

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]

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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]

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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