Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments as follows: comments are due on or before March 11, 2004, and reply comments are due on or before March 25, 2004. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998.

Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html.* Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to <*ecfs@fcc.gov*>, and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other then U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission.

Parties also must send three paper copies of their filing to Sheryl Todd, Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications Commission, 445 12th Street, SW., Room 5–B540, Washington, DC 20554. In addition, commenters must send diskette copies to the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20054.

Pursuant to § 1.1206 of the Commission's rules, 47 CFR 1.1206, this proceeding will be conducted as a permit-but-disclose proceeding in which ex parte communications are permitted subject to disclosure.

Federal Communications Commission.

Sharon Webber,

Deputy Chief, Wireline Competition Bureau, Telecommunications Access Policy Division.

[FR Doc. 04–2241 Filed 2–27–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2647]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceedings

February 23, 2004.

Petitions for Reconsideration and Clarification have been filed in the Commission's Rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of this document is available for viewing and copying in Room CY–A257, 445 12th Street, SW., Washington, DC or may be purchased from the Commission's copy contractor, Qualex International (202) 863–2893. Oppositions to these petitions must be filed by March 16, 2004. *See* Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions have expired.

Subject: In the Matter of the Review of Part 15 and other Parts of Commission's Rules (ET Docket No. 01–278, RM–9375, RM–10051)

Amendment of Parts 2 and 15 of the Commission's Rules to Deregulate the Equipment Authorization Requirements for Digital Devices (ET Docket No. 95–19).

Number of Petitions Filed: 2.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–4454 Filed 2–27–04; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

[Docket No. OP–1184]

Privacy Act of 1974; Notice of Amendment of System of Records

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice: amendment of systems of records.

SUMMARY: In accordance with the Privacy Act, the Board of Governors of the Federal Reserve System (Board) is amending one system of records, entitled Consumer Complaint Information System (BGFRS–18), and removing another system of records, entitled Financial Disclosure Reports and Outside Business Interests Applications (BGFRS–19). We invite public comment on this publication.

DATES: Comment must be received on or before March 31, 2004.

ADDRESSES: Comments should refer to Docket No. OP–1184 and may be mailed to Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551. Please consider submitting your comments through the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm,* by e-mail to *regs.comments@federalreserve.gov,* or by fax to the Office of the Secretary at 202/452–3819 or 202/452–3102. Rules proposed by the Board and other federal agencies may also be viewed and commented on at *http://www.regulations.gov.*

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, except as necessary for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boutilier, Managing Senior Counsel, (202/452–2418), Legal Division. For the hearing impaired *only,* contact Telecommunications Device for the Deaf (TDD) (202/263–4869).

SUPPLEMENTARY INFORMATION: These two systems have not been updated for several years. The system entitled Financial Disclosure Reports and Outside Business Interests Applications (BGFRS–19) covers records contained in OGE/GOVT–1 and OGE/GOVT–2, which are government-wide systems that are maintained by the Office of Government Ethics. Accordingly, the Board's system is being removed as duplicative and unnecessary.

The Consumer Complaints Information system is being amended to clarify that records maintained in the system pertain only to the complainant and do not include investigatory records regarding the institution subject to the complaint. The system has also been amended to include appropriate routine uses.

In accordance with 5 U.S.C. 552a(r), a report of these amended systems of records is being filed with the President of the Senate, the Speaker of the House of Representatives, and the Director of the Office of Management and Budget. These amendments will become effective on April 12, 2004, without further notice, unless the Board publishes a notice to the contrary in the **Federal Register**.

Accordingly, the system of records entitled Financial Disclosure Reports and Outside Business Interests Applications (BGFRS–19) is removed, and the system of records entitled Consumer Complaint Information (BGFRS–18) is amended as follows.

BGFRS–18

SYSTEM NAME:

Consumer Complaint Information.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Board of Governors of the Federal Reserve System, 20th and Constitution Avenue, NW., Washington, DC 20551; and the twelve Federal Reserve Banks, located in Boston, MA; New York, NY; Philadelphia, PA; Cleveland, OH; Richmond, VA; Atlanta, GA; Chicago, IL; St. Louis, MO; Minneapolis, MN; Kansas City, MO; Dallas, TX; and San Francisco, CA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons who have filed consumer complaints with the Federal Reserve Board or the Federal Reserve Banks, or whose complaint to another agency has been referred to the Federal Reserve Board for review.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records primarily consist of complaints regarding state-chartered member banks, as well as other financial institutions, individuals, or organizations that are subject to federal banking supervision. The records may contain the name and address of an individual or organization that referred a matter to the Board. Information in these records includes the complainant's name; the name of the financial institution that is the subject of the complaint; the subject matter of the complaint; and the Board's response to the complaint. Supporting records include, but are not limited to, documents supplied by the complainant. If the complaint concerns an institution that is not subject to supervision by the Board, the record may consist of a referral letter to the appropriate supervisory agency.

PURPOSE:

These files permit the Board to perform its responsibilities under the Federal Reserve Act, the Federal Trade Commission Act, and other consumer protection laws to respond to consumer complaints and inquiries regarding practices by banks and other financial institutions supervised by the Board.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 11 of the Federal Reserve Act (12 U.S.C. 248(a)); Section 5 of the Bank Holding Company Act (12 U.S.C. 1844); and Section 18(f) of the Federal Trade Commission Act (15 U.S.C. 57a(f)).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information maintained in this system may be disclosed to:

a. A Board-regulated entity that is the subject of a complaint or inquiry;

b. Third parties to the extent necessary to obtain information that is relevant to the resolution of a complaint or inquiry;

c. The appropriate governmental, tribal, self-regulatory, or professional organization if the information is relevant to a known or suspected violation of a law or licensing standard within that organization's jurisdiction;

d. The appropriate governmental, tribal, self-regulatory, or professional organization if that entity has jurisdiction over the subject matter of the complaint or inquiry, or the entity that is the subject of the complaint or inquiry;

e. The Department of Justice, a court, an adjudicative body, a party in litigation, or a witness if the Board determines that the information is relevant and necessary to a proceeding in which the Board, any Board employee in his or her official capacity, any Board employee in his or her individual capacity represented by the Department of Justice or the Board, or the United States is a party or has an interest;

f. A congressional office when the information is relevant to an inquiry made at the request of the individual about whom the record is maintained;

g. Contractors, agents, or volunteers performing or working on a contract, service, cooperative agreement, or job for the Board;

h. Third parties when mandated or authorized by statute; or

i. The National Archives and Records Administration in connection with records management inspections and its role as Archivist.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are stored in electronic or printed form.

RETRIEVABILITY:

Files are retrievable by consumer name or as appropriate.

SAFEGUARDS:

Access to and use of these records is restricted to authorized personnel only.

RETENTION AND DISPOSAL:

Records are retained for five years.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, 20th and Constitution, NW., Washington, DC 20551.

NOTIFICATION PROCEDURE:

Inquiries should be sent to the Secretary of the Board, Board of Governors of the Federal Reserve System, 20th and Constitution Avenue, NW., Washington, DC 20551. The request should contain the individual's name, name of the bank that was the subject of the complaint, and date of the complaint.

RECORD ACCESS PROCEDURES:

Same as ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

Same as ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Person(s) who initiates complaint (or his or her representative, which may

include a member of Congress or an attorney); appropriate federal, state, or local regulatory and enforcement agencies; and institutions or individuals that are the subject of the complaint.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, February 24, 2004.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 04–4444 Filed 2–27–04; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0333]

Determination That Cytoxan (Cyclophosphamide for Injection), 2 Gram Vials (NDA 12–142 054), 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 although Bristol Myers Squibb (Bristol) has discontinued marketing CYTOXAN, 2 gram (g) vials (cyclophosphamide for injection), this formulation was not withdrawn from sale for reasons of safety and effectiveness. As a result of this determination, approved abbreviated new drug applications (ANDAs) for cyclophosphamide for injection that referenced Bristol's cyclophosphamide for injection will not be removed from the market. Because Bristol has supplemented its CYTOXAN NDA and obtained approval for a new formulation, cyclophosphamide lyophilized, any unapproved ANDAs seeking to reference CYTOXAN as a reference listed drug must reference the currently approved formulation, cyclophosphamide lyophilized.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 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 typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs 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 (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 § 314.162 (21 CFR 314.162), 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 voluntarily withdrawn from sale by the sponsor for reasons of safety or effectiveness.

Regulations also provide that 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 (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). If the agency determines that a listed drug was withdrawn for reasons of safety or effectiveness, the drug must be removed from the list of approved drug products, and ANDAs referencing that drug may not be approved (§ 314.162). Under § 314.161(a)(2), the agency must also determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that referred to the listed drug have already been approved prior to its market withdrawal. If the agency determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, and there are approved ANDAs that reference that listed drug, FDA will initiate a proceeding to determine whether the suspension of the ANDAs is also required (21 CFR 314.153(b)).

On August 30, 1982, Bristol received approval for CYTOXAN (cyclophosphamide for injection), 2 g vials, under NDA 12–142 054. CYTOXAN is an alkylating agent used to treat various types of cancer. It interferes with the growth of cancer cells, which are eventually destroyed. On January 4, 1984, Bristol received approval for a new formulation of CYTOXAN, cyclophosphamide lyophilized, under NDA 12–142 058. Bristol's lyophilized formulation was approved on the basis of a showing of bioequivalence to the previously approved formulation. No additional clinical trials were required to demonstrate the safety or effectiveness of cyclophosphamide lyophilized. ANDAs were approved before the time the cyclophosphamide lyophilized formulation was approved. These ANDAs referenced cyclophosphamide for injection. Bristol discontinued marketing cyclophosphamide for injection, 2 g vials, in 1997. Cyclophosphamide for injection was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book in May 1997.

On July 26, 2001, ASTA Medica, Inc., submitted a citizen petition (Docket No. 01P–0333/CP1) to FDA under 21 CFR 10.30 requesting that the agency determine whether CYTOXAN, cyclophosphamide for injection, 2 g vials, was withdrawn from sale for reasons of safety or effectiveness. This determination not only affects whether an ANDA may be submitted and approved under §§ 314.122 and 314.161 using CYTOXAN, cyclophosphamide for injection, 2 g, as the reference listed drug, but also affects whether the agency is required to initiate withdrawal proceedings for the ANDAs that reference cyclophosphamide for injection and were approved before its market withdrawal.

The agency has determined that Bristol did not withdraw cyclophosphamide for injection from sale for reasons of safety or effectiveness. Three grounds support the agency's finding. First, Bristol continues to market cyclophosphamide lyophilized (which is pharmaceutically and therapeutically equivalent to Bristol's withdrawn cyclophosphamide for injection) in a variety of strengths. FDA has no reason to believe that cyclophosphamide lyophilized has a different safety or effectiveness profile than cyclophosphamide for injection, and required Bristol to conduct no clinical trials (other than bioequivalence trials) to support the formulation change. Second, the petitioner identified no adverse event data or other information suggesting that Bristol withdrew cyclophosphamide for injection from sale as a result of safety