

information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than April 24, 2025.

*A. Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President), 230 South LaSalle Street, Chicago, Illinois 60690-1414.

Comments can also be sent electronically to

*Comments.applications@chi.frb.org:*

1. *Monica Anderegg, individually and as trustee of the Charles L. Sarazine Family Trust for Monica Anderegg, all of Edina, Minnesota; Lisa Elsenbast, individually and as trustee of the Charles L. Sarazine Family Trust for Lisa Elsenbast, all of Minneapolis, Minnesota; Annette Sarazine-Jensen, individually and as trustee of the Charles L. Sarazine Family Trust for Annette Sarazine-Jensen, all of Gretna, Nebraska; Julia T. Sarazine, Thomas Gorey, both of Chicago, Illinois; Frank Elsenbast, Minneapolis, Minnesota; Monte Jensen, Gretna, Nebraska; Rachel S. Jensen-Blackwell, Seward, Nebraska; and Reid C. Jensen, Fridley, Minnesota;* to join the Sarazine Family Control Group, a group acting in concert, to retain voting shares of Emmetsburg Bank Shares, Inc., and thereby indirectly retain voting shares of Iowa Trust and Savings Bank, both of Emmetsburg, Iowa.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2025-06078 Filed 4-8-25; 8:45 am]

**BILLING CODE P**

## GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0297; Docket No. 2025-0001; Sequence No. 7]

### Information Collection; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

**AGENCY:** General Services Administration (GSA).

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

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be

submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding the Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

**DATES:** Submit comments on or before June 9, 2025.

**ADDRESSES:** Submit comments identified by Information Collection 3090-0297 via <https://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for “Information Collection 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.” Select the link “Submit a Comment” that corresponds with “Information Collection 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “Information Collection 3090-0297” on your attached document.

**Instructions:** Please submit comments only and cite Information Collection 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two-to-three days after submission to verify posting.

#### FOR FURTHER INFORMATION CONTACT:

Camille Tucker, Office of Governmentwide Policy, GSA, at 202-255-1648, or via email at [customer.experience@gsa.gov](mailto:customer.experience@gsa.gov).

#### SUPPLEMENTARY INFORMATION:

##### A. Purpose

The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention

on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance.

Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study.

Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

##### B. Annual Reporting Burden

*Respondents:* 1,010,650.

*Responses per Respondent:* ~1.

*Total Annual Responses:* 1,010,650.

*Hours per response:* ~.063445 hours.

*Total Burden hours:* 128,120.

##### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

##### Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. 3090-0297, Generic Clearance for the Collection of

Qualitative Feedback on Agency Service Delivery, in all correspondence.

**Lois Mandell,**

*Director, Regulatory Secretariat Division,  
General Services Administration.*

[FR Doc. 2025–06029 Filed 4–8–25; 8:45 am]

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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](mailto: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.<sup>1</sup>

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

<sup>1</sup> 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.