

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

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; Cellular, Tissue, and Gene Therapies Advisory Committee; Transmissible Spongiform Encephalopathies Advisory Committee; and the Vaccines and Related Biological Products Advisory Committee. Nominations will be accepted for current vacancies and those that will or may occur through September 30, 2009.

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 document.

ADDRESSES: All nominations for membership should be sent electronically to *CV@OC.FDA.GOV*, or by mail to Advisory Committee Oversight and

Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, rm. 15A-12, Rockville, MD 20857. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/oc/advisory/default.htm>.

FOR FURTHER INFORMATION CONTACT: Linda Amendt, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-1370, e-mail: Linda.Amendt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Vacancies

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

TABLE 1.

Committee and Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Allergenic Products Advisory Committee—allergy, immunology, pediatrics, internal medicine, biochemistry, statistics, and related specialties	3 2	Immediately August 31, 2009
Blood Products Advisory Committee—clinical and administrative medicine, hematology, immunology, blood banking, tissue banking, surgery, anesthesia, critical care, internal medicine, infectious diseases, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, clinical trial design, and other related professions	2 4	Immediately September 30, 2009
Cellular, Tissue, and Gene Therapies Advisory Committee—cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation including biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics	4 3	Immediately March 31, 2009
Transmissible Spongiform Encephalopathies Advisory Committee—clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions	1 4	Immediately January 31, 2009
Vaccines and Related Biological Products Advisory Committee—immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry	4 1	Immediately January 31, 2009

II. Functions

A. Allergic 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, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, of treatment of human diseases.

C. Cellular, Tissue, and Gene Therapies Advisory Committee

The committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions.

D. 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.

E. Vaccines and Related Biological Products Advisory Committee

The 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.

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 years 2008 and 2009 is shown in table 1 of this document. The term of office is up to 4 years depending on the appointment date. Committees meet one to five times a year. Most meetings are for 2 days.

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. Potential candidates will be required 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: January 21, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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