

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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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](mailto: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In the **Federal Register** of April 19, 2018 (83 FR 17420), FDA announced the availability of a draft guidance for industry entitled “Metered Dose Inhaler and Dry Powder Inhaler Drug Products—Quality Considerations; Draft Guidance for Industry.” Interested persons were originally given until June 18, 2018, to comment on the draft guidance.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Persons with access to the internet may obtain the draft guidance at 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](mailto: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](mailto: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