

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**National Institutes of Health**
**Prospective Grant of Start-Up Exclusive Commercialization License: The Development of a Circularly Permuted IL4-Targeted Pseudomonas Exotoxin A (cpIL4-PE38KDEL) for the Treatment of Cancers and Urological Disorders**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, indicates that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive commercialization license to practice the inventions embodied in:

(a) Technology families E-047-1994/0 and E-047-1994/1, including U.S. Patent 5,635,599 entitled "Proteins Comprising Circularly Permuted Ligands" [HHS Ref. E-047-1994/0-US-01], PCT Application PCT/US95/04468 entitled "Circularly Permuted Ligands and Circularly Permuted Chimeric Molecules" [HHS Ref. E-047-1994/0-PCT-02], European Patent 0754192 entitled "Proteins Comprising Circularly Permuted Ligand" [HHS Ref. E-047-1994/0-EP-15, validated in Austria, Belgium, France, Italy, Liechtenstein, The Netherlands, Spain, Switzerland and the United Kingdom], Canadian Patent 2187283 entitled "Proteins Comprising Circularly Permuted Ligands" [HHS Ref. E-047-1994/0-CA-14], Australian Patent 694211 entitled "Proteins Comprising Circularly Permuted Ligands" [HHS Ref. E-047-1994/0-CA-14], and U.S. Patent 6,011,002 entitled "Circularly Permuted Ligands and Circularly Permuted Chimeric Molecules" [HHS Ref. E-047-1994/1-US-01];

(b) Technology family E-021-2010/0, including U.S. Patent Application 61/105,408 entitled "Targeted Cargo Protein Combination Therapy" [HHS Ref. E-021-2010/0-US-01] and U.S. Patent Application 12/579,281 entitled "Targeted Cargo Protein Combination Therapy" [HHS Ref. E-021-2010/0-US-02];

and all related continuing and foreign patents/patent applications for these technology families, to Medicenna Therapeutics, Inc. 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 start-up exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

The treatment of cancers and urological disorders that express the IL4 receptor on their cell surface by using cpIL4-PE38KDEL.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 23, 2013 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive commercialization license should be directed to: David A. Lambertson, 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) 435-4632; Facsimile: (301) 402-0220; Email: [lambertsond@mail.nih.gov](mailto:lambertsond@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** Targeted toxins are fusion proteins which have been designed to direct therapeutic agents to specific diseased cells. Targeted toxins comprise two primary domains: a targeting domain and a toxin domain (the therapeutic agent). Diseased cells are targeted through the interaction of the targeting domain with a protein that is preferentially expressed on the cells. Once targeted to the cells, the toxin domain is able to exert its cytotoxic activity and kill the specific cell without affecting cells which do not express the target. Since there are a number of cell surface proteins that are preferentially expressed on diseased cells, targeted toxins are potential therapeutic candidates in the treatment of several diseases such as cancer and urological disorders.

The specific targeted toxins for which this start-up exclusive license may be granted comprise a targeting domain which contains a circularly permuted interleukin 4 (cpIL4) ligand, which binds to the IL4 receptor. The IL4 receptor is a cell surface protein that is preferentially expressed on several types of cancer cells and cells associated with urological disorders. By linking cpIL4 to the *Pseudomonas* exotoxin A variant PE38KDEL, it is possible to selectively kill the IL4 receptor-expressing cells, leaving non-diseased cells alone. This can result in an effective therapeutic strategy with fewer side effects than a non-targeted therapy.

The prospective start-up exclusive commercialization license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and

conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective start-up exclusive license may be granted unless 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 within fifteen (15) days from the date of this published notice.

Complete 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 start-up 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.

Dates: July 1, 2013.

**Richard U. Rodriguez,**

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

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**BILLING CODE 4140-01-P**

**DEPARTMENT OF HOMELAND SECURITY**
**Coast Guard**

[Docket No. USCG-2013-0574]

**Merchant Marine Personnel Advisory Committee: Intercessional Meeting**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of Federal Advisory Committee Working Group Meeting.

**SUMMARY:** A working group of the Merchant Marine Personnel Advisory Committee (MERPAC) will meet to work on Task Statement 82, entitled "The review and submittal of recommendations for proposed revisions to forms CG-719K, Merchant Mariner Credential Medical Evaluation Report and CG-719K/E, Merchant Mariner Evaluation of Fitness for Entry Level Ratings." This meeting will be open to the public.

**DATES:** A MERPAC working group will meet on July 24, 2013, and July 25, 2013, from 8 a.m. until 4 p.m. Please note that the meeting may adjourn early if all business is finished. Written comments to be distributed to working group members and placed on MERPAC's Web site are due by July 10, 2013.

**ADDRESSES:** The working group will meet at the Jemal Building of U.S. Coast Guard Headquarters, Room 10-0718, 1900 Half St. SW., Washington, DC

20593. Attendees will be required to provide a picture identification card and pass through a magnetometer in order to gain admittance to the Jemal Building. Visitors should also arrive at least 30 minutes in advance of the meeting in case of long lines at the entrance.

For further information about the Coast Guard facilities or services for individuals with disabilities or to request special assistance, contact Mr. Davis Breyer at (202) 372-1445 or [davis.j.breyer@uscg.mil](mailto:davis.j.breyer@uscg.mil).

To facilitate public participation, we are inviting public comment on the issues to be considered by the working group, as listed in the "Agenda" section below. Comments must be submitted in writing on or before July 10, 2013, and must be identified by Docket No. USCG-2013-0574 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments (preferred method to avoid delays in processing).

- *Fax:* 202-493-2251.

- *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.

- *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.

*Instructions:* All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

*Docket:* For access to the docket to read documents or comments related to this notice, go to <http://www.regulations.gov>, enter the docket number in the "Search" field and follow instructions on the Web site.

Public oral comment periods will be held during the working group meeting. Speakers are requested to limit their comments to 3 minutes. Please note that the public oral comment periods may end before the prescribed ending time following the last call for comments. Contact Davis Breyer as indicated above no later than July 10, 2013 to register as a speaker.

**FOR FURTHER INFORMATION CONTACT:** Mr. Davis Breyer, Alternate Designated

Federal Officer of MERPAC, telephone 202-372-1445. If you have any questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Title 5, United States Code (Pub. L. 92-463).

MERPAC is an advisory committee authorized under section 871 of the Homeland Security Act of 2002, Title 6, United States Code, section 451, and chartered under the provisions of the FACA. The Committee acts solely in an advisory capacity to the Secretary of the Department of Homeland Security (DHS) through the Commandant of the Coast Guard and the Director of Commercial Regulations and Standards on matters relating to personnel in the U.S. merchant marine, including but not limited to training, qualifications, certification, documentation, and fitness standards. The Committee will advise, consult with, and make recommendations reflecting its independent judgment to the Secretary.

A copy of all meeting documentation, including the Task Statement, is available at <https://homeport.uscg.mil> by using these key strokes: Missions; Port and Waterways Safety; Advisory Committees; MERPAC; and then use the announcements key. Alternatively, you may contact Mr. Breyer as noted in the **ADDRESSES** section above.

#### Agenda

##### Day 1

The agenda for the July 24, 2013, working group meeting is as follows:

- (1) Review forms CG-719K, Merchant Mariner Credential Medical Evaluation Report and CG-719K/E, Merchant Mariner Evaluation of Fitness for Entry Level Ratings for possible revision;

- (2) Public comment period;

- (3) Discuss and prepare proposed recommendations for the full committee

to consider with regards to Task Statement 82, entitled "The review and submittal of recommendations for proposed revisions to forms CG-719K, Merchant Mariner Credential Medical Evaluation Report and CG-719K/E, Merchant Mariner Evaluation of Fitness for Entry Level Ratings"; and

- (4) Adjournment of meeting.

##### Day 2

The agenda for the July 25, 2013, working group meeting is as follows:

- (1) Continue discussion on proposed recommendations;

- (2) Public comment period;

- (3) Discuss and prepare final recommendations for the full committee

to consider with regards to Task Statement 82, entitled "The review and submittal of recommendations for proposed revisions to forms CG-719K, Merchant Mariner Credential Medical Evaluation Report and CG-719K/E, Merchant Mariner Evaluation of Fitness for Entry Level Ratings"; and

- (4) Adjournment of meeting.

Dated: June 25, 2013.

**J. G. Lantz,**

*Director of Commercial Regulations and Standards.*

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**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0043]

#### Agency Information Collection Activities: Application for Temporary Protected Status, Form I-821; Revision of a Currently Approved Collection

**ACTION:** 60-Day Notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment on the proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

**DATES:** Comments are encouraged and will be accepted for 60 days until September 6, 2013.

**ADDRESSES:** All submissions received must include the OMB Control Number 1615-0043 in the subject box, the agency name and Docket ID USCIS-2007-0013. To avoid duplicate submissions, please use only one of the following methods to submit comments:

- (1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at [www.regulations.gov](http://www.regulations.gov) under e-Docket ID number USCIS-2007-0013;

- (2) *Email.* Submit comments to [USCISFRComment@uscis.dhs.gov](mailto:USCISFRComment@uscis.dhs.gov); or

- (3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and