Qualitative Feedback on Agency Service Delivery, in all correspondence.

Lois Mandell,

Director, Regulatory Secretariat Division, General Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0515]

Determination That FLUMADINE (Rimantadine Hydrochloride) Tablet, 100 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA, the Agency, or we) has determined that FLUMADINE (rimantadine hydrochloride) tablet, 100 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

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 generally known 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FLUMADINE (rimantadine hydrochloride) tablet, 100 mg, is the subject of NDA 019649, held by Sun Pharmaceutical Industries Inc. (Sun Pharma), and initially approved on September 17, 1993. FLUMADINE is indicated for the prophylaxis and treatment of illness caused by various strains of influenza A virus in adults (17 years and older) and for prophylaxis against influenza A virus in children (1 year to 16 years of age).

In a letter dated November 27, 2023, Sun Pharma notified FDA that FLUMADINE (rimantadine hydrochloride) tablet, 100 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FLUMADINE (rimantadine hydrochloride) tablet, 100 mg, was not withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FLUMADINE (rimantadine hydrochloride) tablet, 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 this drug product was not withdrawn for sale for reasons of safety or effectiveness.[1]

Accordingly, the Agency will continue to list FLUMADINE (rimantadine hydrochloride) tablet, 100 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to FLUMADINE. Additional ANDAs that refer to FLUMADINE (rimantadine hydrochloride) tablet, 100 mg, may be approved by the Agency if they comply with relevant legal and regulatory requirements. 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.

Dated: March 28, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0168]

Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids; Request for Information; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a request for information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to

[1] Due to high levels of adamantane resistance among circulating influenza A viruses, the Centers for Disease Control and Prevention currently states on its website that adamantanes (amantadine and rimantadine) are not recommended for antiviral treatment or chemoprophylaxis of currently circulating influenza A virus strains. Consistent with this, the current label for FLUMADINE (rimantadine hydrochloride), 100 mg tablet, was revised to caution prescribers to consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use FLUMADINE.