

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: September 4, 2001.

Jack Spiegel,

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

[FR Doc. 01-22790 Filed 9-10-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Veterinary Vaccine Against Escherichia Coli O157 Infection Composed of Detoxified LPS Conjugated to Proteins

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

ACTION: Notice.

SUMMARY: This is 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 an exclusive license to practice the invention embodied in: United States Patent Application 09/744,289 and its foreign equivalents entitled "Vaccine Against Escherichia Coli O157 Infection Composed of Detoxified LPS Conjugated to Proteins" filed January 22, 2001, with priority back to PCT/US98/14976, filed July 20, 1998 to Fort Dodge Animal Health, a Division of American Home Products, having a place of business in Overland Park, Kansas. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before November 13, 2001 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: ps193c@nih.gov; Telephone: (301) 496-7056, ext. 268; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: This invention comprises the O-specific

polysaccharide of Shiga toxin-producing bacteria, particularly *E. coli* O157, conjugated to a carrier protein such as *Pseudomonas aeruginosa* recombinant exoprotein A or hepatitis B surface or core antigen. This vaccine is suitable for use in humans and animals. Cattle are carriers of *E. coli* O157, and are the primary reservoir of *E. coli* O157 by shedding the bacteria into the environment. Fifty percent (50%) of cattle are estimated to be carriers of *E. coli* O157. Use of this vaccine in cattle could eliminate *E. coli* O157 and prevent contamination of meat in slaughterhouses.

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. The 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 field of use may be limited to *E. coli* conjugate vaccines for veterinary use.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to 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: September 4, 2001.

Jack Spiegel, Ph.D.,

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

[FR Doc. 01-22792 Filed 9-10-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Adeno-Associated Virus with Inverted Terminal Repeat Sequence as Promoter

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 an exclusive world-wide license to practice the inventions

embodied in any U.S. patents 5,587,308 (12/24/1996); 5,989,540 (11/23/1999); 5,866,696 (02/02/1999), and 6,165,781 (12/26/2000) or foreign applications corresponding to PCT Patent Application PCT/US93/05310, entitled "Modified Adeno-Associated Virus Vector Capable of Expression from a Novel Promoter" published as WO 93/24641 (12/09/1993) to Targeted Genetics Corporation of Seattle, Washington. The prospective exclusive license may be limited to the development of compositions and methods utilizing Adeno-Associated Viral Vectors which are useful in the treatment and prophylaxis of human and animal diseases.

DATES: Only written comments and/or applications for a license which are received by NIH on or before November 13, 2001, will be considered.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comment and other materials relating to the contemplated license should be directed to Susan S. Rucker, J.D., Patent and Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext 245; fax: 301/402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The patents describe and claim compositions and methods utilizing adeno-associated viral (AAV) vectors. In particular, these vectors utilize the AAV Inverted Terminal Repeat (ITR) as the promoter element to control expression of the nucleic acid encoding the heterologous protein to be delivered to the patient. The ability of these vectors to utilize the AAV ITR as the promoter increases the capacity of the AAV vector with respect to the size of the heterologous protein which can be encoded and delivered via the vector. The methods of the patent can be used to deliver and produce therapeutic or prophylactic products which are particularly useful in the field of gene therapy.

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 sixty (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 (i.e., a completed "Application for License to Public Health Service Inventions") in the indicated exclusive field of use filed in response to this notice will be treated as objections to the grant of 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 35 U.S.C. 552.

Dated: September 5, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.
[FR Doc. 01-22794 Filed 9-10-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP) Board of Scientific Counselors Technical Reports Review Subcommittee Meeting; Review of Draft NTP Technical Reports

Pursuant to Public Law 92-463, notice is hereby given of the next meeting of the NTP Board of Scientific Counselors Technical Reports Review Subcommittee on October 18, 2001 in the Rodbell Auditorium, Rall Building, South Campus, National Institute of Environmental Health Sciences (NIEHS), 111 Alexander Drive, Research Triangle Park, North Carolina. The meeting will begin at 8:30 a.m. on October 18, and is open to the public. The primary agenda topic is the peer review of draft Technical Reports of rodent toxicology and carcinogenesis studies conducted by the NTP.

Agenda

Tentatively scheduled for review on October 18, are draft Technical Reports of three 2-year studies and a draft Toxicity Report of toxicity and metabolism studies. The reports are listed alphabetically in the attached table and the tentative order of review is given in the far right column.

The agenda and roster of subcommittee members will be available prior to the meeting on the NTP web homepage at <http://ntp-server.niehs.nih.gov> and upon request to the Executive Secretary at the address given below. Following the meeting, summary minutes will be available electronically on the NTP web homepage and in hardcopy upon request to the Executive Secretary.

Attendance at this meeting is limited only by the space available. Individuals who plan to attend and need special assistance are asked to notify the Executive Secretary in advance of the meeting.

Draft Reports Available for Public Review and Comment

Approximately one month prior to the meeting, the draft reports will be available for public review, free of charge, through the Environmental Health Information Service (EHIS) at <http://ehis.niehs.nih.gov>. Printed copies can be obtained, as available, from: Central Data Management (CDM), NIEHS, P.O. Box 12233, MD E1-02, Research Triangle Park, NC 27709, T: 919-541-3419, Fax: 919-541-3687, e-mail: CDM@niehs.nih.gov.

The NTP Board of Scientific Counselors Technical Reports Review Subcommittee meeting is open to the public and public comment on any of the Technical Reports is welcome. Time will be provided at the meeting for public comment on each of the Reports under review. In order to facilitate planning for the meeting, persons requesting time for an oral presentation on a particular Report are asked to notify the Executive Secretary, Dr. Mary S. Wolfe, at P.O. Box 12233, MD A3-07, Research Triangle Park, NC 27709, T: 919-541-3971, Fax: 919-541-0295, e-mail: wolfe@niehs.nih.gov. Persons registering to make comments are asked to provide, if possible, a written copy of their statement by October 11, to enable review by the Subcommittee and NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. Each speaker is asked to provide his/her name, affiliation, mailing address, phone, fax, e-mail, and supporting organization (if any). At least seven minutes will be allotted to each speaker, and if time permits, may be extended to ten minutes. Each organization is allowed one time slot per Report being reviewed. Registration for making public comments will also be available on-site. If registering on-site to speak and reading comments from printed copy, the speaker is asked to provide 25 copies of the statement. These copies will be distributed to the Subcommittee and NTP staff and will supplement the record.

Written comments, in lieu of an oral presentation, are also welcome. The comments should include name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) and preferably be received by October 11, to enable review by the Subcommittee and NTP staff prior to the

meeting as well as to supplement the record.

Request for Additional Information

The NTP would welcome receiving toxicology and carcinogenesis information from completed, ongoing or planned studies as well as current production data, human exposure information, and use patterns for any of the chemicals listed in this announcement. Please forward this information to CDM at the address given above. CDM will forward the information to the appropriate staff scientist.

NTP Technical and Toxicity Report Series

The NTP conducts toxicology and carcinogenesis studies of agents of public health concern. Any scientist, organization, or member of the public may nominate a chemical for NTP testing. Details about the nomination process are available on the NTP web site (<http://ntp-server.niehs.nih.gov>). The results of short-term rodent toxicology studies are published in the NTP Toxicity Report series. Longer-term studies, generally, two-year rodent studies, are published in the NTP Technical Report series. Study abstracts for all reports are available at the NTP web site under NTP Study Information. Hardcopies and PDF files of published reports can be obtained through subscription to the EHIS (<http://ehis.niehs.nih.gov> or 1-800-315-3010).

NTP Board of Scientific Counselors

The Board is a technical advisory body composed of scientists from the public and private sectors who provide primary scientific oversight and peer review to the overall Program. Specifically, the Board advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the Program for the purposes of determining and advising on the scientific merit of its activities and their overall scientific quality. The Technical Reports Review Subcommittee of the Board provides scientific peer review of the findings and conclusions of NTP Technical Reports. The Report on Carcinogens Subcommittee of the Board provides scientific peer review of nominations to the Report on Carcinogens, a Congressionally mandated listing of agents known or reasonably anticipated to be human carcinogens.

The Board's members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk