DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0048 and FDA 2009–E–0047]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEXISCAN 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 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.regulations.gov*.

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 (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 LEXISCAN (regadenoson monohydrate). LEXISCAN is indicated for radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for LEXISCAN (U.S. Patent Nos. 6,403,567 and 6,642,210) from CV Therapeutics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LEXISCAN 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 LEXISCAN is 2,446 days. Of this time, 2,113 days occurred during the testing phase of the regulatory review period, while 333 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*: August 1, 2001. The applicant claims August 2, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 2001, 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*: May 14, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22–161 was submitted on May 14, 2007.

3. *The date the application was approved*: April 10, 2008. FDA has verified the applicant's claim that NDA 22–161 was approved on April 10, 2008.

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 1,024 days and 977 days of patent term extension, respectively.

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 October 23, 2009. 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 February 22, 2010. 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: July 31, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–20307 Filed 8–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Diabetes and Lipids.

Date: September 15–16, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Weinberg, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892. 301–435–1044. *David.Weinberg@nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: September 17–18, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892. 301–435–1779. *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Microbiology and Epidemiology.

Date: September 18, 2009.

Time: 1 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: Liangbiao Zheng, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892. 301–402–5671. *zhengli@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Alcohol and Toxicology.

Date: September 22–23, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Christine L. Melchior, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892. (301) 435–1713. *melchioc@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Immunopathology and Immunotherapy Study Section.

Date: September 23–24, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Denise R. Shaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892. 301–435–0198. *shawdeni@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Cell Death in Neurodegeneration Study Section.

Date: September 24–25, 2009.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, 1250 22nd Street, NW., Washington, DC 20037.

Contact Person: Boris P. Sokolov, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892. 301–435–1197. *bsokolov@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Biological Rhythms and Sleep Study Section.

Date: September 29, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1208, MSC 7844, Bethesda, MD 20892. 301–435–1119. *mselmanoff@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroendocrinology, Neuroimmunology, and Behavior Study Section.

Date: September 30–October 1, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892. 301–435–1119. *mselmanoff@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics B Study Section.

Date: September 30–October 1, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Mark Hopkins San Francisco, One Nob Hill, San Francisco, CA 94108.

Contact Person: Richard A. Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892. (301) 435–1219. *currieri@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 17, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–20329 Filed 8–21–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of 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, National Human Genome Research Institute.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Human Genome Research Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Human Genome Research Institute.

Date: November 16–18, 2009.

Open: November 16, 2009, 5:45 p.m. to 7 p.m.

Agenda: To discuss matters of program relevance.

Place: Eisenhower Hotels, Conference Center and Resort, 2634 Emmitsburg Road, Gettysburg, PA 17325.

Closed: November 16, 2009, 7 p.m. to 9:30 p.m.

Agenda: To review and evaluate personal qualifications and performance and competence of individual investigators.

Place: Eisenhower Hotels, Conference Center and Resort, 2634 Emmitsburg Road, Gettysburg, PA 17325.