(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

Director.

[FR Doc. 95–5156 Filed 3–1–95; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–1044–DR]

Amendment to Notice of a Major Disaster Declarations; CA

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of California, (FEMA–1044–DR), dated January 10, 1995, and related determinations.

EFFECTIVE DATE: February 21, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of California dated January 10, 1995, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of January 10, 1995:

The counties of El Dorado, Madera, and Solano for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Richard W. Krimm,

Associate Director, Response and Recovery Directorate.

[FR Doc. 95–5155 Filed 3–1–95; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

MSL Express Inc., 160–19 Rockaway Boulevard C, Jamaica, NY 11434, Officers: Chester Tong, President, Lily Tong, Vice President

New K.S.A.I. Inc., 9009 La Cienega Boulevard, Inglewood, CA 90301, Officers: Kunihiro Iwahashi, President, Satoshi Hattori, Treasurer

Dated: February 27, 1995.

By the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 95–5124 Filed 3–1–95; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Eastside Holding Corporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than March 27, 1995.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Eastside Holding Corporation, Snellville, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of The Eastside Bank & Trust Company, Snellville, Georgia.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Guaranty Development Company, Livingston, Montana; to acquire 100 percent of the voting shares of American Bank (Whitefish), Whitefish, Montana.

Board of Governors of the Federal Reserve System, February 24, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–5118 Filed 3–1–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94E–0360]

Determination of Regulatory Review Period for Purposes of Patent Extension; Albunex®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Albunex® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The

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 review period.

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.

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)