DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Health Assessment and Translation Evaluation of the State of the Science for Transgenerational Inheritance of Health Effects; Request for Information

SUMMARY: The Office of Health Assessment and Translation (OHAT) of the Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), is initiating one or more systematic reviews to examine the state of the science for transgenerational inheritance of health effects. The specific scope of the evaluation will be determined following a phase of exploratory screening of the literature and consideration of responses to this request for information (RFI). OHAT requests information on the proposed approach for conducting the exploratory screening of the literature and the identification of scientists with knowledge or expertise relevant to this topic.

DATES: The deadline for receipt of information is June 28, 2013.

ADDRESSES: Information should be submitted at *http://ntp.niehs.nih.gov/go/38656*.

FOR FURTHER INFORMATION CONTACT: Vickie R. Walker, Health Scientist, OHAT, DNTP, NIEHS, P.O. Box 12233, MD K2–04, Research Triangle Park, NC 27709; telephone (919) 541–4514; FAX: (301) 480–3337; *vickie.walker@nih.gov*. Courier Address: NIEHS, Room 2163, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: There is a large body of evidence indicating that early life exposures can lead to disease outcomes later in life. The effects of these exposures are thought to be limited to the exposed generation, such that subsequent generations are unaffected by the exposure history of their parents and grandparents. However, recent reports have suggested that this may not be the case, and that adverse outcomes may be carried over to multiple unexposed generations. This phenomenon is known as ''transgenerational inheritance.'' If the effects of exposure can indeed be transmitted to subsequent generations, this would have major public health implications. It is critical to determine how widespread and robust this phenomenon is, the factors that influence it, the mechanism by which it occurs, and the range of possible phenotypic outcomes (see *http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-12-006.html*). To assist with this effort, OHAT is initiating one or more evaluations using systematic review methodology to examine the state of the science for transgenerational inheritance of health effects associated with exposure to a wide range of stressors (e.g., environmental chemicals, drugs of abuse, nutrition and diet, pharmaceuticals, infectious agents, or stress).

The specific scope of the evaluation will be determined following a phase of exploratory screening of the literature and consideration of responses to this RFI.

Request for Information: A document outlining the proposed approach to conduct the exploratory screening is available at *http://ntp.niehs.nih.gov/go/38656*. OHAT requests information on the proposed approach for conducting the exploratory screening of the literature and the identification of scientists with knowledge or expertise relevant to this topic. Specifically, this information will help to (1) refine the proposed literature search strategy and criteria used to conduct the exploratory screening; (2) identify potential areas of focus for the systematic review(s); (3) identify unpublished, ongoing, or planned studies related to transgenerational inheritance; and (4) identify scientists with expertise or knowledge relative to this topic.

Responses are requested from all interested parties, such as the research community, health professionals, educators, policy makers, industry, and the public. Responses to this RFI are voluntary. OHAT does not intend to publish a summary of responses received or any other information provided, except very broad characterizations. Despite this, proprietary, classified, or confidential information should not be included in the response. This RFI is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information. The U.S. Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

Future updates on this project, will be posted at *http://ntp.niehs.nih.gov/go/38159*. Individuals interested in receiving updates on this and other NTP projects are encouraged to register to the NTP Listserv (*http://ntp.niehs.nih.gov/go/getnews*).

Background Information on the NTP and OHAT: The NTP is an interagency program, established in 1978 (43 FR 53060) and headquartered at the NIEHS, whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP carries out literature analysis activities in OHAT and the Office of the Reports on Carcinogens within the DNTP. The NTP also designs and conducts laboratory studies and testing programs and analyzes its findings to assess potential hazards to human health from exposure to environmental substances (see *http://ntp.niehs.nih.gov/*).

OHAT was established to serve as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as ''substances'') cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found at *http://ntp.niehs.nih.gov/go/ohat*.

Dated: April 26, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2013–10726 Filed 5–6–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive License: 1. Catalytic Domains of Beta (1,4)-Galactosyltransferase I Having Altered Donor and Acceptor Specificities Domains, That Promote in Vitro Protein Folding and Methods for Their Use; 2. Targeted Delivery System for Bioactive Agents

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National

Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive patent license to practice the inventions embodied in:

1. U.S. Patent 7,482,133 and AU Patent 2004204463, HHS Ref. E–230–2002/2–US–03 and E–230–2002/2–AU–07; Title: Catalytic Domains of Beta (1,4)-Galactosyltransferase I Having Altered Donor And Acceptor Specificities Domains, That Promote In Vitro Protein Folding And Methods For Their Use; Inventors: Pradman K. Qasba and Boopathy Ramakrishnan (NCI).

2. U.S. Patent Application 10/580,108, HHS Ref E–037–2004/0–US–03; Title: Efficient Tagging of The Modified Galactose to the Free N-acetylglucosamine Moieties Of Glycoproteins With Tyr289Leu-Gal-T1 Mutant; Inventors: Pradman K. Qasba and Boopathy Ramakrishnan (NCI).

to SynAffix B.V., which is located in The Netherlands. The exclusive license is one which qualifies under the Start-Up License Agreement program which is in place from October 1, 2011 through September 30, 2013. 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 that are received by the NIH Office of Technology Transfer on or before May 22, 2013 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: John Stansberry, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: *stansbej@mail.nih.gov*; Telephone: 301–435–5236; Facsimile: 301–402–0220.

SUPPLEMENTARY INFORMATION: The prospective worldwide start-up exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. 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 404.7.

E–230–2002/0,/1,/2—The present invention is based on the discovery that the enzymatic activity of β-(1,4)-galactosyltransferase can be altered such that the enzyme can make chemical bonds that are very difficult to make by other methods. The ability to synthesize these types of bonds has many applications in research and medicine and maybe helpful in developing pharmaceutical agents and improved vaccines that can be used to treat diseases.

E–037–2004/0—This invention describes the synthesis by the genetically engineered enzyme, Y289L-Gal-T1, of a unique disaccharide linkage of a glycoprotein, a modified UDP-α-galactose, that contains a chemically reactive ketone group (-$CH_2C(=O)$-CH3) at the C2 position of galactose. In Y289L-Gal-Tl, the binding pocket for DOP-α-galactose has been enlarged to accommodate modifications at the C_2 position of galactose, like the ketone moiety above, that can serve as a neutral, yet versatile chemical handle. Glycoproteins containing a reactive ketone, such as monoclonal antibodies, could be then labeled with other agents useful for imaging or therapy.

The field of use may be limited to conjugated glycoproteins for pharmaceuticals made using Licensed Patent Rights in combination with Licensee's proprietary or exclusively in-licensed Intellectual Property rights. For the avoidance of doubt, this Licensed Field of Use excludes use of Licensed Patent Rights solely.

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: April 29, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–10721 Filed 5–6–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0082]

Agency Information Collection Activities: Application To Replace Permanent Resident Card, Form I–90, 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 this proposed revision of a currently approved collection. 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 July 8, 2013.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0082 in the subject box, the agency name and Docket ID USCIS–2009–0008. 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* under e-Docket ID number USCIS–2009–0008;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies