Committee meeting concerning planning for the 2005 White House Conference on Aging. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person listed below in advance of the meeting.

DATES: The meeting will be held Friday, October 1, 2004, from 8:30 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Hall of the States, 444 North Capitol Street, Room 333, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Nora Andrews, (202) 357–0150, or e-mail *nora.Andrews@aoa.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to the Older Americans Act Amendments of 2000 (Public Law 106–501, November 2000), the Policy Committee will meet to further organize efforts towards pursuing its duties in support of the 2005 White House Conference on Aging, and to discuss the potential conference agenda topics.

Speakers include Estelle James, Ph.D., formerly of the World Bank and Urban Institute Fellow; Paul Hodge, Director of the Generations Policy Institute and Research Fellow at the Houser Center, JFK School of Government, Harvard University; and Diane Braunstein, Program Director, Health Center for Best Practices, National Governors Association.

Dated: September 8, 2004.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 04–20964 Filed 9–16–04; 8:45 am]

BILLING CODE 4154–01–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.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Allergenic Products 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, 2005.

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:Gail Dapolito, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, e-mail: *dapolito@cber.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Vacancies

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

TABLE 1.

Advisory Committee and Expertise Needed to Fill Vacancies	Number of Vacancies	Approximate Date Members are Needed
Allergenic Products Advisory Committee—immunology, pediatrics, internal medicine, biochemistry, statistics, consumer advocacy, and related scientific fields	3	August 31,2005
Blood Products Advisory Committee—clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, statistics, biological and physical sciences, and other related scientific fields	7	September 30, 2005
Transmissible Spongiform Encephalopathies Advisory Committee—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 scientific fields	4	January 31, 2005
Vaccines and Related Biological Products Advisory Committee—immunology, molecular biology, rDNA, virology, bacteriology, epidemiology, biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, biochemistry, and other related scientific fields	3	January 31, 2005

II. Functions

A. Allergenic Products Advisory Committee

The 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.

B. Blood Products Advisory Committee

The 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.

C. Transmissible Spongiform Encephalopathies Advisory Committee

The 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.

D. Vaccines and Related Biological Products Advisory Committee

The committe 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.

III. 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 need for vacancies on each committee for the calendar year 2005 are shown in table I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. 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.

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: September 9, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–20933 Filed 9–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0162]

Determination That ZOLOFT (Sertraline Hydrochloride) Tablets, 150 Milligrams and 200 Milligrams, 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 ZOLOFT (sertraline hydrochloride (HCl)) Tablets, 150 milligrams (mg) and 200 mg (new drug application (NDA) 19–839), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sertraline HCl tablets, 150 mg and 200 mg.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, 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 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 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 (§ 314.162 (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.

ZOLOFT Tablets, 150 mg and 200 mg, are the subject of approved NDA 19–839 held by Pfizer, Inc. (Pfizer). ZOLOFT (sertraline HCl) is indicated for the treatment of major depressive disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder. Lachman Consultant Services, Inc., submitted a citizen petition dated April 5, 2004 (Docket No. 2004P–0162/CP1), under 21 CFR 10.30, requesting that the agency determine whether ZOLOFT (sertraline HCl) Tablets, 150 mg and 200 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Pfizer's ZOLOFT Tablets, 150 mg and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness. Pfizer has never commercially marketed ZOLOFT Tablets, 150 mg and 200 mg. In previous instances (see, e.g., 67 FR 79640 at 79641, December 30, 2002 (addressing a relisting request for Diazepam Autoinjector)), FDA has concluded that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. There is no indication that Pfizer's decision not to market ZOLOFT Tablets, 150 mg and 200 mg, commercially is a function of safety or effectiveness concerns, and the petitioner has identified no data or other information suggesting that ZOLOFT Tablets, 150 mg and 200 mg, pose a safety risk. FDA's independent evaluation of relevant information has uncovered nothing that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined