

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Prospective Grant of Exclusive Patent License: Use of Scopolamine to Treat Depression**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Antares Pharma Inc., a company having a place of business in Ewing, New Jersey, to practice the inventions embodied in the following patent applications and patents:

1. U.S. Patent Application 11/137,114, filed May 25, 2005, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-US-01];

2. European Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-EP-03];

3. German Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-DE-07];

4. French Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-FR-08];

5. British Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-GB-09]; and

6. Canadian Patent Application 2610025, filed May 18, 2006, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-CA-04].

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Exclusive Patent License may be worldwide, and the field of use may be limited to: "The use of scopolamine for treatment of depression, including major depressive disorder, wherein the route of administration is subcutaneous, intramuscular, or transdermal delivery such as through injection or a patch or topical gel-based product". This announcement is the second notice to grant an exclusive license to this technology.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 26, 2013 will be considered.

ADDRESSES: Requests for copies of the patents, patent applications, inquiries, comments, and other materials relating to the contemplated Exclusive Patent License should be directed to: Betty B. Tong, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 594-6565; Facsimile: (301) 402-0220; Email: tongb@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The subject invention describes 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 a 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 standalone treatment or as a treatment for patients who are unresponsive to currently available drugs.

The prospective Exclusive Patent License will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License may be granted unless within thirty (30) 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 part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent 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: August 22, 2013.

Richard U. Rodriguez,

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

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard**

[USCG-2013-0222]

Collection of Information under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an approval for the following collection of information: 1625-NEW, U.S. Coast Guard Non-Appropriated Fund Employment Application. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before September 26, 2013.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2013-0222] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at <http://www.regulations.gov>. (b) To OIRA by email via: OIRA-submission@omb.eop.gov.

(2) *Mail:* (a) DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF 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:* (a) To DMF, 202-493-2251. (b) To OIRA at 202-395-6566. To