Withdrawal of approval of PEPAXTO (NDA 214383) was effective February 23, 2024; the withdrawal includes all amendments and supplements to the application. As discussed in the decision of the Commissioner's designee, FDA has withdrawn approval of the PEPAXTO NDA for reasons of safety or effectiveness.

Section 505(j)(7) of the FD&C Act (21 U.S.C. 355(j)(7)) requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book,'' available at *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.* Pursuant to section 505(j)(7)(C) of the FD&C Act, drugs are removed from the list if FDA determines that the listed drug has been withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency has removed the application for PEPAXTO from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that reference PEPAXTO.

II. Electronic Access

Persons with access to the internet may obtain the final decision at *https://downloads.regulations.gov/FDA-2023-N-3167-0049/attachment_1.pdf.* The final decision and other documents pertaining to the withdrawal of the NDA for PEPAXTO (NDA 214383) are available at *https://www.regulations.gov* under the docket number found in brackets in the heading of this document.

Dated: April 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08274 Filed 4–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1636]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; LENMELDY (Atidarsagene Autotemcel)

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 LENMELDY (atidarsagene autotemcel), approved on March 18, 2024, manufactured by Orchard Therapeutics (Europe) Ltd., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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 that LENMELDY (atidarsagene autotemcel), manufactured by Orchard Therapeutics (Europe) Ltd., meets the criteria for a priority review voucher.

LENMELDY (atidarsagene autotemcel) is indicated for treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile, or early symptomatic early juvenile metachromatic leukodystrophy.

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about LENMELDY (atidarsagene autotemcel), go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: April 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08276 Filed 4–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4804]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expedited Programs for Serious Conditions—Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 20, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0765. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expedited Programs for Serious Conditions—Drugs and Biologics

OMB Control Number 0910–0765—Extension

This information collection supports regulations governing FDA expedited programs for serious conditions. These provisions are set forth in 21 CFR part 312, subpart E and are intended to speed the availability of new therapies to patients with serious conditions, especially when there are no satisfactory

alternative therapies, while preserving appropriate standards for safety and effectiveness. The regulations call for earlier attention to drugs that have promise in treating such conditions, including early consultation with FDA for sponsors of such products. Respondents to the information collection are sponsors of drug or biologic product applications submitted to FDA.

To assist respondents with the information collection, we developed Agency guidance entitled ''Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014). The guidance is a resource for information on FDA's policies and procedures related to the following expedited programs for serious conditions: (1) fast track designation; (2) breakthrough therapy designation; (3) accelerated approval; and (4) priority review designation, and describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. The guidance addresses the applicability of expedited programs to rare diseases, clarification on available therapy, and additional detail on possible flexibility in manufacturing and product quality. It also clarifies the qualifying criteria for breakthrough therapy designation, provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval, and priority review.

In addition, we developed Agency guidance entitled ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions,'' (February 2019) describing the criteria for participation in the Regenerative Medicine Advanced Therapy (RMAT) program. The RMAT expedited program was approved as part of the 21st Century CURES Act, signed December 13, 2016. An RMAT product is intended to treat, modify, reverse, or cure serious or life-threatening diseases or conditions, and preliminary clinical evidence indicate that the drug has the potential to address unmet medical needs for such diseases or conditions. This is a Center Biologics Evaluation and Research (CBER) program and is included as an expedited program available for serious conditions.

For a sponsor or applicant who seeks fast track, priority, breakthrough, RMAT or accelerated approval designation review, approval is required to submit a request showing that the drug product: (1) is intended for a serious or life-threatening condition and (2) has the potential to address an unmet medical need, demonstrate substantial improvement over available therapy, or fill an unmet need to be approved based on a surrogate endpoint. We expect that most information to support a designation request will have been gathered under existing requirements for preparing an investigational new drug (IND), new drug application (NDA), or biologics license application (BLA). If such information has already been submitted to us, the information may be summarized in the designation request. A designation request should include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request should be sufficient to permit a reviewer to assess whether the criteria for fast track, priority, breakthrough, RMAT or accelerated approval designation have been met.

After we make an expedited programs designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain expedited programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for expedited programs designation, we expect that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, NDA, or BLA. These may include descriptions of clinical safety and efficacy trials not conducted under an IND (*e.g.,* foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to us, the information may be summarized in the premeeting package.

The guidance documents are available on our website at *www.fda.gov/regulatory-information/search-fda-guidance-documents* and were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

In the **Federal Register** of January 9, 2024 (89 FR 1101), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER:					
Priority Review Designation Requests (Expedited Programs for Serious Conditions Guidance (EPSC) Section VIII)	81	1.53	124	30	3,720
Breakthrough Therapy Designation Requests (EPSC Section VI)	71	1.08	77	70	5,390
Fast Track Designation Requests (EPSC Section V)	235	1.18	277	60	16,620
Accelerated Approval Designation (EPSC Section VII)	26	1.27	33	100	3,300
Premeeting Packages (21 CFR 312.82)	163	1.01	165	100	16,500
CDER Subtotal			676		45,530
CBER:					
Priority Review Designation Request (EPSC Section VIII)	8	1	8	30	240
Breakthrough Therapy Designation Request (EPSC Section VI)	15	1.1	17	70	1,190
Fast Track Designation Requests (EPSC Section VII)	64	1.2	77	60	4,620
RMAT Designation Requests (Regenerative Medicine Therapies for Serious Conditions Guidance (RMAT) Section III)	33	1.1	36	60	2,160
Premeeting Packages (RMAT Section V)	146	1.9	277	100	27,700
CBER Subtotal			415		35,910

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total			1,091		81,440

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

Based on FY 2022 receipts, we estimate that for Center for Drug Evaluation and Research (CDER) products, 81 respondents will submit 124 requests for priority review designation annually, and we assume 30 hours are needed to prepare such a request. We estimate 71 respondents will submit 77 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 235 respondents will submit 277 requests for fast-track designation requests annually, and we assume 60 hours are required to prepare such a request. We estimate 26 respondents will submit 33 accelerated approval designation requests annually and we assume 100 hours are required to prepare such a request. Finally, CDER received 165 pre-meeting package submissions from 163 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Similarly, also based on FY 2022 receipts, we estimate that for CBER products, 8 applicants will submit 8 requests for priority review designation annually, and we assume 30 hours are required to prepare such a request. We estimate 15 respondents will submit 17 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 64 respondents will submit 78 requests for fast-track designation annually, and we assume 60 hours is required to prepare such a request. We also estimate 33 respondents will submit 35 requests for RMAT designation annually and assume that 60 hours are needed to prepare each RMAT designation request. Finally, CBER received 283 pre-meeting package submissions from 146 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 143 responses and 10,350 hours to reflect actual submissions we have received. We attribute these changes to increased interest in the expedited programs, new expedited programs, and an increase in the number of submissions we received over the last few years.

Dated: April 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08293 Filed 4–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notification of Lender and Servicer Eligibility Criteria for Participation in the Health Center Loan Guarantee Program

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

ACTION: Request for public comment.

SUMMARY: This notice seeks public comment to update the Health Center Loan Guarantee Program lender and servicer eligibility criteria in accordance with OMB Circular A–129. The original notice of lender eligibility criteria for the Health Center Loan Guarantee Program was published in the Commerce Business Daily on January 7, 2000.

DATES: Submit comments no later than May 20, 2024.

ADDRESSES: Electronic or written comments should be submitted through the Bureau of Primary Health Care (BPHC) Contact Form (new users must request access) or to 5600 Fishers Lane, Rm. 16N–20, Rockville, MD 20857, no later than 30 days after the publication date.

FOR FURTHER INFORMATION CONTACT: Mary Lou Ojeda, Lead Public Health Analyst, or Valerie Green, Loan Specialist, BPHC, Office of Policy and Program Development, Strategic Initiatives, HRSA, 5600 Fishers Lane, Rm. 16N–20, Rockville, MD 20857, 301–594–4300, or the BPHC Contact Form.

SUPPLEMENTARY INFORMATION: Title XVI, part A of the Public Health Service Act established the authority for the Department of Health and Human Services to guarantee the principal and interest on certain loans made by non-Federal lenders. Under this authority, the Health Center Loan Guarantee Program guarantees up to 80 percent of the outstanding principal and interest on eligible loans for the construction, renovation, and modernization of medical facilities that are operated by health centers funded under the Public Health Service Act. These health centers, which are community-based private nonprofit or public entities, provide primary health care services for medically underserved populations. The approximately 1,400 organizations that receive funding are located in urban and rural communities throughout the nation.

HRSA's BPHC administers the Health Center Loan Guarantee Program, which has a total current lending authority of $825 million. Under the Program, lender and servicer eligibility requirements have been established, with participation open to eligible non-Federal lenders. Consistent with the policies set forth in OMB Circular A–129, this notice provides interested parties information regarding eligibility criteria for participating as a lender or servicer in the Loan Guarantee Program. Specifically, to participate in the Program, a lender or servicer must: (a) Be regulated or certified and in good standing with a Federal financial institution regulatory agency, or furnish satisfactory evidence of adequate financial and capital condition showing that the lender has (i) a minimum adjusted net worth of $250,000, or (ii) at least $50,000 in working capital plus 1 percent of the total volume in excess of $25 million in guaranteed loans originated, serviced, or purchased during the lender's prior fiscal year, up to a maximum required adjusted net worth of $2.5 million, and one or more lines of credit with a minimum aggregated of $1 million; (b) Not be currently debarred or suspended from participation in any United States government contract or delinquent on a debt owed to the United Stated government or any agency or instrumentality thereof; (c) Be able to obtain and submit proof of fidelity/surety bonding and/or errors and omissions insurance with the Federal Government as a loss payee if the lender has previously had questionable performance under Federal guarantee programs or is not regulated by the Federal Government or certified by the U.S. Department of the Treasury; (d)