

**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 August 31, 1998.

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

1. *John Edwin Moats, M.D.*, Bryan, Ohio, and Mark Charles Moats, Defiance, Ohio; to acquire voting shares of Sherwood Banc Corporation, Sherwood, Ohio, and thereby indirectly acquire voting shares of Sherwood State Bank, Sherwood, Ohio.

Board of Governors of the Federal Reserve System, August 11, 1998.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

[FR Doc. 98-21946 Filed 8-14-98; 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 September 11, 1998.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. *National City Bancshares, Inc.*, Evansville, Indiana; to merge with Commonwealth Commercial Corp., Crittenden, Kentucky, and thereby indirectly acquire Bank of Crittenden, Crittenden, Kentucky.

Board of Governors of the Federal Reserve System, August 11, 1998.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

[FR Doc. 98-21947 Filed 8-14-98; 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 September 11, 1998.

**A. Federal Reserve Bank of New York** (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. *Cooper Life Sciences, Inc. and Greater American Finance Group, Inc.*, both of New York, New York; to become bank holding companies by acquiring 100 percent of the voting shares of The Berkshire Bank, New York, New York.

**B. Federal Reserve Bank of Atlanta** (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. *Flag Financial Corporation*, LaGrange, Georgia; to merge with Empire Bank Corp., Homerville, Georgia, and thereby indirectly acquire Empire Banking Company, Homerville, Georgia.

In connection with this application, Applicant also has applied to acquire E.B.C. Financial Services, Inc., Homerville, Georgia, and thereby engage in insurance agency activities in a town of less than 5,000, pursuant to § 225.28(b)(11)(iii) of Regulation Y.

**C. Federal Reserve Bank of Dallas** (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Eagle Lake Bancshares, Inc.*, Eagle Lake, Texas, and FINABEL Corporation, Dover, Delaware; to become bank holding companies by acquiring 100 percent of the voting shares of The First National Bank, Eagle Lake, Texas.

2. *Keene Bancorp, Inc.*, 401(k) *Employee Stock Ownership Plan and Trust*, Keene, Texas; to acquire 47.12 percent of the voting shares of Keene Bancorp, Inc., Keene, Texas, and thereby indirectly acquire First State Bank, Keene, Texas.

Board of Governors of the Federal Reserve System, August 12, 1998.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

[FR Doc. 98-22088 Filed 8-14-98; 8:45 am]

BILLING CODE 6210-01-F

**FEDERAL RESERVE SYSTEM****Sunshine Act Meeting**

**TIME AND DATE:** 10:00 a.m., Thursday, August 20, 1998.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 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 matters carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Lynn S. Fox, 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 Web 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: August 13, 1998.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

[FR Doc. 98-22154 Filed 8-13-98; 11:37 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 94P-0110 and 95N-0245]

#### Agency Information Collection Activities; Announcement of OMB Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling: Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 5, 1998 (63 FR

30615), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0351. The approval expires on July 31, 2001.

Dated: August 4, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-21997 Filed 8-14-98; 8:45 am]

BILLING CODE 4160-01-F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0565]

#### Off-the-Shelf Software Use in Medical Devices; Draft Guidance; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Off-the-Shelf Software Use in Medical Devices." This draft guidance document is not final or in effect at this time. The purpose of the draft guidance document is to describe the information that should be provided in a medical device application involving Off-the-Shelf (OTS) software. While the draft guidance document is not intended for compliance with Quality System requirements, many of the principles outlined may be helpful to device manufacturers in establishing design controls and validation plans for use of off-the-shelf software in their devices.

**DATES:** Submit written comments by November 16, 1998. After the close of the comment period, written comments may be submitted at any time to Daniel A. Spyker (address below).

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Off-the-Shelf Software Use in Medical Devices" to the Division of Small Manufacturers

Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Daniel A. Spyker, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320.

**SUPPLEMENTARY INFORMATION:**

### I. Background

This draft guidance document was developed to address the many questions asked by medical device manufacturers regarding what they need to provide to FDA when they use OTS software. The response to these questions depends on the medical device in question and the impact on patient safety when the OTS software fails. Thus, the answer to the question "What do I need to do or document?" will be based on the hazard analysis that is an integral part of designing a medical device. The detail of documentation to be provided to FDA and the level of life cycle control necessary for the medical device manufacturer increase as the hazard to the patient from software failure increases.

This draft guidance document lays out in broad terms how the medical device manufacturer should determine what is necessary to do and to document for submission to the agency. A "BASIC" set of need-to-do items is proposed for OTS software, and a detailed discussion is provided on additional ("SPECIAL") needs and responsibilities of the manufacturer when hazards from OTS software failure become more significant.

### II. Significance of Guidance

This draft guidance document represents the agency's current thinking on use of OTS software in medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 2 guidance document