed to April 3, 2006, from 5 p.m. to 6 p.m. The location remains the same. The meeting is closed to the public.

Dated: March 16, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–2819 Filed 3–22–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Neurological Disorders and Stroke; Notice of Meeting

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

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such