SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that TOLECTIN DS (tolmetin sodium) capsule, equivalent to (EQ) 400 milligrams (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for tolmetin sodium, capsule, EQ 400 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@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, 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, is the subject of NDA 018084, held by Ortho-McNeil-Janssen Pharmaceuticals, Inc., and initially approved on October 30, 1979. TOLECTIN DS is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis. TOLECTIN DS is indicated in the treatment of acute flares and the long-term management of the chronic disease. TOLECTIN DS is also indicated for treatment of juvenile rheumatoid arthritis. The safety and effectiveness of TOLECTIN DS have not been established in pediatric patients under 2 years of age.

In a letter dated May 29, 2008, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., on behalf of Ortho-McNeil-Janssen Pharmaceuticals, Inc., requested withdrawal of NDA 018084 for TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base. In the **Federal Register** of June 8, 2011 (76 FR 33310), FDA announced that it was withdrawing approval of NDA 018084, effective July 8, 2011.

Senores Pharmaceuticals, Inc., submitted a citizen petition dated September 5, 2025 (Docket No. FDA–2025–P–3575), under 21 CFR 10.30, requesting that the Agency determine whether TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, was withdrawn from sale 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 TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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 TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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 TOLECTIN DS (tolmetin sodium) capsule, EQ 400 mg base, 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.

[FR Doc. 2026–03213 Filed 2–17–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0308]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emerging Drug Safety Technology Program

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 March 20, 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. The title of this information collection is ''Emerging Drug Safety Technology Program.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–1244, *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.

Emerging Drug Safety Technology Program

OMB Control Number 0910-New

FDA has a longstanding commitment to ensure medicines marketed in the United States are safe through continued surveillance and research following approval. In the postmarket setting, regulated industry (per 21 CFR 314.80, 314.98, and 600.80) is obligated to review all adverse drug experience information received or otherwise obtained and submit reports to FDA. Both industry and regulatory authorities face challenges with timely and efficient collection, processing, and evaluation of single and aggregate patient safety data compounded by ever-increasing case volumes. Advances in emerging technology have the potential to address some of these challenges by creating more efficiencies within a pharmacovigilance (PV) surveillance system. The pharmaceutical industry is expanding its use of artificial intelligence (AI) and other emerging technologies across the drug product lifecycle, including PV.

FDA is interested in accelerating its understanding of how AI-enabled tools and other emerging technologies are being used for PV, their associated risks and benefits, model evaluation processes (including performance characteristics), and barriers to implementation. The Emerging Drug Safety Technology Program (EDSTP) [1] is a means by which applicants and/or other relevant parties who meet the eligibility and selection criteria for participation can meet with the Center for Drug Evaluation and Research (CDER), through Emerging Drug Safety Technology Meetings (EDSTMs), to share information about their use of AI and other emerging technologies, and their potential applications in post-market PV.

The initial phase of the EDSTP was announced in the **Federal Register** on June 11, 2024 (89 FR 49179). Since then, CDER has received numerous meeting requests and inquiries from the pharmaceutical industry and other relevant parties, seeking to discuss their latest applications of emerging technologies in PV. The requests represent a diverse set of use cases that are of interest to the Agency. Given the current level of interest in the program expressed by respondents, FDA anticipates an increase in the number of meetings granted to expand the Agency's understanding of how AI-enabled tools and other emerging technologies are being used in PV.

The purpose of the EDSTMs is to facilitate discussion and mutual learning of the pharmaceutical industry's application of these technologies in PV. If selected for a meeting, participants will meet with CDER staff to discuss their research, development, and/or use of AI and other emerging technologies in PV. FDA plans to leverage these learnings to help inform potential regulatory and policy approaches around the use of AI and other emerging technologies in PV.

The EDSTP will collect information for the following purposes: (1) serve as the central point of contact for dialogue between industry and CDER on the use of AI and other emerging technologies in PV; (2) enable knowledge management and transfer within FDA specific to the context of use for AI or other emerging technologies in PV; and (3) further thinking about policy and application of potential regulatory approaches within the landscape of AI and other emerging technologies.

Respondents include applicants with at least one approved application regulated by CDER and/or other relevant parties supporting industry's PV activities (*e.g.,* academia, contract research organizations (CROs), PV vendors, software developers) who develop, leverage, or intend to leverage AI or other emerging technologies that can be used to satisfy the postmarketing reporting requirements in 21 CFR 314.80, 314.98, and 600.80.

Respondents will provide an initial submission to FDA detailing their meeting proposal. We estimate this will require 10 hours to prepare. If selected for participation in an EDSTM, the respondent will need to prepare and deliver a 20–50 minute presentation, which will require an additional burden of 30 hours. FDA estimates 25 organizations will submit requests to present at EDSTMs per year, and 12 meetings will be held per year.

In the **Federal Register** of July 3, 2025 (90 FR 29561) FDA published a 60-day notice soliciting comment on the proposed collection of information. FDA received one comment. The submitter provided supportive comments of the FDA's EDSTP. However, the one comment was not responsive to the four collection of information topics solicited and therefore will not be further discussed in this document.

FDA estimates the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Industry request to give presentation at EDSTM	25	1	25	10	250
Industry preparing and delivering presentation at EDSTM after the request has been granted	12	1	12	30	360
Total	.....	.....	37	.....	610

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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