

**STATUS:** This meeting will be open to the public.

**ITEMS TO BE DISCUSSED:**

Correction and Approval of Minutes.  
Draft Advisory Opinion 2003-20: U.S. Representative Silvestre Reyes by J. Fernando Barrueta, Hispanic College Fund, Inc.

Draft Advisory Opinion 2003-22: American Bankers Association and ABA BankPAC, by counsel Kenneth A. Gross and Ki P. Hong.

Notice of Proposed Rulemaking on Mailing Lists.

Notice of Proposed Rulemaking on Telephone Banks.

Routine Administrative Matters.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ron Harris, Press Officer, Telephone: (202) 694-1220.

**Mary W. Dove,**

*Secretary of the Commission.*

[FR Doc. 03-21533 Filed 8-19-03; 11:25 am]

**BILLING CODE 6715-01-M**

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**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 September 4, 2003.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *The Mike Wilson Descendents' Trust*, Jacksonville, Arkansas, to increase its control of First Arkansas Bancshares, Inc., Jacksonville, Arkansas ("Bancshares"). In addition, Larry T. Wilson, Michael K. Wilson, Kathryn W. Roberts, the Kenneth Pat Wilson Annual Gift Trust, the Larry Timothy Wilson Annual Gift Trust, the Kathryn Patricia Wilson Roberts Annual Gift Trust, the Michael K. Wilson Annual Gift Trust, and The Mike Wilson Descendents'

Trust, all of Jacksonville, Arkansas, have applied to retain control of Bancshares.

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

1. *Gale Mark Hoese, David Kurt Hoese, and Terry Clayton Hoese*, all of Glencoe, Minnesota, and Todd Curtis Hoese, Waconia, Minnesota; to acquire control of Commercial Bancshares, Inc., Bloomington, Minnesota, and thereby indirectly acquire control of First Commercial Bank, Bloomington, Minnesota.

Board of Governors of the Federal Reserve System, August 15, 2003.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 03-21394 Filed 8-20-03; 8:45 am]

**BILLING CODE 6210-01-S**

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**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 <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 September 15, 2003.

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

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

2. *RB Bancorporation*, Athens, Alabama; to become a bank holding company by acquiring 100 percent of the voting shares of Reliance Bank, Athens, Alabama.

Board of Governors of the Federal Reserve System, August 15, 2003.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 03-21393 Filed 8-20-03; 8:45 am]

**BILLING CODE 6210-01-S**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003F-0370]

**Unilever United States, Inc.; Filing of Food Additive Petition**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Unilever United States, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of vitamin D<sub>3</sub> as a nutrient supplement in certain foods for special dietary use, such as meal replacement products and snack replacement products.

**FOR FURTHER INFORMATION CONTACT:** Judith L. Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3354.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP No. 3A4746) has been filed by Unilever United States, Inc., 390 Park Ave., New York, NY 10022-4698. The petition proposes to amend the food additive regulations in § 172.380 *Vitamin D<sub>3</sub>* (21 CFR 172.380) to provide for the safe use of vitamin D<sub>3</sub> in certain foods for special dietary use, such as meal replacement products and snack replacement products.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 1, 2003.

**Laura M. Tarantino,**

*Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*

[FR Doc. 03-21396 Filed 8-20-03; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915-0176)—Revision**

Section 602 of Pub. L. 102-585, the Veterans Health Care Act of 1992,

enacted section 340B of the Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Pharmacy Affairs Branch (PAB) has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

*Audit guidelines:* A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B. If the problem cannot be resolved, the

manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA PAB for review. The office will review the documentation to determine if reasonable cause exist. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA PAB for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

*Dispute resolution guidelines:* Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA PAB has developed an informal dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA PAB, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA PAB. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, but two disputes have reached the level where a committee review may be needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting Requirement	No. of Respondents	Responses per Respondent	Total Responses	Hours/Response	Total Burden Hours
<b>AUDITS</b>					
Audit Notification of Entity <sup>1</sup> .....	2	1	2	4	8
Audit Workplan <sup>1</sup> .....	1	1	1	8	8
Audit Report <sup>1</sup> .....	1	1	1	1	1
Entity Response .....	0	0	0	0	0
<b>DISPUTE RESOLUTION</b>					
Mediation Request .....	2	4	8	10	80
Rebuttal .....	2	1	2	16	32
<b>TOTAL</b> .....	<b>8</b>	<b>1.8</b>	<b>14</b>	<b>9.2</b>	<b>129</b>

<sup>1</sup> Prepared by the manufacturer