related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The notice is available for inspection at the Federal Reserve Bank indicated. Once the notice 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 on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 19, 1996.

A. Federal Reserve Bank of Boston (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. The Royal Bank of Scotland Group plc, Edinburgh, Scotland; The Royal Bank of Scotland plc, Edinburgh, Scotland; and Citizens Financial Group, Inc., Providence, Rhode Island; to acquire First NH Mortgage Corporation, Hooksett, New Hampshire, and thereby engage in making, acquiring and servicing mortgage loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 1, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–8443 Filed 4–4–96; 8:45 am]

BILLING CODE 6210–01–F

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificant listed below has 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 notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice have 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 indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 25, 1996.

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

1. Leo A. Greenblatt, III, Chicago, Illinois; Andrew Alvin Jahelka, Hinsdale, Illinois; and Richard Owen Nichols, Oakbrook, Illinois; to collectively retain 24.65 percent of the voting shares of St. James Bancorporation, Inc., Lutcher, Louisana, and thereby indirectly acquire The St. James Bank & Trust Company, Lutcher, Louisiana.

Board of Governors of the Federal Reserve System, April 1, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–8444 Filed 4–4–96; 8:45 am]

BILLING CODE 6210–01–F

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. 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 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, including whether the acquisition of the nonbanking company can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

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 29, 1996.

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

1. Kanabec Credit Company, Mora, Minnesota; to acquire 5.5 percent of the voting shares of First Citizens Financial Corp., Mason City, Iowa, and thereby indirectly acquire First Citizens National Bank, Mason City, Iowa.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Community Bancshares of Marysville, Inc., Marysville, Kansas; to acquire 100 percent of the voting shares of Community State Bank, Hanover, Kansas.

Board of Governors of the Federal Reserve System, April 1, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96-8442 Filed 4-4-96; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m. (edt), April 15, 1996.

PLACE: 4th Floor, Conference Room, 1250 H Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the March 18, 1996, Board meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Review of Arthur Andersen annual financial audit.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs (202) 942–1640.

Dated: April 2, 1996.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 96–8591 Filed 4–3–96; 10:18 am]

BILLING CODE 6760–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0033]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product OPTIMMUNE® (cyclosporine). OPTIMMUNE® is indicated for treatment of chronic keratoconjunctivitis sicca in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OPTIMMUNE® (U.S. Patent No. 4,839,342) 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 February 8, 1996, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of OPTIMMUNE® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the products's regulatory review period.

FDA has determined that the applicable regulatory review period for OPTIMMUNE® is 1,898 days. Of this time, 1,668 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: May 24, 1990. The applicant claims May 10, 1990, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the INAD was May 24, 1990, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: December 16, 1994. The applicant claims December 14, 1994, as the date the new animal drug application (NADA) for OPTIMMUNE® (NADA 141–052) was initially submitted. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the NADA was December 16, 1994, which is considered to be the NADA initially submitted date.

3. *The date the application was approved*: August 2, 1995. FDA has verified the applicant's claim that NADA 141–052 was approved on August 2, 1995.

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 698 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 4, 1996, 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 October 2, 1996, 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.