

comments or submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: March 28, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8-7237 Filed 4-7-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Codon Optimized IL-15 and IL-15R-Alpha Genes for Expression in Mammalian Cells

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 practice the invention embodied in U.S. Serial Numbers 60/758,819, filed January 13, 2006 and 60/812,566, filed June 9, 2006; PCT filed (PCT/US2007/000774) on January 12, 2007, entitled "Codon Optimized IL-15 and IL-15R-Alpha Genes for Expression in Mammalian Cells" (HHS Ref. E-254-2005/2) to Marine Polymer Technologies, Inc., having a place of business in Danvers, Massachusetts. The patent rights in these inventions 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 April 28, 2008 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: Susan Ano, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: anos@od.nih.gov; Telephone: (301) 435-5515; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: This technology provides for optimized nucleic acids for improved expression

of interleukin-15 (IL-15) and IL-15 receptor alpha (IL-15R-alpha) in mammalian cells. IL-15 is a cytokine important for both the innate and adaptive immune systems. Based on its many functions and relative safety in animal models, IL-15 finds use in vaccines, cancer immunotherapeutics, and autoimmune disease and as a vaccine adjuvant. The present technology enhances the production and bioavailability of IL-15 through use of optimized nucleic acid sequences. Native IL-15 coding sequences do not express IL-15 optimally for several reasons, and the optimized sequences of the subject technology overcome these deficiencies. The nucleic acids can be part of expression vectors, which could be utilized either in vitro or in vivo. The expression vectors express IL-15 alone, IL-15R-alpha alone, or both molecules together from a single vector. Further enhanced expression of IL-15 and/or IL-15R-alpha can be achieved through the use of signal peptides or propeptides from heterologous proteins. These nucleic acids can be administered to enhance the immune response of an individual against one or more antigens. Primate studies have shown that co-administration of IL-15 and IL-15R-alpha increased antigen specific cells, cells expressing IL-2, and/or cells expressing IL-2 and IFN-gamma (i.e. multifunctional cells). The present compositions are useful for the increased bioavailability and therefore biological effects of IL-15 after its administration to humans or other mammals.

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 20 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 the prevention, treatment and/or management of diseases involving IL-15 mediated signaling, comprising cancer, Hepatitis B and C infection, and immunotherapy (excluding Human Immunodeficiency Virus).

The licensed territory will be exclusive worldwide.

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: March 31, 2008.

Steven M. Ferguson,

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

[FR Doc. E8-7260 Filed 4-7-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Privacy Office

[Docket No. DHS-2008-0031]

Committee Management; Notice of Committee Charter Renewal

AGENCY: Privacy Office; Department of Homeland Security.

ACTION: Committee Management; Notice of Committee Charter Renewal.

SUMMARY: The Secretary of Homeland Security has determined that the renewal of the charter of the Data Privacy and Integrity Advisory Committee is necessary and in the public interest in connection with the Department of Homeland Security's performance of its duties. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Name of Committee: Data Privacy and Integrity Advisory Committee.

ADDRESSES: If you desire to submit comments on this action, they must be submitted by June 2, 2008. Comments must be identified by DHS-2008-0031 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* privacycommittee@dhs.gov. Include the docket number in the subject line of the message.

- *Fax:* 703-235-0442.

- *Mail:* Ken Hunt, Executive Director, 245 Murray Lane, Mail Stop 0550, Washington, DC 20528.

- *Instructions:* All submissions received must include the words "Department of Homeland Security" and DHS-2008-0031, the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov> including any personal information provided.

- *Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.