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### Determination That FLUMADINE (Rimantadine Hydrochloride) Tablet, 100 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA, the Agency, or we) has determined that FLUMADINE (rimantadine hydrochloride) tablet, 100 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness.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.*

[FR Doc. 2025–06050 Filed 4–8–25; 8:45 am]

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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.

reduce the opiate alkaloid content of poppy seeds. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments. We intend to use the information to help determine what type(s) of actions, if any, we should take to help ensure that poppy seed products do not pose a health risk when consumed.

**DATES:** FDA is extending the comment period on the notice published January 15, 2025 (90 FR 3873). Either electronic or written comments on the notice must be submitted by June 16, 2025.

**ADDRESSES:** You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2021–P–0168 for ''Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

**FOR FURTHER INFORMATION CONTACT:** Jesse Lunzer, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2879.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 15, 2025 (90 FR 3873), we published a notice requesting information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to reduce the opiate alkaloid content of poppy seeds. We intend to use the information to help determine what type(s) of actions, if any, we should take to help ensure that poppy seed products do not pose a health risk when consumed. We provided a 90-day comment period for the request for information.

We have received requests for a 90-day extension of the comment period. In general, the requests explained that industry needed more time to collect, review, and summarize the information requested for the global supply chain.

We have considered the requests and are extending the comment period for an additional 60 days. We believe that this extension will allow adequate time for interested persons to submit comments.

Dated: March 28, 2025.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

[FR Doc. 2025–06049 Filed 4–8–25; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–5925]**

### 21st Century Cures Act: Annual Compilation of Notices of Updates From the Susceptibility Test Interpretive Criteria Web Page; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of the Agency's annual compilation of notices of updates to the Agency's Susceptibility Test Interpretive Criteria web page. The Agency established the Susceptibility Test Interpretive Criteria web page on December 13, 2017, and