Dated: June 26, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–16673 Filed 7–2–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02136]

Reducing Sexual Risk for HIV Transmission in Substance-Using Men Who Have Sex With Men, Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2002 funds for a cooperative agreement program to support research on Reducing Sexual Risk for HIV Transmission in Substance-Using Men Who Have Sex With Men, was published in the **Federal Register** dated May 24, 2002, Vol. 67, No. 101, pages 36608–36610. On page 36609, section E. Application Content, third sentence, should be amended to read: ''The narrative should be no more than 40 double-spaced pages, printed on one side with one inch margins in a 12-point font. The budget and budget justification are not included in the 40 page limit.''

Dated: June 27, 2002.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–16701 Filed 7–2–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Allergenic Products Advisory Committee, Biological Response Modifiers Advisory Committee, Blood Products Advisory Committee, Transmissible Spongiform Encephalopathies Advisory Committee, and the Vaccines and Related Biological Products Advisory Committee in the Center for Biologics Evaluation and Research (CBER). Nominations will be accepted for vacancies that will or may occur through December 31, 2003.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations and curricula vitae should be sent to the appropriate contact person in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding nominations except for consumer representatives: Jane Brown, Scientific Advisors and Consultants Staff, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314.

Regarding nominations for consumer representatives: Linda Sherman, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members with appropriate expertise for vacancies listed as follows:

1. Allergenic Products Advisory Committee: Three vacancies occurring August 31, 2003; immunology, pediatrics, internal medicine, biochemistry, statistics, consumer interest, and related scientific fields.

2. Blood Products Advisory Committee: One vacancy occurring September 30, 2002; and six vacancies occurring September 30, 2003; clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, statistics, biological and physical sciences, and other related scientific fields.

3. Transmissible Spongiform Encephalopathies Advisory Committee: Five vacancies occurring January 31, 2003; clinical administrative medicine, hematology, virology, neurology, infectious diseases, immunology, blood banking, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions.

4. Vaccines and Related Biological Products Advisory Committee: Five vacancies occurring January 31, 2003; immunology, molecular biology, recombinant deoxyribonucleic acid (rDNA), virology, bacteriology, epidemiology, biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, biochemistry, and consumer interest.

Functions

1. Allergenic Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic diseases.

2. Blood Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases.

3. Transmissible Spongiform Encephalopathies Advisory Committee

Reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

4. Vaccines and Related Biological Products Advisory Committee

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.

Qualifications

Persons nominated for membership on the committees shall have adequately diversified experience appropriate to the work of the committee in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the

field of activity of the committee. The particular needs at this time for each committee are shown in the first paragraph of the **SUPPLEMENTARY INFORMATION** section of this document. The term of office is up to 4 years, depending on the appointment date.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member (name of committee(s) must be specified), and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Consumer Representatives

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees to represent consumer interests. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures that include use of a group of consumer organizations that has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vita of each nominee, current address and telephone numbers, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: June 24, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–16692 Filed 7–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0043]

Determination That Piperacillan for Injection USP, 40–Gram Pharmacy Bulk Package, 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 piperacillan for injection USP (PIPRACIL), 40-gram (g) pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for piperacillan for injection USP, 40-g pharmacy bulk package.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, 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 (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. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 FDA 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).

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. FDA may not approve an ANDA that does not refer to a listed drug.

Piperacillan for injection USP, 40-g pharmacy bulk package, is the subject of approved NDA 50–545 held by Lederle (part of Wyeth-Ayerst Pharmaceuticals) under the trade name PIPRACIL. Piperacillan for injection USP, 40-g pharmacy bulk package, is a broad-spectrum penicillin indicated for the treatment of serious infections and for prophylactic use in surgery. According to information from Wyeth-Ayerst submitted in 2001, production of the 40-g pharmacy bulk package was discontinued. On January 17, 2002, Mr. Michael Lisjak submitted a citizen petition (Docket No. 02P–0043) under 21 CFR 10.30 and 314.122, requesting that the agency determine whether piperacillan for injection USP, 40-g pharmacy bulk package, was withdrawn from sale for reasons of safety or effectiveness. The petitioner seeks this determination in preparation for filing an ANDA for piperacillan for injection USP, 40-g pharmacy bulk package.

The agency has determined that Wyeth-Ayerst's piperacillan for injection USP, 40-g pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, Wyeth-Ayerst continues to market PIPRACIL in 2-, 3-, and 4-g vials. The 40-g pharmacy bulk package is a larger package of the same product; it contains up to 20 doses of piperacillan for injection USP. Second, the petitioner identified no data or other information suggesting that PIPRACIL (piperacillan for injection USP, 40-g pharmacy bulk package) was withdrawn