

Licensing Contact

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Dated: July 28, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8-17812 Filed 8-1-08; 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 Depression

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

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 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 11/137,114 entitled "Scopolamine For The Treatment Of Depression And Anxiety" [HHS Ref. E-175-2004/0-US-01], PCT Application PCT/US2006/019335 [HHS Ref. E-175-2004/0-PCT-02] and all continuing applications and foreign counterparts (Europe, Australia and Canada), to Transcept Pharmaceuticals, Inc., which has offices in Pt. Richmond, CA. 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 worldwide exclusive license for the use of scopolamine for treatment of depression, including major depressive disorders (MDD), wherein the administration of scopolamine is intravenous, through the buccal membrane, intranasal, intramuscular or through a skin patch.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 3, 2008, 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, Ph.D., 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.

SUPPLEMENTARY INFORMATION: The invention concerns the use of scopolamine for the treatment of depression, including major depressive disorders (MDD). Although scopolamine has been employed in the treatment of nausea and motion sickness, the suitability of scopolamine for treating MDD was unrecognized prior to this invention. Current MDD treatments can be ineffective in large percentage of patients and typically do not take effect until 4 weeks after administration. In contrast, treatment with scopolamine has a wide-ranging and rapid effect, suggesting it can be effective either as a stand alone treatment or as a treatment for patients who are unresponsive to currently available drugs.

A Cooperative Research and Development Agreement (CRADA) is simultaneously being negotiated to accompany the exclusive license agreement. The CRADA will involve the further development of the licensed technology between the National Institute of Mental Health and Transcept.

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 establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 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. Applicants may also contact the National Institute of Mental Health regarding the CRADA opportunity. 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: July 29, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8-17817 Filed 8-1-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2008-0521]

National Preparedness for Response Exercise Program

AGENCY: Coast Guard, DHS.

ACTION: Notice; request for public comment.

SUMMARY: The Coast Guard, the Pipeline and Hazardous Materials Safety Administration, the Environmental Protection Agency, and the Minerals Management Service, in concert with representatives from various State governments, industry, environmental interest groups, and the general public, developed the National Preparedness for Response Exercise Program (PREP) Guidelines to reflect the consensus agreement of the entire oil spill response community. This notice announces the PREP 5-year exercise cycle, 2009 through 2013, and requests comments from the public, and requests volunteers from industry to participate in the scheduled PREP Area exercises. The new schedule adjustment from 3 years to 5 years was created to align with the Department of Homeland Security's National Exercise 5-year Schedule.

DATES: Comments and related material must reach the Docket Management Facility on or before October 3, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG-2008-0521 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* 202-493-2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, or need general information regarding the PREP or the 5-year exercise schedule, contact Lieutenant Shawn Essert, Office of Contingency Exercises (CG-535), U.S. Coast Guard, telephone 202-372-2149, or e-mail shawn.g.essert@uscg.mil. If