him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Delaney failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mr. Stephen C. Delaney, Jr. has been convicted of a felony under Federal law for conduct relating to the importation of an article of food into the United States and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Delaney is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Delaney is a prohibited act.

Any application by Mr. Delaney for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–0405 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–24528 Filed 10–4–12; 8:45 am]

BILLING CODE 4160–01–P

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.

TABLE 2—Continued

Committee expertise needed	Upcoming vacancies	Approximate date needed
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.

[FR Doc. 2012–24554 Filed 10–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of a nonvoting industry representative to represent the interests of tobacco growers, to serve on its Tobacco Products Scientific Advisory Committee, notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for the upcoming vacancy effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of tobacco growers must send a letter stating the interest to FDA by November 5, 2012, for the vacancy listed in the notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by November 5, 2012.

ADDRESSES: All letters of interest and nominations should be submitted in writing to *TPSAC@fda.hhs.gov,* or by mail to Caryn Cohen (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 4), Fax: 240–276–3655, *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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.

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner. The Committee includes three nonvoting members who represent industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. The representative of the interests of the small business tobacco manufacturing industry may be filled on a rotating basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee. With this notice, nominations are sought for one representative of the interests of tobacco growers, and an alternate to this representative.

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.