approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Albunex® Albunex® is indicated as an aid for ultrasound contrast enhancement of ventricular chambers and improvement of endocardial border definition in patients with suboptimal echoes undergoing ventricular function and regional wall motion studies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Albunex® (U.S. Patent No. 4,844,882) from Molecular Biosystems, 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 December 19, 1994, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Albunex® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory

FDA has determined that the applicable regulatory review period for Albunex® is 2,397 days. Of this time, 975 days occurred during the testing phase of the regulatory review period, while 1,422 days occurred during the approval phase. These periods of time were derived from the following dates:

- 1. The date a clinical investigation involving this device was begun: January 14, 1988. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) for human tests to begin became effective on August 18, 1987. However, FDA records indicate that IDE was conditionally approved on January 14, 1988, which represents the IDE effective date.
- 2. The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

360e): September 14, 1990. The applicant claims September 11, 1990, as the date the premarket approval application (PMA) for Albunex® (PMA P900059) was initially submitted. However, FDA records indicate that PMA P900059 was submitted on September 14, 1990.

3. The date the application was approved: August 5, 1994. FDA has verified the applicant's claim that PMA P900059 was approved on August 5, 1994.

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 763 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 1, 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 August 29, 1995, 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: February 24, 1995.

## Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 95–5183 Filed 3–1–95; 8:45 am] BILLING CODE 4160–01–F

## **National Institutes of Health**

## Division of Research Grants; 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 Division

of Research Grants Special Emphasis Panel (SEP) meetings:

*Purpose/Agenda:* To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

eurosciences.

Date: March 2, 1995.

Time: 1:00 p.m.

*Place:* NIH, Westwood Building, Room 309, Telephone Conference.

Contact Person: Dr. Jane Hu, Scientific Review Administrator, 5333 Westbard Ave., Room 309, Bethesda, MD 20892, (301) 594– 7269.

*Name of SEP:* Behavioral and Neurosciences.

Date: March 20, 1995.

Time: 1:30 p.m.

*Place:* NIH, Westwood Building, Room 303, Telephone Conference.

Contact Person: Dr. Teresa Levitin, Scientific Review Administrator, 5333 Westbard Ave., Room 303, Bethesda, MD 20892, (301) 594–7141.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 20, 1995.

Time: 12:00 noon.

*Place:* NIH, Westwood Building, Room 226, Telephone Conference.

Contact Person: Dr. Gerald Liddel, Scientific Review Admin., 5333 Westbard Ave., Room 226, Bethesda, MD 20892, (301) 594–7167.

Name of SEP: Biological and Physiological Sciences.

Date: March 23, 1995.

Time: 1:00 p.m.

*Place:* NIH, Westwood Building, Room 233A, Telephone Conference.

Contact Person: Dr. Robert Su, Scientific Review Administrator, 5333 Westbard Ave., Room 233A, Bethesda, MD 20892, (301) 594–7320.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 31, 1995.

Time: 10:00 a.m.

*Place:* NIH, Westwood Building, Room 226, Telephone Conference.

Contact Person: Dr. Gerald Liddel, Scientific Review Admin., 5333 Westbard Ave., Room 226, Bethesda, MD 20892, (301) 594–7167.

The meetings will be closed in accordance with the provisions set forth in secs. 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 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 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)