and 4:30 p.m., Monday through Friday, at the following offices:

- Drinking Water Branch, Water Protection Division, U.S. Environmental Protection Agency Region III, 1650 Arch Street, Philadelphia, PA 19103–2029.
- Water Supply Program, Maryland Department of the Environment, Montgomery Park Business Center, 1800 Washington Blvd, Baltimore, MD 21230.

FOR FURTHER INFORMATION CONTACT: Steve Maslowski, Drinking Water Branch(3WP22) at the Philadelphia address given above; telephone (215) 814–2371 or fax (215) 814–2318.

SUPPLEMENTARY INFORMATION: All interested parties are invited to submit written comments on this determination and may request a public hearing. All comments will be considered, and, if necessary, EPA will issue a response. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by November 26, 2004, a public hearing will be held.

A request for public hearing shall include the following: (1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such a hearing; and (3) the signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

Dated: September 14, 2004.

Andrew P. Carlin,

Acting Regional Administrator, Region III.

[FR Doc. 04–23942 Filed 10–25–04; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act; Meeting

DATE AND TIME: Thursday, October 28, 2004, 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

THE FOLLOWING ITEM HAS BEEN ADDED TO THE AGENDA: Report of the Audit Division on the Conservative Leadership Political Action Committee.

PERSON TO CONTACT FOR INFORMATION: Robert Biersack, Acting Press Officer, telephone (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 04–24064 Filed 10–22–04; 2:52 pm]

BILLING CODE 6715–01–M

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 November 19, 2004.

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

1. CTB Holdings, Inc., Waco, Texas, and CTB Holdings Delaware, Inc., Wilmington, Delaware; to become bank holding companies by acquiring 100 percent of the voting shares of The Coupland State Bank of Coupland, Coupland, Texas.

Board of Governors of the Federal Reserve System, October 20, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–23889 Filed 10–25–04; 8:45 am]

BILLING CODE 6210–01–S

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 November 9, 2004.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. Nicholas, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Bradley E. Bakken, St. Louis Park, Minnesota; to acquire voting shares of Bakken Securities, St. Louis Park, Minnesota, and thereby indirectly acquire voting shares of Citizens Independent Bank, St. Louis Park, Minnesota.

Board of Governors of the Federal Reserve System, October 20, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–23890 Filed 10–25–04; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the

companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. 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 the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 9, 2004.

A. Federal Reserve Bank of Cleveland (Cindy C. West, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Tri–State 1st Banc, Inc., East Liverpool, Ohio; to acquire MDH Investment Management, Inc., East Liverpool, Ohio, and thereby engage in permissible investment advisory activities, pusuant to section 225.28(b)(6)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, October 20, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–23891 Filed 10–25–04; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0090]

Determination That SERZONE (Nefazodone Hydrochloride) 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) has determined that SERZONE (nefazodone hydrochloride (HCl)) was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to suspend approval of abbreviated new drug applications (ANDAs) for nefazodone HCl, and FDA may continue to approve ANDAs for nefazodone HCl.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) and (a)(2) (21 CFR 314.161(a)(1) and (a)(2)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness both before an ANDA that refers to that listed drug may be approved and if an ANDA referring to that listed drug has already been approved. FDA may not approve an ANDA that does not refer to a listed drug, and, under § 314.161(d), FDA must pursue suspension of approval for an ANDA if the agency determines the listed drug to which the ANDA refers was withdrawn for reasons of safety or effectiveness.

SERZONE (nefazodone HCl) is the subject of approved NDA 20–152 held by the Bristol-Meyers Squibb Co. (BMS). SERZONE is indicated for the treatment of depression. The Public Citizen Health Research Group (PCHRG) submitted a citizen petition to the agency, dated March 6, 2003, requesting that we immediately remove SERZONE from the market because of adverse events associated with the drug (cases of serious liver toxicity). On May 19, 2004, BMS announced that for commercial business reasons, particularly declining sales and increased generic competition, BMS would be discontinuing all sales and manufacture of SERZONE in the U.S. market effective June 14, 2004. Because of the potential for continued marketing of generic versions of nefazodone after BMS's withdrawal of SERZONE from sale, the issues raised in PCHRG's petition still warranted agency response. FDA responded to the petition in a letter dated June 14, 2004, denying the petition and explaining our reasons for concluding that the available data did not justify the agency's removal of nefazodone from the market. The agency also concluded, however, that the safe use of the drug could be improved through additional risk management measures, and BMS made changes to the product labeling to discourage the drug's use as a first-line drug (i.e., to encourage physicians to consider using other treatments first). The labeling for generic versions of nefazadone now must include these changes.

Having independently evaluated relevant literature and data, including from FDA's Adverse Event Reporting System, for possible postmarketing adverse event reports, FDA has now also determined, under § 314.161, that BMS's voluntary withdrawal from sale of SERZONE was not for reasons of safety or effectiveness. Accordingly, the agency will list SERZONE (nefazodone HCl) in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the SERZONE (nefazodone HCl) are unaffected by the withdrawal of SERZONE from the market. Additional ANDAs for nefazodone HCl may also be approved by the agency.

Dated: October 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–23857 Filed 10–25–04; 8:45 am]

BILLING CODE 4160–01–S