

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]

BILLING CODE 4140-01-P

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>.

FOR FURTHER INFORMATION CONTACT: Ken Hunt, Executive Director, 245 Murray Lane, Mail Stop 0550, Washington, DC 20528, 703-235-0780 and 703-235-0442, privacycommittee@dhs.gov.

Purpose and Objective: Under the authority of 6 U.S.C. section 451, this charter establishes the Data Privacy and Integrity Advisory Committee, which shall operate in accordance with the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. App).

The Committee will provide advice at the request of the Secretary of DHS and the Chief Privacy Officer of DHS on programmatic, policy, operational, administrative, and technological issues within the DHS that relate to personally identifiable information (PII), as well as data integrity and other privacy-related matters.

Duration: The committee's charter is effective March 25, 2008, and expires March 25, 2010.

Responsible DHS Officials: Hugo Teufel III, Chief Privacy Officer and Ken Hunt, Executive Director, 245 Murray Drive, Mail Stop 0550, Washington, DC 20528, privacycommittee@dhs.gov, 703-235-0780.

Dated: April 1, 2008.

Hugo Teufel III,

Chief Privacy Officer.

[FR Doc. E8-7277 Filed 4-7-08; 8:45 am]

BILLING CODE 4410-10-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination; correction.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border of the United States. The notice of determination was published in the **Federal Register** on April 3, 2008. Due to a publication error, the Project Area description was inadvertently omitted from the April 3 publication. For clarification purposes, this document is a republication of the April 3 document including the omitted Project Area description.

DATES: This Notice is effective on April 8, 2008.

Determination and Waiver

The Department of Homeland Security has a mandate to achieve and maintain operational control of the borders of the United States. Public Law 109-367, 2, 120 Stat. 2638, 8 U.S.C. 1701 note. Congress has provided the Secretary of Homeland Security with a number of authorities necessary to accomplish this mandate. One of these authorities is found at section 102(c) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 ("IIRIRA"). Public Law 104-208, Div. C, 110 Stat. 3009-546, 3009-554 (Sept. 30, 1996) (8 U.S.C 1103 note), as amended by the REAL ID Act of 2005, Public Law 109-13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109-367, 3, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110-161, Div. E, Title V, 564, 121 Stat. 2090 (Dec. 26, 2007). In Section 102(a) of the IIRIRA, Congress provided that the Secretary of Homeland Security shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. In Section 102(b) of the IIRIRA, Congress has called for the installation of fencing, barriers, roads, lighting, cameras, and sensors on not less than 700 miles of the southwest border, including priority miles of fencing that must be completed by December of 2008. Finally, in section 102(c) of the IIRIRA, Congress granted to me the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads authorized by section 102 of the IIRIRA.

I determine that the following area of Hidalgo County, Texas, in the vicinity of the United States border, hereinafter the Project Area, is an area of high illegal entry:

- Starting approximately at the intersection of Military Road and an unnamed road (i.e. beginning at the western end of the International Boundary Waters Commission (IBWC) levee in Hidalgo County) and runs east in proximity to the IBWC levee for approximately 4.5 miles.
- Starting approximately at the intersection of Levee Road and 5494 Wing Road and runs east in proximity

to the IBWC levee for approximately 1.8 miles.

- Starting approximately 0.2 mile north from the intersection of S. Depot Road and 23rd Street and runs south in proximity to the IBWC levee to the Hidalgo POE and then east in proximity to the new proposed IBWC levee and the existing IBWC levee to approximately South 15th Street for a total length of approximately 4.0 miles.

- Starting adjacent to Levee Road and approximately 0.1 miles east of the intersection of Levee Road and Valley View Road and runs east in proximity to the IBWC levee for approximately 1.0 mile then crosses the Irrigation District Hidalgo County #1 Canal and will tie into the future New Donna POE fence.

- Starting approximately 0.1 mile east of the intersection of County Road 556 and County Road 1554 and runs east in proximity to the IBWC levee for approximately 3.4 miles.

- Starting approximately 0.1 mile east of the Bensten Groves road and runs east in proximity to the IBWC levee to the Progreso POE for approximately 3.4 miles.

- Starting approximately at the Progreso POE and runs east in proximity to the IBWC levee for approximately 2.5 miles.

In order to deter illegal crossings in the Project Area, there is presently a need to construct fixed and mobile barriers and roads in conjunction with improvements to an existing levee system in the vicinity of the border of the United States as a joint effort with Hidalgo County, Texas. In order to ensure the expeditious construction of the barriers and roads that Congress prescribed in the IIRIRA in the Project Area, which is an area of high illegal entry into the United States, I have determined that it is necessary that I exercise the authority that is vested in me by section 102(c) of the IIRIRA as amended. Accordingly, I hereby waive in their entirety, with respect to the construction of roads and fixed and mobile barriers (including, but not limited to, accessing the project area, creating and using staging areas, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of fences, roads, supporting elements, drainage, erosion controls, safety features, surveillance, communication, and detection equipment of all types, radar and radio towers, and lighting) in the Project Area, all federal, state, or other laws, regulations and legal requirements of, deriving from, or related to the subject of, the following laws, as amended: The National Environmental Policy Act (Pub. L. 91-190, 83 Stat. 852 (Jan. 1,