

National Institutes of Health Peer Review Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Institutes of Health Peer Review Advisory Committee.

*Date:* August 27, 2007.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* Provide technical and scientific advice to the Director, National Institutes of Health (NIH), the Deputy Director for Extramural Research, NIH and the Director, Center for Scientific Review (CSR), on matters relating broadly to review and procedures and policies for the evaluation of scientific and technical merit of applications for grants and awards.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Rooms E1-E2, Bethesda, MD 20892.

*Contact Person:* Cheryl A. Kitt, PhD, Executive Secretary, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, 301-435-1112. [kitt@csr.nih.gov](mailto:kitt@csr.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted the stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 26, 2007.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-3246 Filed 7-3-07; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Method for the Diagnosis and Treatment of Vascular Disease

**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 worldwide to Endothelix, Inc., having a place of business in Houston TX, to practice the invention embodied in HHS Ref. Nos. E-037-2003 and E-125-2003, both entitled "Method for the Diagnosis and Treatment of Vascular Disease", corresponding to U.S. Patent Application No. 60/426,545 filed November 15, 2002, U.S. Patent Application No. 60/445,417 filed February 5, 2003, PCT Patent Application PCT/US03/36317 filed November 12, 2003, and U.S. Patent Application No. 10/534,626 filed May 11, 2005. The contemplated exclusive license may be limited to the following field of use: an FDA-approvable vascular endothelial function diagnostic test. 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 September 4, 2007 will be considered.

**ADDRESSES:** Requests for a copy of the patent, inquiries, comments, and other materials relating to the contemplated license should be directed to: Tara L. Kirby, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: 301-435-4426; Facsimile: 301-402-0220; E-mail: [kirbyt@mail.nih.gov](mailto:kirbyt@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** Cardiovascular disease is a major health risk throughout the industrialized world. Atherosclerosis, the most prevalent of cardiovascular diseases, is the primary cause of heart attack, stroke, and gangrene of the extremities. It is also the principal cause of death in the United States.

The inventors have developed a technique for evaluating vascular function by counting endothelial progenitor cells (EPCs) in a blood

sample. They found that decreased numbers of EPCs correlate significantly with decreased vascular function. A diagnostic test developed utilizing this discovery would have the advantages of being minimally invasive and low cost compared to other currently available diagnostics.

The invention describes methods for diagnosing decreased vascular function, detecting increased cardiovascular risk, and diagnosing atherosclerosis. Also included are methods for assaying the number of endothelial progenitor cells and methods for treating a subject with decreased vascular function by administering a therapeutically effective amount of endothelial progenitor cells.

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, the 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.

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: June 26, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-12898 Filed 7-3-07; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: The Development of Human Therapeutics for the Treatment of Cancer

**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 part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive

patent license to practice the inventions embodied in U.S. Patent Application 60/870,050, entitled "Human Cancer Therapy Using Anthrax Lethal Toxin Activated by Tumor Associated Proteases" [HHS Reference E-070-2007/0-US-01], including background patent rights to U.S. Patent Application 10/088,952, entitled "Mutated Anthrax Toxin Protective Antigen Proteins that Specifically Target Cells Containing High Amounts of Cell-Surface Metalloproteinases or Plasminogen Activator Receptors" [HHS Reference E-293-1999/0-US-03] and foreign counterparts thereto, and U.S. Patents 5,591,631 and 5,677,274, entitled "Anthrax Toxin Fusion Proteins and Uses Thereof" [HHS References E-064-1993/0-US-01 and E-064-1993/1-US-01, respectively] and foreign counterparts thereto, to FP BioPharma, LLC, which has offices in Fort Mill, South Carolina. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

A method for the treatment of cancer involving protease activated cancer toxins, wherein the cancer toxins comprise Anthrax lethal toxin (LeTx) modified at the furin-recognized cleavage site to contain a matrix metalloproteinase cleavage site, as defined by the Licensed Patent Rights, and wherein the cancers include, but are not limited to, melanoma, colon, thyroid, prostate, pancreatic and ovarian cancer. This exclusive licensed field of use shall explicitly exclude vaccines and immunotherapeutics for the prevention or treatment of human diseases.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 4, 2007 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: [lambertsond@od.nih.gov](mailto:lambertsond@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** Anthrax lethal toxin (LeTx) has been shown to have significant toxicity to cancer cells, particularly those associated with melanoma. However, LeTx also shows significant toxicity towards normal cells, preventing widespread use of the molecule as a cancer therapy. NIH

inventors have now engineered LeTx to have increased specificity for cancer cells, with little to no effect on normal cells, enhancing the effectiveness of LeTx for cancer treatment.

Modifying the LeTx to be activated by a matrix metalloprotease (MMP) increases the specificity of LeTx for cancer cells because those cells are more likely to activate the toxin, resulting in more efficient therapy. Mouse data shows that the modified LeTx (called PrAg-L1/LF) is less cytotoxic to "normal" cells in vivo when compared to wild-type LeTx, while maintaining high toxicity towards implanted human tumors. Modification of the LeTx to contain various protease recognition and cleavage sites can potentially extend application of the technology beyond melanomas to the treatment of lung and colon carcinomas, and various other cancers.

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 sixty (60) days from the date of this published notice, the 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 in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive 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: June 26, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-12899 Filed 7-3-07; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### Indian Gaming

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of approved amended Tribal-State compacts.

**SUMMARY:** This notice publishes approval of the Tribal-State Class III Gaming Compact between the State of New Mexico and the Pueblo of Isleta,

Pueblo of Nambe, Pueblo of Picuris, Pueblo of San Felipe, Pueblo of Sandia, Pueblo of Santa Ana, Pueblo of Tesuque, Pueblo of Taos, Pueblo of Santa Clara and Ohkay Owingeh.

**DATES:** *Effective Date:* July 5, 2007.

**FOR FURTHER INFORMATION CONTACT:**

George T. Skibine, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219-4066.

**SUPPLEMENTARY INFORMATION:** Under Section 11 of the Indian Gaming Regulatory Act of 1988 (IGRA), Public Law 100-497, 25 U.S.C. 2710, the Secretary of the Interior shall publish in the **Federal Register** notice of the approved Tribal-State Compacts and Amendments for the purpose of engaging in Class III gaming activities on Indian lands. This Amendment includes a provision that would eliminate any payments to the state should the state permit any licensed horse racetrack to increase number of machines, increase hours of operation, allow operation of gaming machines outside licensed premises or operate table games. This Amendment extends the term of the Compact until June 30, 2037.

Dated: June 18, 2007.

**George T. Skibine,**

*Principal Deputy Assistant Secretary—Indian Affairs.*

[FR Doc. E7-12904 Filed 7-3-07; 8:45 am]

**BILLING CODE 4310-4N-P**

## INTERNATIONAL TRADE COMMISSION

### Agency Form Submitted for OMB Review

**AGENCY:** United States International Trade Commission.

**ACTION:** In accordance with the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Commission has submitted a request for emergency processing for review and clearance of questionnaires to the Office of Management and Budget (OMB).

**EFFECTIVE DATE:** July 5, 2007.

*Purpose of Information Collection:* The form is for use by the Commission in connection with investigation No. TR-5003-1, *Textiles and Apparel: Effect of Special Rules on Trade Markets and Industries*, instituted under section 5003 of Tax Relief and Health Care Act of 2006 (TRHCA) (Public Law No. 109-432). The Commission must submit its report to Congress by June 20, 2008.