

Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Time and Extent Applications." The OTC drug monograph system was established to evaluate the safety and effectiveness of all OTC drug products for the following reasons: (1) Marketed in the United States before May 11, 1972, that were not covered by new drug applications (NDAs), and (2) covered by "safety" NDAs that were marketed in the United States before enactment of the 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act (the act). In 1972, FDA began its OTC drug review of the following procedures: (1) To evaluate OTC drugs by categories or classes (e.g., antacids, skin protectants), rather than on a product-by-product basis, and (2) to develop "conditions" under which classes of OTC drugs are generally recognized as safe and effective (GRAS/E) and not misbranded.

FDA publishes these conditions in the **Federal Register** in the form of OTC drug monographs, which consist primarily of active ingredients, labeling, and other general requirements. Final monographs for OTC drugs that are GRAS/E and not misbranded are codified in part 330 (21 CFR part 330). Manufacturers seeking to market an OTC drug covered by an OTC drug monograph need not obtain FDA approval before marketing.

Previously, interested persons had to prepare and submit an NDA if they wanted to introduce into the United States an OTC drug condition that had been marketed solely in a foreign country. Companies also had to submit an NDA if their OTC drug products were initially marketed in the United States after the OTC drug review began in 1972. In the **Federal Register** of January

23, 2002 (67 FR 3060), FDA published a final rule that amended the OTC drug review procedures in part 330 and included additional criteria and procedures for classifying OTC drugs as GRAS/E and not misbranded. The final rule provided procedures for conditions that previously required an NDA for those conditions to become eligible for inclusion in the OTC drug monograph system. This final rule stated that an applicant must first submit a TEA to show marketing "to a material extent" and "for a material time." Once FDA has determined eligibility, safety and effectiveness data would be submitted and evaluated. This two-step process allows applicants to demonstrate that eligibility criteria are met before expending resources to prepare safety and effectiveness data.

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on time and extent applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Availability of Funds for Loan Repayment Program for Repayment of Health Professions Educational Loans

AGENCY: Indian Health Services, HHS.

ACTION: Notice.

SUMMARY: The Administration's budget request for Fiscal Year (FY) 2004 includes \$11,923,500 for the Indian Health Service (IHS) Loan Repayment Program (LRP) for health professions educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs. It is anticipated that \$11,846,474 will be available to support approximately 276 competing awards averaging \$43,000 per award for a two year contract.

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. Funds must be expended by September 30 of the fiscal year. 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.

DATES: Applications for the FY 2004 LRP will be accepted and evaluated monthly beginning March 12, 2004, and will continue to be accepted each month thereafter until all funds are exhausted. Subsequently monthly deadline dates are scheduled for Friday of the second full week of each month. Notice of awards will be mailed on the last working day of each month.

Loan Repayment Awards will be made only to those individuals serving at facilities which have a site score of 70 or above during the first and second quarters and the first month of the third quarter of FY 2004, if funding is available.

Applicants selected for participation in the FY 2004 program cycle will be expected to begin their service period no later than September 30, 2004.

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or
2. Sent on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a

commercial carrier or U.S. Postal Service. Private metered postmarks are *not* acceptable as proof of timely mailing.)

Applications received after the monthly closing date will be held for consideration in the next monthly funding cycle. Applicants who do not receive funding by September 30, 2004, will be notified in writing.

Form to be Used for Application:

Applications must be submitted on the form entitled "Application for the Indian Health Service Loan Repayment Program," identified with the Office of Management and Budget approval number of OMB #0917-0014 (expires 12/31/05).

ADDRESSES: Application materials may be obtained by calling or writing to the address below. In addition, completed applications should be returned to: IHS Loan Repayment Program, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852, PH: 301/443-3396 [between 8 a.m. and 5 p.m. (EST) Monday through Friday, except Federal holidays].

FOR FURTHER INFORMATION CONTACT:

Please address inquiries to Ms. Jacqueline K. Santiago, Chief, IHS Loan Repayment Program, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852, PH: 301/443-3396 [between 8 a.m. and 5 p.m. (EST) Monday through Friday, except Federal holidays].

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

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 IHCA, as amended by the Indian Health Care Improvement Technical Corrections act of 1996, Pub. L. 104-313, provides that:

"Health Profession" means *allopathic medicine*, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public health nursing, dentistry, psychiatry, osteopathy, optometry, pharmacy, psychology, public health, social work, marriage and family therapy, chiropractic medicine, environmental health and engineering, and allied health profession, or any other health profession.

For the purposes of this program, the term "Indian health program" is defined in section 108(a)(2)(A), as follows:

(A) the term "Indian health program" means any health program or facility funded, in whole or in part, by the Service for the benefit of Indians and administered—

(i) Directly by the Service;
(ii) By and Indian tribe or tribal or Indian organization pursuant to a contract under—

(I) The Indian Self-Determination Act; or

(II) section 23 of the Act of April 30, 1908, (25 U.S.C. 47), popularly known as the Buy Indian Act; or

(iii) By an urban Indian organization pursuant to Title V of this act. Applicants may sign contractual agreements with the Secretary for 2 years. The IHS will repay all, or a portion of the applicant's health profession educational loans (undergraduate and graduate) for tuition expenses and reasonable educational and living expenses in amounts up to \$20,000 per year for each year of contracted service. Payments will be made annually to the participant for the purpose of repaying his/her outstanding health profession educational loans. Payment of health profession education loans will be made to the participant within 120 days, from the date the contract becomes effective.

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.

Section 108 of the IHCA, as amended by Public Laws 100-713 and 102-573, authorizes the IHS to determine specific health professions for which Indian Health Loan Repayment contracts will be awarded. The list of priority health professions that follow are based upon the needs of the IHS as well as upon the needs of the American Indians and Alaska Natives.

(a) *Medicine*: Allopathic and Osteopathic.

(b) *Nurse*: Associate and B.S. Degree.

(c) *Clinical Psychology*: Ph.D. only.

(d) *Social Work*: Masters level only.

(e) *Chemical Dependency Counseling*: Baccalaureate and Masters level.

(f) *Dentistry*.

(g) *Dental Hygiene*.

(h) *Pharmacy*: B.S., Pharm.D.

(i) *Optometry*.

(j) *Physician Assistant*.

(k) *Advanced Practice Nurses*: Nurse Practitioner, Certified Nurse Midwife, Registered Nurse Anesthetist (Priority consideration will be given to Registered Nurse Anesthetists).

(l) *Podiatry*: D.P.M.

(m) *Physical Therapy*: M.S. and D.P.T.

(n) *Diagnostic Radiology Technology*: Certificate, Associate, and B.S.

(o) *Medical Technology*: B.S.

(p) *Public Health Nutritionist/Registered Dietitian*.

(q) *Engineering* (Civil and Environmental): B.S. (Engineers must provide environmental engineering services to be eligible).

(r) *Environmental Health (Sanitarian)*: B.S.

(s) *Health Records*: R.H.I.T. and R.H.I.A.

(t) *Respiratory Therapy*.

(u) *Ultrasonography*.

Interested individuals are reminded that the list of eligible health and allied health professions is effective for applicants for FY 2004. These priorities will remain in effect until superseded.

All health professionals will receive up to \$20,000 per year for the length of their contract. In addition to the loan repayments, participants are provided tax assistance payments in an amount not less than 20 percent and not more than 39 percent of the participant's total amount of loan repayments made for the taxable year involved. The loan repayments and the tax assistance payments are taxable income and will be reported to the Internal Revenue Service (IRS). The tax assistance payment will be paid to the IRS directly on the participant's behalf. LRP award recipients should be aware that the IRS may place them in a higher tax bracket than they would otherwise have been prior to their award.

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; 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 civilian 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

(3) submit to the Secretary an application for a contract to the Loan Repayment Program.

All applicants must sign and submit to the Secretary, a written contract agreeing to accept repayment of educational loans and to serve for the applicable period of obligated service in a priority site as determined by the Secretary, and submit a signed affidavit attesting to the fact that they have been informed of the relative merits of the U.S. PHS Commissioned Corps and the Civil Service as employment options.

Once the applicant is approved for participation in the LRP, the applicant will receive confirmation of his/her loan repayment award and the duty site at which he/she will serve his/her loan repayment obligation.

The IHS has identified the positions in each Indian health program for which there is a need or vacancy and ranked those positions in order of priority by developing discipline-specific prioritized lists of sites. Ranking criteria for these sites include the following:

(a) Historically critical shortages caused by frequent staff turnover;

(b) Current unmatched vacancies in a Health Profession Discipline;

(c) Projected vacancies in a Health Profession Discipline;

(d) Ensuring that the staffing needs of Indian health programs administered by an Indian Tribe or Tribal or health organization receive consideration on an equal basis with programs that are administered directly by the Service; and

(e) Giving priority to vacancies in Indian health programs that have a need for health professionals to provide health care services as a result of individuals having breached LRP contracts entered into under this section.

(f) Consistent with this priority ranking, in determining applications to be approved and contracts to accept, the IHS will give priority to applications made by American Indians and Alaska Natives and to individuals recruited through the efforts of Indian Tribes or Tribal or Indian organizations.

(g) Funds appropriated for the LRP in FY 2004 will be distributed among the health professions as follows: allopathic/osteopathic practitioners will receive 27 percent, registered nurses 20 percent, mental health professionals 10 percent, dentists 12 percent, pharmacists 10 percent, optometrists 5 percent, physician assistants/advanced

practice nurses 6 percent, podiatrists 4 percent, physical therapists 2 percent, other professions 4 percent. This requirement does not apply if the number of applicants from these groups, respectively, is not sufficient to meet the requirement.

Applicants whose applications were complete by September 30, 2000, and who want to compete in the FY 2004 award cycle, will receive a site score equal to either their FY 2000, FY 2001, FY 2002, FY 2003 or the FY 2004 score, whichever is higher.

The following factors are equal in weight when applied, and are applied when all other criteria are equal and a selection must be made between applicants.

One or all of the following factors may be applicable to an applicant, and the applicant who has the most of these factors, all other criteria being equal, would be selected.

(a) An applicant's length of current employment in the IHS, Tribal, or urban program.

(b) Availability for service earlier than other applicants (first come, first served).

(c) Date the individual's application was received.

Any individual who enters this program and satisfactorily completes his or her obligated period of service may apply to extend his/her contract on a year-by-year basis, as determined by the IHS. Participants extending their contracts will receive up to the maximum amount of \$20,000 per year plus an additional 20 percent for Federal Withholding. Participants who were awarded loan repayment contracts prior to FY 2000 will be awarded extensions up to the amount of \$30,000 a year and 31 percent in tax subsidy if funds are available, and will not exceed the total of the individual's outstanding eligible health profession educational loans.

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.

The IHS Area Offices and Service Units are authorized to provide additional funding to make awards to applicants in the LRP, but must be in compliance with any limits in the appropriation and section 108 of the Indian Health Care Improvement Act not to exceed the amount authorized in the IHS appropriation (up to \$27,000,000 for FY 2004.)

Should an IHS Area Office contribute to the LRP, those funds will be used for

only those sites located in that Area. Those sites will retain their relative ranking from the national site-ranking list. For example, the Albuquerque Area Office identifies supplemental monies for dentists. Only the dental positions within the Albuquerque Area will be funded with the supplemental monies consistent with the national ranking and site index within that Area.

Should an IHS Service Unit contribute to the LRP, those funds will be used for only those sites located in that Service Unit. Those sites will retain their relative ranking from the national site-ranking list. For example, Chinle Service Unit identifies supplemental monies for pharmacists. The Chinle Service Unit consists of two facilities, namely the Chinle Comprehensive Health Care Facility and the Tsale PHS Indian Health Center. The national ranking will be used for the Chinle Comprehensive Health Care Facility (Score = 44) and the Tsale PHS Indian Health Center (Score = 46). With a score of 46, the Tsale PHS Indian Health Center would receive priority over the Chinle Comprehensive Health Care Facility.

This program is not subject to review under Executive Order 12372.

The Catalog of Federal Domestic Assistance number is 93.164.

Dated: February 3, 2004.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patents listed below may be obtained by contacting Susan S.