1. *Cordele Bancshares, Inc.*, Cordele, Georgia; to become a bank holding company by acquiring 99.28 percent of the voting shares of Cordele Banking Company, Cordele, Georgia.

2. *Morris State Bancshares, Inc.*, Dublin, Georgia; to become a bank holding company by acquiring 84.11 percent of the voting shares of The Morris State Bank, Dublin, Georgia.

3. *Smoky Mountain Bancorp, Inc.*, Gatlinburg, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of The First National Bank of Gatlinburg, Gatlinburg, Tennessee.

C. **Federal Reserve Bank of Chicago** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Bank of Elmwood Employee Stock Ownership Plan and Trust*, Racine, Wisconsin; to become a bank holding company by acquiring 30 percent of the voting shares of Elmwood Financial Corporation, Racine, Wisconsin, and thereby indirectly acquire Bank of Elmwood, Racine, Wisconsin.

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

1. *Bank of Bolivar Employee Stock Ownership Plan & Trust*, Bolivar, Tennessee; to become a bank holding company by acquiring at least 25.5 percent, but not more than 51 percent of the voting shares of Community Financial Services, Inc., Bolivar, Tennessee, and thereby indirectly acquire The Bank of Bolivar, Bolivar, Tennessee.

E. **Federal Reserve Bank of Minneapolis** (James M. Lyon, vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *International Bancorporation*, Bemidji, Minnesota; to acquire by merger Pelican Bancshares, Inc., Pelican Rapids, Minnesota, and thereby indirectly acquire Pelican Valley State Bank, Pelican Rapids, Minnesota.

2. *MONBAN, Inc.*, Billings, Montana; to become a bank holding company by acquiring 94.78 percent of the voting shares of The Fairview Bank, Fairview, Montana.

3. *Nodak Bancorporation*, Mandan, North Dakota; to acquire 93.57 percent of the voting shares of First Southwest Bank—Mandan, Mandan, North Dakota.

4. *Security Bancshares Company*, Glencoe, Minnesota; to acquire 100 percent of the voting shares of Waconia State Bank, Waconia, Minnesota.

F. **Federal Reserve Bank of Dallas** (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Texas Bancorporation, Inc.*, Odessa, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of Texas Bank, Odessa, Texas.

Board of Governors of the Federal Reserve System, April 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-8727 Filed 4-12-89; 8:45 am]

BILLING CODE 6210-01-M

Security Bancshares, Inc., et al.; Formation of, Acquisition by, or Merger of Bank Holding Companies; and Acquisition of Nonbanking Company

The company listed in this notice has applied under section 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed company has also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The 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 on the question 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." 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.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 28, 1989.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Security Bancshares, Inc.*, Scott City, Kansas; to acquire 93.25 percent of the voting shares of The Farmers State Bank, Oakley, Oakley, Kansas.

In connection with this application, Applicant also proposes to acquire Medlin Insurance Agency, Inc., Oakley, Kansas, and thereby engage in general insurance agency activities pursuant to § 225.25(b)(8)(iii) of the Board's Regulation Y. These activities will be conducted in Logan County, Kansas.

Board of Governors of the Federal Reserve System, April 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-8728 Filed 4-12-89; 8:45 am]

BILLING CODE 6210-01-M

Applications for the Toronto-Dominion Bank; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a) (2) or (f) of the Board's Regulation Y (12 CFR 225.23(a) (2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.23(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The 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 on the question 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." 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.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 4, 1989.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *The Toronto-Dominion Bank*, Toronto, Canada; to acquire American Government Securities, Inc., Morristown, New Jersey, to underwrite and deal in bank-eligible obligations pursuant to § 225.25(b)(16) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-8729 Filed 4-12-89; 8:45 am]

BILLING CODE 6210-01-M

Westdeutsche Landesbank Girozentrale, et al.; Applications To Engage de Novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

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 on the question 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." 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 applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 26, 1989.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Westdeutsche Landesbank Girozentrale*, Federal Republic of Germany; to engage *de novo* through its subsidiary, Touchless High Tech Leasing, Inc., Wilmington, Delaware, in leasing personal and real property pursuant to section 225.25(b)(5) of the Board's Regulation Y.

2. *Westpac Banking Corporation*, New York, New York; to engage *de novo* in providing management advice to nonaffiliated bank and nonbank depository institutions, including commercial banks, savings and loan associations, mutual savings banks, credit unions, and industrial loan companies. Such management consulting advisory services would include, but not necessarily limited to advice concerning bank operations, systems and procedures; computer operations and mechanization and the design and planning of computer and data processing systems to assist in the administration or carrying out of credit policies, documentation, evaluation and debt collection, product development, marketing operations, personnel operations and internal accounting and auditing procedures pursuant to § 225.25(b)(11) of the Board's Regulation Y.

B. **Federal Reserve Bank of Chicago** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Park Ridge Bancshares, Inc.*, Stevens Point, Wisconsin; to engage *de novo* in general insurance activities pursuant to § 225.25(b)(8)(vi) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 6, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-8730 Filed 4-12-89; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 88F-0282]

Diversey Wyandotte Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Diversey Wyandotte Corp., has filing a petition proposing that the food additive regulations be amended to provide for the safe use of phosphoric acid; octenyl succinic acid; octyldimethylamine; and mixture of *N*-carboxylic acids (C_6–C_{12}, consisting of not less than 95 percent C_8 and C_{10} *N*-acids) as components of a sanitizing solution to be used for sanitizing food contact surfaces.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204; 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 8H4092) has been filed by Diversey Wyandotte Corp., 1532 Biddle Ave., Wyandotte, MI 48192, proposing that § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) be amended to provide for the safe use of phosphoric acid; octenyl succinic acid; octyldimethylamine; and a mixture of *N*-carboxylic acids (C_6–C_{12}, consisting of not less than 95 percent C_8 and C_{10} *N*-acids) as components of a sanitizing solution to be used for sanitizing food contact surfaces .

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: April 6, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-8760 Filed 4-12-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89N-0120]

Drug Export; CARDIOLITE® Kit for the Preparation of Technetium Tc99m Sestamibi

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that E.I. Du Pont de Nemours & Co. (Inc.) has filed an application requesting approval for the export of the human drug CARDIOLITE® Kit for the preparation of Technetium Tc99m Sestamibi to Canada.

ADDRESS: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Rudolf Apodaca, Division of Drug Evaluation and Research (HFD-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, HD 20857, 301-295-8063.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that E.I. Du Pont de Nemours & Co. (Inc.), Medical Products Department, 331 Treble Cove Rd., No. Billerica, MA 01862, has filed an application requesting approval for the export of the drug CARDIOLITE® Kit for the preparation of Technetium Tc99m Sestamibi, to Canada. This product is a myocardial imaging agent useful for the detection and localization of myocardial infarction and assessment of ventricular function. The application was received and filed in the Center for Drug Evaluation and Research on March 20, 1989, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 3, 1989, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802, Pub. L. 99-660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 5, 1989.

Daniel L. Michels,

Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 89-8759 Filed 4-12-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88E-0102]

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

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Ceftin 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 (PTO), for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION Philip L. Chao, 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 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 approved for marketing the human drug product Ceftin (cefuroxime axetil) which is indicated for the treatment of patients with infections caused by susceptible strains of certain organisms in several diseases. Subsequent to this approval, PTO received a patent term restoration application for Ceftin (U.S. Patent No. 4,267,320) from Glaxo Operations UK Ltd. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated April 15, 1988, advised PTO that the human drug product had undergone a regulatory review period. FDA also informed PTO that Ceftin is an ester of the active moiety cefuroxime and that FDA had previously approved two drug products which are salts of cefuroxime. After receiving this information, PTO concluded that Ceftin was not eligible for patent extension. On February 22, 1989, the district court in *Glaxo Operations UK Ltd.* v. *Ouigg*, Civ.