

**Jeffrey M. Zirger,**  
*Lead, Information Collection Review Office,  
 Office of Public Health Ethics and  
 Regulations, Office of Science, Centers for  
 Disease Control and Prevention.*

[FR Doc. 2024-01152 Filed 1-22-24; 8:45 am]

BILLING CODE 4163-18-P

**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.

[FR Doc. 2024-01206 Filed 1-22-24; 8:45 am]

BILLING CODE 4184-88-P

#### 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](mailto: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.

[FR Doc. 2024-01164 Filed 1-22-24; 8:45 am]

BILLING CODE 4164-01-P

#### 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: