

**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 Web site at [www.ffiec.gov/nic/](http://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 July 7, 2003.

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

1. *GB&T Bancshares, Inc.*, Gainesville, Georgia; to merge with Baldwin Bancshares, Inc., Milledgeville, Georgia, and thereby indirectly acquire First National Bank of the South, Milledgeville, Georgia.

Board of Governors of the Federal Reserve System, June 5, 2003.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 03-15110 Filed 6-13-03; 8:45 am]

**BILLING CODE 6210-01-M**

**GENERAL SERVICES ADMINISTRATION****Interagency Committee for Medical Records (ICMR); Cancellation of Medical Standard Forms**

**AGENCY:** General Services Administration.

**ACTION:** Notice.

**SUMMARY:** Standard Form 521, Medical Record—Dental is cancelled. The SF 603A, Medical Record—Dental Continuation will replace the SF 521 because the Federal medical community no longer uses it.

**FOR FURTHER INFORMATION CONTACT:** Ms. Barbara Williams, General Services Administration, (202) 501-0581.

**DATES:** Effective June 16, 2003.

Dated: June 9, 2003.

**Barbara M. Williams,**

*Deputy Standard and Optional Forms Management Officer, General Services Administration.*

[FR Doc. 03-15109 Filed 6-13-03; 8:45 am]

**BILLING CODE 6820-34-M**

**GENERAL SERVICES ADMINISTRATION**

[2003-N03]

**GSA Discontinues Printing and Distribution of the Catalog of Federal Domestic Assistance**

**AGENCY:** Office of Governmentwide Policy; Office of Acquisition Policy, GSA.

**ACTION:** Notice.

**SUMMARY:** For years, GSA has published a printed version of the Catalog of Federal Domestic Assistance (CFDA or Catalog), as required by legislation dating to 1977 and 1983. That same legislation allowed GSA to distribute free copies of the printed Catalog to designated recipients. In fiscal year 2003, we distributed nearly 10,000 paper copies of the Catalog at no cost to the recipients.

Current legislation, however, authorizes GSA to determine in what form to prepare and publish the Catalog. Consistent with the Administration's Electronic-Government initiatives, the Government Paperwork Elimination Act, and a move to a paper free environment, GSA will now disseminate the Catalog electronically through the CFDA Web site on the Internet. As a result, effective immediately, GSA will no longer print and distribute free copies of the Catalog.

The Internet and GSA's free CFDA Web site at <http://www.cfda.gov> will be

the primary means of disseminating the Catalog. In addition to what is already there, the Web site will soon contain a version of the Catalog that, when printed by any user, will have the same layout as the printed document that the Government Printing Office (GPO) has provided.

Furthermore, GPO recently indicated that it will continue printing and selling the CFDA to interested buyers. For information about purchasing the Catalog of Federal Domestic Assistance from GPO, call the Superintendent of Documents at 202-512-1800 or toll free at 866-512-1800, or you may reach GPO's on-line bookstore at <http://bookstore.gpo.gov>.

**DATES:** This notice is effective June 16, 2003.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kathy Hospodar, CFDA Team Leader, General Services Administration, by phone at (202) 208-4052.

Dated: June 10, 2003.

**David A. Drabkin,**

*Deputy Associate Administrator, Office of Acquisition Policy.*

[FR Doc. 03-15103 Filed 6-13-03; 8:45 am]

**BILLING CODE 6820-61-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration on Aging****Agency Information Collection Activities; Submission for OMB Review; Comment Request; 2003 National Survey of Older Americans Act Participants**

**AGENCY:** Administration on Aging, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information within 30 days of the publication of this notice.

**ADDRESSES:** Submit written comments on the collection of information by fax 202.395.6974 or by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St., NW., rm. 10235, Washington, DC 20503, Attn: Allison Herron Eydtt, Desk Officer for AoA.

**FOR FURTHER INFORMATION CONTACT:** *Cynthia.Bauer@aoa.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, AoA

has submitted the following proposed collection of information to OMB for review and clearance.

With the 2003 National Surveys of Older Americans Act Participants, the Administration on Aging continues its initiative, started with the Performance Outcomes Measures Project (POMP), to develop and test performance outcome measures for Older Americans Act programs. Surveys to be conducted in 2003 will test consumer assessment instruments at the national and state level for nutrition, transportation, homemaker, information and assistance and caregiver services.

AoA estimates the burden of this collection of information as follows: Area Agency on Aging—Number of Respondents: 120; Number of Responses per Respondent: one; Average Burden per Response: 2 hours; Area Agency on Aging Burden: 240 hours—National Survey—Number of Respondents: 5040; Number of Responses per Respondent: one; Average Burden per Response: .5 hours; National Survey Burden: 2,520 hours—State Surveys—Number of Respondents: 5600; Number of Responses per Respondent: one; Average Burden per Response: .5 hours; State Survey Burden: 2,800 hours—Total Burden—5,560 hours.

Dated: June 3, 2003.

**Josefina G. Carbonell,**

*Assistant Secretary for Aging.*

[FR Doc. 03-15061 Filed 6-13-03; 8:45 am]

BILLING CODE 4154-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0050]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Investigational Device Exemptions Reports and Records

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written or electronic comments on the collection of information by July 16, 2003.

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control Number 0910-0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made either to the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement.

An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects. The safety and effectiveness of the device involving human subjects is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards.

To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to

human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, ones that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements.

The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available.

Section 812.10 allows the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety.

Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations. Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in this original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety and for FDA to make a determination to approve the IDE.

Once FDA approves an IDE application, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation, which affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Under § 812.150, a sponsor is required to submit reports to FDA. These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to assure protection of human subjects and to allow review of the study's progress.

Section 812.36(c) identifies the information necessary to file a treatment IDE application. FDA uses this information to determine if wider distribution of the device is in the interests of the public health. Section