Companhia Maritima Nacional
Companhia de Navegacao Alianca S.A.
Frota Amazonica S.A.
Columbus Line
Hanjin Shipping Company, Ltd.
Transportacion Maritima Mexicana
Sea-Land Service, Inc.
APL Co. Pte. Ltd.
Transroll Navieras Express
Compagnie Generale Maritime, S.A.
TNX Transportes Ltda.
Euroatlantic Container Line S.A.

Synopsis: The proposed modification revises Article 4 of the Agreement to add inland and coastal points in Argentina and Brazil to the geographic scope. Corresponding changes to reflect the above have been made in Article 5.04, as well as, correcting the number of sections from four to five.

Agreement No.: 203–011517–003.
Title: APL/Crowley Space Charter and Sailing Agreement.
Parties:
American President Lines, Ltd.
Crowley American Transport, Inc.

Synposis: The proposed amendment would expand the geographic scope of the Agreement to include service between the Atlantic and Gulf Coasts of the United States, and inland U.S. points via such ports, and ports on the Pacific Coast of South America, ports on the North Coast of Colombia, and Jamaica, and inland points via such ports as well as points in Panama. The amendment also specifies the number of vessels to be utilized in that service and adds APL Co. Pte Ltd. as a party to the Agreement.

Dated: April 1, 1998.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 98–8982 Filed 4–6–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, D.C. 20573.

Thomas G. Madden, Inc., 100 Inwood Court, Greer, SC 29650, Officers: Thomas G. Madden, President, Mildred D. Madden, Vice President.

Dated: April 1, 1998.

Joseph C. Polking,

Secretary.

[FR Doc. 98–9032 Filed 4–6–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks 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 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 22, 1998

A. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 90 Hennepin Avenue, P.O. Box 291, Minneapolis, Minnesota 55480-0291:

1. James Wade Emison Trust, Eden Prairie, Minnesota; to acquire voting shares of Community Bank Group, Inc., Eden Prairie, Minnesota, and thereby indirectly acquire Community Bank Jordan, Jordan, Minnesota; Community Bank New Ulm, New Ulm, Minnesota; Community Bank St. Peter, St. Peter, Minnesota, and Community Bank Winsted, Winsted, Minnesota.

Board of Governors of the Federal Reserve System, April 2, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98–9071 Filed 4–6–98; 8:45 am]

BILLING CODE 6210–01–F

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. 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 May 1, 1998.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105-1521:

1. Mid Penn Bancorp, Inc., Millersburg, Pennsylvania; to acquire 100 percent of the voting shares of Miners Bank of Lykens, Lykens, Pennsylvania.

B. Federal Reserve Bank of Cleveland (Paul Kaboth, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. Peoples Holding Company, Inc., Coldwater, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of The Peoples Bank Co., Coldwater, Ohio, and thereby indirectly acquire The PBC Interim Bank, Coldwater, Ohio. Peoples Bank will merge with Interim Bank, the survivor; thereupon, Interim Bank, as successor, will commence business as The Peoples Bank Co.

2. United Bancorp, Inc., Martins Ferry, Ohio; to merge with Southern Ohio Community Bancorporation, Inc., Glouster, Ohio, and thereby indirectly acquire The Glouster Community Bank, Glouster, Ohio.

Board of Governors of the Federal Reserve System, April 2, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98–9072 Filed 4–6–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, April 13, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Wed site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: April 3, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98–9268 Filed 4–3–98; 3:48 pm]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0182]

Bulk Drug Substances To Be Used in Pharmacy Compounding; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA) is preparing to develop a list of bulk drug substances (bulk drugs) that may be used in pharmacy compounding that do not have a United States Pharmacopeia (USP) or National Formulary (NF) monograph and are not components of approved drugs. FDA is taking this action in accordance with provisions in the Food and Drug Administration Modernization Act of 1997 (FDAMA). To identify candidates for this bulk drugs list, FDA is encouraging interested groups and individuals to nominate specific bulk drug substances and is describing the information that should be provided to the agency in support of each nomination.

DATES: Nominations must be received by June 8, 1998, to receive consideration for inclusion on the bulk drugs list. Nominations received after this date will receive consideration for subsequent amendments to the list.

ADDRESSES: Send nominations to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Tonelli, Center for Drug Evaluation and Research (HFD–332), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0101.

SUPPLEMENTARY INFORMATION: President Clinton signed FDAMA (Pub. L. 105–115) into law on November 21, 1997. One of the issues addressed in this new legislation is the applicability of the Federal Food, Drug, and Cosmetic Act (the act) to the practice of pharmacy compounding. Compounding involves a process whereby a pharmacist or physician combines, mixes, or alters ingredients to create a customized medication for an individual patient. Section 127 of FDAMA, which adds section 503A to the act (21 U.S.C. 353a), describes the circumstances under which compounded drugs qualify for exemptions from certain adulteration, misbranding, and new drug provisions of the act. Section 127 becomes effective 1 year from the date of the FDAMA's enactment (section 503A(b) of the act).

Section 127 contains several restrictions regarding the bulk drug substances[1] that may be used as ingredients in compounding and still qualify for the applicable exemptions. It provides, among other things, that such substances must comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapter on pharmacy compounding; if a monograph does not exist, they must be components of drugs approved by FDA; and if neither of those criteria are satisfied, they must appear on a list that FDA develops and issues through regulations (section 503A(b)(1)(A)(i)(I) through (b)(1)(A)(i)(III) of the act).

In accordance with the bulk drug provisions in section 127, FDA is preparing to develop a list of bulk drug substances that may be used in compounding that do not have a USP or NF monograph and are not components of approved drugs. To identify candidates for this list, FDA is seeking public input in the form of specific bulk drug nominations. All interested groups and individuals are encouraged to nominate specific bulk drug substances for inclusion on the list. FDA intends for this nomination process to serve as its principal means of identifying list candidates. After evaluating the nominations and, as required by Congress, consulting with the United States Pharmacopeial Convention, Inc., and an advisory committee on compounding (section 503A(d) of the act), FDA will issue the list as a regulation under notice-and-comment rulemaking procedures.

Nominations should include the following information about the bulk drug substance being nominated and the product(s) that will be compounded using such substance. If the information requested is unknown or unavailable, that fact should be noted accordingly.

Bulk Drug Substance

- Ingredient name;
- Chemical name;
- Common name(s);
- Chemical grade or description of the strength, quality, and purity of the ingredient;
- Information about how the ingredient is supplied (e.g., powder, liquid);
- Information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development; and
- A bibliography of available safety and efficacy data[2], including any

[1] The term ''bulk drug substance'' is defined in FDA's regulations at 21 CFR 207.3(a)(4) and incorporated in section 127 of FDAMA to mean ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.''

[2] FDA recognizes that the available safety and efficacy data is unlikely to be of the same type, amount, or quality as would be required to support a new drug application, but this fact will not preclude a bulk drug substance from consideration for inclusion on the list.