SUPPLEMENTARY INFORMATION:

I. Vacancies

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

<table>
<thead>
<tr>
<th>Committee expertise needed</th>
<th>Upcoming vacancies</th>
<th>Approximate date needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergenic Products Advisory Committee—individuals knowledgeable in clinical immunology/allergy</td>
<td>3</td>
<td>September 1, 2013.</td>
</tr>
<tr>
<td>Blood Products Advisory Committee—individuals knowledgeable in surgery/trauma, pediatric hematology/oncology, hematology, medical epidemiology</td>
<td>4</td>
<td>October 1, 2013.</td>
</tr>
<tr>
<td>Cellular, Tissue and Gene Therapies Advisory Committee—individuals knowledgeable in tissue engineering/regenerative medicine, orthopedic oncology</td>
<td>2</td>
<td>April 2, 2013.</td>
</tr>
</tbody>
</table>
TABLE 2—Continued

<table>
<thead>
<tr>
<th>Committee expertise needed</th>
<th>Upcoming vacancies</th>
<th>Approximate date needed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transmissible Spongiform Encephalopathies Advisory Committee</strong>—individuals knowledgeable in veterinary medicine, prion molecular biology.</td>
<td>2</td>
<td>February 1, 2013.</td>
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</tbody>
</table>

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 clinical and administrative medicine, hematology, immunology, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, 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.


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

FOR FURTHER INFORMATION CONTACT:
The Agency requests nominations for a nonvoting industry representative on the Tobacco Products Scientific Advisory Committee to represent the interests of tobacco growers. Elsewhere in this issue of the Federal Register, FDA is publishing a separate document announcing the Request for Notification for Voting Members on the Tobacco Products Scientific Advisory Committee.

II. Selection Procedure

Any industry organization interested in participating in the selection of appropriate nonvoting member(s) to represent industry interests should send a letter stating that interest to the FDA contact (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). Within 50 days of publication of this document, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days of the receipt of the letter, to serve as the nonvoting member to represent the interests of the tobacco growers on the Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or organizations may nominate one or more individuals to serve as a nonvoting industry representative (for the roles specified previously in this notice). Nominations must include a current resume or curriculum vitae of the nominee including current business address and/or home address, telephone number, email address if available, and the role for which the individual is being nominated. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

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.

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.