ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
SCWS web-based survey	60	1	0.5	30
SCWS focus group	30	1	1.5	45

Estimated Total Annual Burden Hours: 75.

Authority: Title II, section 203(b)(4) of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (42 U.S.C. 5113(b)(4)).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–19775 Filed 9–12–23; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Serious Medical Procedure Request (SMR) Form (Office of Management and Budget #: 0970–0561)

AGENCY: Office of Refugee Resettlement, 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) Office of Refugee Resettlement is requesting a 3-year extension of the Serious Medical Procedure Request (SMR) Form (Office of Management and Budget #0970–0561, expiration February 29, 2024). Revisions are proposed to the currently approved form.

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's ORR places unaccompanied children in their custody in care provider programs until unification with a qualified sponsor. Care provider programs are required to provide children with a range of services including medical, dental, and mental healthcare. Children identified as having a serious medical or dental condition may require a procedure while in ORR custody to maintain and promote their health and wellbeing. Procedures requiring general anesthesia, surgeries, and invasive diagnostic procedures (*e.g.,* cardiac catheterization, invasive biopsy, amniocentesis) require advance ORR approval. Before ORR can approve, data must be collected on the SMR form and submitted to ORR by the care provider program (*e.g.,* care provider program's contact information, child demographics, authorized consenter, unification status) and the lead surgeon (*e.g.,* reason for the procedure, potential risks/complications/adverse outcomes if the procedure is not performed, timing, recovery timeframe, planned follow-up procedures, hospital points of contact). ORR will waive the completion of the SMR form if it is deemed to be in the best interest of the child (*e.g.,* during a hospitalization or emergency department visit, related to a medical emergency).

The form is used as a worksheet for care provider program staff and surgeons to compile information that would otherwise have been collected during the health evaluation. Once completed, care provider program staff upload the form and supporting documentation into ORR's secure, electronic data record system and send an email notification to ORR staff that the SMR packet is ready for review.

ORR has incorporated changes to the form to streamline the flow of data collection, clarify intent and purpose of the form and fields, improve data quality, and ensure alignment with ORR program policies. The overall estimated time per form has increased by 1 minute and has been adjusted to reflect a decrease by 1 minute for care provider program staff and an increase by 2 minutes for surgeons.

Respondents: Care provider program staff, surgeons.

Annual Burden Estimates

There are currently about 250 programs that use the SMR form. Over the past 2 years, an annual average of 115 SMR forms were submitted across all programs. For each form, a care provider program staff member completes page 1, and a surgeon completes pages 2 and 3.

ESTIMATED REPORTING TIME FOR RESPONDENTS

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SMR Form	Care Provider Program Staff.	250	1.38	.07	24.15	8
	Surgeons	250	1.38	.17	58.65	20
Total Annual Burden Estimate.						28

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SMR Form	Care Provider Program Staff	250	1.38	.08	27.6	9

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: 6 U.S.C 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno*, Attorney General of the United States, et al., Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–19795 Filed 9–12–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0558]

Determination That Oxandrin (Oxandrolone) Tablets, 2.5 Milligrams and 10 Milligrams, Were Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that Oxandrin (oxandrolone) tablets, 2.5 milligrams (mg) and 10 mg, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg.

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–3600, *Alexandria.Fujisaki@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 (§ 314.162 (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.

The anabolic steroid Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, is the subject of NDA 013718, held by Gemini Laboratories LLC (Gemini), and initially approved on July 21, 1964 (for the 2.5 mg strength) and November 5, 2001 (for the 10 mg strength). Oxandrin is indicated as follows: ''as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.'' [1]

In a letter dated March 26, 2019, Gemini requested that FDA withdraw approval of NDA 013718 for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, under § 314.150(c) (21 CFR 314.150(c)), stating that the product was no longer being marketed. Subsequently, on December 16, 2022, FDA notified Gemini that the Agency believes a potential problem associated with oxandrolone tablets is sufficiently serious that the drug product should be removed from the market, and to enable withdrawal of approval of its application under § 314.150(d). After FDA notified Gemini that it believes the potential problems associated with the drug are sufficiently serious that the drug should be removed from the market pursuant to § 314.150(d), Gemini requested in a letter dated December 19, 2022, that FDA withdraw approval of NDA 013718 for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg under § 314.150(d). In the **Federal Register** of June 28, 2023 (88 FR 41970), FDA announced that it was withdrawing approval of NDA 013718, effective June 28, 2023.

Novitium Pharma LLC submitted a citizen petition dated April 6, 2022 (Docket No. FDA–2022–P–0558), under 21 CFR 10.30, requesting that the Agency determine whether Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg,

[1] See Oxandrin (oxandrolone) tablets product labeling (NDA 013718, supplement 023), approved on June 20, 2005, available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/013718s023lbl.pdf.*