

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Request for Nominations for Voting Members on Public Advisory 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 Allergenic Products Advisory Committee; Blood Products Advisory Committee; Cellular, Tissue, and Gene Therapies Advisory Committee; Transmissible Spongiform Encephalopathies Advisory Committee;

and the Vaccines and Related Biological Products Advisory Committee. Nominations will be accepted for current vacancies and those that will or may occur through September 30, 2009.

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 document.

ADDRESSES: All nominations for membership should be sent electronically to CV@OC.FDA.GOV, or

by mail to Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, rm. 15A-12, Rockville, MD 20857. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/oc/advisory/default.htm>.

FOR FURTHER INFORMATION CONTACT:

Linda Amendt, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-1370, e-mail: Linda.Amendt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Vacancies

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

TABLE 1.

Committee and Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Allergenic Products Advisory Committee—allergy, immunology, pediatrics, internal medicine, biochemistry, statistics, and related specialties	3 2	Immediately August 31, 2009
Blood Products Advisory Committee—clinical and administrative medicine, hematology, immunology, blood banking, tissue banking, surgery, anesthesia, critical care, internal medicine, infectious diseases, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, clinical trial design, and other related professions	2 4	Immediately September 30, 2009
Cellular, Tissue, and Gene Therapies Advisory Committee—cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation including biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics	4 3	Immediately March 31, 2009
Transmissible Spongiform Encephalopathies Advisory Committee—clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions	1 4	Immediately January 31, 2009
Vaccines and Related Biological Products Advisory Committee—immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry	4 1	Immediately January 31, 2009

II. Functions

A. Allergenic Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or

treatment of allergies and allergic diseases.

B. Blood Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis,

prevention, of treatment of human diseases.

C. Cellular, Tissue, and Gene Therapies Advisory Committee

The committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are

intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions.

D. Transmissible Spongiform Encephalopathies Advisory Committee

The committee reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

E. Vaccines and Related Biological Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.

III. Qualifications

Persons nominated for membership on the committees shall have adequately diversified experience appropriate to the work of the committee 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 committee. The particular need for vacancies on each committee for the calendar years 2008 and 2009 is shown in table 1 of this document. The term of office is up to 4 years depending on the appointment date. Committees meet one to five times a year. Most meetings are for 2 days.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination. Potential candidates will be required 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: January 21, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Loan Repayment Program for Repayment of Health Professions Educational Loans

Announcement Type: Initial.

CFDA Number: 93.164.

Key Dates: January 16, 2009 first award cycle deadline date, September 30, 2009 entry on duty deadline date.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2009 includes \$17,488,854 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by Section 108 of the Indian Health Care Improvement Act (IHCIA) as amended, 25 U.S.C. 1601 *et seq.* The IHS invites potential applicants to request an application for participation in the LRP.

II. Award Information

The estimated funds available is approximately \$17,488,854 to support approximately 391 competing awards averaging \$44,740 per award for a two year contract. One year contract continuations will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2009 program cycle will be expected to begin their service period no later than September 30, 2009.

III. Eligibility Information

1. Eligible Applicants

Pursuant to Section 108(b), to be eligible to participate in the LRP, an individual must:

(1) (A) Be enrolled—

(i) In a course of study or program in an accredited institution, as determined

by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in such program; or

(ii) In an approved graduate training program in a health profession; or

(B) Have a degree in a health profession and a license to practice in a state; and

(2) (A) Be eligible for, or hold an appointment as a Commissioned Officer in the Regular or Reserve Corps of the Public Health Service (PHS); or

(B) Be eligible for selection for service in the Regular or Reserve Corps of the PHS; or

(C) Meet the professional standards for civil service employment in the IHS; or

(D) Be employed in an Indian health program without service obligation; and

(E) Submit to the Secretary an application for a contract to the LRP. The Secretary must approve the contract before the disbursement of loan repayments can be made to the participant. Participants will be required to fulfill their contract service agreements through full-time clinical practice at an Indian health program site determined by the Secretary. Loan repayment sites are characterized by physical, cultural, and professional isolation, and have histories of frequent staff turnover. All Indian health program sites are annually prioritized within the Agency by discipline, based on need or vacancy.

Any individual who owes an obligation for health professional service to the Federal Government, a State, or other entity is not eligible for the LRP unless the obligation will be completely satisfied before they begin service under this program.

Section 108 of the IHCIA, as amended by Public Laws 100-713 and 102-573, authorizes the IHS LRP and provides in pertinent part as follows:

“(a)(1) The Secretary, acting through the Service, shall establish a program to be known as the Indian Health Service Loan Repayment Program (hereinafter referred to as the “Loan Repayment Program”) in order to assure an adequate supply of trained health professionals necessary to maintain accreditation of, and provide health care services to Indians through, Indian health programs.”

Section 4(n) of the IHCIA, as amended by the Indian Health Care Improvement Technical Corrections Act of 1996, Public Law 104-313, provides that:

“Health Profession” means allopathic medicine, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public health