General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 22, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You'', click on ''Public Meetings at the FDA White Oak Campus''. Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, Fax: (301) 847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–(800) 741–8138 (301) 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 22–580, proposed trade name QNEXA (phentermine/topiramate) Controlled-Release Capsules, manufactured by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related comorbidities.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 7, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 30, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 31, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33059 Filed 12–23–11; 8:45 am]

BILLING CODE 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.
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 Urology Devices 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
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.

TABLE 2—COMMITTEE/PANEL AND VACANCIES—Continued

Committee/Panel expertise needed	Current & upcoming vacancies	Approximate date needed
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	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.

[FR Doc. 2011–33060 Filed 12–23–11; 8:45 am]

BILLING CODE 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 a Public Advisory Committee; Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members with expertise in epidemiology, pediatric development, and analytical chemistry or food science to serve on the Food Advisory Committee, Center for Food Safety and Applied Nutrition, Office of Regulations, Policy, and Social Sciences.

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 received on or before February 27, 2012 will be given first consideration for membership on the Food Advisory Committee. Nominations received after February 27, 2012 will be considered for nomination to the committee if nominees are still 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, the primary contact is:* Carolyn Jeletic, Office of Regulations, Policy, and Social Sciences, Center of Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5100 Paint Branch Ave., College Park, MD 20740, (240) 402–1913, FAX: (301) 436–2657, *Carolyn.Jeletic@fda.hhs.gov.*

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

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Food Advisory Committee.

I. General Description of the Committee Duties

The Food Advisory Committee (the Committee) provides advice to the Commissioner of Food and Drugs (the Commissioner) and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related health issues that FDA considers of primary importance for its food and cosmetics programs.

The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related issues, (2) the safety of new foods and food ingredients, (3) labeling of foods and cosmetics, (4) nutrient needs and nutritional adequacy, and (5) safe exposure limits for food contaminants.

The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these