

contact the Federal Mediation and Conciliation Service as soon as possible to obtain an application kit. Please consult the FMCS Web site (<http://www.fmcs.gov>) to download forms and information.

These kits and additional information or clarification can be obtained free of charge by contacting the Federal Mediation and Conciliation Service, Labor-Management Grants Program, 2100 K Street, NW., Washington, DC 20427; or by calling 202-606-8181.

Dated: January 13, 2003.

John J. Toner,

Chief of Staff, Federal Mediation and Conciliation Service.

[FR Doc. 03-1695 Filed 1-24-03; 8:45 am]

BILLING CODE 6732-01-M

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 10, 2003.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Eldred 2002 Family Trust*, Beloit, Wisconsin; and Co-Trustees Helen M. Eldred, Beloit, Wisconsin; Susan E. Boettcher, Wauwatosa, Wisconsin; Steven M. Eldred, Beloit, Wisconsin; and Richard J. Langer, Madison, Wisconsin; to acquire control of Centre 1 Bancorp, Inc., Beloit, Wisconsin; and thereby indirectly acquire First National Bank and Trust Company of Beloit, Beloit, Wisconsin.

Board of Governors of the Federal Reserve System, January 21, 2003.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 03-1718 Filed 1-24-03; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 03-670) published on page 1851 of the issue for Tuesday, January 14, 2003.

Under the Federal Reserve Bank of Richmond heading, the entry for Forest Merger Corporation and FBR TRS Holdings, both in Arlington, Virginia, is revised to read as follows:

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Forest Merger Corporation and FBR TRS Holdings, Inc.*, both in Arlington, Virginia; to become bank holding companies by merging with Friedman, Billings, Ramsey Group, Inc., and FBR Asset Investment Corporation, both in Arlington, Virginia, and thereby indirectly acquiring FBR Bancorp, Inc., Arlington, Virginia, and FBR National Bank and Trust, Bethesda, Maryland. After the merger, Applicants would be renamed Friedman, Billings, Ramsey Group, Inc.

In addition, Applicants also have applied to acquire more than 5 percent of the voting shares of Hawthorne Financial Corporation, El Segundo, California, and thereby indirectly acquire Hawthorne Savings, F.S.B., El Segundo, California.

Comments on this application must be received by February 18, 2003.

Board of Governors of the Federal Reserve System, January 21, 2003.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 03-1719 Filed 1-24-03; 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 February 20, 2003.

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

1. *Piedmont Bancshares, Inc.*, Atlanta, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Piedmont Bank of Georgia, Atlanta, Georgia.

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

1. *American Eagle Financial Corporation*, Albertville, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of Riverview Community Bank, Otsego, Minnesota, a *de novo* bank.

Board of Governors of the Federal Reserve System, January 21, 2003.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 03-1720 Filed 1-24-03; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0532]

Nonclinical Datasets; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug

Evaluation and Research (CDER), is seeking volunteers to participate in a pilot project involving the evaluation of various analysis tools to facilitate the use of electronic datasets for analysis of animal data submitted to FDA by applicants of new drug applications (NDAs). These analysis tools will allow a reviewer to more efficiently display and evaluate nonclinical datasets submitted in electronic format.

DATES: Submit written requests to participate in the pilot project by March 28, 2003. Comments on this pilot project may be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding the pilot project 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: Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, levinr@cderr.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under current FDA regulations (21 CFR 314.50), applicants must provide nonclinical data in NDAs. In January 1999, the agency published guidance describing how applicants could provide nonclinical data in the form of electronic datasets. In the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—NDAs," FDA provided recommendations on how to organize the datasets and how to provide descriptive information on the datasets and the data variables (metadata). The Center for Biologics Evaluation and Research (CBER) has provided similar recommendations for biologics license applications (BLAs) in their guidance entitled "Providing Regulatory Submissions in Electronic Format—BLAs." A joint CBER and CDER guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—General Considerations," which published in January 1999, provided recommendations for the file formats for nonclinical datasets.

Recently, FDA received recommendations for a standard presentation of certain clinical data from the Clinical Data Interchange Standards Consortium, Inc. (CDISC), a nonprofit organization including members from pharmaceutical companies, biotechnology companies,

contract research organizations, and software vendors. CDISC is currently facilitating the work on similar standards for nonclinical datasets. Where possible, the standards developed for clinical datasets and metadata should be used in the development of standardized presentations of the datasets for routine toxicology studies (e.g., chronic toxicology and carcinogenicity studies).

In addition, CDER has entered into a cooperative research and development agreement with PharmQuest Corp. for the development of analysis tools by which to evaluate the nonclinical datasets prepared using defined standards. The use of these standardized datasets will reduce the amount of effort required of the reviewer to evaluate nonclinical data.

The purpose of the pilot project is to help in the development of analysis tools designed to facilitate the review and evaluation of electronic nonclinical datasets and to obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized nonclinical data and metadata.

II. Pilot Project Description

This pilot project is part of an effort to improve the process for submitting nonclinical data. Eventually, FDA expects to recommend detailed data standards for the submission of nonclinical data. Participants in this pilot project will have the opportunity not only to assist the agency in testing the use of various analysis tools and standardized nonclinical data and metadata, but would also be able to familiarize themselves with the process at an early stage of development. Only a few participants are needed for this pilot.

A. Initial Approach

Because a limited group of voluntary participants are needed, the agency will use its discretion in choosing volunteers, based on their having previously submitted nonclinical datasets to FDA and having demonstrated familiarity with our recommendations for creating nonclinical datasets as presented in the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—NDAs." During the pilot project, specific technical instructions for providing the nonclinical data for testing will be made available to pilot participants. Participants in the pilot project will be asked to provide nonclinical datasets as described in the technical instructions and to provide technical feedback.

B. Scope

Existing requirements for the submission of nonclinical data will not be waived, suspended, or modified for purposes of this pilot project. The pilot project will test the preparation and use of the submitted nonclinical electronic datasets.

C. How to Participate

Written requests to volunteer should be submitted to the Dockets Management Branch (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. We will consider all received comments in making a determination on electronic filing and when drafting a guidance document for submitting nonclinical study data as electronic datasets. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 15, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03-1743 Filed 1-24-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P-0068]

Determination That Chymopapain 10,000 Units/Vial Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that CHYMODIACTIN (chymopapain 10,000 units/vial injection) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to