including imaging, diagnostics, regenerative medicine, genetics/genomics, developmental biology, cellular and gene therapy, and cell and molecular biology related to eye health and eye disease treatments. For more information about the research and investigators in the NEI Division of Intramural Research, please see: *http://www.nei.nih.gov/intramural/.*

An NEI intramural investigator may provide assistance in a collaborative manner by providing technology, reagents and/or discussions during the SBIR award period; however, no SBIR funds are allowed to go to the NIH intramural investigator or the NIH intramural program.

All other aspects of the Funding Opportunity Announcement (FOA) remain unchanged.

Inquiries:

SBIR contact: Jerome Wujek, Ph.D., 5635 Fishers Lane; MSC 9300, Bethesda, MD 20892, (301) 451–2020, *wujekjer@nei.nih.gov*.

Licensing contact: Alan E. Hubbs, Ph.D., 6120 Executive Blvd., Bethesda, MD 20892, (301) 594–4263, *hubbsa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 30, 2012.

David Whitmer,

Executive Officer, NEI, National Institutes of Health.

[FR Doc. 2012–11512 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information Regarding the NIH-Industry Program To Discover New Therapeutic Uses for Existing Molecules

SUMMARY: As part of a larger initiative to help reengineer the process of translating scientific discoveries into new therapies, the recently established National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) will be launching a new collaborative program to support the exploration of promising drug candidates (compounds and biologics) across a broad range of human diseases. As an initial effort, the program will focus on discovering new therapeutic uses of existing molecules (Therapeutics Discovery).

The NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules is designed to be carried out through collaborations between pharmaceutical companies and the biomedical research community. The Program will match drug candidates and associated data from participating companies with the best ideas for new therapeutic uses put forward by the biomedical research community.

NCATS will be initiating this innovative concept as a limited pilot Program. If the pilot is successful, and depending on the level of interest and available funds, the Program may be expanded. To gauge the breadth and depth of potential interest in the Program and to obtain stakeholder input and perspectives on its novel features, NCATS is seeking input from the biomedical research community, prospective industry collaborators, and other members of the public on all aspects of the Program and more broadly on how the government can partner with the private sector in this area.

DATES: Comments in response to this notice are requested by June 1, 2012. The NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules funding announcement will be published in early June, 2012 in the NIH Guide to Grants and Contracts at *http://grants.nih.gov/grants/guide/index.html.*

FOR FURTHER INFORMATION CONTACT: Questions may be submitted electronically to *Therapeutics.Discovery@nih.gov.* For additional information, please contact Dr. Heng Xie, NCATS, at *XieHe@mail.nih.gov* or 301–443–8063.

SUPPLEMENTARY INFORMATION:

Background

On December 23, 2011, Congress created NCATS, (Pub. L. 112–74 passed December 23, 2011, amending the Public Health Service Act, 42 U.S.C. 287). One aspect of the NCATS mission focuses on developing innovative strategies, methods, and tools to reduce or eliminate barriers to drug and diagnostic development. By developing new methods that can be adopted across the entire medical product development sector, NCATS will enhance the capabilities of other sectors to bring safe and effective products to patients.

One of the strategies that NCATS will be pursuing is to advance research and development (R&D) efforts to find uses for therapeutics different from those for which they were originally developed (Therapeutics Discovery). Many discontinued compounds and biologics that have already been tested in human subjects may have promising applications for other indications and many approved drugs may be put to new uses. Harnessing previous R&D efforts and building on data already gathered may be a way to speed the testing of new clinical hypotheses and bring forward new treatments for a range of human diseases. Along with opportunities, however, there are also scientific, economic, and administrative challenges that need to be addressed. These were explored in an April 2011 Roundtable with senior leaders and experts from the pharmaceutical industry, government, academia, and the non-profit sector (*http://www.ncats.nih.gov/files/exploring_new_uses_for_abandoned_and_approved_therapeutics.pdf.pdf*). Some of the challenges identified at the Roundtable include: Resource implications (the time and resources for a pharmaceutical company to maintain, update, and organize their therapeutics libraries for investigating new therapeutic uses prior (drug rescue) or subsequent to (drug repurposing) FDA approval; patent considerations (off-patent or drugs whose patents are close to expiring may not be attractive to industry because the financial return and market incentives for the product may be limited); and transactional hurdles related to developing, negotiating and implementing appropriate legal agreements among the parties, including addressing such concerns as intellectual property rights and liability. The Roundtable participants concluded that because the private sector holds a substantial portion of the requisite assets, data, and knowledge and the public sector has new ideas and the wherewithal to advance new applications, public-private collaborations are central to rescue and repurposing efforts. Streamlining the initiation and execution of such partnerships will help promote collaboration, leverage the strengths of both sectors, and facilitate the formation of partnerships that are so critical to success.

NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules

The NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules Program is designed to be carried out through collaborations between pharmaceutical companies and investigators from the biomedical research community. The Program will match drug candidates and associated data from participating companies with the best ideas for new therapeutic uses put forward by the biomedical research community. Funded investigators will

work to validate novel human mechanisms of disease using drug candidates that have been made available by pharmaceutical companies for use in small interventional clinical validation studies. The Program will be initiated as a limited pilot, (see: *http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/therapeutic-uses.html*), which if successful and depending on availability of funding, may be expanded as to number of participating pharmaceutical companies, number of drugs candidates, areas of interest, and number of projects.

NCATS is currently engaging industry partners to develop a framework under which they will agree to provide drug candidates and partner with potential funding recipients under a pre-negotiated ''Collaborative Research Agreement'' that NCATS anticipates will be executed between each funding recipient and industry partner.

NCATS will be soliciting grant applications from investigators interested in working with a participating company to carry out studies of the company's drug candidate. The Request for Applications will be published in early June in the NIH Guide to Grants and Contracts (*http://grants.nih.gov/grants/guide/index.html*). Each company participating in the Program will have signed a Memorandum of Understanding with NCATS that articulates the goals and general terms of the Program. NCATS also anticipates that applicants will use template agreements (the Collaborative Research Agreement discussed above and a Confidential Disclosure Agreement, to formalize the relationship between the pharmaceutical partner and the biomedical investigator's institution. The template agreements will help streamline interactions among the parties, expediting the initiation of the discovery efforts. The template agreements are available for comment at: *http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/agreements.htm.*

NCATS will use a two-stage application process to identify meritorious projects and a cooperative agreement mechanism to fund the research. The first step in the process is the submission of a pre-application, called an X02. The second step is submission of a full application using a funding mechanism that can be used for clinical research known as UH2/UH3 or stand-alone UH3. Information on the drug candidates such as the drug's mechanism of action and any limitations in use based on the toxicological profile will be available when the X02 funding opportunity announcement is published in the NIH Guide. Investigators who submit pre-applications will be expected to demonstrate that they have the requisite competencies, capabilities, creativity, and environment necessary to carry out clinical trials as well as any necessary pre-clinical studies to provide evidence a drug candidate could target critical biological processes in a new disease area. The pre-application will be peer reviewed. Submitters of the most meritorious of the pre-applications will be invited to submit a full application for funding to conduct pre-clinical or non-interventional clinical studies (UH2) to provide sufficient confidence in the biological rationale for the new therapeutic use and clinical trials (UH3) in the new selected disease area using the drug candidate. The total project period will not exceed three years. Prior to the proposed clinical studies, investigators will be expected to submit an investigator-sponsored Investigational New Drug (IND) application to the Food and Drug Administration (FDA). More details about the funding mechanism and application process are published as NIH Notice of intent NOT–TR–12–001 in the NIH Guide for Grants and Contracts (*http://grants.nih.gov/grants/guide/notice-files/NOT-TR-12-001.html*). A Request for Information, NOT–TR–12–002, is also published in the NIH Guide for Grants and Contracts (*http://grants.nih.gov/grants/guide/notice-files/NOT-TR-12-002.html*).

Request for Information

To gauge the breadth and depth of potential interest in the Program and to obtain stakeholder input and perspectives on its novel features, NCATS is seeking input from the scientific community, potential industry collaborators, and other members of the public on all aspects of the Program. NCATS is particularly interested in but not limited to feedback on the following issues:

1. Partnerships with industry have been used throughout government and the biomedical research community to leverage each sector's expertise to speed scientific research and corresponding commercial development. We are interested in hearing about innovative strategies and practices that have proven successful to develop novel uses for discontinued Agents that have no known development limitations and are safe for use in humans. Your response can include your opinion of the most significant challenges for public-private partnerships that foster drug rescue between biomedical researchers and the pharmaceutical industry as well as your experiences with drug rescue or repurposing partnerships. Your input on options NCATS can consider which promise to nurture academic efforts to foster greater translation through projects such as the NIH–Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules. Your response can also include input on how NIH can identify partners that would like to provide drugs and biologics that are no longer being pursued internally to the NIH research community for investigation for new therapeutic uses.

2. Because this Program involves obtaining permission to use, and work with, privately owned Agents, exclusive patent or regulatory rights will likely be important incentives for the commercial success of the new therapeutic use for a drug candidate identified under the NIH–Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules. The ability to achieve an exclusive right to market a drug product, whether through a new use or other patentable subject matter related to the Agent, is likely to significantly affect the pharmaceutical partner's or other developer's incentive to commercialize rescued drugs or biologics based on new research results arising from the Program.

NCATS understands that a significant impediment to government, academic, non-profit, and industry partnerships involved in discovering and commercializing new uses of Agents is the ''transaction cost'' of negotiating appropriate legal agreements on a case-by-case basis. Thus, to address this concern, a key feature of the Program is that template agreements will be offered as a means of implementing the partnership. We are interested in the views of potential academic and industry partners on the transaction cost of developing individual agreements as well as the desirability of using template agreements and incorporating them into this Program. We are interested in your comments on how the use of template CDAs and CRAs in general and the current CDA and CRA might affect your institution's participation in the therapeutics discovery program. Applicants will be able to access these agreements prior to submitting an NIH X02 pre-application. For more details, please see Notice NOT–TR–12–001.

3. Comments on how working with a Clinical and Translational Science Award site (CTSAs) could advance drug rescue research projects, particularly for rare and neglected diseases.

4. Comments on how working with NIH Intramural Research Program

investigators (*http://www.irp.nih.gov*) and the NIH Clinical Center resources (*http://www.cc.nih.gov/index.html*) could advance your drug rescue research project.

5. Discussion of whether the goals and incentives of the NIH–Industry Program: Discovering New Therapeutic Uses for Existing Molecules are sufficient for biotechnology and pharmaceutical companies and the biomedical research community to participate in the Program. Discuss the most important steps NCATS should take to promote and facilitate partnerships for therapeutics discovery between industry and the biomedical research community. Your perspective on how success of the therapeutics discovery program might be defined.

6. Comments on the resources that a biotechnology or pharmaceutical company partner might realistically contribute to an NCATS program on therapeutics discovery in addition to the Agent and the associated data. You can also comment on the type of information about the molecules that you would be willing to disclose publicly.

7. Comments on the pharmacologic activity or biological target of the drug candidate that you need access to in order to test your biological hypothesis of disease intervention.

Comments in response to the topics above should be submitted to *http://grants.nih.gov/grants/rfi/therapeutics_discovery/index.cfm?ID=24* and will be accepted through June 1, 2012. Other questions or comments relevant to this initiative may be submitted to *Therapeutics.Discovery@nih.gov.*

Dated: May 7, 2012.

Thomas R. Insel,

Acting Director, NCATS, National Institutes of Health.

[FR Doc. 2012–11511 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Customs Modernization Act Recordkeeping Requirements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing information collection.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Customs Modernization Act Record Keeping Requirements. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** (77 FR 13617) on March 7, 2012, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before June 11, 2012.

ADDRESSES: Interested persons are invited to submit written comments on this information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Customs Modernization Act Recordkeeping Requirements.

OMB Number: 1651–0076.

Form Number: None.

Abstract: The North American Free Trade Agreement Implementation Act, Title VI, known as the Customs Modernization Act (Mod Act) amended title 19 U.S.C. 1508, 1509 and 1510 by revising Customs and Border Protection (CBP) laws related to record keeping, examination of books and witnesses, regulatory audit procedures and judicial enforcement. Specifically, the Mod Act expanded the list of parties subject to CBP recordkeeping requirements, distinguished between records which pertain to the entry of merchandise and financial records needed to substantiate the correctness of information contained in entry documentation, and identified a list of records which must be maintained and produced upon request by CBP. The information and records are used by CBP to verify the accuracy of the claims made on the entry documents regarding the tariff status of imported merchandise, admissibility, classification/nomenclature, value and rate of duty applicable to the entered goods. The Mod Act recordkeeping requirements are provided for by 19 CFR part 163.

Action: CBP proposes to extend the expiration date of this information collection with a change to the burden hours as a result of a revised estimate of the number of respondents currently complying with these recordkeeping provisions. There are no changes to these recordkeeping requirements.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 5,459.

Estimated Number of Total Annual Responses: 5,459.

Estimated Time per Response: 1,040 hours.

Estimated Annual Burden Hours: 5,677,360.

Dated: May 8, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2012–11430 Filed 5–10–12; 8:45 am]

BILLING CODE 9111–14–P