

## I. Cellular, Tissue, and Gene Therapies Advisory Committee

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products, which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

## II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter via email stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a notification to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

## III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee, including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify

the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: January 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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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

**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 VEOZAH (fezolinetant), approved May 12, 2023, 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 VEOZAH (fezolinetant) 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 VEOZAH (fezolinetant), go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: January 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## 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; The National Health Service Corps Loan Repayment Programs

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than March 25, 2024.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* The National Health Service Corps Loan Repayment Programs OMB No. 0915-0127—Revision.

*Abstract:* The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in Health Professional Shortage Areas (HPSAs) of the United States with the greatest need. The NHSC Substance Use Disorder Workforce LRP and the NHSC Rural Community LRP were established to recruit and retain a health professional workforce with specific training and credentials to provide evidence-based substance use disorder treatment in HPSAs. Under these programs, HHS agrees to repay the qualifying educational loans of selected primary care health professionals. In

return, the health professionals agree to serve for a specified period of time in an NHSC-approved site located in a federally-designated HPSA approved by the Secretary of HHS for LRP participants.

The forms used by each LRP include the following: (1) the NHSC LRP Application, (2) the Authorization for Disclosure of Loan Information Form, (3) the Privacy Act Release Authorization Form, and, if applicable, (4) the Verification of Disadvantaged Background Form, (5) the Private Practice Option Form, and (6) the NHSC Spanish Language Assessment Proficiency Test Form. The first four of the NHSC LRP Forms collect information that is needed for selecting participants and repaying qualifying educational loans. The Private Practice Option and Spanish Language Assessment forms are needed to collect information from applicants who wish to be considered for those options.

*Need and Proposed Use of the Information:* The need and proposed use of this information collection is to assess an LRP applicant’s eligibility and qualifications for the LRP, and to determine LRP applicants’ Spanish language proficiency if relevant to their

application, and to obtain information for NHSC site applicants. The NHSC LRP application asks for personal, professional, and financial/loan information.

*Likely Respondents:* Likely respondents include licensed primary care medical, dental, and behavioral health providers who are employed or seeking employment and are interested in serving underserved populations.

*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.

**TOTAL ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC LRP Application .....	9,020	1	9,020	1.00	9,020
Authorization for Disclosure of Loan Information Form .....	7,150	1	7,150	0.10	715
Privacy Act Release Authorization Form .....	303	1	303	0.10	30
Verification of Disadvantaged Background Form .....	660	1	660	0.50	330
Private Practice Option Form .....	330	1	330	0.10	33
NHSC Comprehensive Behavioral Health Services Checklist .....	4,400	1	4,400	0.13	572
NHSC Spanish Language Assessment Proficiency Test Form .....	3,006	1	3,006	0.50	1,503
NHSC Site Application (including recertification) .....	4,070	1	4,070	0.50	2,035
<b>Total .....</b>	<b>28,939</b>	<b>.....</b>	<b>28,939</b>	<b>.....</b>	<b>14,238</b>

**Maria G. Button,**

*Director, Executive Secretariat.*

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