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Determination That Cytoxan (Cyclophosphamide for Injection), 2 Gram Vials (NDA 12–142 054), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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has discontinued marketing CYTOXAN, 2 gram (g) vials (cyclophosphamide for injection), this formulation was not withdrawn from sale for reasons of safety and effectiveness.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

or effectiveness concerns. Third, FDA has independently evaluated relevant literature and internal agency data for possible postmarketing reports associated with cyclophosphamide for injection, and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined above, Bristol's cyclophosphamide for injection was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will not initiate proceedings to suspend the approvals of ANDAs referencing cyclophosphamide for injection. However, because Bristol has supplemented its CYTOXAN NDA and obtained approval for a new formulation, cyclophosphamide lyophilized, any unapproved ANDAs seeking to reference CYTOXAN (NDA 12–142 054) must reference the currently approved formulation.

Dated: February 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4505 Filed 2–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cancellation of Grant Opportunities Previously Announced in the HRSA Preview on September 4, 2003 (68 FR 52632)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of cancellation.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the cancellation of eight grant opportunities that were initially published in the (September 4, 2003 (68 FR 52632)) **Federal Register** notice of availability of competitive grant funds for numerous HRSA programs.

EFFECTIVE DATE: March 1, 2004.

FOR FURTHER INFORMATION CONTACT: Gail Lipton, Director, Division of Grants Policy, Office of Financial Policy and Oversight, Telephone (301) 443–6509. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The HRSA Preview is a comprehensive listing of HRSA competitive grant programs scheduled for award in Fiscal Year 2004. However, as indicated in the Frequently Asked Questions section of the Preview, programs may be withdrawn from competition. Based on final Fiscal Year 2004 appropriations and a redirection of priorities, HRSA hereby withdraws the following programs and announcements from Fiscal Year 2004 competition:

HRSA–04–021 Bioterrorism Training and Curriculum Development (BTCDP).

HRSA–04–028 Radiation Exposure Screening and Education Program (RESEP).

HRSA–04–036 National Health Center Technical Assistance Cooperative Agreements (NAT).

HRSA–04–046 Telehealth Resource Centers Cooperative Agreement Program (TRCCP).

HRSA–04–049 Title III: Early Intervention Services Planning Grants (EISPG).

HRSA–04–052 Maternal and Child Health Minority Research Infrastructure Support Program (RMIN).

HRSA–04–061 Partnership for Information and Communication (PIC) Cooperative Agreement Program.

HRSA–04–074 Best Practices to Increase Organ Donation (HIP).

These cancellations will be effective immediately upon publication of this **Federal Register** notice. HRSA will not accept any FY 2004 competitive applications for these funding opportunities, and any applications previously submitted will be returned to the respective applicants. Further information about HRSA programs will be provided through the HRSA Preview at the HRSA Home page at *http://www.hrsa.gov.*

Dated: February 24, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–4506 Filed 2–27–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Meeting

The Office of the Director, National Institutes of Health (NIH), announces a meeting of the NIH Blue Ribbon Panel on Conflict of Interest Policies, a working group of the Advisory Committee to the Director, NIH. The meeting is scheduled for March 1–2, 2004, beginning at 8:30 a.m. each day.

The meeting will be held at the NIH, 9000 Rockville Pike, Bethesda, Maryland, Building 31C, Conference Room 10. Attendance will be limited to space available. In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

On March 1 and until noon on March 2, the meeting will be open to the public. Sessions will include: Federal Conflict of Interest Policies; HHS Conflict of Interest Policies, NIH Conflict of Interest Policies and Procedures, and there will be time set aside for oral presentations by the public. Any person wishing to make a presentation should notify Charlene French, Office of Science Policy, National Institutes of Health, Building 1, Room 103, Bethesda, Maryland 20892, telephone 301–496–2122 by February 26, 2004 or by e-mail: *blueribbonpanel@mail.nih.gov*.

Oral comments will be limited to 5 minutes. Due to time constraints, only one representative from each organization will be allotted time or oral testimony. The number of speakers and the time allotment may also be limited by the number of presentations. The opportunity to speak will be based on a first come first served basis. All requests to present oral comments should include the name, address, telephone number, and business or professional affiliation of the interested party, and should indicate the areas of interest or issue to be addressed. Please provide, if possible, an electronic copy of your comments.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement during the time set aside for public comment, if time permits and at the discretion of the co-chairs.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Charlene French in advance of the meeting at the address listed earlier in this notice.

Dated: February 19, 2004.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–4528 Filed 2–26–04; 11:15 am]

BILLING CODE 4140–01–M