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 Commissioner 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 NISOCOR (nisoldipine). NISOCOR is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NISOCOR (U.S. Patent No. 4,154,839) from Bayer AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 22, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NISOCOR 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 NISOCOR is 4,965 days. Of this time, 4,292 days occurred during the testing phase of the regulatory review period, while 673 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 (21 U.S.C. 355(i)) became effective*: July 2, 1981. The applicant claims May 22, 1989, as the date the investigational new drug application (IND) became effective, based on IND 33,244. However, FDA records indicate that the effective date for the first IND submitted for NISOCOR, IND 18,813, was July 2, 1981, 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 Federal Food, Drug, and Cosmetic Act*: April 1, 1993. The applicant claims March 31, 1993, as the date the new drug application (NDA) for NISOCOR (NDA 20–356) was initially submitted. However, FDA records indicate that NDA 20–356 was submitted on April 1, 1993.

3. *The date the application was approved*: February 2, 1995. FDA has verified the applicant's claim that NDA 20–356 was approved on February 2, 1995.

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 1,377 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 29, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 29, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affiars.

[FR Doc. 95–18687 Filed 7–28–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; 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 of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications
Committee Name: National Institute of Mental Health Special Emphasis Panel
Date: July 30–August 1, 1995
Time: 7 p.m.
Place: Galleria Park Hotel, 191 Sutter Street, San Francisco, CA 94104
Contact Person: Jean G. Noronha, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel
Date: August 2–August 4, 1995
Time: 7 p.m.
Place: Madison Hotel, 1177 15th Street NW., Washington, DC 20036
Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel
Date: August 16, 1995
Time: 8:30 a.m.
Place: Loews, 51st and Lexington, New York, NY
Contact Person: Angela L. Redlingshafer, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443–1367.

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

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, Small Business Innovation Research; 93.242, Mental Health