

dependence and abuse of ULTRAM®; and (3) suggest improvements for surveillance of misuse.

Procedure: On April 28, 1998, from 8:30 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 17, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 28, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 17, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On April 27, 1998, from 1:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The investigational new drug application (IND) and Phase I and Phase II drug products in process will be presented, and recent action on selected new drug applications (NDA's) will be discussed. This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-9102 Filed 4-7-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on April 30, 1998, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194, ext. 118, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a lithotripter used to fragment biliary stones.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 20, 1998. Oral presentations from the public will be scheduled between 9:30 a.m. and 10 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 20, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-9187 Filed 4-7-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indians Into Medicine Programs

AGENCY: Indian Health Service, HHS.

ACTION: Notice of competitive grant applications for the Indians Into Medicine Program.

SUMMARY: The Indian Health Service (IHS) announces that competitive grant applications are being accepted for the Indians Into Medicine (INMED) Program established by sec. 114 of the Indian Health Care Improvement Act of 1976 (25 U.S.C. 1612), as amended by Pub. L. 102-573. There will be only one funding cycle during fiscal year (FY) 1998. This program is described at 93.970 in the Catalog of Federal Domestic Assistance and is governed by regulations at 42 CFR 36.310 et seq. Costs will be determined in accordance with applicable OMB Circulars. Executive Order 12372 requiring intergovernmental review does not apply to this program.

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 Educational and Community-based programs. *Healthy People 2000*, the full report, is currently out of print. You may obtain the objectives from the latest *Healthy People 2000* Review. A copy may be obtained by calling the National Center for Health Statistics, telephone (301) 436-8500.

Smoke Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

DATES: A. Application Receipt Date—An original and two (2) copies of the completed grant application must be submitted with all required documentation to the Grants Management Branch, Division of Acquisition and Grants Operations, Twinbrook Building, Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852, by close of business June 2, 1998. Applications shall be considered as meeting the deadline if they are either: (1) received on or before the deadline with hand carried applications received by close of business 5 p.m.; or (2) postmarked on or before the deadline and received in time to be reviewed along with all other timely applications. A legibly dated receipt from a commercial carrier or the

U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications not accepted for processing will be returned to the applicant and will *not* be considered for funding.

ADDITIONAL DATES:

1. Application Review: July 13, 1998.
2. Applicants Notified of Results (approved, approved unfunded, or disapproved): August 3, 1998.
3. Anticipated Start Date: September 1, 1998.

FOR FURTHER INFORMATION CONTACT: For program information, contact Ms. Patricia Lee-McCoy, Chief, Scholarship Branch, Division of Health Professions Recruitment and Training, Indian Health Service, Twinbrook Building, 12300 Twinbrook Parkway, Suite 100A, Rockville, Maryland 20852, (301) 443-6197. For grants application and business management information, contact M. Kay Carpentier, Grants Management Office, Division of Acquisition and Grants Operations, Indian Health Service, Twinbrook Building, 12300 Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, (301) 443-5204. (The telephone numbers are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: This announcement provides information on the general program purpose, eligibility and priority, fields of health care considered for support, required affiliation, fund availability and period of support, and application procedure for FY 1998.

A. General Program Purpose

The purpose of the INMED program is to augment the number of Indian health professionals serving Indians by encouraging Indians to enter the health professions and removing the multiple barriers to their entrance into the IHS and private practice among Indians.

B. Eligibility and Priority

Public and nonprofit private colleges and universities with medical and other allied health programs are eligible. Nursing programs are not eligible under this announcement since the IHS currently funds the Nursing Recruitment grant program. The existing INMED grant program at the University of North Dakota has as its target population Indian tribes primarily within the States of North Dakota, South Dakota, Nebraska, Wyoming and Montana. A college or university applying under this announcement must propose to conduct its program among Indian tribes in States not

currently served by the University of North Dakota INMED program.

C. Program Objectives

Each proposal must address the following *five* objectives to be considered for funding:

1. Provides outreach and recruitment for health professions to Indian communities including elementary and secondary schools and community colleges located on Indian reservations which will be served by the program.
2. Incorporates a program advisory board comprised of representatives from the tribes and communities which will be served by the program.
3. Provides summary preparatory programs for Indian students who need enrichment in the subjects of math and science in order to pursue training in the health professions.
4. Provides tutoring, counseling and support to students who are enrolled in a health career program of study at the respective college or university.
5. To the maximum extent feasible, employs qualified Indians into the program.

D. Fields of Health Care Considered for Support

The grant program must be developed to locate and recruit students with educational potential in a variety of health care fields. Primary recruitment efforts must be in the field of medicine with secondary efforts in other allied health fields such as pharmacy, dentistry, medical technology, x-ray technology, etc. The field of nursing is excluded since the IHS does fund the IHS Nursing Recruitment grant program.

E. Required Affiliations

The grant applicant must submit official documentation indicating a tribe's cooperation with and support of the program within the schools on its reservation and its willingness to have a tribal representative serving on the program advisory board. Documentation must be in the form prescribed by the tribe's governing body, i.e., letter of support of tribal resolution. Documentation must be submitted from every tribe involved in the grant program.

F. Fund Availability and Period of Support

It is anticipated that approximately \$220,100 will be available for one award. The anticipated start date of the grant will be September 1, 1998, in order to begin recruitment for the 1998-1999 academic year. Projects will be awarded for a budget term of 12 months, with a maximum project period of up to

three (3) years. Grant funding levels include both direct and indirect costs. Funding of succeeding years will be based on the FY 1998 level, continuing need for the program, satisfactory performance, and the availability of appropriations in those years.

G. Application Process

An IHS Grant Application Kit, including the required PHS 5161-1 (OMB Approval No. 0937-0189 expires 7/31/98) may be obtained from the Grants Management Branch, Division of Acquisition and Grants Operations, Indian Health Service, Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, telephone (301) 443-5204. (This is not a toll free number.)

H. Grant Application Requirements

All applications must be single-spaced, typewritten, and consecutively numbered pages using black type not smaller than 12 characters per one inch, with conventional one inch border margins, on only one side of standard size 8½ x 11 paper that can be photocopied. The application narrative (not including abstract, tribal resolutions or letters of support, standard forms, table of contents or the appendix) must not exceed 15 typed pages as described above. All applications must include the following in the order presented:

- Standard Form 424, Application for Federal Assistance
- Standard Form 424A, Budget Information—Non-Construction Programs, (pages 1 and 2)
- Standard Form 424B, Assurances—Non-Construction Programs (front and back)
- Certifications, PHS 5161-1 (pages 17-19)
- Checklist, PHS 5161-1 (pages 25-26)
- Project Abstract (one page)
- Table of Contents
- Program Narrative to include:
 - Introduction and Potential Effectiveness of Project
 - Project Administration
 - Accessibility to Target Population
 - Relationship of Objectives to Manpower Deficiencies
 - Project Budget
- Appendix to include:
 - Tribal Resolution(s) or Letters of Support
 - Resumes (Curriculum Vitae) or key staff
 - Position descriptions for key staff
 - Organizational chart
 - Workplan format
 - Completed IHS Application Checklist
 - Application Receipt Card, PHS 3038-1, Rev. 5-90.

I. Application Instructions

The following instructions for preparing the application narrative also constitute the standards (criteria or basis for evaluation) for reviewing and scoring the application. Weights assigned each section are noted in parenthesis.

Abstract—An abstract may not exceed one typewritten page.

The abstract should clearly present the application in summary form, from a "who-what-when-where-how-cost" point of view so that reviewers can see how the multiple parts of the application fit together to form a coherent whole.

Table of Contents—provide a one page typewritten table of contents.

Narrative

1. Introduction and Potential Effectiveness of Project (30 Pts.)

a. Describe your legal status and organization.

b. State specific objectives of the project, which are measurable in terms of being quantified, significant to the needs of Indian people, logical, complete and consistent with the purpose of sec. 114.

c. Describe briefly what the project intends to accomplish. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

d. Provide a project specific workplan (milestone chart) which lists each objective, the tasks to be conducted in order to reach the objective, and the timeframe needed to accomplish each task. Timeframes should be projected in a realistic manner to assure that the scope of work can be completed within each budget period. (A workplan format is provided.)

e. In the case of proposed projects for identification of Indians with a potential for education or training in the health professions, include a method for assessing the potential of interested Indians for undertaking necessary education or training in such health professions.

f. State clearly the criteria by which the project's progress will be evaluated and by which the success of the project will be determined.

g. Explain the methodology that will be used to determine if the needs, goals, and objectives identified and discussed in the application are being met and if the results and benefits identified are being achieved.

h. Identify who will perform the evaluation and when.

2. Project Administration (20 Pts.)

a. Provide an organizational chart and describe the administrative, managerial and organizational arrangement and the facilities and resources to be utilized to conduct the proposed project (include in appendix).

b. Provide the name and qualifications of the project director or other individuals responsible for the conduct of the project; the qualifications of the principal staff carrying out the project; and a description of the manner in which the application's staff is or will be organized and supervised to carry out the proposed project. Include biographical sketches of key personnel (or job descriptions if the position is vacant) (include in appendix).

c. Describe any prior experience in administering similar projects.

d. Discuss the commitment of the organization, i.e., although not required, the level of non-Federal support. List the intended financial participation, if any, of the applicant in the proposed project specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space, materials or facilities or other contributions.

3. Accessibility to Target Population (20 Pts.)

a. Describe the current and proposed participation of Indian (if any) in your organization.

b. Identify the target Indian population to be served by your proposed project and the relationship of your organization to that population.

c. Describe the methodology to be used to access the target population.

4. Relationship of Objectives to Manpower Deficiencies (20 Pts.)

a. Provide data and supporting documentation to substantiate need for recruitment.

b. Indicate the number of potential Indian students to be contacted and recruited as well as potential cost per student recruited. Those projects that have the potential to serve a greater number of Indians will be given first consideration.

5. Project Budget (10 Pts.)

a. Clearly define the budget. Provide a justification and detailed breakdown of the funding by category for the first year of the project. Information on the project director and project staff should include salaries and percentage of time assigned to the grant. List equipment purchases necessary for the conduct of the project.

b. The available funding level of \$220,100 is inclusive of both direct and

indirect costs. Because this project is for a training grant, the Department of Health and Human Services' policy limiting reimbursement of indirect cost to the lesser of the applicant's actual indirect costs or 8 percent of total direct costs (exclusive of tuition and related fees and expenditures for equipment) is applicable. This limitation applies to all institutions of higher education other than agencies of State and local government.

c. The applicant may include as a direct cost tuition and student support costs related only to the summer preparatory program. Tuition and stipends for regular sessions are not allowable costs of the grant; however, students recruited through the INMED program may apply for funding from the IHS Scholarship Programs.

d. Projects requiring a second and third year must include a program narrative and categorical budget and justification for each additional year of funding requested (this is not considered part of the 15-page narrative).

Appendix—to include:

a. Tribal Resolution(s) or Letters of Support.

b. Resumes (Curriculum Vitae) of key staff.

c. Position descriptions for key staff.

d. Organizational chart.

e. Workplan format.

f. Completed IHS Application

Checklist

g. Application Receipt Card, PHS 3038-1, Rev. 5-90

J. Reporting

1. Progress Report—Program progress reports may be required quarterly or semi-annually. These reports will include a brief description of a comparison of actual accomplishments to the goals established for the period, reasons for slippage and other pertinent information as required. A final report is due 90 days after expiration of the budget/project period.

2. Financial Status Report—Quality or semi-annually financial status reports will be submitted 30 days after the end of the quarter or half year. Final financial status reports are due 90 days after expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

K. Grant Administration Requirements

Grants are administered in accordance with the following documents:

1. 45 CFR 92, HHS, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments or 45 CFR part 74, Administration of Grants,

2. PHS Grants Policy Statement, and
3. OMB Circular A-21, Cost
Principles for Educational Institutions.

L. Objective Review Process

Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed by an Objective Review Committee (ORC) in accordance with IHS objective review procedures. The objective review process ensures a nationwide competition for limited funding. The ORC will be comprised of IHS (40% or less) and other federal or non-federal individuals (60% or more) with appropriate expertise. The ORC will review each application against established criteria. Based upon the evaluation criteria, the reviewers will assign a numerical score to each application, which will be used in making the final funding decision. Approved applications scoring less than 60 points will not be considered for funding.

M. Results of the Review

The results of the objective review are forwarded to the Director, Office of Management Support (OMS), for final review and approval. The Director, OMS, will also consider the recommendations from the Division of Health Professions Support and the Grants Management Branch. Applicants are notified in writing on or about August 3, 1998. A Notice of Grant Award will be issued to successful applicants. Unsuccessful applicants are notified in writing of disapproval. A brief explanation of the reasons the application was not approved is provided with the name of the IHS official to contact if more information is desired.

Dated: April 1, 1998.

Michael H. Trujillo,
Assistant Surgeon General, Acting Director.
[FR Doc. 98-9104 Filed 4-7-98; 8:45 am]

BILLING CODE 4160-16-M

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 agencies 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. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Human Cell Line Which Constitutively Expresses the Nonstructural (NS) Proteins of Hepatitis C Virus

G Sherman, S Feinstone (FDA)
DHHS Reference No. E-012-98/0
Licensing Contact: Carol Salata, 301/
496-7735 ext. 232

Currently there are no good animal models or tissue culture systems which can be used in assaying compounds directed against HCV. A cell line has been developed which may represent a valuable tool in the identification of potential therapeutic agents against hepatitis C. This permanent human cell line contains an expression vector which directs cells to synthesize 5 nonstructural (NS) hepatitis C proteins: NS3, NS4a, NS4b, NS5a, and NS5b. Two of these proteins provide enzymatic activities crucial to virus replication (NS3: protease, helicase; NS5b, RNA polymerase). The cell line will permit the evaluation of antivirals directed against these enzymes.

Plasmodium Falciparum Gene Linked to Chloroquine Resistance in Human Malaria

TE Wellems, X-Z Su (NIAID)
Serial No. 60/058,895 filed 15 Sep 97
Licensing Contact: Carol Salata, 301/
496-7735 ext. 232

Malaria infects over 200 million people annually worldwide, causing at least one million deaths yearly. Particularly affected areas of the world include Africa, Asia, the Indian subcontinent and South America. Malaria is caused by systemic infections with the parasite *Plasmodium* which infects blood and other tissues. Of the four species of *Plasmodium* that can infect humans, *P. falciparum* is the most deadly. Therapeutic and preventive approaches to control malaria include the use of drugs, particularly drugs that are chemically related to quinine, and

the attempted development of vaccines that confer immunological resistance to infection.

Chloroquine, once a first-line drug for control of malaria, now fails frequently against *P. falciparum*. This invention relates to methods and reagents for diagnosis of chloroquine-resistant malarial infections caused by *P. falciparum*, and the development of new antimalarial drugs against these infections. These diagnostics are based on a unique and heretofore unknown gene and its protein product linked to chloroquine resistance in *P. falciparum* malaria. Because of the worldwide incidence of chloroquine-resistant *P. falciparum*, there is a need for diagnostic methods for detecting chloroquine-resistant malaria, thus allowing such infected individuals to be treated with alternative drugs. Furthermore, there is a need to design and/or screen for new antimalarial agent that can take the place of chloroquine. Use of alternative drugs may prevent further spread of chloroquine-resistant *P. falciparum* in infected individuals.

Phage Display of Intact Domains at High Copy Number

AC Steven (NIAMS)

Serial No. 08/837,301 filed 11 Apr 97
Licensing Contact: Carol Salata, 301/
496-7735 ext. 232

Filamentous phage-based display systems have found widespread use in molecular biology, including many immunologic applications such as antigen presentation and the immunization of desired recombinants by "biopanning". The present invention relates to a phage display system in which the molecules to be displayed (i.e., molecules of interest) are covalently connected to dispensable capsid polypeptides such as SOC (small outer capsid) and HOC (highly antigenic outer capsid) polypeptides that are, in turn, bound to a surface lattice protein, such as those on the surface of a virion or polyhead. Polyheads are tubular capsid variants containing much longer numbers of the surface lattice protein. Molecules of interest may be displayed in various ways. For example, a chimeric polypeptide that includes a dispensable polypeptide and a polypeptide of interest can be expressed in *Escherichia coli*, purified, and then bound *in vitro* to separately isolated surface lattice proteins. The surface lattice proteins can be those on the surface of a capsid or polyhead from which the wild type dispensable polypeptides have been deleted. Similarly, a chimera that contains a