

NC, Wait Period Ends: March 8, 2004,  
Contact: Paul Howard (978) 465-0492.

Dated: February 3, 2004.

**Ken Mittelholtz,**

*Environmental Protection Specialist, Office  
of Federal Activities.*

[FR Doc. 04-2628 Filed 2-5-04; 8:45 am]

**BILLING CODE 6560-50-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

[FRL-7619-3]

### **Good Neighbor Environmental Board Meeting**

**AGENCY:** Environmental Protection  
Agency (EPA).

**ACTION:** Notice of meeting.

**SUMMARY:** The next meeting of the Good Neighbor Environmental Board, a Federal advisory committee that reports to the President and Congress on environmental and infrastructure projects along the U.S. border with Mexico, will take place in Washington, DC, on February 24 and 25, 2004. It is open to the public.

**DATES:** On February 24, the meeting will begin at 9:30 a.m. (registration at 9 a.m.) and end at 5:30 p.m. On February 25, the Board will hold its annual Strategic Planning Session from 9 a.m. until 12 noon, and a routine business meeting from 1 p.m. until 4 p.m. (registration at 8:30 a.m.).

**ADDRESSES:** The meeting site is the Chesapeake Room of the Watergate Hotel, 2650 Virginia Avenue, NW., Washington, DC. The nearest metro is Foggy Bottom on the Orange and Blue Line.

**FOR FURTHER INFORMATION CONTACT:**

Elaine M. Koerner, Designated Federal Officer for the Good Neighbor Environmental Board, U.S. Environmental Protection Agency Region 9 Office, 75 Hawthorne St., San Francisco, California, 94105. Tel: Region 9 office: (415) 972-3437; DC office (202) 233-0069. E-mail: [koerner.elaine@epa.gov](mailto:koerner.elaine@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**Meeting Access:** Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact the Designated Federal Officer at least five business days prior to the meeting so that appropriate arrangements can be made.

**Agenda:** On the first day of the meeting, which begins at 9:30 a.m. (registration at 9 a.m.), the Board will host an expert panel session called

Border Environmental Forecast 2004. The morning session will include a panel discussion, followed by a public comment session. After lunch, a second panel discussion will take place, followed by briefings from border-region water experts. In addition, several public officials have been invited to speak throughout the day. The first day of the meeting will conclude at 5:30 p.m.

The second day of the meeting, February 25, begins at 9 a.m., with registration at 8:30 a.m. The morning session will be devoted to the Board's annual Strategic Planning Session. In the afternoon, the Board will hold a routine business meeting. The meeting is scheduled to end at 4 p.m.

**Public Attendance:** The public is welcome to attend all portions of the meeting. Members of the public who plan to file written statements and/or make brief (suggested 5-minute limit) oral statements at the public comment session are encouraged to contact the Designated Federal Officer for the Board prior to the meeting.

**Background:** The Good Neighbor Environmental Board meets three times each calendar year at different locations along the U.S.-Mexico border and in Washington, DC. It was created by the Enterprise for the Americas Initiative Act of 1992. An Executive Order delegates implementing authority to the Administrator of EPA. The Board is responsible for providing advice to the President and the Congress on environmental and infrastructure issues and needs within the States contiguous to Mexico in order to improve the quality of life of persons residing on the United States side of the border. The statute calls for the Board to have representatives from U.S. Government agencies; the governments of the States of Arizona, California, New Mexico and Texas; and private organizations with expertise on environmental and infrastructure problems along the southwest border. The U.S. Environmental Protection Agency gives notice of this meeting of the Good Neighbor Environmental Board pursuant to the Federal Advisory Committee Act (Pub. L. 92-463).

Dated: January 30, 2004.

**Mark Joyce,**

*Associate Director, Committee Management  
Operations.*

[FR Doc. 04-2622 Filed 2-5-04; 8:45 am]

**BILLING CODE 6560-50-P**

## **FEDERAL RESERVE SYSTEM**

### **Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 20, 2004.

**A. Federal Reserve Bank of Atlanta**  
(Sue Costello, Vice President) 1000  
Peachtree Street, N.E., Atlanta, Georgia  
30303:

1. *Thelma Virginia Cummings Guilbeau*, Sunset, Louisiana; to retain voting shares of Sunset Bancorp, Inc., Sunset, Louisiana, and thereby indirectly retain voting shares of Bank of Sunset & Trust Company, Sunset, Louisiana.

Board of Governors of the Federal Reserve System, February 2, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 04-2657 Filed 2-5-04; 8:45 am]

**BILLING CODE 6210-01-S**

## **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 website at [www.ffiec.gov/nic/](http://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 1, 2004.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *LBT Bancshares, Inc.*, Litchfield, Illinois; to acquire 53.98 percent of Security Bancshares, Inc., and thereby indirectly acquire Security National Bank, both of Witt, Illinois.

Board of Governors of the Federal Reserve System, February 2, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 04-2656 Filed 2-5-04; 8:45 am]

**BILLING CODE 6210-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 12% for the quarter

ended December 31, 2003. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: January 29, 2004.

**George Strader,**

*Deputy Assistant Secretary, Finance.*

[FR Doc. 04-2548 Filed 2-5-04; 8:45 am]

**BILLING CODE 4150-04-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003E-0248]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; EXTRANAEL

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for EXTRANAEL 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims 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.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

**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 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 recently approved for marketing the human drug product EXTRANAEL (icodextrin). EXTRANAEL is indicated for a single daily exchange for the long (8-to 16-hour) dwell during continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) for the management of chronic renal failure. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EXTRANAEL (U.S. Patent No. 4,761,237) from Baxter International, 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 July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EXTRANAEL represented the first permitted commercial marketing or use of the product. 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 EXTRANAEL is 2,207 days. Of this time, 1,478 days occurred during the testing phase of the regulatory review period, while 729 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:* December 6, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 6, 1996.

2. *The date the application was initially submitted with respect to the*