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: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the seventh iteration of the Prescription Drug User Fee Act, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making. This included issuing a Request for Information (RFI) available at *https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments* to elicit public input on methodologic challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.[1] The RFI was published on May 2, 2023, and the public comment period was open until July 3, 2023. A summary of the comments was published on December 12, 2023, and is available at *https://www.regulations.gov* by entering the following docket number: FDA–2023–N–1506. The input received in response to the RFI helped inform the topics for the first public workshop in this series, *Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data,* held on December 13, 2024. The discussions from the first workshop helped to inform the topics for this second workshop. These workshops, together with the input received in response to the RFI, will help FDA identify priorities for future work.

II. Topics for Discussion at the Public Workshop

The purpose of this virtual public workshop is to highlight and discuss methodological issues related to patient experience data, including the submission and evaluation of patient experience data in the context of the benefit-risk assessment and product labeling, as well as other areas of greatest interest or concern to stakeholders. This workshop will build upon the previous workshop and will feature presentations and panel discussions with experts on selected methodologies and the challenges and opportunities they present. In addition, this workshop will present a draft version of an updated evidence dossier template to facilitate the submission of evidence to FDA to support a Clinical Outcome Assessment.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_8FiAJfirS3W2WpC_8K0Zww#/registration.* Please provide complete contact information for each attendee, including name, organization, email, and affiliation.

Registration is free. Persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact *Ethan.Gabbour@fda.hhs.gov* no later than September 11, 2025. Please note, closed captioning will be available automatically.

Transcript: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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[1] The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the FDA Reauthorization Act of 2017 (Pub. L. 115–52), defines patient experience data as data that are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers) and are intended to provide information about patients' experiences with a disease or condition, including the impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation and patient preferences with respect to treatment of the disease or condition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–3082]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; MODESYO (dordaviprone)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. 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 award of the priority review voucher. FDA has determined that MODESYO (dordaviprone), approved August 6, 2025, manufactured by Chimerix, Inc.,

meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2771.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined MODESYO (dordaviprone) manufactured by Chimerix, Inc., meets the criteria for a priority review voucher. MODESYO (dordaviprone) capsules are indicated for the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.

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 MODESYO (dordaviprone), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16515 Filed 8–27–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Nurse Corps Scholarship Program, OMB No. 0915–0301—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 29, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Nurse Corps Scholarship Program, OMB No. 0915–0301—Revision.

Abstract: The Nurse Corps Scholarship Program (Nurse Corps SP), administered by HRSA, provides scholarships to nursing students in exchange for a minimum 2-year full-time service commitment (or part-time equivalent), at an eligible health care facility with a critical shortage of nurses (*i.e.,* Critical Shortage Facility [CSF]). The scholarship consists of payment of tuition, fees, other reasonable educational costs, and a monthly support stipend. Program recipients are required to fulfill Nurse Corps SP service commitments at CSFs located in the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

A 60-day notice published in the **Federal Register** on June 11, 2025, vol. 90, No. 111; pp. 24635–36. There were no public comments.

Need and Proposed Use of the Information: The Nurse Corps SP collects data to determine an applicant's eligibility for the program, monitor a participant's continued enrollment in a school of nursing, monitor the participant's compliance with the Nurse Corps SP service obligation, and prepare annual reports to Congress. The following information will be collected: (1) from the applicants to determine their eligibility—an application form consisting of personal (such as proof of citizenship, references, and personal essay), financial (such as the Student Aid Index), and educational information (including verification of acceptance and good standing, tuition costs, and transcripts); (2) from the schools, on a quarterly basis—general applicant and nursing school data such as full name, location, tuition/fees, and enrollment status; (3) from the schools, on an annual basis—data concerning tuition/fees and overall student enrollment status; and (4) from the participants and their employing CSF on a biannual basis—data concerning the participant's employment status, work schedule, and leave usage.

There will be minor changes to this information collection, including replacing ''gender'' with ''sex'' and a discontinuation of the collection of resumes within the application as they are not used to determine eligibility.

Likely Respondents: Nurse Corps SP applicants, participants who are in school, graduates, educational institutions, and CSFs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.