

Health, 6701 Rockledge Drive, Room 4040-A, MSC 7850, Bethesda, MD 20892, 301-435-1235, geoffreys@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: October 16-17, 2014.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW., Washington, DC 20008.

Contact Person: Fungai Chanetsa, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301-408-9436, fungai.chanetsa@nih.hhs.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroimmunology and Brain Tumors Study Section.

Date: October 16-17, 2014.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Jay Joshi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, (301) 408-9135, joshij@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-13-095: Differentiation and Integration of Stem Cells (Embryonic and Induced-Pluripotent) into Developing or Damaged Tissues.

Date: October 17, 2014.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Washington DC/ Downtown, 1199 Vermont Avenue, Washington, DC 20005.

Contact Person: Rass M. Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435-2359, shayiqr@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 12, 2014.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-22213 Filed 9-17-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Therapeutics for the Treatment of Lysosomal Storage Disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the following invention as embodied in the following patent applications:

1. U.S. Provisional Patent Application No. 61/365,712, filed July 19, 2010 HHS Ref. No. E-294-2009/0-US-01
Titled: Use of Delta-Tocopherol for the Treatment of Lysosomal Storage Disorders
2. PCT Application No. PCT/US2011/044590, filed July 19, 2011 HHS Ref. No. E-294-2009/0-PCT-02
Titled: Use of Delta-Tocopherol for the Treatment of Lysosomal Storage Disorders
3. European Patent Application No. 11741023.3, filed July 19, 2011 HHS Ref. No. E-294-2009/0-EP-03
Titled: Use of Delta-Tocopherol for the Treatment of Lysosomal Storage Disorders
4. U.S. Patent Application No. 13/810,774, filed January 17, 2013 HHS Ref. No. E-294-2009/0-US-04
Titled: Use of Delta-Tocopherol for the Treatment of Lysosomal Storage Disorders
5. U.S. Provisional Patent Application No. 61/679,668, filed on August 3, 2012 HHS Ref. No. E-050-2012/0-US-01
Titled: Cyclodextrin for the Treatment of Lysosomal Storage Diseases
6. PCT Patent Application No. PCT/US2013/053527, filed on August 3, 2013 HHS Ref. No. E-050-2012/0-PCT-02
Titled: Cyclodextrin for the Treatment of Lysosomal Storage Diseases
7. U.S. Provisional Patent Application No. 61/727,296, filed November 16, 2012 HHS Ref. No. E-148-2012/0-US-01
Titled: Tocopherol and Tocopheryl Quinone Derivatives as Correctors of Lysosomal Storage Disorders
8. PCT Application No. PCT/US2013/070156, November 14, 2013 HHS Ref. No. E-148-2012/0-PCT-02
Titled: Tocopherol and Tocopheryl

Quinone Derivatives as Correctors of Lysosomal Storage Disorders,

to Vtesse, Inc., having a place of business in Cambridge, Massachusetts, United States of America. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before October 3, 2014 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Suryanarayana Vepa, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: vepas@mail.nih.gov; Telephone: (301) 435-5020; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: These technologies relate to the use of cyclodextrin (CD), delta-tocopherol and their derivatives for the treatment of lysosomal storage disorders (LSDs). LSDs are inherited metabolic disorders caused by a deficiency in lysosomal enzymes, of which approximately fifty (50) have been described to date. These diseases usually affect children, many of whom die within several years of birth and some following years of dealing with symptoms of the disease that may include developmental delay, movement disorders, seizures, dementia, deafness and blindness. LSDs affect a significant number of individuals and some can be treated with enzyme-replacement therapies. However, because enzymes cannot cross the blood-brain barrier, replacement therapeutics are unable to address the central nervous system manifestations of the disorders. The inventors have identified an unexpected and previously unrecognized use for delta-tocopherol, which is a form of vitamin E, in the treatment of diseases and conditions related to LSDs. Further, the inventors showed that CD (alpha-, beta- and gamma-CDs) in combination with delta-tocopherol synergistically/additively reduced cholesterol accumulation in cells derived from patients suffering from Niemann Pick Type C disease (NPC) and Wolman diseases. The inventors have also discovered that tocopherol and tocopheryl quinone derivatives with side chain modifications (such as terminal trihalogenated methyl groups) exhibit improved pharmacokinetics, modulation of mitochondrial potential

and restoration of some LSDs phenotypes. These technologies can be used to develop novel therapeutics for LSDs including NPC, Wolman, Niemann Pick Type A, Farber, TaySachs, MSIIIB and CLN2 (Batten) diseases.

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. The prospective exclusive license may be granted unless, within fifteen (15) 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.

The fields of use may be limited to "Use of cyclodextrin, delta-tocopherol, or derivatives thereof, alone or in combination, for the treatment of lysosomal storage disorders in humans."

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: September 12, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014-22210 Filed 9-17-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2014-0664; OMB Control Number 1625-0012]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of an extension to the following collection of information: 1625-0012, Certificate of Discharge to Merchant Mariner. Our ICR describes the information we seek to collect from

the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before November 17, 2014.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2014-0664] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

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

(2) *Mail:* DMF (M-30), DOT, 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. To ensure your comments are received in a timely manner, mark the fax, to 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>.

Copies of the ICR are 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 202-372-8405, for questions on these documents. Contact Ms. Cheryl Collins, 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 the ICR should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise these ICRs or decide not to seek approval of revisions of the Collections. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2014-0664], and must be received by November 17, 2014. 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-2014-0664], 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, 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