received by NIH on or before December 26, 1997 will be considered.

ADDRESSES: Requests for a copy of these patents, inquiries, comments and other materials relating to the contemplated license should be directed to: Elaine F. Gese, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852; Telephone: (301) 496–7056, ext. 282; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: U.S. Patent No. 5,157,110 describes a synthetic protein which is capable of inhibiting the complement cascade by binding to the C4b component of complement, and thereby provides a method for controlling the complement cascade. U.S. Patent No. 5,187,268 describes the cloned gene encoding this protein. Complement inhibitors may be used in compositions to prevent complement mediated attack and injury to cells prior to or during transplantation, or to prevent transplant rejection. In addition, complement inhibitors may be used in developing products for allogeneic and xenogeneic transplantation.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. This prospective exclusive license may be granted unless within 60 days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 15, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–28381 Filed 10–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: IL–4 Pseudomonas Exotoxin Fusion Protein Therapeutics

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

ACTION: Notice.

SUMMARY: This notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR § 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a limited field of use exclusive world-wide license to practice the invention embodied in USPA SN 06/911,227 (U.S. Patent 4,892,827) entitled, ''Recombinant Pseudomonas Exotoxins: Construction of an Active Immunotoxin with Low Side Effects''; USPA SN 08/225,224 (U.S. Patent 5,635,599) entitled, ''Circularly Permuted Ligands and Circularly Permuted Chimeric Molecules''; USPA SN 08/722,258 entitled, ''Proteins Comprising Circularly Permuted Ligands''; and USPA SN 08/616,785 entitled, ''Convection-Enhanced Drug Delivery'', to Neurocrine Biosciences of San Diego, California. The patent rights in these inventions have been assigned to the United States of America.

The field of use would be limited to IL–4 pseudomonas exotoxin fusion protein therapeutics.

DATES: Only written comments and/or applications for a license which are received by NIH on or before January 26, 1998 will be considered.

ADDRESSES: Requests for copies of the subject issued patents and pending patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Mr. Steven Ferguson, Senior Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852. Telephone: (301) 496–7056, ext. 266; Facsimile: (301) 402–0220. A signed Confidentiality Agreement will be required to receive copies of the pending patent applications.

SUPPLEMENTARY INFORMATION: The present inventions relate to a fusion protein construct which is able to target malignant glial cells in the brain and potentially other malignant cells throughout the body which overexpress the IL–4 receptor protein. The construct has two parts; a targeting moiety and a toxin. The targeting moiety is the IL–4 cytokine while the toxin is a modified pseudomonas-exotoxin. The construct can be delivered to the brain using a convention-enhanced methodology to target and destroy cancerous cells.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S. 209 and 37 CFR § 404.7. The prospective exclusive license may be granted unless, within 90 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of the 35 U.S.C. 209 and 37 CFR § 404.7.

Applications for a license to the field of use described in this Notice will be treated as objections to the contemplated license. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 17, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–28380 Filed 10–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences (NIEHS); Notice of Meeting To Discuss the Procedures and Activities of the National Toxicology Program (NTP) Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)

SUMMARY: Pursuant to Public Law 103–43, notice is hereby given of a public meeting sponsored by the NIEHS and the NTP, U.S. Public Health Service, to discuss the planned procedures and activities of a new NTP Center for the Evaluation of Alternative Toxicological Methods and the ICCVAM, and to receive comments from invited participants and the public to assist with future activities and priorities.

The meeting will be held in the Conference Center, Building 101, South Campus, NIEHS, 111 Alexander Drive, Research Triangle Park, North Carolina 27709, on November 7, 1997, from 8:45 a.m. to 4:00 p.m.

Background Information: 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 14 other Federal agencies and programs with broad input and participation 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. The Report's recommendations include the establishment of an interagency coordinating committee whose functions would include the coordination of interagency reviews of toxicological test methods and communication with stakeholders throughout the process of test method development and validation. In response to these recommendations, the NIEHS, in collaboration with 13 other Federal agencies and programs, recently established the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM is composed of representatives from NTP Executive Committee agencies and several other federal regulatory and research agencies. The ICCVAM addresses toxicological test method issues that are common to multiple agencies without impinging on considerations unique to individual programs and agencies. Coordinated test method peer reviews are expected to facilitate the acceptance decision process, with final regulatory acceptance recognized as the purview of each Federal agency according to its regulatory mandates.

A NTP Center for the Evaluation of Alternative Toxicological Methods is being established to work with ICCVAM to carry out related activities and to implement the Report's recommendations. The Center proposal includes the opportunity for public-private partnerships to enhance the level and scope of the Center's activities. The planned procedures and activities of the Center and ICCVAM will be discussed at this meeting. NIEHS has invited knowledgeable individuals to participate in this meeting from a cross section of stakeholder organizations and institutions concerned with the development, validation, and use of alternative toxicological methods.

Tenetative Agenda: The NIEHS and Interagency Staff will present the proposed procedures and activities of the Center and the ICCVAM; opportunities for public-private partnerships in the development, validation, and review of alternative methods; and the role of the Advisory Committee on Alternative Toxicological Methods.

8:45 a.m. Welcome and Introduction
9:05 a.m. Procedures and Activities of the Center and ICCVAM
11:45 a.m. Public comment
12:00 p.m. Lunch Break
1:00 p.m. Partnership Opportunities
2:45 p.m. Discussion on the Role of the Advisory Committee
3:30 p.m. Public Comment
4:00 p.m. Adjourn

A description of the Center follows this announcement.

Public Participation: The entire meeting will be open to the public with attendance limited only by space available. Members of the public who wish to present oral statements should contact Dr. Larry Hart below by telephone, fax, or mail as soon as possible, but no later than October 31, Speakers will be assigned on a first come, first serve basis, and will be limited to five minutes in length to allow for a maximum number of presentations. Written comments accompanying the oral statements are encouraged and should be submitted in advance if possible by mail or fax to Dr. Hart, NIEHS, P.O. Box 12233, MD: A3–07, Research Triangle Park, North Carolina 27709, telephone (919) 541–3971 or FAX (919) 541–0295. Persons needing special assistance, such as sign language interpretation or other special accommodations should contact Dr. Hart as soon as possible.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Co-Chair, ICCVAM, Environmental Toxicology Program, P.O. Box 12233, NIEHS, Research Triangle Part, North Carolina 27709, telephone (919) 541–7997, FAX (919) 541–0947. The NIH Publication 97–3981, Validation and Regulatory Acceptance of Toxicological Test Methods, a Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods, can be located on the internet at httpp://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM.html, or a copy may be requested from the NTP Liaison Office, P.O. Box 12233, MD A3–01, Research Triangle Park, NC, 27709, Fax 919–541–0295, tel 919–541–0530, or email: britton@niehs.nih.gov.

Attachment

Dated: October 20, 1997.

Kenneth Olden,

Director, National Toxicology Program.

[Revised 10–15–97 [1]]

NTP Center for the Evaluation of Alternative Toxicological Methods

Background/Need: Government, industry, and public interest groups have the responsibility to protect public health and the environment, and to prevent unnecessary exposure to hazards. In carrying out these responsibilities, scientists develop and adopt health and ecotoxicological testing methods to evaluate the potential adverse effects of chemicals or to demonstrate their safety. These methods are used to generate hazard identification and dose-response data to support health and environmental risk assessments for chemicals and products during their development, manufacture, distribution, use, and disposal.

Toxicological testing methods are being developed and revised by the public and private sector with increasing frequency to provide for improved assessment of toxicity, to evaluate toxicity endpoints not previously assessed, to incorporate advances in biotechnology and out understanding of toxic mechanisms at the molecular and cellular level, to provide for improved efficiency (less time and expense), and to replace, reduce, and refine animal use. Requirements for the use of new test methods to generate information for regulatory purposes are twofold. First, the method must meet the criteria for validation, i.e., there must be scientific evidence that the method is reliable and relevant for its proposed use. Second, the method must meet the criteria for acceptance, e.g., there must be a determination that the use of the method will fulfill a specific need for one or more federal agencies. Until now, there has been no established process for federal agencies to coordinate the review of proposed methods with other federal agencies that may find the method useful.

Participants at a recent National Toxicology Program (NTP) sponsored workshop [2] and an ad hoc interagency committee [3] recommended that an interagency coordinating committee be established whose functions would include the coordination of interagency reviews of toxicological test methods and communication with stakeholders throughout the process of test method

[1] This proposal was originally discussed at an NIEHS/NTP Workshop on ''Developing Partnerships for the Validation of New Approaches for Toxicological Evaluation,'' held July 22, 1996 at the NIEHS, Research Triangle Park, NC.

[2] Final Report: National Toxicology Program Workshop on Validation and Regulatory Acceptance of Alternative Toxicological Test Methods,'' March, 1996, National Institute of Environmental Health Sciences, Research Triangle Park, NC, USA.

[3] 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. National Institute of Environmental Health Sciences, Research Triangle Park, NC. USA.

development and validation. The NIEHS, in collaboration with 13 other federal agencies and programs, has recently established a standing committee that will carry out these functions. Designated as the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), it is composed of representatives form the NTP Executive Committee agencies and several other federal regulatory and research agencies. The ICCVAM focuses on toxicological test method issues that are common to multiple agencies without impinging on considerations unique to individual programs and agencies. Final regulatory acceptance will be the purview of each Federal agency according to its regulatory mandates; however, the ICCVAM coordinated peer review should facilitate the acceptance decision process.

In order to implement the NTP workshop and ad hoc interagency committee recommendations, an NTP Center for the Evaluation of Alternative Toxicological Methods is being established to work with ICCVAM to carry out related activities. The Center includes the opportunity for public-private partnerships to enhance the level and scope of its activities. The Interagency Committee and Center initiatives implement Public Law 103–43 that directs NIEHS to develop a process to achieve regulatory acceptance of alternative test methods.

Goal: The goal of the Center and ICCVAM is to promote the scieitnifc validation and regulatory acceptance of new test methods that are more predictive of human and ecological effects than currently available methods.

Objective: To achieve this goal, the Center will collaborate with the ICCVAM to facilitate scientific peer review and interagency consideration of new test methods of multi-agency interest. Emphasis will be on methods with an appropriate biological basis for the species of concern that provide: improved toxicity characterization; savings in time and costs; and where possible, the refinement, reduction, and replacement of animal use.

Regulatory Impact/Benefits: The expected benefits of this initiative include:

- Increased efficiency and effectiveness of test method review;
- Elimination of duplicative efforts across regulatory agencies;
- Utilization of shared expertise across the Federal system;
- Optimal utilization of scientific expertise outside the Federal government;
- Decreased total transaction costs and time to evaluate new and revised test methods;
- Elimination of redundant testing;
- Increased likelihood that new test methods will meet the needs of agencies; and
- Increased harmonization of testing requirements across the federal government and internationally.

This program will benefit all parties by creating a forum to solicit expert input and provide communication during development, validation and review of proposed new test methods. Such methods, after acceptance by regulatory agencies, will provide for improved human health and ecological risk assessment and potential savings in time and costs. The program will also benefit animal welfare by the adoption of methods that refine, reduce, or replace the use of animals where scientifically feasible.

Structure/Function: The overall structure encompasses the ICCVAM, a Center Office, Peer Review and Expert Panels, and a Federal Advisory Committee.

The ICCVAM consists of representatives from federal regulatory and research agencies that generate or use information from toxicological test methods to support human health or environmental risk assessments. Members serve as points of contact and as sources to identify technical experts from their agencies to serve on specific topical workgroups. Committee activities may include the following, as appropriate:

- Evaluate the status of validation and make recommendations to agencies regarding the scientific usefulness of test methods and their potential applicability;
- Coordinate technical reviews of proposed new and revised test methods of interagency interest;
- Facilitate interagency communication and information sharing;
- Serve as an interagency resource and communication link with parties outside of the Federal government, including academic, other government, industry, and public interest groups;
- Assist agencies in assessing test method needs;
- Provide guidance to agencies and other stakeholders on criteria and processes for the development, validation and acceptance of tests;
- Promote awareness of accepted U.S. test methods; and
- Advocate harmonization of test methods nationally and internationally.

The Center Office is located at NIEHS and consists of 3–5 government professional and administrative staff augmented with appropriate contract support.[4] The Center will collaborate with the ICCVAM to carry out activities to accomplish the following;

- Communicate with interested stakeholders, and facilitate communication during the development and validation process with appropriate agencies; and
- Assess the completeness of submissions and determine if there are sufficient data for test methods to undergo independent public scientific peer review;
- Arrange for scientific peer reviews;
- Organize expert panels and/or workshops to assess the validation status of a method or group of methods;
- Provide recommendations and results to research and regulatory agencies;
- Prepare, publish, and distribute reports and information about new test methods.

Peer Review Panels will be asked to develop scientific consensus on the usefulness of test methods to generate information for specific human health and/or ecological risk assessment purposes. They will discuss the biological relevance of the new test to the toxicity of interest. They will address how and when the new test method can partially or fully replace existing methods or approaches. When appropriate, panels will be asked to identify whether additional validation studies are necessary to adequately evaluate a method, and to identify additional research to support the development of mechanism-based test methods.

It is anticipated that expert review panels will also be convened to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new methods, and to evaluate proposed validation studies. Agencies would use this information to establish priorities for appropriate research, development, and validation efforts in collaboration with interested parties.

Products of the review process will be published reports that present a comprehensive peer review of the data substantiating the validity of a new method. The ICCVAM will forward recommendations regarding the scientific validity and potential acceptability of test methods to agencies for consideration. Each Federal agency will then, according to its regulatory mandates, determine the regulatory acceptability of a method.

A Federal Advisory Committee on Alternative Toxicological Methods, composed of knowledgeable representatives from academia, industry, public interest/animal welfare organizations, federal and state government agencies, and the international community will review and provide advice on the activities and priorities of the Center, and advice on ways to foster partnership activities and interactions among all the stakeholders.

Funding: Activities of the Center will be funded by a pooling of financial resources from interested partners, which may include federal agencies, industry, and other parties. NIEHS will provide core funding and professional and administrative staff for the Center. Other agencies will provide appropriate representatives and expert staff for the ICCVAM and its associated activities, including appropriate agency liaisons for peer review activities.

Conflict of Interest Issues: Scientific peer review must be conducted by persons that are financially unencumbered with the outcome of the evaluation. All peer reviews will be required to comply with Federal government conflict of interest standards. Similarly, financial support of peer review activities must be free of any direct or apparent conflict of interest. To this end, funds to support Center activities will normally be deposited to the federal government and designated for the Center. NIEHS will disburse funds in accordance with federal regulations and guidelines.

[FR Doc. 97–28373 Filed 10–24–97; 8:45 am]

BILLING CODE 4140–01–M

[4] The project concept was peer reviewed and approved by the NTP Board of Scientific Counselors at their December 13, 1996 meeting.