

efficacy of somatic cell and gene therapy products. This limited access may, in the long term, unduly restrict progress in the field of somatic cell and gene therapy in the United States.

To obtain more information, FDA would like to discuss several issues related to the limited access to ancillary components on the development of somatic cell and gene therapies, including: (1) What are the ancillary components that are most critical to somatic cell and gene therapy trials? (2) What are the main reasons for the lack of availability of ancillary components? (3) Are there alternate suppliers of ancillary components? and (4) What is the impact of the limited supply of ancillary components on somatic cell and gene therapy development?

FDA is soliciting public testimony from biomedical researchers, university faculty and administrators, biotechnology associations, other Federal and government agencies, and other individuals and organizations with relevant information concerning limited access to critical ancillary components for gene therapy and somatic cell therapy manufacturing. FDA also solicits testimony, in particular, from affected individuals and consumer organizations. All interested parties are invited to participate in the meeting.

Every effort will be made to accommodate each person who wants to participate in the public meeting. However, because presentations will be limited to the first 30 minutes of the meeting, the time allotted for each presentation will be restricted to 5 minutes. Due to the time limitations of the meeting, all requests may not be granted. Therefore, each person who wants to participate in the meeting is encouraged, by close of business on February 27, 1995, to do the following: (1) File a written request of participation containing the name, address, phone number, facsimile number, affiliation, if any, of the participant, and topic of the presentation, and (2) submit a copy or summary of their presentation. The requested information, including the written notice of participation, may be submitted to the Dockets Management Branch (address above). After the presentations, the remainder of the meeting will be used to allow for discussion.

Before the meeting, CBER will determine the schedule for the presenters. A schedule of the presenters will be filed with the Dockets Management Branch (address above) and mailed or FAX'ed to each participant before the meeting. Interested persons attending the meeting

who did not request an opportunity to make a presentation or those who did request an opportunity to make a presentation but due to the time limitations were not granted the request will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits.

FDA will consider information presented and discussed at the meeting in the developing of future points to consider and regulatory and guidance documents, and in identifying topics for future discussion.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and copies of information and comments submitted to the meeting record will be available for examination at the Dockets Management Branch (address above) approximately 15 working days after the meeting, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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Indian Health Service

Health Professions Preparatory, Pregraduate and Indian Health Scholarship (Professions) Programs

AGENCY: Indian Health Service, HHS.

ACTION: Standing Notice of Availability of Funds for Health Professions Preparatory, Pregraduate and Indian Health Scholarship (Professions) Programs for Fiscal Years (FYs) 1995 and 1996.

SUMMARY: The Indian Health Service (IHS) announces the availability of approximately \$3,578,200 to fund scholarships for the Health Professions Preparatory and Pregraduate Scholarship Programs for FY 1995 awards. Pending the availability of funds, a similar amount is anticipated in FY 1996. These programs are authorized by section 103 of the Indian Health Care Improvement Act (IHCA), Pub. L. 94-437, as amended by Pub. L. 100-713 and by Pub. L. 102-573.

The Indian Health Scholarship (Professions) Program, authorized by section 104 of the IHCA, Pub. L. 94-437, as amended by Pub. L. 100-713

and by Pub. L. 102-573, has approximately \$8,160,751 available for FY 1995 awards. Pending the availability of funds, a similar amount is anticipated in FY 1996.

Scholarships under the three programs will be awarded utilizing the Notice of Grant Award, form PHS-5152-1 (Rev. 7/92). For academic years 1995-1996 and 1996-1997, full-time and part-time scholarships will be funded for each of the three scholarship programs.

The Health Professions Preparatory Scholarship Program is listed as No. 93-123 in the Office of Management and Budget Catalog of Federal Domestic Assistance (CFDA). The Health Professions Pregraduate Scholarship Program is listed as No. 93.971, and the Indian Health Scholarship (Professions) Program 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 2000*, 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 *Healthy People 2000*, (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone 202-783-3238).

DATES: The application deadline is April 1, 1995 and 1996. If April 1 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 IHS Scholarship Program application forms include: IHS-856, 856-2 through 856-8, 815, 816, 818 and, F-01 through L-04 (approved under OMB No. 0917-0006, expires 12/31/97).