

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Appendix G: Input Transactions Layout	54	390	0.0333	701

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 will 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 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. 653(h); 42 U.S.C. 654a(e); 42 U.S.C. 654a(f)(1).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026-08934 Filed 5-5-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget: 0970-0558]

Proposed Information Collection Activity; Generic for Administration for Children and Families Program Monitoring Activities

AGENCY: 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) intend to request from the Office of Management and Budget (OMB) an extension of approval for an umbrella generic clearance for information collections related to ACF program office monitoring activities. ACF programs promote the economic and social well-being of families, children, individuals, and communities. The Generic for ACF Program Monitoring Activities allows ACF program offices to collect standardized information from recipients that receive federal funds to ensure oversight, evaluation, support purposes, and stewardship of federal funds. There are no changes proposed to the terms of the generic. Burden estimates have been updated.

DATES: *Comments due* July 6, 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: Program monitoring is a post-award process through which ACF assesses a recipient’s programmatic performance and business management performance. Monitoring activities are necessary to ensure timely action by ACF to support grantees and protect federal interests.

Program offices use information collected under this generic clearance to monitor funding recipient activities and to provide support or take appropriate action, as needed. The information gathered is or will be used primarily for internal purposes, but aggregate data may be included in public materials such as reports to Congress or program office documents. Following standard OMB requirements, ACF will submit a request for each individual data collection activity under this generic clearance. Each request will include the individual form(s) or instrument(s), a justification specific to the individual information collection, and any supplementary documents.

Respondents: ACF funding recipients.

Annual Burden Estimates

The following burden estimates include burden associated with currently approved individual requests that ACF intends to include with this extension request and an estimate of burden for potential new requests under this generic. Note that new individual requests may be approved between this publication and submission of the full extension request.

All currently approved individual requests are available here: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202604-0970-004

ESTIMATED BURDEN—ONGOING REQUESTS

Instrument	Number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Annual burden (in hours)
Annual Data Collection on Sexual Abuse and Sexual Harassment Involving Unaccompanied Children	200	1	1.5	300
Community Services Block Grant (CSBG) Training and Technical Assistance Tracking Form	20	4	0.75	60
Community Services Block Grant (CSBG) Work Plan Template	20	1	3.25	65
Office of Head Start Child Incident Reporting	1,000	4.8	0.167	800
Office of Head Start Improper Payment Reviews	300	2	3	1,800
Office of Refugee Resettlement (ORR) Care Provider Healthcare Delivery Report (HDR)	225	1	1.50	338
Office of Refugee Resettlement Emergency Operations Plan Survey	300	0.33	0.74	74
Office of Refugee Resettlement Refugee Microenterprise Development (MED) Program Case File Requirements	30	1	20	600

ESTIMATED BURDEN—ONGOING REQUESTS—Continued

Instrument	Number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Annual burden (in hours)
Office of Refugee Resettlement Refugee Microenterprise Development (MED) Program Pre-Monitoring Questionnaire (PMQ)	15	1	5	75
Total Annual Ongoing Burden	2,110	4,112

Based on the past 3 years and with a goal to reduce burden moving forward the estimated annual burden for potential new requests is 31 percent less than the currently approved umbrella generic.

ESTIMATED BURDEN—FUTURE REQUESTS

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
New Program Monitoring Forms	2,000	3	1.85	11,100

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: This generic is related to and will be of use to all ACF program offices that award federal funds (e.g., grants, cooperative agreements) and monitor activities related to funding. Each individual program use will be related to a specific statutory authority.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–1306]

Determination That DEXAMETHASONE (Dexamethasone) Elixir, 0.5 Milligrams/5 Milliliters, Was 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 DEXAMETHASONE (dexamethasone) elixir, 0.5 milligrams (mg)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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.

DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 mL, is the subject of ANDA 088254, approved on July 27,