

requirements on access to the services of such facilities in such areas; and whether there will exist a sufficient number of medical physicists after October 1, 1999, and the costs and benefits of compliance with these requirements.

### Consumer and Industry Representation

#### Medical Device Panels

Section 520(f)(3) of the Federal Food, Drug, and Cosmetic Act (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 consumer interests and one nonvoting representative of interests of the medical device manufacturing industry.

#### National Mammography Quality Assurance Advisory Committee

Section 354n of the Public Health Service Act (42 U.S.C. 263b), as amended by the Mammography Quality Standards Act of 1992, provides that at least four of the individuals nominated for membership should be from among national breast cancer or consumer health organizations with expertise in mammography. The committee may include one technically qualified member who is identified with consumer interests.

### Nomination Procedures

#### Consumer 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. Self-nominations are also accepted. 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.

Nominations shall include a complete curriculum vitae 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 panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

#### Industry Representatives

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 industrial 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 vitae of each nominee. The term of office is up to 4 years, depending on the appointment date.

### Selection Procedures

#### Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which 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.

#### Industry Representatives

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: February 21, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*

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### Request for Nominations for Voting Members on Public Advisory Panels or Committees in the Center for Devices and Radiological Health

**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 and on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and those vacancies that will or may occur through February 28, 1996.

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 and curricula vitae for the panels should be sent to Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ-400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

All nominations and curricula vitae for the National Mammography Quality Assurance Advisory Committee should be sent to Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

**FOR FURTHER INFORMATION CONTACT:** Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6932.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations of voting members for the vacancies listed below.

1. *Anesthesiology and Respiratory Therapy Devices Panel:* One vacancy occurring November 30, 1995; general anesthesiologists, anesthesiologists specializing in regional anesthesia, physicians with expertise in ventilatory support, or nurse anesthetists.

2. *Circulatory System Devices Panel*: Three vacancies occurring June 30, 1995; 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, 1996; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, or oncology.

4. *Dental Products Panel*: Two vacancies occurring October 31, 1995; dentists who have experience with lasers, endosseous implants, and temporomandibular joint implants; or experts in bone physiology relative to the oral and maxillofacial area.

5. *Ear, Nose, and Throat Devices Panel*: One vacancy occurring October 31, 1995; audiologists, otolaryngologists, neurophysiologists, statisticians, or electrical or biomedical engineers.

6. *Gastroenterology and Urology Devices Panel*: Three vacancies occurring December 31, 1995; nephrologists, urologists, and gastroenterologists with expertise in diagnostic and therapeutic management of adult and pediatric patient populations.

7. *Hematology and Pathology Devices Panel*: One vacancy occurring February 28, 1996; cytopathologists and histopathologists; hematologists (blood banking, coagulation, and hemostasis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

8. *Immunology Devices Panel*: Two vacancies occurring February 28, 1996; medical or surgical oncologists experienced with tumor markers, or clinical immunologists.

9. *Microbiology Devices Panel*: One vacancy occurring February 28, 1996; infectious disease clinicians; clinical microbiologists with expertise in antimicrobial and antimycobacterial susceptibility testing and chemotherapy; clinical virologists with expertise in diagnosis and assays; clinical oncologists experienced with antitumor resistance and susceptibility; and molecular biologists.

10. *Neurological Devices Panel*: Two vacancies occurring November 30, 1995; neurologists, biomedical engineers, interventional neuroradiologists, neurosurgeons with interest in medical devices, or persons experienced with neurological devices with a strong background in biostatistics.

11. *Obstetrics and Gynecology Devices Panel*: One vacancy occurring January

31, 1996; experts in reproductive endocrinology, endoscopy, electrosurgery, laser surgery, assisted reproductive technologies, and contraception.

12. *Ophthalmic Devices Panel*: Two vacancies occurring October 31, 1995; ophthalmologists specializing in glaucoma, surgical pediatric ophthalmology (experienced in correction of aphakia), retinal diseases or corneal diseases; and optometrists with expertise in contact lenses.

13. *Orthopedic and Rehabilitation Devices Panel*: One vacancy occurring August 31, 1995; 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.

14. *Radiological Devices Panel*: One vacancy occurring January 31, 1996; physicians and scientists with expertise in nuclear medicine, diagnostic or therapeutic radiology, mammography, thermography, transillumination, hyperthermia, bone densitometry, magnetic resonance, computed tomography, or ultrasound.

15. *National Mammography Quality Assurance Advisory Committee*: Four vacancies occurring January 31, 1996; physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography.

## Functions

### Medical Device Panels

The functions of the 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; (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.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the drug panel are to: (1) Evaluate and recommend whether various prescription drug products should be changed to over-the-counter status; (2) evaluate data and make recommendations concerning the approval of new dental drug products for human use; (3) evaluate data and make recommendations concerning drug products that may also be cosmetics; and (4) using a Plaque Subcommittee, review and evaluate data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed dental drug products for human use, and the adequacy of their labeling. The subcommittee will advise on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

### 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; and (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities.

The committee will also determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and the effects of personnel or other requirements on access to the services of such facilities in such areas; whether there will exist a sufficient number of medical physicists after October 1, 1999, and the costs and benefits of compliance with these requirements.

## Qualifications

### Medical Device Panels

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 above. The term of office is up to 4 years, depending on the appointment date.

#### *National Mammography Quality Assurance Advisory Committee*

Persons nominated for membership should be physicians, practitioners, and other health professionals, whose clinical practices, research specializations, or professional expertise include a significant focus on mammography. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise. The particular needs for this committee are shown above. The term of office is up to 4 years, depending on the appointment date.

#### **Nomination Procedures**

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or the National Mammography Quality Assurance Advisory Committee. 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.

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: February 21, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*  
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#### **Health Resources and Services Administration**

#### **Program Announcement for Contracts for the Disadvantaged Health Professions Faculty Loan Repayment Program for Fiscal Year 1995**

The Health Resources and Services Administration (HRSA) announces that applications for contracts for fiscal year (FY) 1995, for the Disadvantaged Health Professions Faculty Loan Repayment Program (FLRP) are now being accepted under section 738(a) of the Public Health Service Act (The Act).

In FY 1995, approximately \$823,000 is available for competing applications for the Disadvantaged Health Professions Faculty Loan Repayment Program. It is expected that 30 contracts averaging \$27,433 (\$13,717 per year for two years) will be supported with these funds.

#### **Previous Funding Experience**

Previous funding experience information is provided to assist potential applicants to make better informed decisions regarding submission of an application for this program. In fiscal years 1991, 1992, 1993 and 1994, HRSA entered into a total of 129 contracts under this program, averaging \$25,030 (\$12,515 per year for 2 years).

#### **Purpose**

The purpose of the Disadvantaged Health Professions Faculty Loan Repayment Program (FLRP) is to attract disadvantaged health professions faculty members for accredited health professions schools. The program provides a financial incentive for degree-trained health professions personnel from disadvantaged backgrounds who will serve as members of the faculties of those schools. The FLRP is directed at those individuals available to serve immediately or within a short time as "new" full-time faculty members. Loan repayment may be provided only for an individual who has *not* been a member of the faculty of any school at any time during the 18-month period preceding the date on which the Secretary receives the request of the individual for a repayment contract (i.e., "new" faculty).

Section 738(b) makes available grants and contracts with schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, health administration, clinical psychology and other public or private nonprofit health or educational entities to assist in increasing the number of

underrepresented minority faculty. Section 738(b) will be implemented as a separate program.

#### **Eligible Individuals**

Individuals from disadvantaged backgrounds are eligible to compete for participation in the FLRP if they:

1. Have degrees in medicine, osteopathic medicine, dentistry, nursing, pharmacy, podiatric medicine, optometry, veterinary medicine, public health or clinical psychology; or
2. Are enrolled in an approved graduate training program in one of the health professions listed above; or
3. Are enrolled as full-time students in the final year of health professions training, leading to a degree from an eligible school.

Established faculty members are not eligible to apply for funds under the FLRP. Only individuals that have not taught in the last 18 (eighteen) months prior to application to the program will be considered.

#### **Statutory Requirements**

Prior to submitting an application for a contract for loan repayment, individuals must sign a contract with an eligible school, as prescribed by the Secretary, setting forth the terms and conditions of the FLRP. This contract with the school must require the individual to serve as a full-time member of the faculty, as determined by the school, for not less than 2 years, whereby the school agrees to pay, for each year, a sum (in addition to faculty salary) equal to that paid by the Secretary towards the repayment of principal due on the applicant's health professions educational loans. Additionally, the individual involved may not have been a member of the faculty of any school at any time during the last 18 months prior to application to the program.

#### **Eligible Schools**

Eligible schools are public or nonprofit private accredited schools of medicine, nursing, as defined in section 853 of the Act, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine or public health, or schools that offer graduate programs in clinical psychology and which are located in States as provided in section 799 of the Act.

#### **Provisions of the Loan Repayment Program**

Section 738(a) authorizes repayment, for any year for which repayments are made, not to exceed 20 percent of the outstanding principal and interest on