2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–437A and CMS–437B Rehabilitation Unit and Hospital Criteria Worksheet

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Rehabilitation Unit and Hospital Criteria Worksheet; *Use:* Inpatient Rehabilitation Facility (IRF) hospitals and units must initially attest that they meet the Inpatient Prospective Payment System (IPPS) exclusion criteria set forth at 42 CFR 412.20 to § 412.29 prior to being placed into IPPS exempt status. Form CMS–437A must be completed by IRF units and form CMS–437B must be completed by IRF hospitals.

For first time verification requests for exclusion from the IPPS, an IRF unit or hospital must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new IRF units or hospitals must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. The completed CMS–437A and 437B forms are submitted to the State Agency (SA) no later than 5 months before the date the IRF unit or hospital would become subject to Inpatient Rehabilitation Facility Prospective Payment System (IRF–PPS). For IRF units and hospitals already excluded from the IPPS, annual onsite re-verification surveys by the SA are no longer required. IRF units and hospitals must now re-attest to meeting the exclusion criteria every 3 years thereafter.

IRF units and hospitals that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria. For the tri-annual re-verification, IRF units and hospitals will be provided with a copy of the appropriate CMS–437 worksheet at least 5-months prior to the beginning of its cost reporting period, so that the IRF unit or hospital official may complete and sign an attestation statement and complete and return the appropriate form CMS–437A or CMS–437B at least 5-months prior to the beginning of the cost reporting period. However, Fiscal Intermediaries (FIs) will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for IRF units and hospitals through a sample of medical records and the SA will verify the medical director requirement.

The SA will notify the RO at least 60 days prior to the end of the IRF unit's or hospital's cost reporting period of the status of compliance or non-compliance with the payment requirements. The information collected on the 437A and 437B forms, along with other information submitted by the IRF is necessary for determining the IRF's IPPS exclusion status. We have revised the CMS–437A and 437B forms so that they more adequately reflect the regulatory requirements of § 412.20 to § 412.29. More specifically, we have updated the text in the 3rd column of the form, which tells the facility what actions must be taken and what information must be verified to receive IPPS excluded status.; *Form Number:* CMS–437A and CMS–437B (OMB control number: 0938–0986); *Frequency:* tri-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 497; *Total Annual Responses:* 497; *Total Annual Hours:* 497. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705).

Dated: August 4, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022–17063 Filed 8–8–22; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Office of Refugee Resettlement Cash and Medical Assistance Program Quarterly Report on Expenditures and Obligations (ORR–2) (OMB #0970–0407)

**AGENCY:** Office of Refugee Resettlement, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Office of Refugee Resettlement (ORR) is requesting a 3-year extension of the ORR–2, Cash and Medical Assistance Program Quarterly Report on Expenditures and Obligations (OMB #0970–0407, expiration 9/30/2022). There are no changes requested to the form.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed

requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* ORR reimburses, to the extent of available appropriations, certain non-federal costs for the provision of cash and medical assistance (CMA) to refugees, along with allowable expenses for the administration of the refugee resettlement program at the state level. States and Replacement Designees currently submit the ORR–2 Quarterly Report on Expenditures and Obligations, which provides aggregate expenditure and obligation data. The ORR–2 collects expenditures and obligations data separately for each of the four following CMA program components: refugee cash assistance, refugee medical assistance, CMA administration, and services for unaccompanied minors. This breakdown of financial status data allows ORR to track program expenditures in greater detail to anticipate any funding issues and to meet the requirements of ORR regulations at CFR 400.211 to collect these data for use in estimating future costs of the refugee resettlement program. ORR must implement the methodology at CFR 400.211 each year after receipt of its annual appropriation to ensure that appropriated funds will be adequate for reimbursement to states of the costs for assistance provided to entering refugees. The estimating methodology prescribed in the regulations requires the use of actual past costs by program component. If the methodology indicates that appropriated funds are inadequate, ORR must take steps to reduce federal expenses, such as by limiting the number of months of eligibility for Refugee Cash Assistance and Refugee Medical Assistance. The ORR–2 is a single-page financial report that allows ORR to collect the necessary data to ensure that funds are adequate for the projected need and thereby meet the requirements of both the Refugee Act and ORR regulations.

*Respondents:* State governments and Replacement Designees.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Annual burden hours |
|---|---|---|---|---|
| ORR–2, Cash and Medical Assistance Program, Quarterly Report on Expenditures and Obligations | 63 | 4 | 1.5 | 378 |

*Estimated Total Annual Burden Hours:* 378.

*Authority:* 8 U.S.C. 1522 Sec. 412 and 8 U.S.C. 524 (Title IV), Sec. 414.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2022–17078 Filed 8–8–22; 8:45 am]

**BILLING CODE 4184–45–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–1694]**

### Determination That AVC (Sulfanilamide) Vaginal Cream, 15%, and Other Drug Products 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 the drug products listed in this document were 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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.