(d) Summary of Past Work
(e) Budget Appropriateness
9. Any appendices or attachments;
10. Certification Regarding Drug-Free Workplace;
11. Certification Regarding Debarment, Suspension, or other Responsibility Matters;
12. Certification and, if necessary, Disclosure Regarding Lobbying;
13. Supplement to Section II—Key Personnel;
14. Application for Federal Assistance Checklist.

Dated: June 10, 2002.

William Raub,

Principal Deputy for Secretary for Planning and Evaluation.

[FR Doc. 02–15232 Filed 6–17–02; 8:45 am]

BILLING CODE 4110–60–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Contract Review Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C., appendix 2), announcement is made of an Agency for Healthcare Research and Quality (AHRQ) Technical Review Committee (TRC) meeting. This TRC's charge is to review contract proposals and provide recommendations to the Acting Director, AHRQ, with respect to the technical merit of proposals submitted in response to a Request for Proposals (RFP) regarding a ''Patient Safety Program Evaluation Center''. The RFP was published in the FedBizOpps on April 5, 2002.

The upcoming TRC meeting will be closed to the public in accordance with the Federal Advisory Committee Act (FACA), section 10(d) of 5 U.S.C., appendix 2 and procurement regulations, 41 CFR 101–6.1023 and 48 CFR 315.604(d). The discussions at this meeting of contract proposals submitted in response to the above-referenced RFP are likely to reveal proprietary information and personal information concerning individuals associated with the proposals. Such information is exempt from disclosure under the above-cited FACA provision that protects the free exchange of candid views, and under the procurement rules that prevent undue interference with Committee and Department operations.

Name of TRC: The Agency for Healthcare Research and Quality—''Patient Safety Program Evaluation Center''.

Date: July 8, 2002.

Place: Agency for Healthcare Research & Quality, 6010 Executive Blvd, 4th Floor Conference Center, Rockville, Maryland 20852.

Contact Person: Anyone wishing to obtain information regarding this meeting should contact James Battles, Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, 6011 Executive Blvd, Suite 200, Rockville, Maryland, 20852, 301–594–9892.

Dated: June 11, 2002.

Carolyn M. Clancy,

Acting Director.

[FR Doc. 02–15219 Filed 6–17–02; 8:45 am]

BILLING CODE 4160–AD–M

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 (MDAC), the National Mammography Quality Assurance Advisory Committee (NMQAAC), the Device Good Manufacturing Practice Advisory Committee (DGMPAC), and the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC) in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2003.

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: *See* table 1, in section IV.B of **SUPPLEMENTARY INFORMATION.**

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*: Two vacancies immediately, two vacancies occurring November 30, 2002; 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*: Two vacancies immediately, two vacancies occurring June 30, 2003; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

3. *Dental Products Panel*: Two vacancies occurring October 31, 2002; dentists 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.

4. *Gastroenterology and Urology Devices Panel*: One vacancy occurring December 31, 2002; urologists and gastroenterologists.

5. *General and Plastic Surgery Devices Panel*: Four vacancies occurring August 31, 2002, and 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. *General Hospital and Personal Use Devices Panel*: Three vacancies immediately; internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

7. *Hematology and Pathology Devices Panel*: Three vacancies occurring February 28, 2003; gynecologists, cytopathologists, histopathologists, hematologists (blood banking, coagulation and hemostasis), molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

8. *Immunology Devices Panel*: One vacancy occurring February 28, 2003; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy,

molecular diagnostics, or clinical laboratory medicine.

9. *Molecular and Clinical Genetics Devices Panel*: Three vacancies occurring May 31, 2003; experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, and 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.

10. *Obstetrics and Gynecology Devices Panel*: Two vacancies occurring January 31, 2003; 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.

11. *Radiological Devices Panel*: One vacancy occurring January 31, 2003; statistician with biomedical expertise including the design of clinical trials, ROC (receiver operating characteristic) analysis, diagnostic test evaluation, and data testing.

12. *National Mammography Quality Assurance Advisory Committee*: One vacancy occurring January 31, 2003; physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.

13. *Device Good Manufacturing Practice Advisory Committee*: three vacancies occurring immediately; one government representative, one industry representative, and one general public representative; four vacancies occurring May 31, 2003; two government representatives, one industry representative, and one health professional.

14. *Technical Electronic Product Radiation Safety Standards Committee*: Five vacancies occurring December 31, 2002, one government representative, three industry representatives, and one general public 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, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the act; advises on the necessity to ban a device; and 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 (21 U.S.C. 360kk(f)), as amended by the Safe Medical Devices Act of 1990, 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 shown 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 are shown 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 are shown 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 are shown 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 a 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.

A. Consumer/General Public Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures that include use of a consortium of consumer organizations that has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vita of each nominee 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. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

B. TABLE 1.—ADDRESSES FOR CURRICULUM VITAE AND NOMINATIONS

Advisory Committee	Type of Representative	Contact Person	Office/Center/ Mail Code	Addresses/ E-mail	Telephone
For device panels of the MDAC	All types	Nancy J. Pluhowski	Office of Device Evaluation (HFZ–400), CDRH	9200 Corporate Blvd., Rockville, MD 20850, or njp@cdrh.fda.gov	301–594–2022 ext. 133
NMQAAC	All, excluding consumer representatives	Charles A. Finder	CDRH (HFZ–240)	1350 Piccard Dr., Rockville, MD 20850, or caf@cdrh.fda.gov	301–827–0009

B. TABLE 1.—ADDRESSES FOR CURRICULUM VITAE AND NOMINATIONS—Continued

Advisory Committee	Type of Representative	Contact Person	Office/Center/ Mail Code	Addresses/ E-mail	Telephone
DGMPAC	Industry and government representatives	Sharon Kalokerinos	CDRH (HFZ–300)	2094 Gaither Rd., Rockville, MD 20850, or smk@cdrh.fda.gov	301–594–4613 ext. 139
TEPRSSC	Industry and government representatives	Orhan Suleiman	CDRH (HFZ–240)	1350 Piccard Dr., Rockville, MD 20850, or ohs@cdrh.fda.gov	301–594–3533
NMQAAC, DGMPAC, TEPRSSC	Consumer and general public representatives	Linda A. Sherman	Office of the Senior Associate Commissioner for Office of External Relations (HF–4)	5600 Fishers Lane, Rockville, MD 20857, or lsherman@oc.fda.gov	301–827–1220

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: June 10, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–15210 Filed 6–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Protection of Human Subjects in Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Protection of Human Subjects in Clinical Trials. The topics to be discussed are the role of FDA, institutional review boards, and other stakeholders in the protection of human subjects in clinical trials as it relates to minority participation.

Date and Time: The meeting will be held on August 22, 2002, from 7:30 p.m. to 9 p.m.

Location: The meeting will be held at Meharry Medical School, West Basic Science Building Auditorium, rm. M001, 21st Avenue North at Meharry Blvd., Nashville, TN 37208.

Contact: Sandra S. Baxter, Southeast Region, New Orleans District Office, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217, 615–781–5385, ext. 122, FAX 615–781–5383, e-mail: sbaxter@ora.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by August 8, 2002.

If you need special accommodations due to a disability, please contact Sandra S. Baxter at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: June 10, 2002.

John Marzilli,

Acting Senior Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–15279 Filed 6–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5199]

Medical Devices; Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery.'' This guidance is intended to provide guidance on the preclinical testing recommended for resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. This guidance is being issued to finalize the previous draft version issued on December 16, 1999.

DATES: Submit written or electronic comments concerning this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joyce M. Whang, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document is intended to provide guidance on the preclinical and clinical testing recommended for resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. It was developed jointly by the Division of General, Restorative and Neurological Devices, and the Division of Reproductive, Abdominal and Radiological Devices. The final version of this guidance supersedes the draft