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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Clearance for Financial Reports Used for ACF Mandatory Grant Programs (Office of Management and Budget #: 0970–0510)

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) proposes to extend approval of the existing overarching generic clearance for Financial Reports used for ACF Mandatory Grant Programs (OMB #0970–0510) as well as all information collections currently approved under the overarching generic. There are no changes to the proposed types of information collection or uses of data as described in the overarching generic, and there are no changes proposed to currently approved information collections for which we are requesting an extension. Burden estimates for the next 3 years have been adjusted based on use to date.

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 *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF programs require detailed financial information from their grantees that allows ACF to monitor various specialized cost categories within each program, to closely manage program activities, and to have sufficient financial information to enable periodic thorough and detailed audits.

The information included on the standard Federal Financial Report Form (SF–425; OMB #4040–0014) provides only minimal, bare-bones, non-program specific financial information insufficient for these purposes. This generic clearance allows ACF programs to efficiently develop and receive approval for financial reports that are tailored to specific funding recipients and the associated needs of the program. This umbrella generic is a mechanism that is available to all ACF mandatory grant programs to use to obtain OMB approval of financial forms. Currently only a small number of ACF's mandatory grant program financial forms are covered under this umbrella; it does *not* cover all ACF mandatory grant program financial forms. Program offices use the information collected under this generic information collection to:

- Monitor program operations and prepare technical assistance and guidance as needed
- Assess the effect of program changes and make informed decision
- Assist in the computation of the grant awards issued to each program's grantees
- Assist in the computation of the Child Support Services program's annual incentive payments
- Determine that child support collections are being properly distributed (Child Support Services Program only)
- Ensure funding recipients are meeting funding requirements established by Congress
- Produce annual financial and statistical reports as may be required by Congress and respond to periodic detailed inquiries from Congress

ACF may require an information collection approved under this generic from funding recipients to obtain or retain benefits.

Prior to a new form being submitted for review under this umbrella generic, ACF will publish a notice in the **Federal Register** announcing the agency's intention to request an OMB review of the form and providing a 14-day period for public comment on that specific request. ACF will review any comments received and address them as appropriate. ACF will provide a copy of any comments received and will provide a description of how comments were considered in the submission form along with the request package for the individual collection. ACF will then follow standard OMB requirements for a generic information collection and submit a generic information collection request for each individual data collection activity under this generic clearance. Each request will include the individual form(s) and instructions, a summary of any comments received, and a short overview of the proposed purpose and use of the data collected. OMB should review requests within 10 days of submission.

Respondents: ACF-funded mandatory grant programs.

Annual Burden Estimates

Find currently approved information collections here: *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202308-0970-008.* The request to OMB will include an extension request for approved information collections that are planned to continue beyond spring 2024. The current list of ongoing collections follows, but more collections may be approved prior to submission of the extension request to OMB. We will update the list in the subsequent **Federal Register** notice, if needed.

Burden Estimates—Ongoing Requests

Study	Number of respondents	Number of responses per respondent	Average burden hours per response	Burden hours
ACF–196P, TANF Pandemic Emergency Assistance Fund (PEAF) Financial Report for States, Territories and Tribes	137	1	6	822
Child Care and Development Fund (CCDF) ACF–696 Financial Report for States and Territories	56	4	5	1,120
Child Care and Development Fund (CCDF) ACF–696T Financial Report for Tribal Grantees	221	1	7	1,547
Child Support Services Program Financial Reporting Forms (OCSE–34 and OCSE–396)	168	4	14	9,408
Form CB–496: Title IV–E Programs Quarterly Financial Report	67	4	25	6,700

Study	Number of respondents	Number of responses per respondent	Average burden hours per response	Burden hours
Refugee Cash and Medical Assistance Federal Financial Report (ORR–2) Supplemental Data Collection	66	1	1.67	110
Refugee Support Services Federal Financial Report (SF–425) Supplemental Data Collection	53	4	4	848
Totals	768	Avg: 2.7	Avg: 8.9	20,555

Burden Estimates—New Requests

Based on use of this generic, we have revised burden estimates for the next 3 years.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Burden hours
Mandatory Grant Financial Reports	1,200	3	9	32,400

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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. 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 issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application (Supplement-35) for COSENTYX (secukinumab), approved June 16, 2020, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application (Supplement-35) for COSENTYX (secukinumab) meets the redemption criteria.

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/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about COSENTYX (secukinumab), go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: January 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5430]

Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices.'' This draft guidance document provides recommendations for premarket submissions for orthopedic devices that contain metallic coatings and/or calcium phosphate coatings on the surface. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 25, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows: