



October 22, 2025

William Vogt
 Director, Global Regulatory Sciences
 Pfizer Inc.
 66 Hudson Boulevard East
 New York, NY 10001

Re: Revocation of EUA220490

Dear William Vogt:

This letter is in response to the request from Pfizer Inc., in a letter dated October 10, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira by Pfizer COVID-19 & Flu Home Test issued on February 24, 2023, revised and reissued on June 15, 2023, and amended on March 22, 2023, August 3, 2023, and September 6, 2023. FDA understands that as of the date of this letter there is no viable Lucira by Pfizer COVID-19 & Flu Home Test reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Pfizer Inc. has requested that FDA revoke the EUA for the Lucira by Pfizer COVID-19 & Flu Home Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220490 for the Lucira by Pfizer COVID-19 & Flu Home Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira by Pfizer COVID-19 & Flu Home Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

Ellen J.
 Flannery -S

Digitally signed by Ellen J.
 Flannery -S
 Date: 2025.10.22 14:19:05
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Ellen J. Flannery, J.D.
 Deputy Center Director for Policy
 Director, Office of Policy
 Center for Devices and Radiological Health
 Food and Drug Administration

Lowell M. Zeta,

*Acting Deputy Commissioner for Policy,
 Legislation, and International Affairs.*

[FR Doc. 2025-24155 Filed 12-31-25; 8:45 am]

BILLING CODE 4164-01-C

**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2022-P-3118]

**Determination That MYSOLINE
 (Primidone) Suspension, 250
 Milligrams/5 Milliliters, Was Withdrawn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 MYSOLINE (primidone) suspension, 250 milligrams (mg)/5 milliliters (mL), was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for primidone suspension, 250 mg/5 mL.

FOR FURTHER INFORMATION CONTACT:
 Aaron Young, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993-0002, 301-796-8083, aaron.young@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.

MYSOLINE (primidone) suspension, 250 mg/5 mL, is the subject of NDA 010401, held by FHTA LLC, and initially approved on July 5, 1956. MYSOLINE, used alone or concomitantly with other anticonvulsants, is indicated in the control of grand mal, psychomotor, and focal epileptic seizures. It may control grand mal seizures refractory to other anticonvulsant therapy.

MYSOLINE (primidone) suspension, 250 mg/5 mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated

December 8, 2022 (Docket No. FDA-2022-P-3118), under 21 CFR 10.30, requesting that the Agency determine whether MYSOLINE (primidone) suspension, 250 mg/5 mL, 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 MYSOLINE (primidone) suspension, 250 mg/5 mL, was withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MYSOLINE (primidone) suspension, 250 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MYSOLINE (primidone) suspension, 250 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

MYSOLINE (primidone) suspension, 250 mg/5 mL, was discontinued in 2001 after antimicrobial effectiveness testing raised concerns about potential microbial contamination, in particular with *Pseudomonas aeruginosa*. As a scientific matter, before MYSOLINE (primidone) suspension, 250 mg/5 mL, could be considered for reintroduction to the market, a reformulation would be required including establishment of preservative content acceptance criteria and correlation with passing antimicrobial effectiveness testing results. The NDA holder for MYSOLINE (primidone) suspension, 250 mg/5 mL, would have to demonstrate the safety and effectiveness of the reformulated product. At this time, no new formulation has been approved for MYSOLINE (primidone) suspension, 250 mg/5 mL.

Accordingly, under § 314.162 the Agency will remove MYSOLINE (primidone) suspension, 250 mg/5 mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-24196 Filed 12-31-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: Pipeline Corporate Security Reviews and TSA Security Directive Pipeline-2021-02 Series

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0056, abstracted below, to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection allows TSA to assess the current security practices in the pipeline industry through TSA’s Pipeline Corporate Security Review (CSR) program and allows for the continuation of mandatory cybersecurity requirements under the TSA Security Directive (SD) Pipeline-2021-02 series.

DATES: Send your comments by February 2, 2026. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” and by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology, TSA-11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598-6011; telephone (571) 227-2062; email TSAPRA@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 1, 2025, 90 FR 36169. TSA did not receive any comments on the notice.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501