

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Louis T. Mulligan, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6984, e-mail: [lmulliga@cvm.fda.gov](mailto:lmulliga@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH steering committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health, Committee on Veterinary Medicinal Products; the United States' FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the Government of Australia/New Zealand, one representative from industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from industry in Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

**II. Draft Guidance on Microbiological Acceptable Daily Intakes**

The VICH Steering Committee held a meeting on May 8, 2003, and agreed that the draft guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing" (VICH GL-37) should be made available for public comment. This draft VICH guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes (ADIs) for veterinary drug residues in human food. This draft guidance was developed after consideration of the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, United States, Australia, New Zealand, and Canada. It also took account of available data from subchronic and chronic toxicity studies.

FDA and the VICH Expert Working Group on Toxicity Safety will consider comments about the draft guidance document. Information collection is covered under Office of Management and Budget control number 0910-0032.

**III. Significance of Guidance**

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115).

The draft VICH guidance (#160) represents the agency's current thinking

on the general approach to establish a microbiological ADI. This guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative method as long as it satisfies the requirements of the applicable statutes and regulations.

**IV. Comments**

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document. Written comments should be submitted to the Division of Dockets Management (see **ADDRESSES**). Two copies of any 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. A copy of 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.

**V. Electronic Access**

Comments may be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments> (select "[docket number] entitled 'Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing' (VICH GL-37)."

Copies of the draft guidance may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: October 14, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-26697 Filed 10-22-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Health Professions Preparatory, Pregraduate and Indian Health Professions Scholarship Programs**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice of Availability of Funds for Health Professions Preparatory, Pregraduate, and Indian Health Professions Scholarship Programs for Fiscal Year (FY) 2004.

**SUMMARY:** The Indian Health Service (IHS) is publishing a Notice of Availability of Funds for Health Professions Preparatory, Pregraduate,

and Indian Health Professions Scholarship Programs for Fiscal Year (FY) 2004.

The IHS announces the availability of approximately \$3,733,332 to fund scholarships for the Health Professions Preparatory and Pregraduate Scholarship Programs for FY 2004 awards. These programs are authorized by section 103 of the Indian Health Care Improvement Act (IHCIA), Pub. L. 94-437, as amended by Pub. L. 100-713, Pub. L. 102-573, and Pub. L. 104-313.

The Indian Health Scholarship (Professions), authorized by section 104 of the IHCIA, Pub. L. 94-437, as amended by Pub. L. 100-713, by Pub. L. 102-573, and by Pub. L. 104-313 has approximately \$8,177,245 available for FY 2004 awards.

Full-time and part-time scholarships will be funded for each of the three scholarship programs.

The Indian Health Professions Preparatory Scholarship is listed as No. 93.123 in the Office of Management and

Budget *Catalog of Federal Domestic Assistance* (CFDA). The Health Professions Pregraduate Scholarship is listed as No. 93.971, and the Indian Health Scholarship (Professions) is listed as No. 93.972 in the CFDA.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2010*, a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Education and Community-Based Programs. Potential applicants may obtain a copy of *Health People 2020*, (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2010* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-783-3238).

**DATES:** The application deadline for both new and continuing applicants is

February 28, 2004. If February 28, falls on the week-end, the application will be due on the following Monday.

Applications shall be considered as meeting the deadline if they are received by the appropriate Scholarship Coordinator on the deadline date or postmarked 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 shall not be acceptable as proof of timely mailing.) Applications received after the announced closing date will be returned to the applicant and will not be considered for funding.

**ADDRESSES:** Application packets may be obtained by calling or writing to the addresses listed below. The application form number is IHS 856, 856-2 through 856-8, 815, 816, 818 (approved under OMB No. 0917-0006 (expires 12/31/2004)).

IHS Area Office and States/Locality Served:	Scholarship Coordinator/Address
Aberdeen Area IHS: Iowa, Nebraska, North Dakota, South Dakota .....	Ms. Alice LaFontaine, Scholarship Coordinator, Aberdeen Area IHS, Federal Building, Room 309, 115 4th Avenue, SW, Aberdeen, SD 57401, Tele: 605-226-7553.
Alaska Area Native Health Service: Alaska .....	Ms. Evangelyn Dotomain, Scholarship Coordinator, Alaska Area IHS, 3925 Tudor Centre Drive, Anchorage, Alaska 9508, Tele: 907-729-1913.
Albuquerque Area IHS: Colorado, New Mexico .....	Ms. Alvina Waseta, Scholarship Coordinator, Albuquerque Area IHS, 5300 Homestead Road, NE, Albuquerque, NM 87110, Tele: 505-248-4513.
Bemidji Area IHS: Illinois, Indiana, Michigan, Minnesota, Wisconsin .....	Mr. Tony Buckanaga, Scholarship Coordinator, Bemidji Area IHS, 522 Minnesota Avenue, NW, Room 209, Bemidji, MN 56601, Tele: 218-759-3415.
Billings Area IHS: Montana, Wyoming .....	Mr. Sandy Macdonald, Scholarship Coordinator, Billings Area IHS, Area Personnel Office, P.O. Box 36600, 2900 4th Avenue, North, Billings, MT 59103, Tele: 406-247-7210.
California Area IHS: California, Hawaii .....	Ms. Mona Celli, Scholarship Coordinator, California Area IHS, 650 Capitol Mall, 6th Floor, Sacramento, CA 95814, Tele: 916-930-3981.
Nashville Area IHS: Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, District of Columbia, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, West Virginia.	Ms. Alvina Waseta, Scholarship Coordinator, Nashville Area IHS, 5300 Homestead Road, NE, Albuquerque, NM 87110, Tele: 505-248-4513.
Navajo Area IHS: Arizona, New Mexico, Utah .....	Ms. Roselinda Allison, Scholarship Coordinator, Navajo Area IHS, P.O. Box 9020, Window Rock, AZ 86515, Tele: 928-871-1358.
Oklahoma City Area IHS: Kansas, Missouri, Oklahoma .....	Mr. Jim Ingram, Scholarship Coordinator, Oklahoma City Area IHS, HC 67, Box 132, Marietta, OK 73448, Tele: 580-276-5983.
Phoenix Area IHS: Arizona, Nevada, Utah .....	Norm Cavanaugh, Scholarship Coordinator, Phoenix Area IHS, Two Renaissance Square, 40 North Central Avenue, Suite #600, Phoenix, AZ 85004, Tele: 602-364-5220.
Portland Area IHS: Idaho, Oregon, Washington .....	Ms. Darlene Marcellay-Hyland, Scholarship Coordinator, Portland Area IHS, 1220 SW Third Avenue, Rm. 440, Portland, OR 97204-2892, Tele: 503-326-2625.
Tucson Area IHS: Arizona, Texas .....	Ms. Malinda Paul, Scholarship Coordinator, Tucson Area IHS, 7900 South "J." Stock Rd., Tucson, AZ 85746, Tele: 520-295-2441.

**FOR FURTHER INFORMATION CONTACT:** Please address application inquiries to the appropriate Indian Health Service Area Scholarship Coordinator. Other programmatic inquiries may be addressed to Mr. Jess Brien, Chief,

Scholarship Branch, Indian Health Service, 801 Thompson Avenue, Suite 120, Rockville, Maryland, 20852; Telephone 301-443-6197. (This is not a toll free number.) For grants information, contact Mr. Bernard Covers

Up, Grants Scholarship Coordinator, Grants Management Branch, Division of Acquisition and Grants Operations, Indian Health Service, 801 Thompson Avenue, Suite 120, Rockville, Maryland

20852; Telephone 301-443-5204. (This is not a toll-free number.)

### A. General Program Purpose

These grants programs are intended to encourage American Indians and Alaska Natives to enter the health professions and to assure the availability of Indian health professionals to serve Indians.

### B. Eligibility Requirements

1. The Health Professions Preparatory Scholarship awards are made to American Indians or Alaska Natives who meet the criteria in section 4(c) of the IHClA, as amended, who have successfully completed high school education or high school equivalency and who have been accepted for enrollment in a compensatory, pre-professional general education course or curriculum. Support is limited to 2 years for full-time students and the part-time equivalent of 2 years not to exceed 4 years for part-time students.

2. The Health Professions Pregraduate Scholarship awards are made to American Indians or Alaska Natives who meet the criteria in section 4(c) of the IHClA, as amended, who have successfully completed high school education or high school equivalency and who have been accepted for enrollment or are enrolled in an accredited pregraduate program leading to a baccalaureate degree in pre-medicine or pre-dentistry. Support is limited to 4 years for full-time students and the part-time equivalent of 4 years not to exceed 8 years for part-time students.

3. The Indian Health Scholarship (Professions) may be awarded only to an individual who is a member of a federally recognized tribe as provided by section 104, 4(c), and 4(d) of the IHClA. Membership in a Tribe recognized only recognized only by a state does not meet this statutory requirement. To receive an Indian Health Scholarship (Professions) an otherwise eligible individual must be enrolled in an appropriately accredited school and pursuing course of study in a health profession as defined by section 4(n) of the IHClA. Support is limited to 4 years for full-time students and the part-time equivalent of 4 years not to exceed 8 years for part-time students.

Awards for the Indian Health Scholarships (Professions) will be made in accordance with 42 CFR 36.330. Recipients shall incur a service obligation prescribed under section 338C of the Public Health Service Act (43 U.S.C. 244m) which shall be met by service:

(1) In Indian Health Service;

(2) In a program conducted under a contract or compact entered into under the Indian Self-Determination Act;

(3) In a program assisted under Title V of the Indian Health Care Improvement Act (Pub. L. 94-437) and its amendments; and

(4) In private practice of his or her profession, if the practice (a) is situated in a health professional shortage area, designated in regulations promulgated by the Secretary and (b) addresses the health care needs of a substantial number of Indians as determined by the Secretary in accordance with guidelines of the Service;

Pursuant to the Indian Health Amendments of 1992 (Pub. L. 104-313), a recipient of an Indian Health Professions Scholarship may, at the election of the recipient, meet his/her active duty service obligation prescribed under section 338c of the Public Health Service Act (42 U.S.C. 254m) by a program specified in options (1)-(4) above that:

(i) Is located on the reservation of the Tribe in which the recipient is enrolled; or

(ii) Serves the Tribe in which the recipient is enrolled.

In summary, all recipients of the Indian Health Scholarship (Professions) are reminded that recipients of this scholarship incur a service obligation. Moreover, this obligation shall be served at a facility determined by the Director, IHS, consistent with IHClA, Pub. L. 94-437, as amended by Pub. L. 100-713, and Pub. L. 102-573.

### C. Fund Availability

Both part-time and full-time scholarship awards will be made in accordance with regulations at 42 CFR part 36.320, incorporated in the application materials, for Health Professions Preparatory Scholarship Program for Indians and 42 CFR part 36.370, incorporated in the application materials, for Health Professions Pregraduate Scholarship Program for Indians. Approximately 200 awards, 100 of which are continuing, will be made under the Health Professions Preparatory and Pregraduate Scholarship Programs for Indians. The awards are for 10 months induration and the average award to a full-time student is approximately \$20,000. In FY 2004, approximately \$1,500,000 is available for continuation awards and approximately \$2,233,000 is available for new awards.

Approximately 340 awards, 179 of which are continuing, will be made under the Indian Health Scholarship (Professions) Program. Awards will be made to both full-time and part-time

students. The awards are for 12 months in duration and the average award to a full-time student is for approximately \$23,500. In FY 2004, approximately \$3,551,000 is available for continuation awards, and \$4,626,000 is available for new awards.

No more than 5% of available funds will be used for part-time scholarships this fiscal year. Students are considered part-time if they are enrolled for a minimum of 6 hours of instruction and are not considered in full-time status by their college/university. Documentation must be received from part-time applicants that their school and course curriculum allows less than full-time status.

### D. Criteria for Evaluation

Applications will be evaluated against the following criteria:

1. Needs of the IHS. Applicants are considered for scholarship awards based on their desired career goals and how these goals relate to current Indian health manpower needs. Applications for each health career category are reviewed and ranked separately.

2. Academic Performance. Applicants are rated according to their academic performance as evidenced by transcripts and faculty evaluations. In cases where a particular applicant's school has a policy not to rank students academically, faculty members are asked to provide a personal judgement of the applicant's achievement. Health Professions applicants with a cumulative GPA below 2.0 are not eligible to apply.

3. Faculty/Employer Recommendations. Applicants are rated according to evaluations by faculty members and current and/or former employers regarding the applicant's potential in the chosen health related professions.

4. Stated Reasons for Asking for the Scholarship and Stated Career Goals. Applicants must provide a brief written explanation of reasons for asking for the scholarship and of career goals. The applicant's narrative will be judged on how well it is written and content.

5. Applicants who are closest to graduation or completion are awarded first. For example, senior and junior applicants under the Health Professions Pregraduate Scholarship receive funding before freshmen and sophomores.

### E. Priority Categories

Regulations at 42 CFR part 36.304 provide that the IHS shall, from time to time, publish a list of health professions eligible for consideration for the award of Indian Health Professions Preparatory and Pregraduate Scholarships and

Indian Health Scholarships (Professions). Section 104(b)(1) of the IHCA, as amended by the Indian Health Care Amendment of 1988, Pub. L. 100-713, authorizes the IHS to determine specific health professions for which Indian Health Scholarships will be awarded. The list of priority health professions that follow, by scholarship program, and based upon the needs of the IHS as well as upon the needs of the American Indians and Alaska Natives for additional service by specific health profession.

1. Health Professions Preparatory Scholarship Scholarships. (Below is the list of disciplines to be supported and priority is based on academic level)

- A. Pre-Dietetics.
- B. Pre-Engineering.
- C. Pre-Medical Technology.
- D. Pre-Nursing.
- E. Pre-Pharmacy.
- F. Pre-Physical Therapy (Jr. and Sr. undergraduate years).
- G. Pre-Social Work (Jr. and Sr. undergraduate years).

2. Health Professions Pregraduate Scholarships. (Below is the list of disciplines to be supported and priority is based on academic level: Senior, Junior, Sophomore, Freshman)

- A. Pre-Dentistry.
- B. Pre-Medicine.

3. Indian Health Scholarships (Professions). (Below is a list of disciplines to be supported and priority is based on academic level, unless specified: Graduate, Senior, Junior, Sophomore, Freshman)

- A. Associate Degree Nurse.
- B. Chemical Dependency Counseling: Baccalaureate and Masters level.
- C. Clinical Psychology: Ph.D. only.
- D. Coding Specialist: Certificate.
- E. Counseling Psychology: Ph.D. only.
- F. Dental Hygiene: B.S.
- G. Dentistry: B.S. and M.S.
- H. Diagnostic Radiology Technology: Certificate, Associate, and B.S.
- I. Dietitian: B.S.
- J. Engineering (Civil and Environmental): B.S.
- K. Environmental Health (Sanitarian): B.S.
- L. Health Care Administration: B.S. and M.S.
- M. Health Education: B.S. and M.S.
- N. Health Records: R.H.I.T and R.H.I.A.
- O. Injury Prevention Specialist.
- P. Medical Technology: B.S.
- Q. Medicine: Allopathic and Osteopathic.
- R. Nurse: B.S.\*
- S. Nurse: R.N.A.

\* (Priority consideration will be given to Registered Nurses employed by the Indian Health Service; in a program

assisted under a contract entered into under the Indian Self-Determination Act; or in a program assisted under Title V of the Indian Health Care Improvement Act.)

- T. Optometry.
- U. Pharmacy: B.S., Pharm D.
- V. Physician Assistant.
- W. Physical Therapy: M.S. and D.P.T.
- X. Podiatry: D.P.M.
- Y. Public Health: M.P.H. only (Applicants must be enrolled or accepted in a school of public health in specialty areas such as Dietetics and Community Development in health).
- Z. Public Health Nutrition: Masters level only.
- AA. Respiratory Therapy: Associate.
- BB. Social Work: Masters level only (Clinical, Community, and Gerontology).

CC. Ultrasonography (Prerequisite: Diagnostic Radiology Technology).

Interested individuals are reminded that the list of eligible health and allied health professions is effective for applicants for the 2004-2005 academic year. These priorities will remain in effect until superseded. Applicants for health and allied health professions not on the above priority list will be considered pending the availability of funds and dependent upon the availability of qualified applicants in the priority areas.

Dated: October 14, 2003.

**Charles W. Grim,**

*Assistant Surgeon General, Director, Indian Health Service.*

[FR Doc. 03-26698 Filed 10-22-03; 8:45 am]

**BILLING CODE 4160-16-M**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### Radiological Emergency Preparedness: Planning and Preparing for a Fast-Breaking Event; Notice of Extension of Comment Period

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice of extension of comment period.

**SUMMARY:** On August 19, 2003, FEMA published a notice with request for comments on Radiological Emergency Preparedness: Planning and Preparing for a Fast-Breaking Event, 68 FR 49783. With this notice, FEMA extends the

comment period until December 5, 2003.

**DATES:** This notice is effective October 23, 2003. FEMA must receive comments on or before December 5, 2003.

**ADDRESSES:** Please send your comments to the Rules Docket Clerk, Office of the General Counsel, FEMA, Room 840, 500 C Street, SW., Washington, DC 20472; or e-mail to [rules@fema.gov](mailto:rules@fema.gov). Please reference "REP: Planning and Preparing for a Fast-Breaking Event" in the subject line of your comment letter or e-mail.

**FOR FURTHER INFORMATION CONTACT:** Vanessa E. Quinn, Chief, Radiological Emergency Preparedness Section, Nuclear and Chemical Hazards Division, FEMA, 500 C Street, SW., Washington, DC 20472; (phone) 202-646-3664; or e-mail [vanessa.quinn@dhs.gov](mailto:vanessa.quinn@dhs.gov).

**SUPPLEMENTARY INFORMATION:** On August 19, 2003, FEMA published a notice with request for comments on Radiological Emergency Preparedness: Planning and Preparing for a Fast-Breaking Event, 68 FR 49783. With this notice, FEMA extends the comment period until December 5, 2003.

Dated: October 20, 2003.

**R. David Paulison,**

*Director of Preparedness Division, Emergency Preparedness and Response, Department of Homeland Security.*

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**BILLING CODE 6718-06-P**

## INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701-TA-430A and 430B and 731-TA-1019A and 1019B (Final)]

### Durum and Hard Red Spring Wheat From Canada

#### Determinations

On the basis of the record<sup>1</sup> developed in the subject investigations, the United States International Trade Commission (Commission) determines, pursuant to sections 705(b) and 735(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)) (the Act), that an industry in the United States is materially injured by reason of imports from Canada of hard red spring wheat, provided for in subheadings 1001.90.10 and 1001.90.20 of the Harmonized Tariff Schedule of the United States (HTS), that have been found by the Department of Commerce (Commerce) to be subsidized by the Government of Canada and sold in the United States at less than fair value

<sup>1</sup> The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).