form at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032* and identify which topic(s) you wish to address. All requests to make a public comment during the meeting must be received by September 2, 2026, 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and plan to select and notify participants by September 9, 2026. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: When available, the virtual link to the hybrid public meeting will be posted on FDA's public web page at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032.* FDA will also distribute the link via email to registered attendees.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16650 Filed 8–13–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–3166]

Determination That ANSAID (Flurbiprofen) Tablets, 50 Milligrams and 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA, Agency, or we) has determined that ANSAID (flurbiprofen) tablets, 50 milligrams (mg) and 100 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for flurbiprofen tablets, 50 mg and 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Arndt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6281, Silver Spring, MD 20993–0002, *Molly.Arndt@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.

ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, are the subject of NDA 018766, held by Pharmacia and Upjohn Company, and initially approved on October 31, 1988. ANSAID is indicated for relief of the signs and symptoms of rheumatoid arthritis, and relief of the signs and symptoms of osteoarthritis.

ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of October 4, 2016 (81 FR 68427), FDA announced that it was withdrawing approval of NDA 018766, effective November 3, 2016.

Premier Research International, LLC submitted a citizen petition dated March 25, 2026 (Docket No. FDA–2026–P–3166), under 21 CFR 10.30, requesting that the Agency determine whether ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, were 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 ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, 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 ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, 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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