

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Enforcement Notifications—21 CFR 100.2(d)
OMB Control Number 0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own

jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d); notification	1	1	1	10	10

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: January 18, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–01238 Filed 1–22–24; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Cellular, Tissue, and Gene Therapies Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the CTGTAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests

must send a letter stating that interest to FDA by February 22, 2024 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by February 22, 2024.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent via email to Cicely Reese or Marie DeGregorio (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives must be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: <https://www.accessdata.fda.gov/scripts/FACTRS/Portal/FACTRS/index.cfm>. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA’s website at: <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Cicely Reese or Marie DeGregorio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1232, Silver Spring, MD 20993–0002, 240–620–9987, email: CBERCTGTAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

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.

[FR Doc. 2024–01154 Filed 1–22–24; 8:45 am]

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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.

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 or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.