FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 3987N.
Name: Abdulrazak Morgan Farah dba Overseas Express Services.
Address: 17206 S. Figueroa Street, Gardena, CA 90248.
Date Revoked: January 1, 2003.
Reason: Failed to maintain a valid bond.

License Number: 16183F.
Name: AJ International Shipping/ Logistics, Inc.
Address: 4548 Mundy Road, Jacksonville, FL 32207.
Date Revoked: September 25, 2002.
Reason: Surrendered license voluntarily.

License Number: 3883N.
Name: Brye International, Inc.
Address: 108 So. Franklin Avenue, Suite 15, Valley Stream, NY 11580.
Date Revoked: December 3, 2002.
Reason: Surrendered license voluntarily.

License Number: 17662N.
Name: Cargozone Trans Corporation.
Address: 19550 Dominguez Hills Drive, Rancho Dominguez, CA 90220.
Date Revoked: January 11, 2003.
Reason: Failed to maintain a valid bond.

License Number: 17037N.
Name: Global Network Financial Services, Inc. dba Global Network.
Address: 1237 NW 93 Court, Miami, FL 33178.
Date Revoked: January 2, 2003.
Reason: Failed to maintain a valid bond.

License Number: 5892N and 5892F.
Name: Greenbriar Forwarding Co., Inc.
Address: 108 Liberty Street, Metuchen, NJ 08840.
Date Revoked: November 22, 2002 and December 22, 2002.
Reason: Failed to maintain valid bonds.

License Number: 11972N and 11972F.
Name: Magna Transportation Inc.
Address: 515 N. Sam Houston Pkwy. East, Suite 340, Houston, TX 77060.
Date Revoked: December 25, 2002 And December 6, 2002.
Reason: Failed to maintain valid bonds.

License Number: 4648F.
Name: Mega Express, Inc.
Address: 6481 Orangethorpe Avenue, #21, Buena Park, CA 90620.
Date Revoked: November 18, 2002.
Reason: Surrendered license voluntarily.

License Number: 12367N.
Name: Maritime Express, Inc.
Address: 9009 Pinehill Line, #226, Houston, TX 77041.
Date Revoked: November 30, 2002.
Reason: Failed to maintain a valid bond.

License Number: 13709N.
Name: Pac West Trading and Transport Inc. dba Pacwest Transport.
Address: 2531 W. 237th Street, Suite 122, Torrance, CA 90505.
Date Revoked: January 8, 2003.
Reason: Failed to maintain a valid bond.

License Number: 1636N.
Name: Packers Enterprises Inc. dba American Export International.
Address: 100 Broad Avenue, Wilmington, CA 90744.
Date Revoked: November 23, 2002.
Reason: Failed to maintain a valid bond.

License Number: 4175N.
Name: Silken Fortress Corporation dba Transcargo International.
Address: 4564 W. 130th Street, Hawthorne, CA 90250.
Date Revoked: December 8, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17742N.
Name: Vankor Logistics Int'l (U.S.A.), Inc.
Address: 1031 W. Manchester Blvd., Unit D, Inglewood, CA 90301.
Date Revoked: October 16, 2002.
Reason: Surrendered license voluntarily.

License Number: 16556N.
Name: YKL America Inc.
Address: 500 Carson Plaza Drive, Suite 213, Carson, CA 90746.
Date Revoked: January 11, 2003.
Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,
Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 03–2811 Filed 2–5–03; 8:45 am]
BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the 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 application 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 Web site 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 March 3, 2003.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02106-2204:

1. South Shore Mutual Holding Company, Weymouth, Massachusetts; to become a bank holding company by acquiring 100 percent of the voting shares of South Shore Co-operative Bank, Weymouth, Massachusetts.

Board of Governors of the Federal Reserve System, January 31, 2003.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 03–2813 Filed 2–5–03; 8:45 am]
BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

Office of Management Services; Cancellation of an Optional Form by the Department of Defense

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The Department of Defense cancelled the following Optional Form because of low usage: OF 81, 999 Label (4 x 4″)

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

DATES: Effective February 6, 2003.

Dated: January 30, 2003.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 03–2958 Filed 2–5–03; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1238]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TEMODAR 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 human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov.dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 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 TEMODAR (temozolomide). TEMODAR is indicated for the treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients at first relapse who have experienced disease progression on a drug regimen containing a nitrosourea and procarbazine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TEMODAR (U.S. Patent No. 5,260,291) from Schering Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 13, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TEMODAR 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 TEMODAR is 2,032 days. Of this time, 1,668 days occurred during the testing phase of the regulatory review period, while 364 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*: January 19, 1994. The applicant claims January 20, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 1994, 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*: August 13, 1998. The applicant claims August 12, 1998, as the date the new drug application (NDA) for TEMODAR (NDA 21–029) was initially submitted. However, FDA records indicate that NDA 21–029 was submitted on August 13, 1998.

3. *The date the application was approved*: August 11, 1999. FDA has verified the applicant's claim that NDA 21–029 was approved on August 11, 1999.

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 1,136 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 7, 2003. Furthermore, any interested person may petition FDA by for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period August 5, 2003. 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 (see **ADDRESSES**). Three copies of any information are to be submitted, except that individuals may submit single copies. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–2970 Filed 2–5–03; 8:45 am]

BILLING CODE 4160–01–S