SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10453 Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of the previously approved collection; *Title of Information Collection:* Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits; *Use:* Sections 1852(k)(2)(C)(i) and 1860D–(4)(a)(4) of the Act give CMS authority to require EOBs in MA and Part D, respectively. Corresponding MA and Part D regulations at 42 CFR 422.111(k) and 423.128(e) further specify the requirements to provide a written EOB directly to enrollees following their use of benefits.

These requirements and the CMS model documents help ensure that MA and Part D enrollees receive consistent and timely information about costs associated with their medical claims. Part C and Part D EOBs allow enrollees to track their out-of-pocket expenses and benefit utilization in relation to their plan's deductible and out-of-pocket threshold. This customized information positions enrollees to make informed decisions about their healthcare options. It also enables them to make a more practical use of the information found in plans' Annual Notice of Change and Evidence of Coverage documents, as well as information available through tools such as the Medicare Plan Finder.

MAOs and Part D sponsors use the model documents attached to this information collection to set up the EOB templates in their systems and ensure that EOBs conform with the requirements at 42 CFR 422.111(k) and 423.128(e). MAOs and Part D sponsors populate EOBs to reflect individual enrollee benefits under the plan. CMS issues model EOBs annually through the Health Plan Management System (HPMS). *Form Number:* CMS–10453 (OMB control number: 0938–1228); *Frequency:* Monthly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,065; *Total Annual Responses:* 1,065; *Total Annual Hours:* 10,650. (For policy questions regarding this collection contact Valerie Yingling at 667–290–8657.)

Dated: June 1, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–11996 Filed 6–5–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Replication of Recovery and Reunification Interventions for Families-Impact Study (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Replication of Recovery and Reunification Interventions for Families-Impact Study (R3-Impact). The R3-Impact Study aims to satisfy the legislative requirements called for by the 2018 SUPPORT for Patients and Communities Act by replicating and testing the efficacy of two recovery coaching interventions for families engaged in the child welfare system due to parental substance use disorders.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The R3-Impact study will use experimental and quasi-experimental designs to test the effectiveness of the recovery coaching interventions on key child welfare and parent well-being outcomes. The implementation study will document the fidelity of program implementation, describe the services participants receive under each approach, and provide operational lessons gathered directly from practitioners. These goals represent ACF's interest in understanding whether recovery coaching interventions yield successful parental recovery and child welfare outcomes, and if so, whether the potential exists to scale the interventions for the benefit of more affected families. The proposed information collection activity consists of (1) Baseline data collection: collection of baseline demographic and parent well-being data from study participants; (2) Contact form: short form sent to study participants quarterly for one year after study enrollment to keep contact information current and generally maintain the participant's connection to the study; (3) Validation interviews: short interviews with a subset of study participants to monitor the quality of data collection interviews and to validate that the interviewer spoke with the participant; (4) Implementation study interviews: using topic guides, collect information from program supervisors and frontline staff, community providers, child welfare staff, and parents enrolled in the programs to assess the fidelity of implementation, document program services, and gather operational lessons; and (5) Parent Interview Information Form: demographic information to support analysis of parent perspectives by personal characteristics and history. Future information collection requests will be submitted to collect follow-up data.

Respondents: Parents enrolled in the R3-Impact Study, and program and agency staff involved in implementing the R3 interventions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Baseline Parent Survey	2,750	1	.75	2063	688
Contact Form	1843	4	.17	1,253	418
Topic Guide—Child Welfare Lead Staff	60	1	1	60	20
Topic Guide—Child Welfare Frontline Staff	60	1	1	60	20
Topic Guide—Partners	120	1	1	120	40
Topic Guide—Program Managers	60	1	1.5	90	30
Topic Guide—Mentor Supervisors	60	1	1.5	90	30
Topic Guide—Parent/Family Mentors	60	1	1.5	90	30
Topic Guide—Parents	30	1	1	30	10
Parent Interview Information Form	30	1	.1	3	1
Validation Interviews	275	1	.08	22	7

Estimated Total Annual Burden Hours: 1,294.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT for Patients and Communities Act; Public Law 115–271)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–11989 Filed 6–5–23; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

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 VYJUVEK (beremagene geperpavec-svdt), manufactured by Krystal Biotech, Inc., 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 VYJUVEK (beremagene geperpavec-svdt), manufactured by Krystal Biotech, Inc., meets the criteria for a priority review voucher. VYJUVEK is indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

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 VYJUVEK, 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: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11907 Filed 6–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2008]

Vintage Pharmaceuticals; Withdrawal of Approval of Abbreviated New Drug Application for Pemoline Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 075328 for pemoline tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811 (Vintage). Vintage requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of June 6, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New