assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 9, 2008.

A. Federal Reserve Bank of Chicago (Burl Thornton, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Premier Bancorp of Illinois, Inc., Farmer City, Illinois, to retain 20.8 percent of the voting shares of F M Bancorp, Inc., and thereby indirectly retain voting shares of Farmers–Merchants National Bank of Paxton, both of Paxton, Illinois.

B. Federal Reserve Bank of San Francisco (Kenneth Binning, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105–1579:

1. Bank of Whitman Employee Stock Ownership Plan, Colfax Washington, to acquire 56 percent of the voting shares of Whitman Bancorporation Incorporated, Colfax, Washington, and thereby indirectly acquire voting shares of Bank of Whitman, Colfax, Washington.

Board of Governors of the Federal Reserve System, May 12, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc.E8–10859 Filed 5–14–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the Announcement of Availability of Funds for Grants regarding Ambulatory Safety and Quality Program: Improving Management of Individuals with Complex Healthcare Needs through Health IT (R18) applications are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: Ambulatory Safety and Quality Program: Improving Management of Individuals with Complex Healthcare Needs through Health IT (R18).

Date: June 18–20, 2008 (Open on June 18 from 5 p.m. to 5:15 p.m. and closed for the remainder of the meeting).

Place: Crowne Plaza, Conference Room TBD, 3 Research Blvd, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: May 5, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–10565 Filed 5–14–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0035 (formerly Docket No. 2007E–0133) and [Docket No. FDA–2007–E–0227 (formerly Docket No. 2007E–0148)]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TYZEKA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submissions 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 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