

Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI, 0925- 0641. Extension. National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for OMB to approve the extension of the generic collection titled, “A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI” for an additional three years of data collection. The Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks input and

feedback, and facilitates collaboration to advance NCI’s authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities and materials while they are under development. Additionally, administrative forms are a necessary part of collecting demographic information and areas of interest for advocates. Since OAR is responsible for matching advocates to NCI programs and initiatives across the cancer continuum, it is necessary to measure the satisfaction of both internal and external stakeholders with this collaboration. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many initiatives and products that OAR and NCI produce. The OAR will use a variety of qualitative (interviews) methodology to conduct this research,

allowing NCI to: (1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective strategies, concepts, activities; (2) use a feedback loop to help refine, revise, and enhance OAR’s efforts—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and (3) expend limited program resource dollars wisely and effectively. The anticipated respondents will consist of: Adult cancer research advocates; members of the public; health care professionals; and organizational representatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 45.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Individual In-Depth Interviews	40	1	30/60	20
Profile Completion	50	1	30/60	25
Total	90	90	45

Dated: December 2, 2017.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2017-26495 Filed 12-7-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: N-Acetyl Mannosamine as a Therapeutic Agent

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute, an institute of 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 the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to Leadiant Biosciences, Inc, located in Gaithersburg, Maryland, USA.

DATES: Only written comments and/or applications for a license which are received by the National Human Genome Research Institute’s Technology Transfer Office on or before December 26, 2017 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: Eggerton Campbell, Ph.D., Senior Licensing and Patenting Manager, Technology Transfer Office (TTO), National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH), 5635 Fishers Lane, Suite 3058, MSC 9307, Bethesda, MD 20892-9307. Telephone: 301-402-1648. Fax: 301-402-9722. email: eggerton.campbell@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application No.: 60/932,451, [HHS Ref. No.: E-217-2007/0-US-01], Filed May 31, 2007; PCT Patent Application No.: PCT/US2008/006895, [HHS Ref. No.: E-217-2007/0-PCT-02], Filed: May 30, 2008; CA Patent Application 2680842, [HHS Ref. No.: E-217-2007/0-CA-03], Filed: May 30, 2008; EP Patent Application No.: 08767999.9, [HHS Ref. No.: E-217-

2007/0-EP-04], Filed: September 14, 2009; IL Patent Application No.: 200872, [HHS Ref. No.: E-217-2007/0-IL-05], Filed: May 30, 2008; JP Patent Application No.: 2010-510363, [HHS Ref. No.: E-217-2007/0-JP-06], Filed: May 30, 2008; U.S. Patent Application No.: 12/530,433, [HHS Ref. No.: E-217-2007/0-US-07], Filed: Sept 8, 2009; U.S. Patent Application No.: 13/791,576, [HHS Ref. No.: E-217-2007/0-US-08], Filed: March 8, 2013; JP Patent Application No.: 2014-208695, [HHS Ref. No.: E-217-2007/0-JP-09], Filed: May 30, 2008; U.S. Patent Application No.: 14/754,304, [HHS Ref. No.: E-217-2007/0-US-10], Filed: June 29, 2015; CA Patent Application No.: 2903133, [HHS Ref. No.: E-217-2007/0-CA-11], Filed: May 30, 2008; IL Patent Application No.: 245026, [HHS Ref. No.: E-217-2007/0-IL-12], Filed: March 8, 2013; JP Patent Application No.: 2016-159061, [HHS Ref. No.: E-217-2007/0-JP-13], Filed: August 15, 2016; EP Patent Application No.: 16196935.7, [HHS Ref. No.: E-217-2007/0-EP-14], Filed: March 8, 2013; U.S. Patent Application No.: 15/702,529, [HHS Ref. No.: E-217-2007/0-US-08], Filed: September 12, 2017; and all continuing applications and foreign counterparts.

The patent rights in these inventions have been assigned 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 the use of Licensed Patent Rights for the following: “Treating GNE Myopathy (also referred to as distal myopathy with rimmed vacuoles (DMRV), Nonaka myopathy, muscular dystrophy hereditary inclusion body myopathy (HIBM) or inclusion body myopathy type 2 (IBM2)) and kidney disorders due to hyposialylation of the glomerulae or sialic acid deficiency including but not limited to minimal change disease glomerulopathy, focal segmental glomerulosclerosis and membranous nephropathy, in humans with oral formulations of N-acetyl mannosamine (ManNAc) or derivative.”

N-Acetyl Mannosamine is a precursor for the synthesis of sugar molecules known as sialic acids which play an important role in specific biological processes such as cellular adhesion, cellular communication and signal transduction. Lack of sialic acids also play an important role in disease processes such as cancer, inflammation and immunity.

This invention relates to methods of administering ManNAc or its derivative (to produce sialic acid in patients who are deficient in the sugar molecule) to treat GNE Myopathy (also referred to as distal myopathy with rimmed vacuoles (DMRV), Nonaka myopathy, muscular dystrophy hereditary inclusion body myopathy (HIBM) or inclusion body myopathy type 2 (IBM2)), and kidney disorders due to hyposialylation of the glomerulae or sialic acid deficiency may be treated by this method as well.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Human Genome Research Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business

confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 30, 2017.

Claire T. Driscoll,

Director, NHGRI Technology Transfer Office.

[FR Doc. 2017-26540 Filed 12-7-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Revenue Modernization: Mobile Collections & Receipt (MCR) Pilot

AGENCY: U.S. Customs and Border Protection; DHS.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) will be conducting a pilot test program to allow for the electronic payment of certain taxes and fees imposed on commercial vessels prior to or upon a vessel’s arrival at four designated ports of entry. The pilot also introduces portable, electronic devices that authorized CBP employees will use to electronically process payments of certain taxes and fees and to send electronic receipts via email. The pilot will not affect the amount of taxes and fees due, the clearance process, or the proof of documentation required to be presented to CBP. This notice describes the pilot, including its purpose, procedures, locations, and how to participate, and invites public comment on any aspect of the pilot.

DATES: The pilot will begin no earlier than January 8, 2018 and will continue for 18 months at the designated ports of entry. Comments concerning this notice and all aspects of the pilot may be submitted at any time during the pilot to the address set forth below.

ADDRESSES: Written comments concerning any aspect of the pilot should be submitted to the CBP Revenue Modernization (“Rev Mod”) Office at revmod@cbp.dhs.gov. In the subject line of your email please indicate “Comment on Mobile Collections & Receipt Pilot.”

FOR FURTHER INFORMATION CONTACT:

Kathleen Druiitt, Rev Mod Program Manager, Office of Finance, U.S. Customs and Border Protection, via email at kathleen.c.druiitt@cbp.dhs.gov or by telephone at (202) 427-8448. For

additional information, please visit www.cbp.gov/368.

SUPPLEMENTARY INFORMATION:

Background

U.S. Customs and Border Protection (CBP) collects various maritime taxes and fees with regard to commercial vessels that enter ports of entry, proceed coast-wise, or utilize certain customs services at a port. These maritime taxes and fees include tonnage taxes and light money, Consolidated Omnibus Budget Reconciliation Act (COBRA) user fees, Agriculture Quarantine and Inspection (AQI) user fees, and navigation fees.¹ CBP regulations require payment of these taxes and fees by cash or check and specify a paper-based payment process that occurs at the ports.

Current Payment Methods

CBP regulations require that most customs duties, taxes, fees, interest, and other charges be paid by cash or check. See title 19 Code of Federal Regulations section 24.1 (19 CFR 24.1). Accordingly, a party responsible for the payment of commercial vessel maritime taxes and fees must pay all applicable tonnage taxes, light money, COBRA user fees, AQI user fees, and navigation fees, including the prepayment of annual COBRA user fees, by cash or check only. Maritime taxes and fees cannot be paid by credit card or through any other electronic method.

Current Payment Process

Pursuant to CBP regulations, maritime taxes and fees are paid at the port to an authorized CBP employee either onboard the vessel or at the port office. See 19 CFR 24.2. Specifically, all applicable tonnage taxes, light money, and COBRA user fees must be paid to an authorized CBP employee on arrival at a port of entry. See 19 CFR 4.20 (tonnage taxes and light money) and 19 CFR 24.22(b) (COBRA user fee). Annual COBRA user fees may be prepaid. In such case, they must be paid at the port office. See 19 CFR 24.22(b)(3). Navigation fees and AQI user fees must be paid at the time the applicable service is provided. See 19 CFR 4.98 (navigation fees) and 7 CFR 354.3(b) (AQI user fee).

When a cash register is unavailable to process a payment, such as when

¹ See 46 U.S.C. 60301-60303 and 19 CFR 4.20-4.23 (tonnage tax and light money); 19 U.S.C. 58c and 19 CFR 24.22(b) (COBRA user fees); 19 U.S.C. 58a and 19 CFR 4.98 (navigation fees); and 21 U.S.C. 136a and 7 CFR 354.3(b) (AQI user fees). CBP collects AQI user fees pursuant to an inter-agency agreement with the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service.