or the offices of the Board of Governors not later than June 9, 1998.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105-1521:

1. Commerce Bancorp, Cherry Hill, Pennsylvania; to acquire Commerce Capital, Philadelphia, Pennsylvania, and thereby engage in Tier II securities underwriting and dealing and related activites, including bonds issued by not-for-profit entities that qualify under Section 501(c)(3) of the Internal Revenue Code for a tax exempt status; and bonds issued by private entities that qualify under Section 142(d) of the Internal Revenue Code for a partially tax exempt status (subject to only to the alternative minimum tax). *See* Citicorp, 75 Fed. Res. Bull., 751 (1989) & 83 Fed. Res. Bull. 510 (1997).

B. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. CITBA Financial Corporation, Mooresville, Indiana; to acquire Independent Bankers Life Insurance Company of Indiana, Phoenix, Arizona, a reinsurance subsidiary, and thereby indirectly engage in underwriting credit life, accident and health insurance directly related to extensions of credit by the banks and bank holding companies owning stock in the insurance agency, pursuant to § 225.28(b)(11)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, May 19, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–13788 Filed 5–21–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

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

TIME AND DATE: 10:00 a.m., Wednesday, May 27, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 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: Joseph R. Coyne, 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: May 20, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–13862 Filed 5–20–98; 12:55 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0160]

Determination That Cimetidine 100 mg Tablets Were 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 cimetidine 100 milligram (mg) tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for drugs that refer to cimetidine 100 mg tablets.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, 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 (Pub. L. 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 under a new drug application (NDA). Sponsors of ANDA's 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 included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), 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's 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). Regulations also provide that the agency must make a determination as to 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 (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

In citizen petitions dated March 9, 1998 (Docket No. 98P–0160/CP 1), and March 13, 1998 (Docket No. 98P–0160/CP 2), submitted in accordance with 21 CFR 314.122, Apotex Corp. and Novopharm Limited, respectively, requested that the agency determine whether cimetidine (Tagamet HB) 100 mg tablets were withdrawn from sale for reasons of safety or effectiveness. Cimetidine 100 mg tablets are the subject of approved NDA 20–238 held by SmithKline Beecham Consumer Healthcare LP (SmithKline Beecham). In 1997, SmithKline Beecham withdrew cimetidine 100 mg tablets from sale.

FDA has reviewed its records and, under § 314.161, has determined that cimetidine 100 mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain cimetidine 100 mg tablets 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. ANDA's that refer to cimetidine 100 mg tablets may be approved by the agency.