

of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: 301-435-5031; Facsimile 301-402-0220; email [joycec@mail.nih.gov](mailto:joycec@mail.nih.gov).

**Technology Brief:** The above-referenced patent(s)/patent application(s) relate to the discovery that a humanized antibody to the interleukin-2 receptor alpha chain (IL-2R $\alpha$ ) (humanized anti-Tac antibody), dacluzimab, is effective in treating multiple sclerosis (MS). In particular, it has been discovered that patients who failed to respond to therapy with interferon-beta showed dramatic improvement when treated with dacluzimab, with patients showing both a reduction in the total number of lesions and cessation of appearance of new lesions during the treatment period.

**SUPPLEMENTARY INFORMATION:** 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 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: December 10, 2003.

**Steven M. Ferguson,**

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

[FR Doc. 03-31326 Filed 12-18-03; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: "Methods of Making, Using and Pharmaceutical Formulations Comprising 7 $\alpha$ , 11 $\beta$ -dimethyl-17 $\beta$ -hydroxyestra-4,14-dien-3-one and 17 Esters Thereof and 17 Esters of 7 $\alpha$ -methyl-17 $\beta$ -hydroxyestra-4,14-dien-3-one"**

**AGENCY:** National Institutes of Health, Public Health Service, 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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: USSN 60/193,530 and USSN 60/194,440, converted into combined PCT Application, PCT/US01/10293, and national stage filed in the U.S., Canada, Australia, Europe and Japan. A PCT-CIP was also filed and given a PCT Application Number of PCT/US02/09886, followed by national stage filings in the U.S., Canada, Australia, Europe, and Japan. The potential licensee is Torotech, LLC, having a place of business in the State of Maryland. The field of use may be limited to the therapeutic treatment of hypogonadism and human reproduction therapy. The United States of America is the assignee of the patent rights in this invention. This announcement is the first notice to grant an exclusive license to this technology.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before February 17, 2004 will be considered.

**ADDRESSES:** Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Marlene Shinn-Astor, 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: [MS482M@NIH.GOV](mailto:MS482M@NIH.GOV).

**SUPPLEMENTARY INFORMATION:** This technology relates to compounds that possess potent androgenic activity. These compounds offer a potential therapeutic benefit in the treatment of hypogonadism, regardless of cause, as an adjuvant in hormone replacement therapy for both men and women and for androgen stimulation of anabolism in a broad spectrum of disease entities involving debilitation.

These compounds are far more active and retain their potency after oral administration more than that achieved with the current oral androgen standard, methyltestosterone. An additional expected benefit is that liver toxicity, if any, should be minimal because 7 $\alpha$ , 11 $\beta$ -dimethyl-17 $\beta$ -hydroxy-4-estren-3-one bucyclate is not alkylated at the C17 position.

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.

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: December 12, 2003.

**Steven M. Ferguson,**

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

[FR Doc. 03-31325 Filed 12-18-03; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: Postnatal Stem Cells and Uses Thereof**

**AGENCY:** National Institutes of Health, Public Health Service, 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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: PCT application number PCT/US03/12276 filed April 19, 2003 entitled, "Postnatal Stem Cells and Uses Thereof" to Dentigenix, having a place of business in the State of Washington. The field of use may be limited to the treatment of dental regeneration. The United States of America is the assignee of the patent rights in this invention. This announcement is the first notice to grant an exclusive license to this technology.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before February 17, 2004 will be considered.

**ADDRESSES:** Requests for a copy of the patent applications, inquiries,

comments and other materials relating to the contemplated license should be directed to: Marlene Shinn-Astor, 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: [MS482M@NIH.GOV](mailto:MS482M@NIH.GOV).

**SUPPLEMENTARY INFORMATION:** This technology encompasses human postnatal deciduous dental pulp stem cells commonly known as "baby teeth", that are used to create dentin and have been shown to differentiate into cells of specialized function such as neural cells, adipocytes, and odontoblasts. It is believed that these cells could be manipulated to repair damaged teeth, induce the regeneration of bone, and treat neural injury or disease.

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.

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: December 12, 2003.

**Steven M. Ferguson,**

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

[FR Doc. 03-31324 Filed 12-18-03; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Submission for OMB Emergency Review; Reinstatement With Change for Previously Approved Information Collection Request (Product and Service Information Site)

**AGENCY:** Office of the Under Secretary for Management, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** The Department of Homeland Security (DHS), has resubmitted OMB

1600-0001 information collection request (ICR) (Product and Service Information Site) for reinstatement with change for a previously approved collection, utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104-106). OMB approval has been requested by December 22, 2003.

**ADDRESSES:** Comments and questions about the ICR listed below should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for Homeland Security, Office of Management and Budget, Room 10235, Washington, DC 20503; telephone (202) 395-7316. The Office of Management and Budget is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

**FOR FURTHER INFORMATION CONTACT:** A copy of this ICR, with applicable supporting documentation, may be obtained by calling Yvonne Pollard, Program Analyst and Paperwork Reduction Act Contact, Office of the Chief Information Officer, Department of Homeland Security, Washington, DC 20528; telephone (202) 692-4221.

### SUPPLEMENTARY INFORMATION:

#### Analysis

*Agency:* Department of Homeland Security, Under Secretary of Management, Office of the Chief Information Officer.

*Title:* Product and Service Information Site.

*OMB Number:* 1600-0001.

*Frequency:* On occasion.

*Affected Public:* Individuals or households; businesses or other for-

profit; not-for-profit institutions; farms, State, local or tribal government.

*Estimated Number of Respondents:* 20,000.

*Estimated Time Per Respondent:* 30 minutes for startup; 30 minutes for maintaining.

*Total Burden Hours:* 20,000.

*Total Burden Cost:* (capital/startup): \$25.00 per respondent; \$500,000 annually.

*Total Burden Cost:* (operating/maintaining): \$25.00 per respondent, \$500,000 annually.

*Description:* The Product and Service Information site is a supplement of the Central Contractor Registration database that will provide a uniform voluntary way for companies to provide descriptions of their product-and-service ideas to DHS for enhancing homeland security.

Dated: December 16, 2003.

**Steve Cooper,**

*Chief Information Officer.*

[FR Doc. 03-31438 Filed 12-17-03; 1:28 pm]

BILLING CODE 4410-10-P

## DEPARTMENT OF HOMELAND SECURITY

### Citizenship and Immigration Services

#### Agency Information Collection Activities: Proposed Collection; Comment Request

*Action:* 30-day notice of information collection under review: Petition for Nonimmigrant Worker; Form I-129.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (CIS), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 22, 2003 at 68 FR 43364, allowing for emergency OMB review and a 60-day public comment period. No comments were received by the CIS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until January 20, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget,