TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response	Total hours
Labeling Requirements in §§ 201.56 and 201.57	406	1.332	541	2,327	1,258,907

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates may not sum due to rounding.

Our estimated burden for the information collection reflects an overall increase of 602,503 hours and a corresponding increase of 345 records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: July 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15512 Filed 7–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1098]

Metered Dose Inhaler and Dry Powder Inhaler Drug Products—Quality Considerations; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is reopening the comment period for the ''Metered Dose Inhaler and Dry Powder Inhaler Drug Products—Quality Considerations; Draft Guidance for Industry,'' published in the **Federal Register** of April 19, 2018. FDA is reopening the comment period to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the notice published April 19, 2018 (83 FR 17420). Submit either electronic or written comments by September 18, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 18, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 18, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1098 for ''Metered Dose Inhaler and Dry Powder Inhaler Drug Products—Quality Considerations; Draft Guidance for Industry.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for

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