have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 (BLAs) have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 207 (domestic and foreign facility registration, including assignment of an NDC) have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 1 (general enforcement regulations) have been approved under OMB control number 0910–0046; the collections of information in 21 CFR part 201 (labeling) have been approved under OMB control number 0910–0572; the collections of information pertaining to current good manufacturing practice requirements for finished pharmaceuticals and combination products under 21 CFR parts 4, 210, 211, 610, and 680 have been approved under OMB control numbers 0910–0139 and 0910–0834; the collection of information pertaining to Dear Health Care Provider Letters has been approved under OMB control number 0910–0754; and the collections of information pertaining to suspect product identification and notification under section 582 of the FD&C Act have been approved under OMB control number 0910–0806.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs; https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances; https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents;* or *https://www.regulations.gov.*

Dated: September 23, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–21521 Filed 9–25–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Medicaid Reentry Stakeholder Group

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

ACTION: Notice of Establishment of the Medicaid Reentry Stakeholder Group and Request for Nominations.

SUMMARY: The Secretary of HHS has determined that establishment of the Medicaid Reentry Stakeholder Group, as required by the Medicaid Reenty Act, is desirable to provide advice and consultation to the Secretary on innovative strategies to help individuals who are inmates of public institutions, and otherwise eligible for Medicaid, ensure continuity of coverage and seamless transitions back to the community. HHS is soliciting nominations for non-Federal members of the Stakeholder Group.

DATES: Submit nominations by email before COB on October 23, 2020.

ADDRESSES: Nominations should be sent to Jhamirah Howard at *jhamirah.howard@hhs.gov* ; Jhamirah Howard, MPH., Office of the Assistant Secretary for Planning and Evaluation, Room 424E Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jhamirah Howard (202) 690–1721, *jhamirah.howard@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Medicaid Reentry Act, Public Law 115–271, title IV, subtitle D, 132 Stat. 3965 (Oct. 24, 2018) (42 U.S.C. 1396a note) requires that the Secretary of Health and Human Services (HHS) establish the Medicaid Reentry Stakeholder Group. The Stakeholder Group is governed by provisions of Public Law 92–463 (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees. The Secretary signed the charter establishing the Stakeholder Group on July 30, 2020. HHS is soliciting nominations for non-Federal members of the Stakeholder Group. Nominations should include the nominee's contact information (current mailing address, email address, and telephone number) and a current curriculum vitae or resume.

The Stakeholder Group will meet once, to develop best practices (and submit to the Secretary and Congress a report on such best practices) for States—(A) to ease the health care-related transition of an individual who is an inmate of a public institution from the public institution to the community, including best practices for ensuring continuity of health insurance coverage or coverage under the State Medicaid plan under title XIX of the Social Security Act, as applicable, and relevant social services; and (B) to carry out, with respect to such an individual, such health care-related transition not later than 30 days after such individual is released from the public institution.

The Stakeholder Group shall consist of at least 24 members: 2 shall be federal members, appointed by the Secretary or his designee. The federal members shall include designees from federal jail and prison systems, which includes the Federal Bureau of Prisons. Federal members will serve as regular government employees.

The Stakeholder Group shall also consist of 22 non-federal members who are representatives of managed care organizations, Medicaid beneficiaries, health care providers, the National Association of Medicaid Directors, state Medicaid agencies, and representatives from local and state prison systems, The Secretary shall appoint one of the members to serve as the Chair. Non-federal members will serve as Special Government Employees.

The Secretary, or his designee, shall appoint all members of the Stakeholder Group (both federal and non-federal), including one of the members to serve as the Chair. The federal and non-federal members shall be appointed to serve for the duration of the time that the Stakeholder Group is authorized to operate. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2020–21591 Filed 9–30–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting 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 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 Heart, Lung, and Blood Advisory Council.

Date: October 27, 2020.

Closed: 10:00 a.m. to 12:00 p.m.

Agenda: To Review and Evaluate Grant Applications and/or Proposals.

Place: NIH, Bethesda, MD (Virtual Meeting).

Open: 12:30 p.m. to 5:00 p.m.

Agenda: To Discuss Program Policies and Issues.

Place: NIH, Bethesda, MD (Virtual Meeting).

Virtual Access: The meeting will be videocast and can be accessed from the NIH Videocast. *https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council.* Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–Q, Bethesda, MD 20892, 301–827–5517, *moenl@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Any member of the public may submit written comments no later than 15 days after the meeting.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 25, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21673 Filed 9–30–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 Human Genome Research Institute Special Emphasis Panel; Advancing Genomic Medicine Research.

Date: December 1, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 300, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 300, Bethesda, MD 20892–9306, 301–402–0838, *barbara.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: September 25, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21674 Filed 9–30–20; 8:45 am]

BILLING CODE 4140–01–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 in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing Brian W. Bailey, Ph.D., *bbailey@mail.nih.gov,* the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Methods To Produce Very Long-Chain Fatty Acids (VLCFA)

Available for licensing and commercial development are patent rights covering methods for synthetically producing highly pure, polyunsaturated very long-chain fatty acids (C20–C40) that are highly scalable, do not require toxic mercury, and are applicable to the synthesis of highly deuterated (≤90%), partially deuterated, and non-deuterated lipids. VLCFAs, while present in very small concentrations in living organisms, nonetheless play vital roles in certain biological processes. The present invention addresses an unmet need for VLCFAs for experimental and therapeutic uses that is currently inadequately met through labor intensive and time consuming extractions from natural sources or technically difficult overexpression in cell cultures, which give very small yields. This invention also includes a method for treating and preventing macular degeneration using VLCFAs.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Synthesis of very-long chain fatty acids for *in vitro* and *in vivo* research purposes
- Synthesis of very-long chain fatty acids for therapeutic purposes
- Treatment and prevention of macular degeneration, inflammatory disorders and other disorders and conditions associated with very long-chain fatty acid deficiencies

Development Stage:

- Preclinical
- Mouse data

Inventors: Rolf Swenson (NHLBI), Zhen-Dan Shi (NHLBI), Zhi-Hong Yang (NHLBI) and Alan Remaley (NHLBI).