

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2008-N-0581]

**Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representative on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representative on Public Advisory Committees**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CBER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by *[insert date 30 days after date of publication in the Federal Register]*, for vacancies listed in the notice.

Concurrently, nomination materials for prospective candidates should be sent

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to FDA by [insert date 30 days after date of publication in the **Federal Register**].

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Gail Dapolito (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Gail Dapolito, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20892, 301-827-1289, *gail.dapolito@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The agency requests nominations for nonvoting industry representatives to the following advisory committees.

## **I. CBER Advisory Committees**

### *A. The 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 (the Commissioner).

### *B. 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, and, as required, any other product for which FDA has regulatory responsibility. The Committee as 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.

### *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 as determined by the Commissioner. The Committee will make recommendations to the Commissioner regarding the regulation of such products.

## **II. Selection Procedure**

Any industry organization interested in participating in the selection of an appropriate nonvoting member 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 the subsequent 30 days, 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 after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular 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.

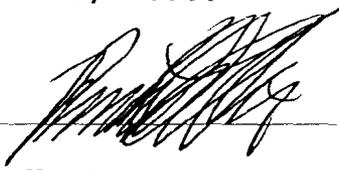
### III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within the 30 days (see **DATES**). 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 has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for 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.

Dated: 11/5/08  
November 5, 2008.

  
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Randall W. Lutter,  
Deputy Commissioner for Policy.

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