

any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 601 and 640, and Form FDA 356h have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: June 28, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–14537 Filed 7–6–18; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Pregnancy in Women with Disabilities.

*Date:* July 23, 2018.

*Time:* 12:00 p.m. to 1:30 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:* Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, [wieschd@csr.nih.gov](mailto:wieschd@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Networks and Behavior in Psychiatric Disorders.

*Date:* July 25, 2018.

*Time:* 2:00 p.m. to 5:00 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:* Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, [cinquej@csr.nih.gov](mailto:cinquej@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR17–158: Epigenomes and Connectomes in Psychiatric Disorders.

*Date:* July 26, 2018.

*Time:* 2:00 p.m. to 5:00 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:* Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, [cinquej@csr.nih.gov](mailto:cinquej@csr.nih.gov).

(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: July 3, 2018.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–14647 Filed 7–6–18; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Environmental Determinants of Diabetes.

*Date:* July 9, 2018.

*Time:* 1:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, [sanoviche@mail.nih.gov](mailto:sanoviche@mail.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.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Review of Planning Grant Application (U34).

*Date:* July 12, 2018.

*Time:* 6:00 p.m. to 7:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, [woynarowskab@niddk.nih.gov](mailto:woynarowskab@niddk.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.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK U34 Telephone Review.

*Date:* July 13, 2018.

*Time:* 3:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, [guox@extra.niddk.nih.gov](mailto:guox@extra.niddk.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.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Mechanisms and Treatments of Lower Urinary Tract Dysfunction after Spinal Cord Injury.

*Date:* July 23, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7345, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Urologic P20 Applications.

*Date:* August 2-3, 2018.

*Time:* 8:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

*Contact Person:* Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-4721, [ryan.morris@nih.gov](mailto:ryan.morris@nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes Ancillary Studies (R01).

*Date:* August 2, 2018.

*Time:* 1:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@niddk.nih.gov](mailto:jerkinsa@niddk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 2, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-14648 Filed 7-6-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2017-0915]

### Waterway Suitability Assessment for Operation of Liquefied Natural Gas Terminal; Cameron, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of inquiry; request for comments.

**SUMMARY:** We are requesting your comments on a Letter of Intent and Preliminary Waterway Suitability Assessment we received from Sabine Pass LNG, L.P. (SPLNG) regarding SPLNG's plans to construct a new berth at its Cameron Parish, LA facility and to increase the number of liquefied natural gas vessels calling at the facility from approximately 400 to 580 annually. The Coast Guard is notifying the public of this proposed increase in LNG marine traffic on the Sabine-Neches Waterway and is soliciting comments relevant to the Coast Guard's preparation of a Letter of Recommendation for issuance to the federal, state, or local agency with jurisdiction over the proposed facility.

**DATES:** Comments and related material must be received on or before August 8, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG-2017-0915 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of inquiry, call or email Mr. Scott K. Whalen, Vessel Traffic Service Director, Marine Safety Unit Port Arthur, U.S. Coast Guard; telephone 409-719-5086, email [Scott.K.Whalen@uscg.mil](mailto:Scott.K.Whalen@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Table of Abbreviations**

CFR	Code of Federal Regulations
COTP	Captain of the Port Marine Safety Unit Port Arthur
DHS	Department of Homeland Security
LNG	Liquefied Natural Gas
LOI	Letter of Intent
LOR	Letter of Recommendation
NVIC	Navigation and Vessel Inspection Circular
U.S.C.	United States Code
WSA	Waterway Suitability Assessment

## II. Background and Purpose

Under 33 CFR 127.007(a), an owner or operator planning to build a new facility handling liquefied natural gas (LNG), or an owner or operator planning new construction to expand or modify marine terminal operations in an existing facility handling LNG, where the construction, expansion, or modification would result in an increase in the size and/or frequency of LNG marine traffic on the waterway associated with the proposed facility or modification to an existing facility, must submit a Letter of Intent (LOI) to the Captain of the Port of the zone in which the facility is or will be located. Under 33 CFR 127.007(e), an owner or operator planning such new construction or expansion of an existing facility must also file or update a Waterway Suitability Assessment (WSA) that addresses the proposed increase in LNG marine traffic in the associated waterway.

Under 33 CFR 127.009, after receiving an LOI, the Captain of the Port issues a Letter of Recommendation (LOR) as to the suitability of the waterway for LNG marine traffic to the appropriate jurisdictional authorities. The LOR is based on a series of factors listed in 33 CFR 127.009 that relate to the physical nature of the affected waterway and issues of safety and security associated with LNG marine traffic on the affected waterway.

## III. Information Requested

On January 29, 2018, Sabine Pass LNG, L.P. (SPLNG), located in Cameron Parish, LA, submitted an LOI and Preliminary WSA regarding the company's proposed plans to develop a new marine berth and expand the number of vessels calling on the facility each year from approximately 400 to 580. The purpose of this notice is to solicit public comments on the proposed increase in LNG marine traffic on the Sabine-Neches Waterway. The Coast Guard believes that public input may be useful to the Captain of the Port Marine Safety Unit Port Arthur (COTP) with respect to validating the information provided in SPLNG's Preliminary WSA and development of the LOR. A brief summary of SPLNG's proposal is available in the docket where indicated under **ADDRESSES**.

On January 24, 2011, the Coast Guard published Navigation and Vessel Inspection Circular (NVIC) 01-2011, titled "Guidance Related to Waterfront Liquefied Natural Gas (LNG) Facilities". NVIC 01-2011 provides guidance for owners and operators seeking approval to build and operate LNG facilities. The