effectiveness, and considers the factors identified in the January 21, 1998, FR notice (63 FR 3142), and as explained in FDA's guidance ''Procedures for Class II Device Exemptions from Premarket Notification,'' including whether (1) the device has had a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) any device characteristics necessary for its safe and effective performance are well established; (3) any changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. These factors are relevant to understanding whether a premarket notification is necessary to assure the safety and effectiveness of a device. FDA has consistently used them since 1998, when section 510(m) was first enacted. However, these factors were not considered as part of the January 15, 2021, Notice. As mentioned above, the January 15, 2021, Notice only considered one piece of information—MAUDE data—which is a drastically narrower approach to the evaluation of whether a device should be exempt than the factors FDA has consistently considered.

It was also an error for HHS to propose to exempt the unclassified device type with product code LXV from the premarket notification requirements. Unclassified devices require submission of a 510(k) premarket notification. The January 15, 2021, Notice proposes to exempt this unclassified device type from 510(k) under the process and standard of 510(m). Section 510(m), however, provides only for the exemption of class II devices. Unclassified devices are not class II devices. Therefore, 510(m) does not provide the standard or process for exemption of unclassified devices. The January 15, 2021, Notice did not cite to any other statutory provision that authorizes the exemption of unclassified devices from 510(k).

As noted, the January 15, 2021, Notice contained numerous errors and ambiguities, such as mismatched product descriptions, product codes, and regulatory citations. For example, table 6 in the Notice lists the 84 devices it proposed to exempt. One entry gives the Device description as ''Oxygenator, Long Term Support Greater than 6 Hours,'' the Product code as ''BZG,'' and the section in 21 CFR as ''868.1840.'' The same table has a second listing for ''Oxygenator, Long Term Support Greater than 6 Hours,'' this one giving the Product code as ''FXY'' and the section in 21 CFR as ''878.4040.'' However, ''Oxygenator, Long Term Support Greater than 6 Hours'' is Product code BYS and is classified in 21 CFR 870.4100. These errors and ambiguities make it difficult or impossible in some circumstances to discern which class II devices the Notice is proposing to exempt, as noted by some commenters.

Finally, we did not find evidence that HHS consulted with or otherwise involved FDA in its proposed exemption or the issuance of the January 15, 2021, Notice. Section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) provides that the Secretary ''shall be responsible for executing'' the FD&C Act ''through the [FDA] Commissioner.'' Here, the January 15, 2021, Notice is clearly an action ''executing'' the FD&C Act. Moreover, it is particularly important that FDA have at least some level of involvement in this type of an action given the expertise needed in evaluating whether a submission under 510(k) of the FD&C Act is necessary to assure the safety and effectiveness of a device.

For these reasons, HHS and FDA are withdrawing the proposed exemptions of the 83 class II devices and 1 unclassified device published on January 15, 2021, at 86 FR 4088. Elsewhere in this issue of the **Federal Register**, HHS and FDA are stating their belief that the class I devices that are the subject of the January 15, 2021, Notice meet the criteria for reserved class I devices and that it is appropriate to reverse the determination of exemption for those devices.

Dated: April 12, 2021.

**Janet Woodcock,**

*Acting Commissioner of Food and Drugs.*

Dated: April 12, 2021.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021–07760 Filed 4–15–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R25 and Fellowship Application Review.

*Date:* April 26, 2021.

*Time:* 9:00 a.m. to 10:30 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* John F. Connaughton, Ph.D., Chief, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7007, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, *connaughtonj@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

(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: April 13, 2021.

**Miguelina Perez,**

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

[FR Doc. 2021–07888 Filed 4–15–21; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Advisory Allergy and Infectious Diseases Council.

The meetings will be open to the public as indicated below. The open session will be videocast and can be accessed from the NIH Videocasting and