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That RASUVO (Methotrexate) Solution, 27.5 Milligrams/0.55 Milliliter (27.5 Milligrams/0.55 Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that RASUVO (methotrexate) solution, 27.5 milligrams (mg)/0.55 milliliter (mL) (27.5 mg/0.55 mL), was not withdrawn from sale for reasons of safety or effectiveness.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

adequately responsive to other forms of therapy.

RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated April 15, 2026 (Docket No. FDA–2026–P–4232), under 21 CFR 10.30, requesting that the Agency determine whether RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), has been voluntarily withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list RASUVO (methotrexate) solution, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to RASUVO (methotrexate) Injection, 27.5 mg/0.55 mL (27.5 mg/0.55 mL), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Advanced Nursing Education Program Specific Form OMB No. 0906–0089—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 21, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Advanced Nursing Education (ANE) Program Specific Form OMB No. 0906–0089—Revision

Abstract: HRSA provides advanced nursing education grants to educational institutions to increase the supply, distribution, quality of, and access to advanced education nurses through the Advanced Nursing Education (ANE) Programs. The ANE Programs are authorized by Section 811 of the Public Health Service (PHS) Act (42 U.S.C. 296j), as amended. This clearance request is for continued approval of the information collection OMB No. 0906–0089 with revisions.

The proposed revision to Table 2 of the ANE Program Specific Form is to remove the Part-Time column under the Nurse Midwife and Nurse Anesthetist specialty headers. This change reflects current program requirements, as these programs support only full-time trainees. This requirement applies to all trainees enrolled in either master's or doctoral programs. Because part-time enrollment is not an eligible training status under these programs, the Part-Time column is unnecessary and minimizes confusion for applicants.

Need and Proposed Use of the Information: Section 811 of the PHS Act provides the Secretary of Health and Human Services with the authority to award grants to and enter into contracts with eligible entities to meet the costs of: (1) projects that support the enhancement of advanced nursing education and practice; and (2) traineeships for individuals in advanced nursing education programs. Under this section, HRSA makes awards to entities who train and support nurses characterized as ''advanced education nurses.'' Section 805 of the PHS Act (42 U.S.C. 296d) requires that in awarding such grants, a statutory funding preference is given to ''applicants with projects that will substantially benefit rural or medically underserved populations or help meet public health nursing needs in state or local health departments.'' For traineeship awards, PHS Act section 811(h)(2) requires special consideration be given to an eligible entity that agrees to expend the award to train advanced education nurses who will practice in designated Health Professional Shortage Areas.

The ANE Program Specific Form allows HRSA to effectively target funding and measure the impact of the ANE Programs in meeting the legislative intent and program goals of supporting the enhancement of advanced nursing education and creating opportunities for individuals in advanced nursing education programs to increase the number of advanced practice nurses, especially in rural and medically underserved areas. Additionally, collecting this data assists HRSA in carrying out the most impactful program and ensuring resources are used responsibly.

Likely Respondents: Likely respondents will be current ANE Programs awardees and new applicants to ANE Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose