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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Request for Nominations for Voting Consumer Representative 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 consumer representatives to serve on the Cellular, Tissue, and Gene Therapies Advisory Committee and the Allergenic Products Advisory Committee in the Center for Biologics Evaluation and Research (CBER).

Nominations will be accepted for vacancies that will occur through August 31, 2008.

DATES: Nominations will be accepted for those voting consumer representative vacancies that will occur on or before August 31, 2008. Nominations submitted on or before April 1, 2008, will be given first consideration for membership on the Cellular, Tissue, and Gene Therapies Advisory Committee and the Allergenic Products Advisory Committee. Nominations received after April 1, 2008, will be considered for nomination to the committee should nominees still be needed.

ADDRESSES: All nominations for membership should be sent electronically to CV@OC.FDA.GOV, or by mail to Advisory Committee Oversight and Management Staff (HF-4), 5600 Fisher Lane, rm. 15A-12, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is Gail Dapolito, Center for Biologics

Evaluation and Research, 301-827-0314, FAX: 301-827-0294, e-mail:

Gail.Dapolito@fda.hhs.gov. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/oc/advisory/default.htm>.

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting consumer representative members on the following CBER committees:

I. Functions

A. 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 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. 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. The committee also makes appropriate recommendations to the Commissioner on its findings regarding the affirmation or revocation of biological product licenses, the safety, effectiveness, and labeling of the products, clinical and laboratory studies of such products, 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.

II. Criteria for Members

Persons who are nominated for membership as consumer representatives on the committees must meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committee on scientific issues that affect consumers.

III. Selection Procedures

The selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

IV. Nomination Procedures

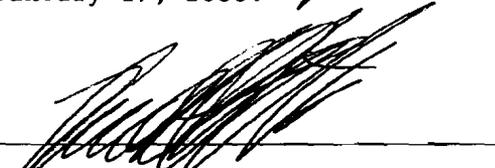
All nominations must include a cover letter, a curriculum vitae or resume (that includes the nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation. Any interested person or organization may nominate one or more qualified persons for membership to represent consumer interests on one or more of the advisory committees. Self-nominations are also accepted. FDA will ask the potential candidates to

provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of a conflict of interest. The nomination should specify the committee(s) of interest. The term of office is up to 4 years, depending on the appointment date.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on its advisory committees and, therefore, encourages nominations of 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: 1/17/08
January 17, 2008.



Randall W. Lutter,
Deputy Commissioner for Policy.

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Dawn P. Hawkins