4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, and the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through December 31, 2012.

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: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations for membership should be sent electronically to cv@oc.fda.gov, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002.

Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm.

FOR FURTHER INFORMATION CONTACT: For specific Committee/Panel questions, contact the following persons listed in table 1 of this document.

Table 1.--Contact Persons and Committee/Panel Names

Contact Person	Committee/Certain Device Panels of the Medical Devices Advisory Committee
LCDR Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301-796-7046, email: Sara.Anderson@fda.hhs.gov.	National Mammography Quality Assurance Advisory Committee. Clinical Chemistry and Clinical Toxicology Devices Panel. Dental Products Panel. General Hospital and Personal Use Devices Panel. Ophthalmic Devices Panel.
Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993, 301-796-6639, email: Shanika.Craig@fda.hhs.gov.	Microbiology Devices Panel. Obstetrics and Gynecology Devices Panel.
Lt. Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993, 301-796-3805, email: Avena.Russell@fda.hhs.gov.	Device Good Manufacturing Practice Advisory Committee. Gastroenterology and Urology Devices Panel. General and Plastic Surgery Devices Panel. Neurological Devices Panel. Orthopedic and Rehabilitation Devices Panel.
Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301-796-3036, email Jamie.Waterhouse@fda.hhs.gov.	Circulatory System Devices Panel. Ear, Nose and Throat Devices Panel. Molecular and Clinical Genetics Devices Panel.

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations of voting members for vacancies listed as follows:

Table 2.--Committee/Panel and Vacancies

Committee/Panel Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Circulatory System Devices Panel of the Medical Devices Advisory Committee--Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	2	July 1, 2012

Committee/Panel Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee--Doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, endocrinology, and diabetes.	2	March 1, 2012
Dental Products Panel of the Medical Devices Advisory Committee--Dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	1	November 1, 2012
Ear, Nose and Throat Devices Panel of the Medical Devices Advisory Committee--Otologists, neurotologists, and audiologists.	1	November 1, 2012
Gastroenterology and UrologyDevices Panel of the Medical Devices Advisory Committee–Transplant specialists, gastroenterologists, urologists, and nephrologists.	3	January 1, 2013
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee--Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	1 2	Immediately September 1, 2012
General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee--Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.	1	January 1, 2013
Microbiology Devices Panel of the Medical Devices Advisory Committee--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	March 1, 2012

Committee/Panel Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee--Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, and neonatologists. Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, and clinical molecular genetics testing (e.g., genotyping, array CGH, etc.). Individuals with experience in genetics counseling and medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	1	June 1, 2012
Neurological Devices Panel of the Medical Devices Advisory Committee--Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	2	December 1, 2012
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee--Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/ gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	1	February 1, 2012
Ophthalmic Devices Panel of the Medical Devices Advisory Committee--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 1	Immediately November 1, 2012
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee--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.	2	September 1, 2012
National Mammography Quality Assurance Advisory Committee--Physicians, practitioners, or other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography.	3	February 1, 2012
Device Good Manufacturing Practice Advisory Committee--Vacancies include a public representative and a health professional representative.	2	June 1, 2012

II. Functions

A. 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 (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area performs the following duties: (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 FD&C 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.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

B. National Mammography Quality Assurance Advisory Committee

The functions of the committee are to advise 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.

C. Device Good Manufacturing Practice Advisory Committee

The functions of the committee are to review proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations.

The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

Section 520 of the FD& C Act, (21 U.S.C. 360(j)), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: (1) Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government; (2) two shall be representatives of the interests of the device manufacturing industry; (3) two shall be representatives of the interests of physicians and other health professionals; and (4) two shall be representatives of the interests of the general public.

III. Qualifications

A. Panels of the Medical Devices Advisory Committee

Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

B. National Mammography Quality Assurance Advisory Committee

Persons nominated for membership should be physicians, practitioners, and other health

professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography and individuals identified with consumer interests. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise.

The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

C. Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, and their current business address and/or home address, telephone number, and email address if available. Nominations must specify the advisory panel(s) or advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research

grants and/or contracts to permit evaluation of possible sources of conflict of interest.

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: December 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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