representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through July 31, 2004.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups, as well as nominations from small businesses that manufacture medical devices subject to the regulations.

DATES: Nominations for vacancies listed in this notice should be received by July 7, 2003.

ADDRESSES: All nominations and curricula vitae (which includes nominee's office address, telephone number and e-mail address) for industry representatives should be submitted in writing to Kathleen L. Walker, Office of Systems and Management (HFZ–17), CDRH, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 114, e-mail: *klw@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting members representing industry interests for the vacancies listed as follows:

Medical Devices Panels	Approximate Date Representative Is Needed
Clinical Chemistry and Clinical Toxicology	Mar. 1, 2004
Gastroenterology and Urology	Jan. 1, 2004
General and Plastic Surgery	Sept. 1, 2003
Hematology and Pathology	Mar. 1, 2004
Microbiology	Mar. 1, 2004
Molecular and Clinical Genetics	June 1, 2004
Radiological	Feb. 1, 2004

I. Functions

The functions of the medical device panels are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act)); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Industry Representation

Section 520(f)(3) of the act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include as members one nonvoting representative of interests of the medical device manufacturing industry.

III. Nomination Procedure

Any organization in the medical device manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vita of each nominee. The term of office is up to 4 years, depending on the appointment date.

IV. Selection Procedure

Regarding nominations for members representing the interests of industry, a letter will be sent to each person that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

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: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–14213 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, the Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2004.

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: Send all nominations and curricula vitae to:

1. For the device panels: Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022, e-mail: *NJP@CDRH.FDA.GOV*.

2. *For the National Mammography Quality Assurance Advisory Committee, excluding consumer representatives*: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *CAF@CDRH.FDA.GOV*.

3. *For health professional, industry representatives and government representatives for the Device Good Manufacturing Practice Advisory Committee*: Sharon Kalokerinos, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, e-mail: *SMK@CDRH.FDA.GOV*.

4: *For government representatives and industry representatives for the Technical Electronic Product Radiation Safety Standards Committee*: Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, *RVK@CDRH.FDA.GOV*.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 114, e-mail: *KLW@CDRH.FDA.GOV*.

SUPPLEMENTARY INFORMATION:

I. Vacancies

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

1. *Anesthesiology and Respiratory Therapy Devices Panel*: Four vacancies immediately, one vacancy occurring November 30, 2003; anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilatory support, pharmacology, physiology, or the effects and complications of anesthesia.

2. *Circulatory System Devices Panel*: Three vacancies occurring June 30, 2004; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

3. *Clinical Chemistry and Clinical Toxicology Devices Panel*: Three vacancies occurring February 28, 2004; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, and/or clinical laboratory medicine.

4. *Dental Products Panel*: Two vacancies immediately, three vacancies occurring October 31, 2003; dentists, engineers and scientists who have expertise in the areas of lasers, temporomandibular joint implants and/or endodontics; or experts in tissue engineering and/or bone physiology relative to the oral and maxillofacial area.

5. *General and Plastic Surgery Devices Panel*: Four vacancies immediately, one vacancy occurring August 31, 2003; general surgeons, plastic surgeons, thoracic surgeons, abdominal surgeons, pelvic surgeons and reconstructive surgeons, biomaterials experts, laser experts, wound healing experts, or endoscopic surgery experts.

6. *Hematology and Pathology Devices Panel*: Three vacancies immediately; hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular biologists with special interests in development of predictive and prognostic biomarkers.

7. *Immunology Devices Panel*: Three vacancies occurring February 28, 2004; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.

8. *Molecular and Clinical Genetics Devices Panel*: Four vacancies occurring May 31, 2004; experts in human genetics and in the clinical management of patients with genetic disorders, *e.g.*, pediatricians, obstetricians, neonatologists. The agency is also interested in considering candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics as well as ancillary fields of study will be considered.

9. *Obstetrics and Gynecology Devices Panel*: One vacancy occurring January 31, 2004; experts in perinatology, embryology, reproductive endocrinology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, post-operative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; expert in gynecology in the older patient; experts in diagnostic (optical) spectroscopy.

10. *Ophthalmic Devices Panel*: One vacancy occurring October 31, 2003; ophthalmologists specializing in cataract and refractive surgery, vitreo-retinal surgery, pediatric ophthalmology, and the treatment of glaucoma; in addition to vision scientists, electrophysiologists, and optometrists.

11. *Orthopaedic and Rehabilitation Devices Panel*: Two vacancies occurring August 31, 2004; doctors of medicine or philosophy with experience in tissue engineering, calcification or biomaterials; orthopedic surgeons experienced with prosthetic ligament devices, joint implants, or spinal instrumentation; physical therapists experienced in spinal cord injuries, neurophysiology, electrotherapy, and joint biomechanics; rheumatologists; or biomedical engineers.

12. *Radiological Devices Panel*: One vacancy immediately, two vacancies occurring January 31, 2004; statistician with biomedical expertise including the design of clinical trials, ROC (receiver operating characteristic) analysis, diagnostic test evaluation, and data testing.

13. *National Mammography Quality Assurance Advisory Committee*: Three vacancies occurring January 31, 2004; physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.

14. *Device Good Manufacturing Practice Advisory Committee*: six vacancies occurring immediately; three government representatives, two industry representatives, and one health professional.

15. *Technical Electronic Product Radiation Safety Standards Committee*: Four vacancies immediately, one government representative and three industry representatives; three vacancies occurring December 31, 2003, two government representatives and one industry representative.

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 the Federal Food, Drug, and Cosmetic Act (the act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area: (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.

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: (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 for promulgation 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 act (21 U.S.C. 360j), 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 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.

D. Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Section 534(f) of the act, as amended by the Safe Medical Devices Act of 1990 (21 U.S.C. 360kk(f)), provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from governmental agencies, including State or Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor.

III. Qualifications

A. Panels of the Medical Devices Advisory Committee

Persons nominated for membership on the panels shall 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 each panel 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 government representative or health professional 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 or industry, nominees should possess appropriate qualifications to understand and contribute to the committee's work. 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.

D. Technical Electronic Product Radiation Safety Standards Committee

Persons nominated must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. 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.

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 shall include complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. 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 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: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–14210 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

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 July 9, 2003, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *spelllesaned@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–366, CRESTOR (rosuvastatin calcium) tablets, AstraZeneca Pharmaceuticals LP, agent for iPR Pharmaceuticals, Inc., for the proposed indication of treatment of hypercholesterolemia and mixed dyslipidemia.

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 by July 1, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 1, 2003, 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.

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 Dornette Spell-LeSane at least 7 days in advance of the meeting.

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

Dated: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–14214 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0203]

Innovative Systems for Delivery of Drugs and Biologics: Scientific, Clinical, and Regulatory Challenges Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss innovative systems for delivery of drugs and biologics. The purpose of this workshop is to serve as a forum for the academic and clinical communities, industry, consumer and patient advocacy groups, and FDA to discuss the latest scientific and clinical developments for these products, as well as any regulatory concerns and challenges. FDA hopes to facilitate the development of new technology by addressing and clarifying regulatory uncertainty and by increasing the predictability of product development. This project is a part of the Commissioner of the Food and Drug Administration's initiative entitled ''Improving Innovation in Medical Technology: Beyond 2002.'' For reference, the white paper describing the entire initiative is available at *http://www.fda.gov/bbs/topics/NEWS/2003/NEW00867.html*. The input received at the workshop and from written comments will be considered in drafting guidance or other information for industry.

Date and Time: The public workshop will be held on July 8, 2003, from 8 a.m. to 5:30 p.m.

Addresses: The public workshop will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814, 301–897–9400, FAX 301–897–0192. Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: *FDADockets@oc.fda.gov*. Additional information about the meeting and directions to the facility are available on the Internet at: *http://www.fda.gov/cdrh/meetings/070803.html*.

Contact Person: Cynthia Benson, Center for Devices and Radiological Health (HFZ–3), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–7989, e-mail: *cmh@cdrh.fda.gov*.