

reporting requirements directing persons to notify FDA if they intend to use a form of advertising or labeling that is not addressed in the regulations. Section 1140.30(a)(2) requires tobacco product manufacturers, distributors, and retailers to notify FDA if they intend to use advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in section 1140.30(a)(1). The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The notifications must be made 30 days prior to the use of such media.

We allow electronic and written submission of these notifications. Respondents can mail notifications as prescribed in section 1140.30(a)(2) to FDA. Instructions providing clarification on how to format the notification may be found in the guidance document entitled "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (2013) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-regulations-restricting-sale-and-distribution-cigarettes-and-smokeless-tobacco-protect>).

In the **Federal Register** of August 22, 2024 (90 FR 41085), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received four

comments. Two comments were responsive to the Paperwork Reduction Act (PRA) information collection topics solicited. Two comments were not responded to the PRA and will not be addressed here.

The comments generally supported FDA's collection of information. The comments supported FDA's maintaining oversight related to youth tobacco access through the regulatory provision related to this collection, encouraged the FDA to enhance transparency of this collection by clearly providing better explanation about how retailer and manufacturer data is analyzed and used for enforcement or policy interventions, and recommended expanding digital tools and providing plain language guidance materials in multiple languages to minimize administrative burden and help retailers understand submission requirements.

The comments also believed FDA has underestimated burden and suggested that there were ways to improve the collection by providing standardized submission templates, clearer definitions of unlisted media, illustrative examples, clarification of material changes requiring new notices, and different ways to provide supporting documentation. The comments believe FDA should provide target review and timelines and should implement an electronic submission portal, accept machine-readable attachments, allow consolidated annual or semiannual notification, provide a

fillable submission template, and establish a safe-harbor correction window.

In response, FDA thanks the commenters and agrees that this information collection has practical utility and is necessary for the proper performance of FDA's functions. Regarding burden estimates, FDA encourages detailed information be submitted and acknowledges burden for each respondent to the collection could vary and that it may take some respondents longer to complete the requirements than others. FDA tries to minimize burden by efficiently collecting information without compromising FDA's ability to identify and address violations by providing options to comply and allowing both electronic and mail submission of information. FDA believes that the average burden estimates per response are sufficient. FDA is always open to improve the quality, utility, and clarity of information we collect, and offers guidance regarding the types of information that should be included with a cover letter describing the information. FDA also provides a clear list of media that should be provided and options for providing supporting documentation and notes that any notification returned to the submitter is not intended to imply that prior approval is required before use of a medium.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30(a)(2)—Notification of other advertising or labeling medium .....	4	1	4	1	4
Total .....	.....	.....	.....	.....	4

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on submissions regarding cigarette and smokeless tobacco product advertising expenditures. FDA has received 12 such notifications to date since 2022. Based on a review of the information collection and the number of notifications received since 2022, FDA estimates that approximately four respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take one hour to provide such notice. Therefore, our estimated burden for the information collection reflects an

overall decrease of 21 hours and a corresponding decrease of 21 responses.

**Grace R. Graham,**  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2025-P-3575]

**Determination That TOLECTIN DS (Tolmetin Sodium) Capsule, Equivalent to 400 Milligrams Base, 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 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](mailto: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.*

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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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).