DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Anthrax Toxin Fusion Proteins and Uses Thereof,'' ''Anthrax Toxin Fusion Proteins and Related Methods,'' and ''Targeting Agents to the MHC Class I Processing Pathway with an Anthrax Toxin Fusion Protein''

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the Food and Drug Administration and the Department of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in ''Anthrax toxin fusion proteins and uses thereof'', by Leppla *et al.*, issued as U.S. patent 5,591,631 on January 7, 1997; ''Anthrax toxin fusion proteins and related methods'' by Leppla *et al.*, issued as U.S. patent 5,677,274 on October 14, 1997; and ''Targeting agents to the MHC class I processing pathway with an anthrax toxin fusion protein'' by Klimpel *et al.* filed internationally as PCT/US97/16452, and claiming priority to U.S. provisional patent application 60/025,270, filed September 17, 1996 to Avant Immunotherapeutics, Inc., which is located in Needham, MA. The patent rights in these inventions have been assigned to the United States of America. This technology is currently licensed to Avant Immunotherapeutics, Inc. on a non-exclusive basis in the area of immune diseases.

The prospective exclusive license territory will be worldwide and the field of use may be limited to vaccines and immunotherapeutics for the prevention or treatment of the following human and animal diseases: Human immunodeficiency, hepatitis B virus and hepatitis C virus.

DATES: Only written comments and/or license applications that are received by the National Institutes of Health on or before November 30, 2004 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Brenda J. Hefti, 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; and e-mail: *heftib@od.nih.gov.*

SUPPLEMENTARY INFORMATION: In this technology, an anthrax binary toxin system provides antigen access to MHC Class I processing pathway. The *Bacillus antracis* binary toxin consists of two proteins, a protective antigen (PA) combines with lethal factor (LF) to make anthrax toxin. In this system PA binds to the protein receptor on the target cell, is cleaved to produce the PA63 fragment, PA63 binds to LF and the binary anthrax toxin is endocytosed and transported into the cell to be processed by the MHC Class I processing pathway. Advantages of this system include its ability to accommodate large fusion proteins and the fact that anthrax toxin is not widely used for immunization.

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 Part 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 establish 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: September 27, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–22146 Filed 9–30–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Monoclonal Antibodies Against the IL–2 Receptor Alpha Chain as a Novel Treatment for Multiple Sclerosis

AGENCY: National Institutes of Health, Public Health Services, DHHS.

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, Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the inventions embodied in U.S. Provisional Patent Application No. 60/393,021, filed June 28, 2002, ''Method of Treating Autoimmune Diseases with Interferon-Beta and IL–2R Antagonist'' (DHHS ref. no. E–143–2002/0–US–01), International Patent Application No. PCT/US2002/038290, filed November 27, 2002, International Publication No. WO 2004/002500 A1, published January 8, 2004, ''Method of Treating Autoimmune Diseases with Interferon-Beta and IL–2R Antagonist'' (DHHS ref. no. E–143–2002/0–PCT–02), International Application No. PCT/US2003/020428, filed June 27, 2003, International Publication No. WO 2004/002421 A2, published January 8, 2004, ''Method For the Treatment of Multiple Sclerosis'' (DHHS ref. no. E–143–2002/0–PCT–04), and U.S. Patent Application No. 10/607,598, filed June 27, 2003, Publication No. U.S. 2004/0109859 A1, published June 10, 2004, ''Method For the Treatment of Multiple Sclerosis'' (DHHS ref. no. E–143–2002/0–US–03), and all corresponding foreign patent applications to Serono S.A., of Geneva, Switzerland. The patent rights in these inventions have been assigned to the United States of America. This notice is a correction of a notice published in the **Federal Register** in 69 FR 52515–52516, Aug. 26, 2004.

The prospective co-exclusive license territory will be worldwide. The field of use may be limited to the treatment of multiple sclerosis using monoclonal antibodies against the interleukin-2 receptor. Two co-exclusive licenses may be granted.

DATES: Only license applications which are received by the National Institutes of Health on or before October 25, 2004 will be considered.

ADDRESSES: Requests for information, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Thomas P. Clouse, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4076; Facsimile: 301–402–0220; E-mail: *clouset@mail.nih.gov.* Copies of the international publications can be obtained from *http://ep.espacenet.com.* Copies of the U.S. publication can be obtained from *http://www.uspto.gov.*

SUPPLEMENTARY INFORMATION: The above-identified patent applications relate to the discovery that administration of an interleukin-2

receptor antagonist to a patient is effective in the treatment of autoimmune disorders. Examples in the patent applications show that a humanized antibody to the interleukin-2 receptor alpha chain (IL–2Rα) (humanized anti-Tac antibody), daclizumab, is effective in treating MS. In particular, it has been discovered that patients who failed to respond to therapy with interferon-beta showed dramatic improvement when treated with daclizumab, with patients showing both a reduction in the total number of lesions and cessation of appearance of new lesions during the treatment period. Pending claims in the above-referenced patent applications are directed to methods of treating a patient with multiple sclerosis (MS) by administering a therapeutically effective amount of an IL–2 receptor antagonist. IL–2 receptor antagonists can be antibodies, peptides, chemical compounds, and small molecules.

The prospective co-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 co-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 establish 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 co-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: September 27, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–22147 Filed 9–30–04; 8:45 am]

BILLING CODE 4140–01–U

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

[CIS No. 2333–04]

Termination and Re-designation of Liberia for Temporary Protected Status; Correction

AGENCY: Bureau of Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice of correction.

SUMMARY: The Bureau of Citizenship and Immigration Services (BCIS) is correcting a notice that was published in the **Federal Register** on August 25, 2004 at 69 FR 52297 which announced the termination and re-designation of Temporary Protected Status (TPS) for nationals of Liberia. In the supplemental information to the notice, BCIS inadvertently misstated that the termination would be effective, and benefits obtained through the Liberia TPS designation will expire, on October 1, 2004. However, under section 244(b)(3)(B) of the Immigration and Nationality Act (Act), a TPS designation may be terminated no earlier than 60 days after publication of the termination notice in the **Federal Register**. Pursuant to section 244(a)(2) of the Act and 8 CFR 274a.12(a)(12), persons granted TPS retain that status and employment authorization until the effective date of termination unless their TPS is withdrawn before then.

Therefore, BCIS is notifying affected Liberians and their employers that termination of the Liberian TPS designation is effective October 24, 2004, sixty (60) days after the August 25, 2004 termination notice. Accordingly, BCIS is extending until October 24, 2004 the validity of Form I–688B employment authorization documents issued to Liberian TPS beneficiaries that bear an expiration date of October 1, 2004 and a notation of ''274a.12(a)(12)'' or ''274a.12(c)(19).'' The effective date of the re-designation remains October 1, 2004.

DATES: This correction is effective October 1, 2004.

FOR FURTHER INFORMATION CONTACT: Jonathan Mills, Residence and Status Services, Office of Programs and Regulations Development, Bureau of Citizenship and Immigration Services, Department of Homeland Security, 111 Massachusetts Avenue, NW., 3rd floor, Washington, DC 20529, telephone (202) 514–4754.

SUPPLEMENTARY INFORMATION:

Need for Correction

As published in the **Federal Register** on August 25, 2004 (69 FR 52297), the notice contains an error that is in need of correction.

Correction of Publication

Accordingly, the publication on August 25, 2004 (69 FR 52297), of the notice that was the subject of FR Doc. 04–19448 is corrected as follows:

1. On page 52297, in the second column, in the third line under **SUMMARY** the date ''October 1, 2004'' is corrected to read: ''October 24, 2004''

2. On page 52298, in the third column, the paragraph under the heading ''If I Currently Have TPS Through the Liberia TPS Designation, Do I Have to Register for the New TPS Designation?'' is corrected to read:

Yes. If you already have received TPS benefits through the Liberia TPS designation, your benefits will expire on October 24, 2004. Accordingly, BCIS is extending until October 24, 2004 the validity of Form I–688B employment authorization documents issued to Liberian TPS beneficiaries that bear an expiration date of October 1, 2004 and a notation of ''274a.12(a)(12)'' or ''274a.12(c)(19).''

After October 24, 2004, individual TPS beneficiaries must comply with the registration requirements described below in order to maintain their TPS benefits through October 1, 2005. TPS benefits include temporary protection against removal from the United States, as well as employment authorization, during the TPS designation period and any extension thereof. 8 U.S.C. 1254a(a)(1).''

Dated: September 29, 2004.

Richard A. Sloan,

Director, Regulatory Management Division, Bureau of Citizenship and Immigration Services.

[FR Doc. 04–22198 Filed 9–29–04; 10:08 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD01–04–125]

Announcement of Public Scoping Meetings for Environmental Impact Statement Preparation in Conjunction With Proposed Replacement of the Goethals Bridge

AGENCY: Coast Guard, DHS.

ACTION: Notice of public scoping meetings.