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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

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, and Transmissible Spongiform and Encephalopathies Advisory Committee, Center for Biologics Evaluation and Research. Nominations will be accepted for vacancies that will or may occur through December 31, 2013.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately 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 for membership should be sent electronically to cv@oc.fda.gov, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm.

FOR FURTHER INFORMATION CONTACT: For specific Committee questions, contact the following persons listed in Table 1 of this document:

TABLE 1

Contact Person	Committee
Donald Jehn, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, HFM-71, Rockville, MD 20852, 301-827-1293; email: donald.jehn@fda.hhs.gov	Allergenic Products Advisory Committee
Bryan Emery, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, HFM-71, Rockville, MD 20852, 301-827-1277, email: bryan.emery@fda.hhs.gov	Blood Products Advisory Committee and Transmissible Spongiform Encephalopathies Advisory Committee
Gail Dapolito, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, HFM-71, Rockville, MD 20852, 301-827-1289, email: gail.dapolito@fda.hhs.gov	Cellular, Tissue and Gene Therapies Advisory Committee

SUPPLEMENTARY INFORMATION:

I. Vacancies

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

TABLE 2

Committee expertise needed	Upcoming Vacancies	Approximate Date Needed
Allergenic Products Advisory Committee – individuals knowledgeable in clinical immunology/allergy	3	September 1, 2013
Blood Products Advisory Committee – Individuals knowledgeable in surgery/trauma, pediatric hematology/oncology, hematology, medical epidemiology	4	October 1, 2013
Cellular, Tissue and Gene Therapies Advisory Committee – individuals knowledgeable in tissue engineering/regenerative medicine, orthopedic oncology	2	April 2, 2013
Transmissible Spongiform Encephalopathies Advisory Committee –individuals knowledgeable in veterinary medicine, prion molecular biology	2	February 1, 2013

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 disease, and makes appropriate recommendations to the Commissioner of Food and Drugs of its findings regarding the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations governing the manufacture, testing and

licensing of allergenic biological products, and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

B. Blood Products 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, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings regarding the safety, effectiveness, screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

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. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

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 as determined by the Commissioner of Food and Drugs. The Committee will make recommendations to the Commissioner regarding the regulations of such products.

III. Qualifications

A. Allergenic Products Advisory Committee

Persons nominated for membership should be authorities knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

B. Blood Products Advisory Committee

Persons nominated for membership should be authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.
The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

C. Cellular, Tissue and Gene Therapies Advisory Committee

Persons nominated for membership should be authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation (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). The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

D. Transmissible Spongiform Encephalopathies Advisory Committee

Persons nominated for membership should be authorities knowledgeable in the fields of 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.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, and their current business address and/or home address, telephone number, and email address if available. Nominations must specify the advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to 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 25, 2012

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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