ESTIMATED BURDEN—ONGOING REQUESTS

Instrument	Number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Annual burden (in hours)
Annual Data Collection on Sexual Abuse and Sexual Harassment Involving Unaccompanied Children	200	1	1.5	300
Community Services Block Grant (CSBG) Training and Technical Assistance Tracking Form	20	4	0.75	60
Community Services Block Grant (CSBG) Work Plan Template	20	1	3.25	65
Office of Head Start Child Incident Reporting	1,000	4.8	0.167	800
Office of Head Start Improper Payment Reviews	300	2	3	1,800
Office of Refugee Resettlement (ORR) Refugee Microenterprise Development (MED) Program Case File Requirements	30	1	20	600
Office of Refugee Resettlement Refugee Microenterprise Development (MED) Program Pre-Monitoring Questionnaire (PMQ)	15	1	5	75
Office of Refugee Resettlement (ORR) Care Provider Healthcare Delivery Report (HDR)	225	1	1.50	338
Office of Refugee Resettlement Emergency Operations Plan Survey	200	0.33	0.74	49.5
Tribal MIECHV Nutrition One-Time Supplemental Funding Monitoring Supplement	53	1	.75	40
Total Annual Ongoing Burden	2,063			4,127

Based on the past 3 years and with a goal to reduce burden moving forward the estimated annual burden for potential new requests is 31 percent less than the currently approved umbrella generic.

ESTIMATED BURDEN—FUTURE REQUESTS

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
New Program Monitoring Forms	2,000	3	1.85	11,100

Authority: ACF monitors award performance through a combination of financial and programmatic requirements, including: 31 U.S.C. 503; 31 U.S.C. 6101–6106; 31 U.S.C. 6307; 31 U.S.C. 7501–7507.

This generic is related to and will be of use to all ACF program offices that award federal funds (*e.g.,* grants, cooperative agreements) and monitor activities related to funding. Each individual program use will be related to a specific statutory authority.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–14795 Filed 7–21–26; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1849]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notifications Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 21, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. [*Note to drafter: choose one of these statements. If there is a complete (8 digit) OMB control number, state:* ''The OMB control number for this information collection is 0910–0120. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notifications Submission 510(k),—21 CFR, Part 807 Subpart E

OMB Control Number 0910–0120—Extension

This information collection helps support implementation of statutory provisions that govern premarket clearance of devices. Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), establish premarket notification procedures. Persons who intend to market a medical device, for which a premarket approval application (PMA) is not required, must submit a premarket notification to FDA, unless the device is exempt from 510(k) requirements and does not exceed the limitations of exemptions of the device classification regulations, at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device. If a device is determined to be not substantially equivalent to a legally marketed device, it must have an approved PMA, product development protocol, humanitarian device exemption (HDE), request for an evaluation of automatic class III designation (De Novo request), or be reclassified into class I or class II before being marketed. The information collection also helps support section 510(l) of the FD&C Act, which provides for exemption from premarket notification.

The following instruments are included in the information collection:

- Form FDA 3514, ''CDRH Premarket Review Submission Cover Sheet''
- Form FDA 3881, ''Indications for Use''
- Voluntary eSTAR Program Interactive PDF Form and instructional web page
- Form FDA 4062, ''Electronic Submission Template and Resource (eSTAR)'' (for non-In Vitro Diagnostic (IVD) 510(k) submissions)
- Form FDA 4078, ''Electronic Submission Template and Resource (eSTAR)'' (for In Vitro Diagnostic (IVD) 510(k) submissions)

We are revising the information collection to include Form FDA 3674, ''Certification of Compliance, Under 42 U.S.C., 282(j)(5)(B), with Requirements of *ClinicalTrials.gov.* '' Under applicable authorities, applications under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the Public Health Service Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act, must be accompanied by a certification. Where available, such certification must include the appropriate National Clinical Trial numbers.

The information collection also includes an ''Acceptance Checklist.'' As discussed in the guidance document ''Refuse to Accept Policy for 510(k)s'' (April 2022), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks,* we believe the checklist can be a helpful resource for 510(k) submitters and may simplify preparation of the 510(k). Similarly, the guidance document ''Recognition and Withdrawal of Voluntary Consensus Standards'' (September 2020), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards,* communicates procedures followed by the Center for Devices and Radiological Health (CDRH) when requests for recognition of a voluntary consensus standard for medical products are received. The guidance document outlines principles for recognizing a standard wholly, partly, or not at all, as well as reasons and rationales for withdrawing a standard. Section 514 of the FD&C Act (21 U.S.C. 360d) allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions, including premarket notifications or other requirements. We publish and update the list of recognized standards regularly at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* As instructed in the guidance document, any interested party may submit a request for recognition of a standard by mail directed to the CDRH Standards Program (*i.e.,* paper copy) or electronically via email.

For efficiency of Agency operations, we are also revising the information to include activities associated with section 520(b) of the FD&C Act, governing custom devices. Regulations in 21 CFR 812.3 define a custom device and implementing regulations in 21 CFR 807.85 provide for exemption from premarket notification. Section 520(b) of the FD&C Act also provides for the issuance of guidance. The guidance document entitled, ''Custom Device Exemption'' (September 2014), and available for download at *https://www.fda.gov/media/89897/download,* explains how FDA interprets provisions in section 520(b)(2)(B) of the FD&C Act, describes what information should be submitted in a Custom Device Annual Report (''annual report''), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption.

Finally, we discuss the guidance document entitled, ''Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency,'' announced in the **Federal Register** of March 27, 2023 (88 FR 18153), which describes a phased approach intended to help avoid disruption in device supply and help facilitate compliance with applicable legal requirements. The recommendations discussed in the guidance document result in the one-time collection of information intended to ensure an orderly and transparent transition from temporary policies established during the COVID–19 public health emergency to normal operations. Because the information collection recommendations apply to specific medical devices already in distribution, we believe the information discussed is appropriately characterized as nonstandardized followup designed to clarify responses to approved collections of information (*i.e.,* plans for compliance with applicable requirements unique to that distributed device). We therefore believe the activity constitutes the collection of non-identical and/or followup information, as defined under 5 CFR 1320.3. At the same time, we expect some degree of fluctuation in future submissions under part 807, subpart E, as a result of implementation of the medical device transition plan.

In the **Federal Register** of March 19, 2026 (91 FR 13310), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity and 21 CFR Part/Section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 CFR Part 807, Subpart E, PREMARKET NOTIFICATION PROCEDURES						
510(k) submission (807 subpart E)	FDA 3881	3,800	1	3,800	79.25	301,150
Summary cover sheet (807.87)	FDA 3514	1,906	1	1,906	0.5 (30 minutes)	953
Status request (807.90(a)(3))		1	1	1	0.25 (15 minutes)	1
510(k) summary (807.92)		2,742	1	2,742	4	10,968
510(k) statement (807.93)		130	1	130	0.08 (5 minutes)	10
510(k) submission (807 subpart E)—using eSTAR format.	FDA 4062, FDA 4078	3,800	1	3,800	40	152,000
Guidance Document Recommendations:						
Request for recognition of a voluntary consensus standard.		5	1	5	1	5
Annual reporting for custom devices under 520(b) of the FD&C Act.		31	1	31	40	1,240
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"						
Certification to accompany 510(k) submissions.	FDA 3674	3,800	1	3,800	0.75 (45 minutes)	2,850
Electronic Submission Template and Resource (eSTAR)						
eSTAR setup—one-time burden		80	1	80	0.08 (5 minutes)	6
Total				16,295		469,183

The information collection reflects program changes and adjustments. We have also made nominal adjustments on individual provisions to reflect expected fluctuations in submissions. Cumulatively these actions result in an overall increase of 145,804 hours and a corresponding increase of 3,625 responses annually. The increase was attributed to the 510(k) submissions increase from 100 to 3,800.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14707 Filed 7–21–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4232]

Determination That RASUVO (Methotrexate) Solution, 27.5 Milligrams/0.55 Milliliter (27.5 Milligrams/0.55 Milliliter), Was 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, Agency, or we) has determined that RASUVO (methotrexate) solution, 27.5 milligrams (mg)/0.55 milliliter (mL) (27.5 mg/0.55 mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@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 (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.

RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), is the subject of NDA 205776, held by Medexus Pharma, Inc., and initially approved on July 10, 2014. RASUVO is a folate analog metabolic inhibitor indicated for the management of patients with severe, active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis who are intolerant of or had an inadequate response to first-line therapy, and for symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not