

## 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](mailto: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.*

[FR Doc. 2013-20880 Filed 8-26-13; 8:45 am]

**BILLING CODE 4140-01-P**

## 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](mailto: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

ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at Room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at <http://www.regulations.gov>.

A copy of the ICR is available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG-612), ATTN: PAPERWORK REDUCTION ACT MANAGER, US COAST GUARD, 2703 MARTIN LUTHER KING JR AVE. SE., STOP 7710, WASHINGTON DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532 or fax 202-475-3929, for questions on these documents. Contact Ms. Barbara Hairston, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

#### **SUPPLEMENTARY INFORMATION:**

#### **Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated

collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG-2013-0222], and must be received by September 26, 2013. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the "Privacy Act" paragraph below.

#### **Submitting Comments**

If you submit a comment, please include the docket number [USCG-2013-0222], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via <http://www.regulations.gov>), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via [www.regulations.gov](http://www.regulations.gov), it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to <http://www.regulations.gov>, and type "USCG-2013-0222" in the "Keyword" box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

#### **Viewing Comments and Documents**

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to <http://www.regulations.gov>, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG-2013-0222" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the DMF in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-NEW.

#### **Privacy Act**

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

#### **Previous Request for Comments**

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (78 FR 26798, May 8, 2013) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collection.

#### **Information Collection Requests**

*Title:* U.S. Coast Guard Non-Appropriated Fund Employment Application.

*OMB Control Number:* 1625-NEW.

*Type of Request:* New collection.

*Respondents:* Public applying for positions with the USCG Non-Appropriated Fund Workforce.

*Abstract:* The employment application is needed to allow individuals without resumes and/or computers access to apply for employment in the Coast Guard non-appropriated fund (NAF) workforce. Application needed to fill the void created when the OPM form OF-612, Optional Application for Federal Employment was cancelled.

*Forms:* CG-1227B, U.S. Coast Guard Non-appropriated Fund Employment Application.

*Hour Burden Estimate:* The estimated annual burden 5544 hours.

Dated: August 20, 2013.

**R.E. Day,**

*Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.*

[FR Doc. 2013-20787 Filed 8-26-13; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2013-0799]

#### Cooperative Research and Development Agreement: Next Generation Arctic Navigational Safety Information System

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of intent; request for public comments.

**SUMMARY:** The Coast Guard is announcing its intent to enter into a Cooperative Research and Development Agreement (CRADA) with Marine Exchange of Alaska (MXAK) to develop, demonstrate, and evaluate, in an operational setting, at least one promising technology approach to the "Next Generation Arctic Maritime Navigational Safety Information System," which provides important, time-critical, information to mariners, in order that they may better assess and manage their voyage risks, as they transit the remote and hostile waters of the U.S. Arctic Exclusive Economic Zone (EEZ). While the Coast Guard is currently considering partnering with MXAK, it is soliciting public comment on the possible nature of and participation of other parties in the proposed CRADA. In addition, the Coast Guard also invites other potential non-Federal participants, who have the interest and capability to bring similar contributions to this type of research, to consider submitting proposals for consideration in similar CRADAs.

**DATES:** Comments and related material on the proposed CRADA must either be submitted to the online docket via <http://www.regulations.gov> on or before September 26, 2013, or reach the Docket Management Facility by that date.

Synopses of proposals regarding future, similar CRADAs must reach the Docket Management Facility on or before February 24, 2014.

**ADDRESSES:** You may submit comments on this notice identified by docket number USCG-2013-0799 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

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

(3) *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.

(4) *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.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, contact Mr. James E. Fletcher, Project Official, U.S. Coast Guard Research and Development Center, 1 Chelsea Street, New London, CT 06320, telephone 860-271-2659, email [James.E.Fletcher@uscg.mil](mailto:James.E.Fletcher@uscg.mil). If you have questions on viewing or submitting material to the docket, call Ms. Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Public Participation and Request for Comments**

We encourage you to submit comments and related material on this notice. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

Do not submit detailed proposals for future CRADAs to the Docket Management Facility. Potential non-Federal CRADA participants should submit these documents directly to James E. Fletcher, U.S. Coast Guard Research and Development Center, 1 Chelsea Street, New London, CT 06320, email [James.E.Fletcher@uscg.mil](mailto:James.E.Fletcher@uscg.mil).

##### **Submitting Comments**

If you submit a comment, please include the docket number for this notice (USCG-2013-0799), and provide a reason for each suggestion or recommendation. You may submit your comments and material online via <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the

comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and locate this notice by using "USCG-2013-0799" as your search term. Click the "Comment Now" box opposite this notice and follow the instructions to submit your comment. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

##### **Viewing Comments and Related Material**

To view the comments and related material, go to <http://www.regulations.gov> and locate this notice by using "USCG-2013-0799" as your search term. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

##### **Privacy Act**

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act, system of records notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

##### **Cooperative Research and Development Agreements**

Cooperative Research and Development Agreements are authorized by the Federal Technology Transfer Act of 1986 (Pub. L. 99-502, codified at 15 U.S.C. 3710(a)). A CRADA