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 April 15, 2003.

A. Federal Reserve Bank of Minneapolis (Richard M. Todd, Vice President and Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. Suzanne L. Meyerson Revocable Trust dated December 4, 2002; Robert E. Meyerson Revocable Trust dated December 4, 2002; Robert E. Meyerson; and Suzanne L. Meyerson, Trustees, all of Atwater, Minnesota; to acquire voting shares of Cattail Bancshares, Inc., Atwater, Minnesota, and thereby indirectly acquire voting shares of Atwater State Bank, Atwater, Minnesota, and State Bank of Kimball, Kimball, Minnesota.

Board of Governors of the Federal Reserve System, March 26, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–7726 Filed 3–31–03; 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/.

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 April 25, 2003.

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

1. Triangle Financial Group, Inc., Loganville, Georgia; to become a bank holding by acquiring 100 percent of the voting shares of The Community Bank, Loganville, Georgia.

Board of Governors of the Federal Reserve System, March 26, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–7727 Filed 3–31–03; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interagency Committee on Smoking and Health: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the charter for the Interagency Committee on Smoking and Health (ICSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, has been renewed for a 2-year period, through March 20, 2005.

For further information, contact Dana Shelton, Executive Secretary, Interagency Committee on Smoking and Health, Centers for Disease Control Prevention, of the Department of Health and Human Services, CDC, 4770 Buford Highway, N.E., M/S K–50, Atlanta, Georgia 30341–3717 telephone: 770–488–5709 or fax: 770/488–5767.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 26, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–7739 Filed 3–31–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1404]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEVULAN KERASTICK

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEVULAN KERASTICK 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 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 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 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 LEVULAN KERASTICK (aminolevulinic acid HCl). THE LEVULAN KERASTICK for topical solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of nonhyperkeratotic actinic keratoses of the face or scalp. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LEVULAN KERASTICK (U.S. Patent No. 5,079,262) from DUSA Pharmaceuticals, 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 May 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LEVULAN KERASTICK 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 LEVULAN KERASTICK is 2,528 days. Of this time, 2,007 days occurred during the testing phase of the regulatory review period, while 521 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: January 2, 1993. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: July 1, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for LEVULAN KERASTICK (NDA 20–965) was initially submitted on July 1, 1998.

3. *The date the application was approved*: December 3, 1999. FDA has verified the applicant's claim that NDA 20–965 was approved on December 3, 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 1,524 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 2, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 29, 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. Three copies of any information are to be submitted, except that individuals may submit one copy. 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: February 7, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–7711 Filed 3–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0014]

Draft Guidance on Human Subject Protection; HHS Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation of comments by HHS.

SUMMARY: The Food and Drug Administration (FDA) is announcing that in the issue of the **Federal Register** published March 31, 2003, the Department of Health and Human Services, Office of the Secretary, Office of Health and Science is soliciting public comment on a draft guidance document for Institutional Review Boards, investigators, research institutions, and other interested parties, entitled ''Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection.'' This draft guidance document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This draft guidance applies to human subjects research conducted or supported by HHS or regulated by FDA.

DATES: HHS is accepting written or electronic comments on the draft guidance until 4:30 p.m. on May 30, 2003.

Dated: January 21, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–7957 Filed 3–28–03; 2:22 pm]

BILLING CODE 4160–01–S