ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the following inventions embodied in the following patent applications, entitled ''CB1 receptor mediating compounds'':

1. U.S. Provisional Patent Application No.: 61/991,333, HHS Ref. No.: E–140–2014/0–US–01, Filed: May 09, 2014.
2. PCT Application No.: PCT/US2015/029946, HHS Ref. No.: E–140–2014/0–PCT–02, Filed: May 08, 2015.
3. U.S. Provisional Patent Application No.: 61/725,949, HHS Ref. No.: E–282–2012/0–US–01, Filed: November 13, 2012.
4. PCT Application No.: PCT/US2013/069686, HHS Ref. No.: E–282–2012/0–PCT–02, Filed: November 12, 2013.
5. U.S. Patent Application No.: 14/442,383, HHS Ref. No.: E–282–2012/0–US–03, Filed: May 12, 2015.
6. Canadian Patent Application No.: 2889697, HHS Ref. No.: E–282–2012/0–CA–04, Filed: April 27, 2015.
7. European Patent Application No.: 13802153.0, HHS Ref. No.: E–282–2012/0–EP–05, Filed: June 01, 2015.
8. Indian Patent Application No.: 3733/DELNP/2015, HHS Ref. No.: E–282–2012/0–IN–06, Filed: May 01, 2015.
9. Japanese Patent Application No.: 2015–542015, HHS Ref. No.: E–282–2012/0–JP–07, Filed: May 11, 2015.
10. Chinese Patent Application No.: 201380069389.9, HHS Ref. No.: E–282–2012/0–CN–08, Filed: July 3, 2015.
11. US Provisional Application No.: 62/171,179, HHS Ref. No.: E–282–2012/1–US–01, Filed: June 04, 2015.

to Kalytera Therapeutics Inc., (''Kalytera''), a company incorporated under the laws of Delaware and having an office in Hermosa Beach, California. The patent rights in these inventions have been assigned to the United States of America. This license may be worldwide. The field of use may be limited to the use of the Licensed Patent Rights to the development of select compounds from the patents listed above.

DATES: Only written comments and/or applications for a license which are received by the Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases on or before May 4, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty Tong, Ph.D., Sr. Licensing and Patenting Manager, Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892; Email: *betty.tong@nih.gov.* A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology, and its corresponding patent applications, is directed to methods of treating fibrosis, obesity and associated diseases such as type 2 diabetes by administering an agent that reduces appetite, body weight, hepatic steatosis, and insulin resistance. This technology may be useful as a means for treating various fibrotic diseases and metabolic syndromes without serious adverse neuropsychiatric side effects.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the Technology Advancement Office 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 404.7.

Properly filed competing applications for a license in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 13, 2016.

Anna Amar,

Acting Deputy Director, Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2016–08986 Filed 4–18–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings 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: Cures Acceleration Network Review Board.

Date: May 12, 2016.

Time: 8:30 a.m. to 2:45 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: May 12, 2016.

Open: 8:30 a.m. to 2:45 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 13, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–08992 Filed 4–18–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR part 8 (OMB No. 0930–0206) and Opioid Treatment Programs (OTPs)—Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. ''Certification'' is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168), which may be used by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11, and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation, and documentation by an OTP of the following: A patient's medical examination when admitted to treatment, a patient's history, a treatment plan, any prenatal support provided to the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

A number of changes have been made to the forms. Forms have been reworded for clarification, updated with current SAMHSA mailing and web-submission information, and a few additional fields have been provided for clarity and for providers to best explain their services (*e.g.,* expanding the former global patient census in the SMA–162 to request patient census by drug type—methadone, buprenorphine, naltrexone, or other) and the needs of their patients (*e.g.,* including urinalysis results on the SMA–168 and adding ''weather crisis'' as a standard option for physician justification of the requested exception). Amendments also include the removal of information pertaining to faxing the forms to SAMHSA, as this is no longer an acceptable form of submission. The burden hours have increased slightly (by 28% or approximately 639 hours) due to an increase in the number of facilities accredited and certified by SAMHSA since the previous submissions of these forms. The forms are available online with a unique feature for both the SMA–162 and SMA–168 that pre-populates certain information within the form. This in turn reduces the program's time spent filling out the forms as well as the staff time spent on processing it.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163)	1	1	1	6.00	6.00