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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committee and Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) and certain devices panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH).

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on 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 October 31, 2009. Because vacancies occur on various dates throughout the year, there is no cutoff date for the receipt of nominations.

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 Fishers Lane, Rockville, MD 20857.

Information about becoming a member on an FDA advisory committee can also

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be obtained by visiting FDA's Web site at <http://www.fda.gov/oc/advisory/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/Panel
Geretta P. Wood, Center for Devices and Radiological Health (HFZ-400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3993, e-mail: Geretta.Wood@fda.hhs.gov	Certain Device Panels of the Medical Devices Advisory Committee
Nancy M. Wynne, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: Nancy.Wynne@fda.hhs.gov	National Mammography Quality Assurance Advisory Committee

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations for voting and nonvoting consumer representatives for the vacancies listed in table 2 of this document:

TABLE 2.

Committee/Panel Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
<i>Circulatory System Devices Panel of the Medical Devices Advisory Committee</i> —interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure	1—nonvoting	Immediately
<i>Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee</i> —doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, endocrinology, and diabetes	1—nonvoting	March 1, 2009
<i>Dental Products Panel of the Medical Devices Advisory Committee</i> —dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy	1—nonvoting	November 1, 2009
<i>General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee</i> —surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians	1—nonvoting	Immediately
<i>Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee</i> —experts with broad, cross-cutting scientific, clinical, analytical or mediation skills	1—nonvoting	Immediately
<i>Microbiology Devices Panel of the Medical Devices Advisory Committee</i> —infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, biofilm development; mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists	1—nonvoting	March 1, 2009
<i>Ophthalmic Devices Panel of the Medical Devices Advisory Committee</i> —ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials	1—nonvoting	November 1, 2009
<i>Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee</i> —orthopedic surgeons (joint, spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians	1	January 31, 2009
<i>National Mammography Quality Assurance Advisory Committee</i> —physicians, practitioners, or other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography	2—nonvoting	February 1, 2009

II. Functions

A. NMQAAC

The committee advises FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

B. *Certain Panels of the Medical Devices Advisory Committee*

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions of the Federal Food, Drug, and Cosmetic Act's (the act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, does the following: (1) Advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development

protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the act, (7) advises on the necessity to ban a device, and (8) responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

III. Criteria for Members

Persons nominated for membership as a consumer representatives on the committee/panels 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.

IV. Selection Procedures

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.

V. Nomination Procedures

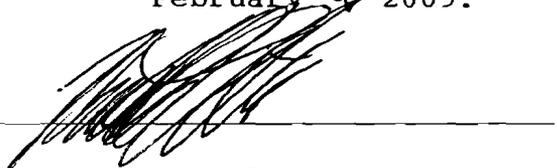
All nominations must include a cover letter, a curriculum vita or resume (that includes the nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations will specify the advisory committee or panel(s) for which the nominee is recommended. Nominations will include confirmation that the nominee is aware of the nomination.

Any interested person or organization may nominate one or more qualified persons for membership as consumer representatives on the advisory committee/panels. Self-nominations are also accepted. Potential candidates will be required to provide detail 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/panels 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: 2/4/09
February 4, 2009.



Randall W. Lutter,
Deputy Commissioner for Policy.

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