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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](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/DevelopingProductsforRareDiseases/Conditions/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: