

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for a Nonvoting Member Representing Industry Interests on a Public Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) requests nominations for a nonvoting industry representative to serve on the Cellular Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee) under the purview of the Center for Biologics Evaluation and Research (CBER).

DATES: Industry organizations interested in participating in the selection of a nonvoting member to represent industry for the vacancy listed in this notice must send a letter to FDA by *[insert date 30 days after date of publication in the **Federal Register**]*.

Concurrently, nomination materials for prospective candidates should be sent to FDA by *[insert 30 days after date of publication in the **Federal Register**]*. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

ADDRESSES: All letters of interest and nominations should be sent to the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Division of Scientific Advisors and Consultants (HFM-71), Food and Drug Administration, 1401

Rockville Pike, Rockville, MD 20857–1448, 301–827–0314, e-mail:
dapolito@cber.fda.gov.

SUPPLEMENTARY INFORMATION: The agency requests nominations for a no-voting industry representative to the advisory committee identified below.

I. Function

The Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory 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.

II. Selection Procedure

Any organization in the biologics manufacturing industry wishing to participate in the selection of a nonvoting member to represent industry on the Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee) should send a letter stating that interest to FDA contact identified above within 30 days of publication of this notice. Persons who nominate themselves as an industry representative for the advisory committee will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association, or firm who is willing to participate

in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing industry interests on the advisory committee. If no individual is selected within the 60 days, the Commissioner of Food and Drugs may select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may nominate themselves or an organization representing the biologics manufacturing industry may nominate one or more individuals to serve as nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the committee of interest should be sent to FDA contact person. FDA will forward all nominations to the organizations that have expressed interest in participating in the selection process for that committee.

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. Therefore, the agency 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: November 29, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

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