DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0428]

Proposed Information Collection Activity; Case Plan Requirement, Title IV–E of the Social Security Act

AGENCY: Children's Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the information collection Case Plan Requirement, Title IV–E of the Social Security Act, (Office of Management and Budget (OMB) #0970–0428, expiration September 30, 2026). There are no changes to the requirements, but burden estimates have been updated to reflect a reduction in average time to complete a case plan and the current numbers of children in foster care.

DATES: *Comments due* April 24, 2026.

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

SUPPLEMENTARY INFORMATION:

Description: The case plan information collection is authorized in sections 422(b)(8)(A)(ii) and 471(a)(16), and defined in sections 475 and 475A of the Social Security Act (the Act). Statutory requirements in the Act mandate that states, territories, and tribes with an approved title IV–E plan develop a case review system and case plan for each child in the foster care system for whom the state, territory, or tribe receives title IV–E reimbursement of foster care maintenance payments. The case review system assures that each child has a case plan designed to achieve placement in a safe setting that is the least restrictive, most family-like setting available and near the child's parental home, consistent with the best interest and special needs of the child. States, territories, and tribes meeting these requirements also partly comply with title IV–B, section 422(b), of the Act, which assures certain protections for children in foster care. The case plan is a written document that provides a narrative description of the child-specific program of care. Federal regulations at 45 CFR 1356.21(g) and sections 475 and 475A of the Act delineate the specific information that must be addressed in the case plan. ACF does not specify a format for the case plan nor does ACF require submission of the document to the federal government. Case plan information is recorded in a format developed and maintained by the state, territorial, or tribal title IV–E agency.

Respondents: State, territorial, and tribal title IV–E agencies.

Annual Burden Estimates: Burden estimates have been adjusted to reflect one additional title IV–E agency, a decrease in average hours to complete a case plan due to technology, fewer children entering foster care, and an increased number of children exiting foster care. Overall, the estimated annual burden has decreased by about 32 percent.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Case Plan Requirement	67	19,490	3.8	4,962,154	1,654,051

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: 42 U.S.C. 622; 42 U.S.C. 671; 42 U.S.C. 675; 42 U.S.C. 675a.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–1808]

Determination That Klonopin (Clonazepam) Tablets, 0.125 Milligrams and 0.25 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that KLONOPIN (clonazepam) tablets, 0.125 milligrams (mg) and 0.25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for clonazepam tablets, 0.125 mg and 0.25 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Lars Flores, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6281, Silver Spring, MD 20993–0002, 301–796–0724, *lars.flores@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, are the subject of NDA 017533, held by Cheplapharm Arzneimittel GmbH, and initially approved on April 9, 1997. KLONOPIN is indicated for seizure disorders and panic disorder.

KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated June 20, 2025 (Docket No. FDA–2025–P–1808), under 21 CFR 10.30, requesting that the Agency determine whether KLONOPIN (clonazepam) tablets, 0.25 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 0.125 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to KLONOPIN (clonazepam) tablets, 0.125 mg and 0.25 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03495 Filed 2–20–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0672]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; WASKYRA (etuvetidigene 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 WASKYRA (etuvetidigene autotemcel), approved on December 9, 2025, manufactured by Fondazione Telethon ETS, 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 WASKYRA (etuvetidigene autotemcel), manufactured by Fondazione Telethon ETS, meets the criteria for a priority review voucher. WASKYRA (etuvetidigene autotemcel) is indicated for the treatment of pediatric patients aged 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene and for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.

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 WASKYRA (etuvetidigene 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.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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