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.

Dated: May 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13650 Filed 5–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices; Implementation of Third Party Review Under the Food and Drug Administration Modernization Act of 1997; Emergency Processing Request Under OMB Review

[Docket No. 98N–0331]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a program under which persons may be accredited to review premarket notifications and recommend initial classification of certain medical devices. At the same time, FDA is announcing the termination of the Third Party Review Pilot Program. This notice announces the criteria to accredit or deny accreditation to persons (Accredited Persons) who request to conduct premarket notification reviews consistent with provisions of the FDA Modernization Act of 1997 (FDAMA). FDA is also announcing that this proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA is requesting OMB approval within 45 days of receipt of this submission. FDA is taking this action to implement section 210 of FDAMA. The availability of guidance detailing the review of submissions, training for third party reviewers, and basic document processing by FDA is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the collection of information by June 22, 1998. FDA will begin accepting applications for accreditation of Accredited Persons on July 20, 1998, and intends to make a list of Accredited Persons available on or about September 23, 1998. Beginning November 21, 1998, the agency will accept reviews and recommendations from Accredited Persons. On that same date, FDA plans to terminate the Third Party Review Pilot Program that began on August 1, 1996. FDA is currently planning to provide periodic training sessions for Accredited Persons, with the first such session scheduled for October 14-16, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

A. Third Party Review Pilot Program

In the **Federal Register** of April 3, 1996 (61 FR 14789), FDA announced that it would begin a 2-year voluntary pilot program to test the feasibility of using third party reviewers to improve the efficiency of the agency's review of 510(k)'s for selected low-and-moderate risk medical devices. FDA had previously solicited public comments on its plans for the pilot program in a notice issued in the **Federal Register** of June 1, 1995 (60 FR 28618), and at a public workshop held June 19, 1995. The comments received by the agency were addressed in the **Federal Register** notice (61 FR 14789).

The program announced in the April 3, 1996, notice provided for third party review for 251 types of devices that were included in the pilot program. These included all class I devices that were not exempt from 510(k) at that time (221 devices), and 30 class II devices, 24 of which were to be phased into the program over time.

Under the pilot program, persons required to submit 510(k)'s for the eligible devices were permitted to contract with an FDA Recognized Third Party and submit a 510(k) directly to the third party for review. Persons who did not wish to participate in the pilot continued to submit 510(k)'s directly to FDA. The third party applied FDA's 510(k) review criteria and submitted its documented review and recommendation on the substantial equivalence of the device to FDA. FDA then checked the review and issued a decision letter. FDA established a 30-day performance goal for its issuance of final decisions based on third party reviews.

The purpose of the pilot program was to: (1) Provide manufacturers of eligible devices with an alternative review process that could yield more rapid marketing clearance decisions, and (2) enable FDA to target its scientific review resources at higher-risk devices while maintaining confidence in the review by third parties of low-to-moderate risk devices. The pilot program was intended to determine the feasibility of these outcomes.

The agency received applications for recognition as third party reviewers from 37 prospective third parties. These applications were reviewed by a Third Party Recognition Board established by FDA. On July 11, 1996, FDA made publicly available a list of seven Recognized Third Parties, and immediately began a training program for third party review.

The pilot program began August 1, 1996, as scheduled. During the first 18 months of the pilot program, FDA received 22 510(k)'s that were reviewed by Recognized Third Parties. In contrast, during the same period, FDA received more than 1,300 510(k)'s for third party-eligible devices that were not reviewed by third parties.

B. FDA Modernization Act of 1997

The President signed FDAMA into law on November 21, 1997. Section 210 of FDAMA codifies and expands the ongoing Third Party Review Pilot Program by establishing a new section 523 of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to conduct the initial review of 510(k)'s for selected low-to-moderate risk devices. This section specifies that an Accredited Person may not review class III devices or class II devices that are permanently implantable, life-supporting, life-sustaining, or for which clinical data are required. This section also sets limits on the number of class II devices requiring clinical data that may be ineligible for Accredited Person review.

II. FDAMA Third Party Review Program

Under the provisions of FDAMA, FDA is establishing the criteria it will use to determine whether it will accredit or deny accreditation of persons for the purpose of reviewing reports submitted under section 510(k) of the act (21 U.S.C. 360(k)) and making recommendations to FDA regarding the initial classification of devices under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). As intended by Congress,