products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product 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 approved for marketing the human drug product TYZEKA. TYZEKA is indicated for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for TYZEKA (U.S. Patent Nos. 6,395,716 and 6,569,837) from Idenix Pharmaceuticals, Inc., Centre National de La Recherche Scientifique, and L'Universite Montpellier II, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 16, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TYZEKA 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 TYZEKA is 2,309 days. Of this time, 2,009 days occurred during the testing phase of the regulatory review period, while 300 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: July 1, 2000. The applicant claims the investigational new drug application (IND) was under clinical hold until August 15, 2000, and claims that date as the date the IND became effective. However, according to FDA records, the IND was considered safe to proceed with some recommendations that were sent to the sponsor to consider prior to commencement of the study. The IND effective date was July 1, 2000, 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: December 30, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for TYZEKA (NDA 22–011) was initially submitted on December 30, 2005.

3. The date the application was approved: October 25, 2006. FDA has verified the applicant's claim that NDA 22–011 was approved on October 25, 2006.

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 442 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 July 14, 2008. 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 November 12, 2008. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

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

[FR Doc. E8–10857 Filed 5–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Biophysics of Neural Systems Study Section, June 12, 2008, 8 a.m. to June 12, 2008, 8 p.m., Hotel Lombardy, 2019 Pennsylvania Avenue, NW., Washington, DC 20006 which was published in the **Federal Register** on April 29, 2008, 73 FR 23257–23259.

The meeting will be held June 12, 2008, 8 a.m. to June 13, 2008, 4 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 7, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–10671 Filed 5–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, June 10, 2008, 6 a.m. to June 11, 2008, 6 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 29, 2008, 73 FR 23257–23259.

The meeting is cancelled due to the applications being withdrawn.

Dated: May 7, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–10672 Filed 5–14–08; 8:45 am]

BILLING CODE 4140–01–M