

download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Eleni Whatley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2267, Silver Spring, MD 20993–0002, 301–796–6372.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is issuing this draft guidance to clarify the FDA’s recommendations for testing and information to include in 510(k) submissions for PTA catheters and specialty catheters to promote consistency across submissions. These devices are catheter-based devices

intended to treat lesions in the peripheral vasculature. This draft guidance expands on the FDA’s current thinking for testing of PTA balloon catheters and specialty catheters (e.g., infusion catheters, PTA balloon catheters for ISR, scoring/cutting balloons), and provides specific recommendations regarding performance testing and anatomy-specific assessments. This document supplements other FDA documents regarding the specific content requirements of premarket submissions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff.” It does not establish 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by

downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16018 and complete title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in the following FDA regulations and guidance 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 |
| 812 | Investigational Device Exemption | 0910–0078 |
| “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”. | Q-Submissions | 0910–0756 |
| 801 | Medical Device Labeling Regulations | 0910–0485 |
| 820 | Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation. | 0910–0073 |
| 50, 56 | Protection of Human Subjects: Informed Consent; Institutional Review Boards. | 0910–0755 |
| 56 | Institutional Review Boards | 0910–0130 |
| 58 | Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies. | 0910–0119 |

Dated: January 7, 2020.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
 [FR Doc. 2020–00296 Filed 1–10–20; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS or Department) is hereby

giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration by January 24, 2020, is required for the public to attend the meeting, provide comments, and/or distribute printed material(s) to ACMH members. Information about the meeting is available from the designated contact person and will be posted on the website for the Office of Minority Health (OMH), www.minorityhealth.hhs.gov. Information about ACMH activities can

be found on the OMH website under the heading *About OMH*.

DATES: The meeting will be held on Thursday, January 30, 2020, 9:00 a.m. to 5:00 p.m. ET, and Friday, January 31, 2020, 9:00 a.m. to 3:00 p.m. ET. Day 2 may end earlier than 3:00 p.m. ET if ACMH completes its work before 3:00 p.m. ET.

ADDRESSES: The meeting will be accessible by attendance in-person or by webcast on the internet. In-person and webcast participants must register prior to the meeting. The meeting will be held at the 5600 Fishers Lane Building, Room 05E49, 5600 Fishers Lane, Rockville, Maryland 20187. Registered webcast participants will receive the webcast information prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Plaza Level, Rockville, Maryland 20852. Phone: 240-453-2882; fax: 240-453-2883; email OMH-ACMH@hhs.gov.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

The topics to be discussed during this meeting will include strategies to improve access to and success of clinical prevention services among racial and ethnic minority populations. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to the Department's community-wide, chronic disease prevention strategies.

The meeting is open to the public. Any individual who wishes to attend the meeting in person or by webcast must register by sending an email to OMH-ACMH@hhs.gov by January 24, 2020. Each registrant should provide their name, affiliation, phone number, email address, days attending, and if participation is in-person or via webcast. After registration, individuals participating by webcast will receive webcast access information via email. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact BLH Technologies, Inc. at (240) 399-8735 and reference this meeting. Requests for special accommodations

should be made at least ten (10) business days prior to the meeting.

Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals who would like to submit written statements should email OMH-ACMH@hhs.gov or mail their comments to the Designated Federal Officer contact cited above so it is received by the Designated Federal Officer at least five (5) business days prior to the meeting.

Any members of the public who wish to distribute electronic or printed material(s) related to this meeting's topic to ACMH members should email OMH-ACMH@hhs.gov or mail their material to the Designated Federal Officer contact cited above. The material should be received by the Designated Federal Officer at least five (5) business days prior to the meeting.

Dated: December 30, 2019.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2020-00307 Filed 1-10-20; 8:45 am]

BILLING CODE 4150-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 Allergy and Infectious Diseases Special Emphasis Panel; PAR-16-412: NIAID Resource-Related Research Projects (R24).

Date: February 4, 2020.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Program Management & Operations Branch, Division of Extramural Activities, Scientific Review Program, Room 3E71, National Institutes of Health, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane Rockville, MD 20852, 301-761-3100, AnnMarie.Cruz@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 7, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-00270 Filed 1-10-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 on Minority Health and Health Disparities Special Emphasis Panel; ZMD1 DRI M1 Special Emphasis Panel for Review of Mentored Research Scientist Development Award (K01).

Date: February 12-13, 2020.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Ave., Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, National Institutes of Health, NIMHD, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 402-1366, ismondr@mail.nih.gov.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Research Career Development Awards (Ks).