

[lecb.ncifcrf.gov/~dimitrov/dimitrov.html](http://lecb.ncifcrf.gov/~dimitrov/dimitrov.html).

Dated: February 7, 2002.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 02-3568 Filed 2-13-02; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant Of Exclusive License: Prophylactic and/or Therapeutic Vaccine Against Pseudomonas aeruginosa, Chlamydia trachomatis and Mycoplasma pneumoniae, Influenza virus, Nisseria gonorrhoea and Vibrio cholerae**

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

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 15 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 worldwide license to practice the inventions embodied in: U.S. Provisional Patent Application Serial Number 60/257,877, filed December 21, 2000, entitled "A Chimeric Protein Comprising Non-Toxic Pseudomonas Exotoxin A and Type IV Pilin Sequences"; U.S. Patent Number 5,869,608 issued February 9, 1999, entitled "Nucleotide and Amino Acid Sequences of the Four Variable Domains of the Major Outer Membrane Proteins of Chlamydia Trachomatis"; U.S. Patent Application Serial Number 09/247,137 filed February 9, 1999, entitled "Nucleotide and Amino Acid Sequences of the Four Variable Domains of the Major Outer Membrane Proteins of Chlamydia trachomatis"; U.S. Patent Number 4,892,827 issued January 9, 1990, entitled "Recombinant Pseudomonas Exotoxins: Construction of an Active Immunotoxin with Low Side Effects"; U.S. Provisional Patent Application 60/160,923 filed October 22, 1999, entitled "Delivery of Proteins Across Polar Epithelial Cell Layers"; and U.S. Patent Number 5,328,984 issued July 12, 1994, entitled "Recombinant Chimeric Proteins Deliverable Across Cellular Membranes into Cytosol of Target Cells" to Trinity BioSystems, L.L.C. of Los Altos Hills, California, U.S.A. The United States as represented by the Department of Health

and Human Services is an assignee of these patent rights.

**DATES:** Only written comments and/or applications for a license, which are received by the NIH Office of Technology Transfer on or before April 15, 2002, will be considered.

**ADDRESSES:** Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to: Carol A. Salata, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 496-7735 ext 232; Facsimile: (301) 402-0220; E-mail: [salatac@OD.NIH.GOV](mailto:salatac@OD.NIH.GOV).

**SUPPLEMENTARY INFORMATION:** 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. It is anticipated that this license may be limited to the field of use as a prophylactic and/or therapeutic vaccine against Pseudomonas aeruginosa, Chlamydia trachomatis, Mycoplasma pneumoniae, Influenza virus, Nisseria gonorrhoea and Vibrio cholerae. Trinity BioSystems will use Pseudomonas exotoxin A to target and deliver pathogen Type IV pilin peptide epitopes wherein said pathogen peptide epitopes are inserted into or replace a domain of Pseudomonas exotoxin A. 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.

The patent Application Serial Number 60/257,877 describes a chimeric protein wherein key sequences from a Type IV pilin protein are inserted into a non-toxic version of Pseudomonas aeruginosa exotoxin A. This invention provides candidate chimeric vaccines that generate antibodies that interfere with adherence of Pseudomonas aeruginosa exotoxin A to epithelial cells and neutralize the cytotoxicity of exotoxin A. U.S. Patent Number 5,869,608 and U.S. Patent Application Serial Number 09/247,137 relate to Chlamydia epitopes needed for the Chlamydia vaccine. U.S. Provisional Patent Application Number 60/160,923 provides methods for parenteral administration of a protein by transmucosal delivery and without injection. U.S. Patent Number 4,892,827 describes Pseudomonas exotoxins with a deletion in the Ia domain that makes them less toxic. U.S. Patent Number

5,328,984 contains claims relating to the chimeric Pseudomonas exotoxin protein compositions.

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 in response 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: February 7, 2002.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 02-3567 Filed 2-13-02; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Center for Substance Abuse Prevention; Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board to be held in March 2002.

A portion of the meeting will be open and will include a Department of Health and Human Services drug testing program update, a Department of Transportation drug testing program update, and an update on the draft guidelines for alternative specimen testing and on-site testing. If anyone needs special accommodations for persons with disabilities, please notify the Contact listed below.

The meeting will include developing the final requirements for specimen validity testing that had been published in the **Federal Register** on August 21, 2001 (66 FR 43876), and evaluation of sensitive National Laboratory Certification Program (NLCP) internal operating procedures and program development issues. Therefore, a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator in accordance with Title 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App.2, 10(d).

A roster of the board members may be obtained from: Mrs. Giselle Hersh, Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, MD 20857, Telephone: (301) 443-6014. The transcript for the open session will be available on the following Web site: <http://>

workplace.samhsa.gov. Additional information for this meeting may be obtained by contacting the individual listed below.

*Committee Name:* Center for Substance Abuse Prevention, Drug Testing Advisory Board.

*Meeting Date:* March 13, 2002; 8:30 a.m.–4:30 p.m., March 14, 2002; 8:30 a.m.–Noon.

*Place:* Residence Inn by Marriott, 7335 Wisconsin Avenue, Bethesda, Maryland 20814.

*Type:* Open: March 13, 2002; 8:30 a.m.–10:00 a.m.; Closed: March 13, 2002; 10:00 a.m.–4:30 p.m.; Closed: March 14, 2002; 8:30 a.m.–Noon.

*Contact:* Donna M. Bush, Ph.D., Executive Secretary, Telephone: (301) 443-6014, and FAX: (301) 443-3031.

Dated: February 5, 2002.

**Toian Vaughn,**

*Committee Management Officer, Substance Abuse and Mental Health, Services Administration.*

[FR Doc. 02-3565 Filed 2-13-02; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF THE INTERIOR

### Office of the Secretary; Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Office of American Indian Trust, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice announces that the Department of the Interior is seeking to renew the information collection request for *Evaluation of the performance of trust functions performed by tribes under Self-Governance compacts*, OMB Control Number 1076-0146. Under the Paperwork Reduction Act, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice.

**DATES:** Submit comments on or before April 15, 2002.

**ADDRESSES:** Send comments to: James I. Pace, Acting Director, Office of American Indian Trust, United States Department of the Interior, 1849 C Street, NW, Room 2472, Washington, DC 20240; Fax No. (202) 208-7503.

**FOR FURTHER INFORMATION CONTACT:** James I. Pace, (202) 208-3338.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. It

is also a requirement of the PRA that agencies provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the Department of the Interior, Office of American Indian Trust, is publishing notice of the proposed collection of information listed below.

The Department of the Interior invites comments by the public on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have a practical use; the accuracy of the Department's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; ways to enhance the quality, usefulness, and clarity of the information to be collected; and minimizing the burden of collection on those who are to respond. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection. They also will become a matter of public record.

This collection of information will be made to ensure compliance with 25 U.S.C. 458cc(d) which requires that the Secretary of the Interior monitor the performance of trust functions which have been assumed under Self-Governance funding agreements negotiated between the Secretary and an Indian tribe/consortia (hereinafter the respondent).

This information collection addresses those statutory and regulatory performance requirements imposed upon the respondent through the assumption of a particular trust function, through a formal Self-Governance agreement pursuant to the Self-Governance Act (Pub. L. 103-413) which, if not performed properly, may create imminent jeopardy to a trust asset. The information will be used by the Department of the Interior to determine if there is imminent jeopardy to any asset held in trust by the United States for an Indian tribe or individual Indian that are being managed by a tribe/consortium on behalf of the United States pursuant to a Self-Governance agreement.

Currently there are 70 respondents. There is no preliminary work required of the respondents nor any follow-up work required. There are no forms for the respondent to fill out. The annual hour burden is calculated by the amount

of time that the reviewer spends at each program site interviewing the respondents and collecting file information. The time required for each information collection is determined by the complexity and size of the program and ranges from 4 person/hours to 80 person/hours. Weighing the size and complexity of the 70 current programs, it has been determined that the average hours spent for each annual evaluation will be approximately 24 person/hours. This number, multiplied by the current number of evaluations, yields a total number of 1,680 person/hours per year for the collection of information for the purposes described herein.

The trust evaluation information collection process has four basic components:

#### 1. Interview Process

*Entrance Interview:* Each trust evaluation commences with an entrance interview with tribal leadership and senior management. The purpose of this interview is to review generally the programs and functions subject to be evaluated and to clarify the specific nature of the tribe's responsibilities under its annual funding agreement. If specific issues or concerns were raised in the previous evaluation, they may be addressed during this interview as well.

*Management Interviews:* These interviews are conducted with tribal/consortia program directors and staff on a program-by-program basis. During this process, reviewers collect information pertaining to the respondent's compliance with all relevant statutory, regulatory, and other legal requirements for the management of the particular trust resource or function under review as well as compliance with any special terms and conditions contained in the annual funding agreement. Depending on information provided, reviewers may make additional inquiry with regard to specific programs or functions. Where tribal governments have enacted different or additional regulations or guidelines for the management of trust functions, compliance with these measures will be verified as well. Respondents are also provided the opportunity to address issues of concern during this phase of the process. Interviewers will also elicit relevant data during this phase of the process depending on the nature of the function under review.

*Exit Interviews:* The exit interview is designed to provide both the respondents and the interviewers the opportunity to clarify any outstanding issues or address particular concerns raised during the review process.