

## 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.

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**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting consumer representatives to serve on its advisory committees that are under the purview of the Center for Drug Evaluation and Research (CDER).

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.

**DATES:** Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2005. Because vacancies occur on various dates throughout the year, there is no cutoff date for the receipt of nominations.

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

**FOR FURTHER INFORMATION CONTACT:** Igor Cerny, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, 301-827-7001, e-mail: [cerny@cder.fda.gov](mailto:cerny@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting consumer representatives to all of its advisory committees identified in section I of this document.

**I. Functions**

The functions of advisory committees under the purview of CDER are listed in the following paragraphs.

*A. Arthritis Advisory Committee*

The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

*B. Anti-Infective Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner.

*C. Cardiovascular and Renal Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner.

*D. Dermatologic and Ophthalmic Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use

in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner.

*E. Endocrinologic and Metabolic Drugs Advisory Committee*

The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders and makes appropriate recommendations to the Commissioner.

*F. Nonprescription Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the issuance of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded, or on the approval of new drug applications for such drugs. The committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

*G. Pulmonary-Allergy Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or

immunologic mechanisms and makes appropriate recommendations to the Commissioner.

## **II. Criteria for Members**

Persons who are nominated for membership on the committees as consumer representatives 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 committees 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 on one or more of the advisory committees to represent consumer interests. 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.

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: April 1, 2005.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

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