submit a premarket notification (510(k)) to FDA. The device may not be marketed until FDA finds it ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. FDA must publish in the **Federal Register** notice of its intent to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the **Federal Register** of January 21, 1998 (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff*).

Accordingly, FDA generally considers the following factors to determine whether a report under section 510(k) is necessary or if an exemption would be appropriate for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) 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. FDA may also consider that, even when exempting devices from the 510(k) requirements, these devices would still be subject to the general limitations on exemptions (see 21 CFR 892.9).

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting partial exemption from the premarket notification requirements for certain class II devices: Nancy Stade, J.D., of Rubrum Advising, LLC, 404 Pembroke Rd., Bala Cynwyd, PA 19004, on behalf of Harrison.ai, for the following devices:

- Radiological computer-assisted diagnostic software for lesions suspicious of cancer, classified under § 892.2060 (21 CFR 892.2060), product code POK.
- Medical image analyzer, classified under § 892.2070 (21 CFR 892.2070), product code MYN.
- Radiological computer aided triage and notification software, classified under § 892.2080 (21 CFR 892.2080), product codes QAS and QFM.
- Radiological computer-assisted detection and diagnosis software, classified under § 892.2090 (21 CFR 892.2090), product codes QBS and QDQ.

The petition requests exemption from the premarket notification requirements for these devices when:

- The manufacturer has previously obtained a 510(k);
- For devices under § 892.2080, the manufacturer must have at least one clearance under the same classification regulation;
- For devices under § 892.2060, 892.2070, or 892.2090, the manufacturer must have at least one clearance under any of those same three classification regulations;
- The manufacturer must implement a robust post-market plan, transparency, and training measures as described in the petition; and
- All existing special controls, quality systems, establishment registration, and device listing requirements will remain in force.

FDA seeks comment on the petition in accordance with section 510(m)(2) of the FD&C Act.

IV. Paperwork Reduction Act of 1995

While this notice contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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 part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23901 Filed 12–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

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 open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

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 Advisory Council on Minority Health and Health Disparities.

Date: February 6, 2026.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.

Closed: 3:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Meeting Format: Virtual Meeting.

Address: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Paul Cotton, Ph.D., RDN, Director, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–402–1366, *paul.cotton@nih.gov.*

The meeting identified below has been scheduled in the event the Council is unable to complete all agenda items identified for the February 6, 2026, meeting. Information on the agenda items and/or the necessity to hold the meeting listed below will be posted on the Institute/Center homepage (link identified below).

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: March 27, 2026.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council not completed at the February meeting.

Closed: 3:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications not completed at the February meeting.

Meeting Format: Virtual Meeting.

Address: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Paul Cotton, Ph.D., RDN, Director, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–402–1366, *paul.cotton@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.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NIMHD: *https://www.nimhd.nih.gov/about/advisory-council/,* where an agenda and any additional information for the meeting will be posted when available.

Zieta M. Charles,

Program Analyst,Office of Federal Advisory Committee Policy.

[FR Doc. 2025–23889 Filed 12–23–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be held as a virtual meeting and open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should submit a request using the following link: *https://www.nigms.nih.gov/Pages/ContactUs.aspx* at least 5 days prior to the event. The open session will also be videocast, closed captioned, and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

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.

The meeting identified below has been scheduled in the event the Council is unable to complete all agenda items identified for the February 5, 2026, meeting. Information on the agenda items and/or the necessity to hold the meeting listed below will be posted on the Institute/Center homepage (link identified below).

Name of Committee: National Advisory General Medical Sciences Council.

Date: March 18, 2026.

Open: 9:30 a.m. to 12:00 p.m.

Agenda: For the discussion of programs; opening remarks; report of the Director, NIGMS; and other business of the NAGMSC not completed at the February meeting.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, Virtual Meeting.

Closed: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications not completed at the February meeting.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, Virtual Meeting.

Contact Person: Ariel Zane, Ph.D., Acting Director, Division of Extramural Activities, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 2AN24C, Bethesda, MD 20892, 301–594–3584, *ariel.zane@nih.gov.*

Registration is not required to attend the open portion of this meeting.

Any interested person may file written comments with the committee by forwarding the statement to *NIGMS_DEA_Mailbox@nigms.nih.gov* at least 3 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nigms.nih.gov/about/council/Pages/default,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Zieta M. Charles,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–23835 Filed 12–23–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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.