1. Providing intellectual, scientific, and technical expertise and experience related to human melanoma cell cultures expressing shared melanoma antigens.

2. Providing human melanoma cell cultures shown to express several shared melanoma antigens.

3. Engineering the cell cultures to secrete large quantities of human GM–CSF using a vector supplied by the CRADA Collaborator.

4. Conducting Phase I/II clinical trials in melanoma patients to evaluate the therapeutic efficacy of allogeneic whole melanoma cell vaccines expressing multiple shared melanoma-associated antigens in association with GM–CSF, using vaccines manufactured by the Collaborator.

5. Developing model *in vitro* systems to optimize methods to monitor T helper cell immunity based on nominal antigens in normal donors and cancer patients. Applying these model *in vitro* systems to study and characterize immune responses generated in vaccinated patients as part of the Phase I/II clinical trials.

6. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Obtaining a background license in the appropriate fields of use to the relevant Government patent rights.

3. Providing an efficient vector for introducing the gene encoding human GM–CSF into select melanoma cell lines for vaccine development.

4. Manufacturing GMP certifiable GM–CSF-transduced whole melanoma cell vaccines for the conduct of Phase I/II clinical trials at the NCI, including all necessary pre-clinical safety information and preparation, filing, and maintaining of the Drug Master File or IND as required for gene therapy clinical studies.

5. Providing peripheral blood lymphocytes and serum from select vaccinated patients for *in vitro* use in NCI studies of T helper cell reactivities to shared melanoma antigens, if the Collaborator also sponsors clinical trials outside the NCI.

6. Providing technical and financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.

7. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on the research and development of this technology and obtain a background license to relevant NCI patent rights. The ability to collaborate with NCI can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development. The licensing contact at the Office of Technology Transfer is Elaine Gese (301–496–7735).

2. The demonstration of adequate resources to perform the research and development of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.

4. The demonstration of expertise in the commercial development and production of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

8. The willingness to accept the legal provisions and language of the CRADA with only minor modification, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: October 15, 1998.

Kathleen Sybert,

Acting Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 98–28711 Filed 10–26–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; National Institute of Environmental Health Sciences (NIEHS); National Institute of Health (NIH) Notice of Meeting to Review the Corrositex® Assay as an Alternative Test Method for Assessing the Skin Corrosivity Potential of Chemicals; Request for Comments

SUMMARY: Pursuant to Public Law 103–43, notice is hereby given of a public meeting sponsored by the NIEHS and the National Toxicology Program (NTP), and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicology Methods (NICEATM). The agenda topic is the scientific peer review of the Corrositex® assay, which is proposed as an in vitro alternative toxicological test method for assessing the skin corrosivity potential of chemicals and products. The meeting will be held on January 21, 1999, at the Natcher Center, National Institute of Health, 45 Center Drive, Bethesda, MD, 20892. The meeting will take place from 8:30 a.m. to 5:30 p.m. and is open to the public.

Background

Public Law 103–43 directed the NIEHS to develop and validate alternative methods that can reduce or eliminate the use of animals in acute or chronic toxicity testing, establish criteria for the validation and regulatory acceptance of alternative testing methods, and recommend a process through which scientifically validated alternative methods can be accepted for regulatory use. Criteria and processes for validation and regulatory acceptance were developed in conjunction with 13 other Federal agencies and programs with broad input from the public. These are described in the document ''Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods'' NIH publication 97–3981, March 1997, which is available on the internet at http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM htm. Additional information on ICCVAM and NICEATM can be found through the ICCVAM/NICEATM web site http://iccvam.niehs.nih.gov.

An Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was

subsequently established in a collaborative effort by NIEHS and 13 other Federal regulatory and research agencies and programs. The Committee's functions include the coordination of interagency reviews of toxicological test methods and communication with stakeholders throughout the process of test method development and validation. The following Federal regulatory and research agencies and organizations are participating in this effort:

Consumer Product Safety Commission
Department of Defense
Department of Energy
Department of Health and Human Services
  Agency for Toxic Substances and Disease Registry
  Food and Drug Administration
  National Institute for Occupational Safety and Health/CDC
  National Institutes of Health
  National Cancer Institute
  National Institute of Environmental Health Sciences
  National Library of Medicine
Department of the Interior
Department of Labor
  Occupational Safety and Health Administration
Department of Transportation
  Research and Special Programs Administration
Environmental Protection Agency.

The Corrositex® assay was proposed to ICCVAM for consideration as a test to identify the potential of chemicals to cause skin corrosion. An ICCVAM Corrosivity Working Group composed of Federal employees determined that there was sufficient information available to merit an independent scientific peer review of the Corrositex® assay test method. Peer review has been determined to be an essential prerequisite for consideration of a method for regulatory acceptance. The peer review panel will be charged with developing a scientific consensus on the usefulness of the test method to generate information for human hazard identification purposes. Following evaluation at this peer review meeting, the proposed test method and results of the peer review will be forwarded by ICCVAM to Federal agencies for consideration. Federal agencies will determine the regulatory acceptability of a method according to their mandates.

Agenda

There will be a brief orientation on ICCVAM and the ICCVAM review process, followed by peer review of the proposed Corrositex® test method and supporting information. The peer review panel will discuss the usefulness of the Corrositex® assay as an alternative to test methods currently accepted by government regulatory authorities for the assessment of skin corrosivity potential of chemicals and products. Copies of the Corrositex® Test Method Protocol and supporting documentation may be obtained from NICEATM, MD EC–17, P.O. Box 12233, Research Triangle Park, NC, 27709 (919–541–3398), FAX (919–541–0947), e-mail: ICCVAM@niehs.nih.gov. The Corrositex® test method documents and copies of written public comments can also be viewed at the Consumer Products Safety Commission, Reading Room, 4330 East West Highway, Bethesda, MD 20814 on Monday through Friday from 8 am. to 5 pm.

Public Comment

NICEATM invites the submission of written comments on the proposed Corrositex® test method, and other available information regarding the usefulness of the Corrositex® assay, including information about completed, ongoing, or planned studies. Written comments and additional information should be sent by mail, fax, or e-mail to NICEATM at the address listed above by December 10, 1998. Written comments will be made available to the peer review panel members, ICCVAM agency representatives and experts, and will be made available for attendees at the meeting. Members of the public who wish to present oral statements at the meeting should also contact NICEATM as soon as possible, but no later than January 10, 1999. Speakers will be assigned on a first-come, first-serve basis and will be limited to a maximum of five minutes in presentation length. Written comments accompanying the oral statement should be submitted in advance so that copies can be made and distributed to the peer panel members.

NICEATM will furnish an agenda and a roster of peer review panel members just prior to the meeting. Summary minutes and a final report of the Corrositex® assay peer review meeting will be available subsequent to the meeting upon request to the Center. Persons needing special assistance, such as sign language interpretation or other special accommodations should contact NICEATM as described above.

Dated: October 20, 1998.

Kenneth Olden,

Director, National Toxicology Program.

[FR Doc. 98–28713 Filed 10–26–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4328–FA–04]

Announcement of Funding Awards for Fiscal Year 1998 Hispanic Serving Institutions Work Study Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102 (a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for Fiscal Year 1998 Hispanic-Serving Institutions Work Study Program (HSI–WSP). The purpose of this document is to announce the names and addresses of the award winners and the amount of the awards to community colleges to be used to attract economically disadvantaged and minority students to pre-professional careers in community and economic development, community planning and community management, and to provide a cadre of well-qualified professionals to work in local community building programs.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships, Department of Housing and Urban Development, Room 8110, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–1537, extension 5918. To provide service for persons who are hearing-or speech-impaired, this number may be reached via TTY by dialing the Federal Information Relay Service on (800) 877–8339, or 202–708–1455. (Telephone numbers, other than the ''800'' TTY number, are not toll free.)

SUPPLEMENTARY INFORMATION: The HSI–WSP is administered by the Office of University Partnerships under the Assistant Secretary for Policy Development and Research. The Office of University Partnerships administers HUD's ongoing grant programs to institutions of higher education and creates initiatives through which colleges and universities can bring their traditional missions of teaching, research, service, and outreach to bear on the pressing local problems in their communities.

The HSI–WSP was created through an earmark of funds appropriated for the Community Development Work Study Program. Eligible applicants are private non-profit Hispanic-serving community colleges having qualifying academic degrees. Each participating institution of