PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g. Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C. Matters concerning participation in civil actions or proceedings or arbitration. Internal personnel rules and procedures or matters affecting a particular employee.

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

Mary W. Dove,

Secretary of the Commission.

[FR Doc. E8–20786 Filed 9–8–08; 8:45 am]

BILLING CODE 6715–01–M

FEDERAL HOUSING FINANCE AGENCY

Establishment of a New Independent Agency

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of establishment.

SUMMARY: This Notice is to announce the establishment of a new independent agency. Division A of the Housing and Economic Recovery Act of 2008, Public Law 110–289, 122 Stat. 2654 (2008), titled the Federal Housing Finance Regulatory Reform Act of 2008 (Act), created the Federal Housing Finance Agency (FHFA) as an independent agency of the Federal Government. FHFA was established on the date of enactment, July 30, 2008, and the Act provides for the abolishment of the Office of Federal Housing Enterprise Oversight (OFHEO) and the Federal Housing Finance Board (FHFB) one year after the date of enactment. These agencies, together with the Housing and Urban Development Government-Sponsored Enterprise Mission Teams, are combined to establish FHFA. Regulations of FHFA will be found in 12 CFR chapter XII, parts 1200–1299.

FOR FURTHER INFORMATION CONTACT: Alfred M. Pollard, General Counsel (OFHEO), telephone (202) 414–3788 or Christopher Curtis, General Counsel (FHFB), telephone (202) 408–2802 (not toll free numbers), Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION: FHFA has regulatory authority over the Federal National Mortgage Association (Fannie Mae), the Federal Home Loan Mortgage Corporation (Freddie Mac) and the Federal Home Loan Banks (collectively, the ''regulated entities'') and the Bank System's Office of Finance. The establishment of FHFA strengthens the nation's housing finance system. This new regulator has the authorities necessary to enhance oversight of Fannie Mae, Freddie Mac and the Federal Home Loan Banks—vital components of the nation's secondary mortgage markets.

FHFA was established to oversee the prudential operations of each regulated entity and to ensure:

- That each regulated entity operates in a safe and sound manner, including maintenance of adequate capital and internal controls;
- That the operations and activities of each regulated entity foster liquid, efficient, competitive, and resilient national housing finance markets (including activities relating to mortgages on housing for low- and moderate-income families involving a reasonable economic return that may be less than the return earned on other activities);
- That each regulated entity complies with this title and the rules, regulations, guidelines, and orders issued under this title and the authorizing statutes;
- That each regulated entity carries out its statutory mission only through activities that are authorized under and consistent with this title and the authorizing statutes; and
- That the activities of each regulated entity and the manner in which such regulated entity is operated are consistent with the public interest.

The authorities, powers and responsibilities of FHFA are contained in Titles 12 U.S.C. 1421 *et seq.* and 4501 *et seq.*, as amended by Division A of Public Law 110–289, 122 Stat. 2654 (2008).

Dated: August 30, 2008.

James B. Lockhart III,

Director, Federal Housing Finance Agency.

[FR Doc. E8–20839 Filed 9–8–08; 8:45 am]

BILLING CODE 4220–01–P

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 24, 2008.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. Larry T. Wilson Descendents Trust and The Kathryn W. Roberts Descendants Trust to join the Wilson Family Control Group, all of Jacksonville, Arkansas, and thereby acquire control of First Arkansas Bancshares, Inc., and thereby indirectly acquire control of First Arkansas Bank and Trust, both of Jacksonville, Arkansas.

Board of Governors of the Federal Reserve System, September 4, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–20881 Filed 9–8–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 12:00 p.m., Monday, September 15, 2008.

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 items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202–452–2955.

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.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, September 5, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–20989 Filed 9–5–08; 4:15 pm]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2006–P–0081 (formerly Docket No. 2006P–0178) and FDA–2005–P–0369 (formerly Docket No. 2005P–0023)]

Determination That TEQUIN (Gatifloxacin) Was 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 TEQUIN (gatifloxacin) Tablets, Injection, and Oral Suspension, were withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not accept or approve abbreviated new drug applications (ANDAs) for gatifloxacin oral tablets, injection, or oral suspension that refer to any previously approved dosage forms and strengths of TEQUIN (gatifloxacin).

FOR FURTHER INFORMATION CONTACT: Elena Cohen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6228, Silver Spring, MD 20993–0002, 301–796–3602.

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 under an ANDA procedure. ANDA applicants 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 under a new drug application (NDA). ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 (the 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.'' Drugs are removed 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 (section 505(j)(7)(C) of the act; § 314.162 (21 CFR 314.162)).

FDA will not approve an ANDA if the listed drug has been withdrawn from sale for safety or effectiveness reasons (section 505(j)(4)(I) of the act). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. A drug that has been withdrawn from the market for safety or effectiveness reasons is not a listed drug (21 CFR 314.3(b)). FDA may not approve an ANDA that does not refer to a listed drug. FDA currently has pending one or more ANDAs that refer to TEQUIN (gatifloxacin).

Bristol-Myers Squibb Co. (BMS) is the holder of three NDAs[1] for TEQUIN tablets, injection, and oral suspension as listed in the following table:

TABLE 1.—APPROVED TEQUIN PRODUCTS

NDA No.	Active Ingredients	Strength	Dosage Form/Route
21–061	Gatifloxacin	200 milligrams (mg)	Tablet; oral
21–061	Gatifloxacin	400 mg	Tablet; oral
21–062	Gatifloxacin	Equivalent to 10 mg/milliliter (mL) (200 mg)	Injectable; injection
21–062	Gatifloxacin	400 mg/40 mL (10 mg/mL)	Injectable; injection
21–062	Gatifloxacin in dextrose 5% in plastic container	200 mg/100 mL (2 mg/mL)	Injectable; injection
21–062	Gatifloxacin in dextrose 5% in plastic container	400 mg/200mL (2 mg/mL)	Injectable; injection
21–678	Gatifloxacin	200 mg/5 mL	Suspension; oral

TEQUIN is an antibacterial drug indicated for the treatment of infections due to susceptible strains of designated microorganisms in the following conditions: Acute bacterial exacerbation of chronic bronchitis; acute sinusitis;

[1] On December 17, 1999, FDA approved NDAs 21–061 and 21–062 for community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, acute bacterial sinusitis, uncomplicated urinary tract infections, complicated urinary tract infections, pyelonephritis, and uncomplicated gonorrhea. The December 17, 1999, approval letter also stated that indications for uncomplicated skin and skin structure infections were approvable pending the submission of certain postmarketing data. For administrative purposes, the agency assigned administrative NDAs 21–404 (TEQUIN Tablets) and 21–405 (TEQUIN Injections) for the treatment of uncomplicated skin and skin structure infections. BMS provided a complete response, and upon approval on October 17, 2002, NDAs 21–404 and 21–405 were retired by FDA. The approvals and all other submissions for the treatment of uncomplicated skin and skin structure infections were incorporated in the original NDAs, 21–061 and 21–062. NDAs 21–404 and 21–405 are not listed in the Orange Book, but can be found through a search at *Drugs@FDA*.