

**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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## 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.*

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## 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