State Enforcement Notifications

OMB Control Number 0910–0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in its own name and within its own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of February 7, 2018 (83 FR 5438), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in support of the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part	Number of respondents	Number of responses per respondents	Total annual responses	Average burden per response	Total hours
21 CFR Section 100.2(d)	1	1	1	10	10

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden for this information collection has not changed since the last OMB approval. The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: June 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–13868 Filed 6–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Developmental Therapeutics.

Date: July 9, 2018.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sharon K. Gubanich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6195D, MSC 7804, Bethesda, MD 20892, (301) 408–9512, *gubanics@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 22, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–13894 Filed 6–27–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to Atara Biotherapeutics Inc. (''Atara'') located in South San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before July 13, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Rose M. Freel, Ph.D., Licensing and Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick, MD 21701; Telephone: (301)–624–8775; Facsimile: (240)–276–5504; Email: *rose.freel@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 61/040,005, filed March 27, 2008 and entitled ''Human Monoclonal Antibodies Specific for Mesothelin'' [HHS Reference No. E–079–2008/0–US–01];

PCT Patent Application PCT/US2009/038228, filed March 25, 2009 and entitled ''Human Monoclonal Antibody Against Mesothelin'' [HHS Reference No. E–079–2008/0–PCT–02]; and US Patent No. 8,357,783, filed September 22, 2010, Issued January 22, 2013 and entitled ''Human Anti-Mesothelin Monoclonal Antibodies'' [HHS Reference No. E–079–2008/0–US–06].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: ''The development of a mesothelin chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic T cells either transduced with a retroviral vector (including lentiviral vectors) or modified using a gene-editing technology, wherein the vector expresses a CAR comprising:

(1) Single antigen specificity for binding to mesothelin, and

(2) at least (a) the complementary determining region (CDR) sequences of the anti-mesothelin antibody known as m912, and (b) a T cell signaling domain; for the prophylaxis and treatment of mesothelin-expressing human cancers.''

This technology discloses a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, stomach/gastric cancer, ovarian cancer, and pancreatic cancer. The specific antibody covered by this technology is designated as m912, which is a fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer. The m912 antibody selectively binds to the mesothelin on the surface of cancer cells and induces cell death of those cancer cells while leaving healthy cells unharmed. This selectivity may lead to fewer side effects due to decreased non-specific killing of cells.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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 part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 21, 2018

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2018–13893 Filed 6–27–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Interagency Pain Research Coordinating Committee, July 09, 2018, 02:00 p.m. to July 09, 2018, 04:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD, 20892 which was published in the **Federal Register** on May 18, 2018, 83 FR 23283.

The meeting notice is amended to change the time of the meeting from 2–4 p.m. to 4–6 p.m. Date has not changed. The meeting is open to the public.

Dated: June 22, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–13895 Filed 6–27–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meetings

AGENCY: Substance Abuse and Mental Health Services Administration; Centers for Disease Control and Prevention; Department of Health and Human Services.

ACTION: Notice of meetings.

SUMMARY: Notice is hereby given of the meetings on July 22–23, 2018, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Tribal Technical Advisory Committee (TTAC); on July 23 and July 25, 2018, of the Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) Tribal Advisory Committee (TAC); and on July 24, 2018, of the Joint Tribal Advisory Committee (JTAC).

DATES:

SAMHSA TTAC

July 22, 2018, 1:00 p.m. to 5:00 p.m. EDT (OPEN)

July 23, 2018, 9:00 a.m. to 5:00 p.m. EDT (OPEN)

- CDC/ATSDR TAC

July 23, 2018, 8:00 a.m. to 6:00 p.m. EDT (OPEN)

July 25, 2018, 8:00 a.m. to 12:00 p.m. EDT (OPEN)

- JTAC

July 24, 2018, 1:00 p.m. to 5:00 p.m. EDT, (OPEN)

ADDRESSES:

- SAMHSA TTAC
  Marriott Wardman Park Hotel, 2660 Woodley Road NW, Washington, DC 20008
- CDC/ATSDR TAC
  HHS Headquarters, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201
- JTAC
  HHS Headquarters, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

TTAC and JTAC, Mirtha Beadle, MPA, Director, Office of Tribal Affairs and Policy, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (240) 276–0641, Email: *otap@samhsa.hhs.gov*.

CDC/ATSDR/TAC, Carmen Clelland, PharmD, MPA, MPH, Associate Director for Tribal Support, Office for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention, 4770 Buford Highway, Mailstop E–70, Atlanta, GA 30341–3717, Telephone: (404) 498–2205, Email: *cclelland@cdc.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to Presidential Executive Order 13175 signed on November 6, 2000 and the Presidential Memorandum of September 23, 2004, SAMHSA established the