Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301–796–1697, *Richard.Lostritto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 19, 2018 (83 FR 17420), FDA announced the availability of a draft guidance for industry entitled ''Metered Dose Inhaler and Dry Powder Inhaler Drug Products—Quality Considerations; Draft Guidance for Industry.'' Interested persons were originally given until June 18, 2018, to comment on the draft guidance. The Agency believes that reopening the comment period for an additional 60 days from the date of publication of this notice will allow adequate time for interested persons to submit comments without significantly delaying Agency decision making on these important issues.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: July 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15508 Filed 7–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Chris Kornak, 240–627–3705, *chris.kornak@nih.gov.* Licensing information and copies of the U.S. patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office (TTIPO), 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20892, tel: 301–496–2644, fax: 240–627–3117. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Inhibition of CD300f Function on Dendritic Cells Promotes Tumor Destruction

Description of Technology: Cancer immunotherapy aims to enhance the ability of a patient's own immune response to destroy tumors. The magnitude of the immune response is determined by the balance between immune activating signals and negative inhibitory signals. Checkpoint receptors are negative regulators that normally deliver inhibitory signals which limit immune activation. Blockade of immune checkpoints represents an effective strategy to enhance the immune response against cancer cells.

NIAID researchers have discovered that blocking CD300f function in dendritic cells markedly enhances their ability to phagocytose and process apoptotic tumor cells, leading to substantial inhibition of tumor growth. In this light, CD300f may be viewed as a dendritic cell checkpoint receptor analogous to T cell checkpoint receptors like PD–1 and CTLA–4. As a result, inhibiting CD300f function on dendritic cells could be a promising anti-cancer therapy, especially in the settings where blocking of T cell checkpoint receptors has been ineffective.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Cancer immunotherapy

Competitive Advantages:

- A novel approach

Development Stage:

- Pre-Clinical
- Proof-of-concept studies in mouse models

Inventors: John E. Coligan, Konrad Krzewski, Linjie Tian, Ha-Na Lee, all of NIAID, NIH.

Publications: Tian, L. et al., Enhanced efferocytosis by dendritic cells underlies memory T-cell expansion and susceptibility to autoimmune disease in CD300f-deficient mice. Cell Death and Differ (2016) 23, 1086–1096.

Intellectual Property: HHS Reference No. E–257–2016/0—U.S. Patent Application No. 62/408,596 filed on 10/14/2016;—PCT/US2017/056192 filed on 10/11/2017.

Licensing Contact: Chris Kornak, 240–627–3705, *Chris.Kornak@nih.gov.*

Collaborative Research Opportunity: The Technology Transfer and Intellectual Property Office (TTIPO) is not seeking parties interested in collaborative research to further develop the technology.

Dated: July 9, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–15489 Filed 7–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance To Conduct Voluntary Customer/Partner Surveys (NLM)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the

National Library of Medicine (NLM) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number 301–827–6361 or Email your request to *sharlipd@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Generic Clearance to Conduct Voluntary Customer/Partner Surveys (NLM), 0925–0476, Expiration Date 09/30/2018, EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: In 1994, the NLM was designated a ''Federal Reinvention Laboratory'' with a major objective of improving its methods of delivering information to the public. At a minimum, necessary elements in improving the delivery of information include: (1) Development of easy-to-use access and delivery mechanisms that promote the public's understanding of health information, drawing on research in lay terminology, graphical and multimedia presentations; (2) assisting those providing health information to the public to make effective use of electronic services through internet connections, training, and other means, with an emphasis on those serving minority groups, low income populations, and seniors; (3) promoting integrations of NLM services with other electronic services covering regional, state, or local health information; and (4) conducting and supporting research, development, and evaluation of the public's health information needs, information seeking behavior and learning styles, information systems that meet the public's needs, and the impact of access to information.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 750.

ESTIMATED ANNUALIZED BURDEN HOURS

Table A.12–1 Estimates of annual burden hours

Type of collection	Type of respondents	Number of respondents	Annual frequency per response	Average time per response (minutes/hour)	Total burden hours
Customer Satisfaction Surveys	General Public	1,000	1	20/60	333
Focus Groups	Health Professionals	500	1	15/60	125
Usability and Pilot Testing	Librarians	500	1	20/60	167
Interviews or Small Discussion Groups	Health Educators	500	1	15/60	125
Total		2,500	2,500		750

Dated: July 3, 2018.

David Sharlip,

Project Clearance Liaison, National Library of Medicine, National Institutes of Health.

[FR Doc. 2018–15490 Filed 7–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of RFA–AA–18–011—Interaction of HIV Infection and Alcohol Abuse on Central Nervous System Morbidity.

Date: August 27, 2018.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)