

**SUMMARY:** Notice is hereby given of the appointment of new members to the GSA Senior Executive Service Performance Review Board. The Performance Review Board assures consistency, stability, and objectivity in the performance appraisal process.

**DATES:** *Applicable:* October 11, 2024.

**FOR FURTHER INFORMATION CONTACT:** Mr. Nathaniel Williams, Acting Director, Executive Resources Division, Office of Human Resources Management, GSA, 1800 F Street NW, Washington, DC 20405, or via telephone at (571) 513-9451.

**SUPPLEMENTARY INFORMATION:** Section 4314(c)(1) through (5) of title 5 U.S.C requires each agency to establish, in accordance with regulation prescribed by the Office of Personnel Management, one or more SES performance review board(s). The board is responsible for making recommendations to the appointing and awarding authority on the performance appraisal ratings and performance awards for employees in the Senior Executive Service.

The following have been designated as members of the Performance Review Board of GSA:

- Katy Kale, Deputy Administrator—PRB Chair.
- Christopher Bennethum, Assistant Commissioner for Assisted Acquisition Services, Federal Acquisition Service.
- Lesley Briante, Associate Chief Information Officer of Digital Management, Office of GSA IT.
- Aluanda Drain, Associate Administrator for Civil Rights, Office of Civil Rights.
- Andrew Heller, Deputy Commissioner for Enterprise Strategy, Public Buildings Service.
- Arron Helm, Chief Human Capital Officer, Office of Human Resources Management.
- Dena McLaughlin, Executive Director, Catalog and Solicitation Management Program Management Office, Federal Acquisition Service.
- Tanisha Palermo, Regional Commissioner, Public Buildings Service, Rocky Mountain Region.
- Flavio Peres, Assistant Commissioner for Real Property Disposition, Public Buildings Service.
- Camille Sabbakhan, Deputy General Counsel, Office of the General Counsel.

**Robin Carnahan,**

*Administrator, General Services Administration.*

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**BILLING CODE 6820-FM-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-1262]

#### Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; TREMFYA (guselkumab)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application for TREMFYA (guselkumab), approved September 11, 2024, meets the criteria for redeeming a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1394, email: [Cathryn.Lee@fda.hhs.gov](mailto:Cathryn.Lee@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for TREMFYA (guselkumab) meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about TREMFYA (guselkumab), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: October 8, 2024.

**Eric Flamm,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2024-23629 Filed 10-10-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-1021]

#### Notice to Public of Website Location of Center for Devices and Radiological Health Fiscal Year 2025 Proposed Guidance Development

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH) intends to publish in fiscal year (FY) 2025. In addition, FDA has established a docket where interested parties may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide any other comments that could benefit the CDRH guidance program and its engagement with interested parties. This feedback is critical to the CDRH guidance program to ensure that we meet the needs of interested parties.

**DATES:** Either electronic or written comments on the notice must be submitted by December 10, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 10, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to

the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2012-N-1021 for "Notice to Public of website Location of CDRH Fiscal Year 2025 Proposed Guidance Development." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

During negotiations on the Medical Device User Fee Amendments of 2012, title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), FDA agreed to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. Among these commitments included:

- Annually posting a list of priority medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the "A-list"), and
- Annually posting a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the "B-list").

The Medical Device User Fee Amendments of 2017 (MDUFA IV), Title II, FDA Reauthorization Act of 2017 (Pub. L. 115-52), maintained these commitments.

In addition, to ensure that final guidance documents continue to provide interested parties with the Agency's current thinking, CDRH

annually conducts a staged review of previously issued final guidances in collaboration with interested parties. CDRH intends to annually provide lists of previously issued final guidances that are subject to review in 10-year increments to facilitate a continuous and systematic assessment of the applicability of existing guidances. For instance, in FY 2025, CDRH is providing a list of the final guidance documents that issued in 2015, 2005, 1995, and 1985; in FY 2026 we expect to provide a list of the final guidance documents that issued in 2016, 2006, 1996, and 1986, and so on. Consistent with the Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda website, feedback on any guidance is appreciated and will be considered.

FDA welcomes comments on any or all of the guidance documents on the lists as explained in 21 CFR 10.115(f)(5). FDA has established Docket No. FDA-2012-N-1021 where comments on the FY 2025 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see **ADDRESSES**). FDA believes this docket is a valuable tool for receiving information from interested parties. FDA anticipates that feedback from interested parties will allow CDRH to better prioritize and more efficiently draft guidances to meet the needs of the Agency and interested parties.

In addition to posting the lists of prioritized device guidance documents, CDRH has identified as a priority, and has devoted resources to, finalization of draft guidance documents. To ensure the timely completion or reissuance of draft guidances, in FY 2015 CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, reopen the comment period, or issue new draft guidance on the topic for 80 percent of the documents within 3 years of the close of the comment period and for the remaining 20 percent, within 5 years. As part of MDUFA IV commitments, FDA reaffirmed this commitment, as resources permit.

Fulfillment of these commitments will be reflected through the issuance of updated guidance on existing topics, withdrawal of guidances that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

## II. Website Location of Guidance Lists

This notice announces the website location of the document that provides the A- and B-lists of guidance documents, which CDRH is intending to publish during FY 2025. To access these two lists, visit FDA's website at <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidance-development>. We note that the topics on these lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (e.g., newly identified safety issues). The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Dated: October 7, 2024.

**Eric Flamm,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2024-23544 Filed 10-10-24; 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, U.S. 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) 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 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 HHS Office of Minority Health (OMH) website: [www.minorityhealth.hhs.gov](http://www.minorityhealth.hhs.gov).

Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups*.

**DATES:** The ACMH meeting will be held on November 14–15, 2024 from 8:30 a.m. to 5:30 p.m. EST each day. If the Committee completes its work before 5:30 p.m., the meeting will adjourn early.

**ADDRESSES:** The meeting will be held at the Tower Building at 1101 Wootton Parkway, Lower-Level Conference Room, Rockville, Maryland 20852 and will be accessible by webcast. Members of the public must register for the meeting by 5:00 p.m. EST on October 29, 2024. Registered webcast participants will receive webcast access information prior to the meeting.

**FOR FURTHER INFORMATION CONTACT:**

Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240-453-6816; email: [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov).

**SUPPLEMENTARY INFORMATION:**

Establishment of the ACMH is mandated under section 1707(c) of the PHS Act (42 U.S.C 300u-6(c)) to provide advice to the Deputy Assistant Secretary for Minority Health on the development of goals and program activities related to OMH's duties.

The topic to be discussed during the meeting is the implementation of the updated Office of Management and Budget (OMB) federal race and ethnicity data collection standards. The focus will be opportunities for engagement with racial, ethnic, and tribal community-level organizations to support increased awareness of the race and ethnicity data collection standards and their intended goals within their communities. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to implementation of the revised OMB standards. Information on OMB's updated federal race and ethnicity data collection standards can be found on this website: [spd15revision.gov](http://spd15revision.gov).

The meeting is open to the public. Any individual who wishes to attend the meeting must register by sending an email to [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) by 5:00 p.m. EST on October 29, 2024. Each registrant should provide their name, affiliation, email address, days attending, if planning to provide public verbal comments or printed statement, and if participation is in-person or via webcast. Registrants 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 [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) and reference this meeting. Requests for special accommodation should be made during registration or at least ten (10) business days prior to the meeting.

Registered members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per registered speaker during the time allotted. Individuals of the public may also submit and distribute electronic or printed statements or material(s) related to this meeting's topic. Written statements or material(s) should be double-spaced with one-inch margins and not exceed two pages in length. Any content beyond the two-page limit will not be presented to the Committee. Individuals planning to submit electronic or printed material should email the material to [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) at least ten (10) business days prior to the meeting.

**Violet Woo,**

*Designated Federal Officer, Advisory Committee on Minority Health.*

[FR Doc. 2024-23582 Filed 10-10-24; 8:45 am]

**BILLING CODE 4150-29-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.

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.

*Date:* November 7–8, 2024.

*Time:* 8:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* Hyatt Place Georgetown, 2121 M Street, Washington, DC 20037.

*Meeting Format:* In Person.