

Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Feasibility and Early Feasibility Clinical Studies for Certain

Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 19045 and complete title to identify the guidance you are requesting.

### III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to

previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E .....	Premarket Notification .....	0910–0120
814, subparts A through E .....	Premarket Approval .....	0910–0231
812 .....	Investigational Device Exemption .....	0910–0078
“Requests for Feedback on Medical Device Submissions: The Q-Submission Program”.	Q-submissions; Pre-submissions .....	0910–0756
50, 56 .....	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: April 28, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–09738 Filed 5–5–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Global Affairs: Virtual Stakeholder Listening Session in Preparation for the 75th World Health Assembly

**Time and date:** The session will be held on Friday, May 13, 2022, from 10:00 a.m.–12:00 p.m. Eastern Time (ET).

**Place:** The session will be held virtually, and registration is required. Please RSVP by May 6, 2022 by sending your full name, email address, and organization to [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov). OGA encourages early registration.

**Status:** Open, but requiring RSVP to [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov) to register.

**Purpose:** The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 75th World Health Assembly—will hold an informal Stakeholder Listening Session on Friday, May 13, 10:00 a.m.–12:00 p.m. ET. The listening session will be held virtually, and the meeting link will be shared with registered participants prior to the session.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation to the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all

communities interested in and affected by agenda items to be discussed at the 75th World Health Assembly. The U.S. Government will consider contributions received from the stakeholders as it develops the U.S. positions.

The listening session will be organized by agenda item, and participation is welcome from stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 75th World Health Assembly can be found at this website: [https://apps.who.int/gb/e/e\\_who75.html](https://apps.who.int/gb/e/e_who75.html).

**RSVP:** Registration is required for the event. Please send your full name, email address, and organization to [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov) to register. Please RSVP no later than Friday, May 6, 2022.

Written comments are welcome and encouraged, even if you are planning on attending the virtual session. Please send written comments to the email address: [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov).

We look forward to hearing your comments related to the 75th World Health Assembly agenda items.

Dated: May 2, 2022.

**Susan C. Kim,**

*Chief of Staff, Office of Global Affairs.*

[FR Doc. 2022–09710 Filed 5–5–22; 8:45 am]

**BILLING CODE 4150–38–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood 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:** Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Study Section.

**Date:** June 9–10, 2022.

**Time:** 9:00 a.m. to 6:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

**Contact Person:** Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205-H, Bethesda, MD 20892, (301) 827–7969, [Pintuccig@nhlbi.nih.gov](mailto:Pintuccig@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and