

[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.*

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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.*

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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://>