

requesting that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements of its Rule Governing Pre-Sale Availability of Written Warranty Terms. The current clearance expires on July 31, 2026.

DATES: Comments must be received by July 22, 2026.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the **SUPPLEMENTARY INFORMATION** section below. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection and its accompanying supporting statement by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. The reginfo.gov web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB’s Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: Sung W. Kim, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, (202) 326–2211; skim6@ftc.gov.

SUPPLEMENTARY INFORMATION:

Title: Pre-Sale Availability of Written Warranty Terms (Pre-Sale Availability Rule or Rule), 16 CFR part 702.

OMB Control Number: 3084–0112.

Type of Review: Extension of currently approved collection.

Affected Public: Businesses and other for-profit entities.

Estimated Annual Burden Hours: 2,611,826 hours (143,721 hours for manufacturers + 2,468,105 hours for retailers).

- Manufacturers account for approximately 143,721 hours (26,131 manufacturers × 5.5 hours)
- Retailers account for approximately 2,468,105 hours (493,621 retailers × 5.0 burden hours)

Estimated Annual Labor Costs: \$74,437,041 (which is derived from \$39,177,390 for sales associates + \$35,259,651 for clerical workers)¹

¹ This estimate is updated from the prior estimate of \$73,131,128 that was included in the 60-day Federal Register notice and is based on more current information from the Bureau of Labor

• *Sales Associates:* 1,305,913 hours × \$30/hour = \$39,177,390

• *Clerical Workers:* 1,305,913 hours × \$27/hour = \$35,259,651

Estimated Annual Non-Labor Costs: *De minimis.*

Abstract

The Pre-Sale Availability Rule, 16 CFR part 702 (Pre-Sale Availability Rule or Rule) requires sellers and warrantors to make the text of any written warranty on a consumer product costing more than \$15 available to the consumer before sale. The Rule has no recordkeeping or reporting requirements. On March 30, 2026, the Commission sought comment on the disclosure requirements associated with the Rule. 91 FR 15616. No relevant comments were received.

Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.*, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the information collection requirements associated with this Rule.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas,

Statistics. See Table 1. National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2025, at <https://www.bls.gov/news.release/ocwage.t01.htm>, which was made publicly available on May 15, 2026.

patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2026–12503 Filed 6–18–26; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6402]

Epizyme, Inc.; Withdrawal of Approval of New Drug Application for TAZVERIK (Tazemetostat) Tablet, 200 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) for TAZVERIK (tazemetostat) tablet, 200 milligrams (mg), held by Epizyme, Inc., an Ipsen Company (Epizyme), 1 Main St., Cambridge, MA 02142. Epizyme has voluntarily requested withdrawal of its NDA and has waived the expedited withdrawal procedures.

DATES: Approval is withdrawn as of June 22, 2026.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On January 23, 2020, FDA approved NDA 211723 for TAZVERIK (tazemetostat) tablet, 200 mg, for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection, under the Agency’s accelerated approval pathway pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)) and 21 CFR 314.510. On June 18, 2020, FDA approved the following two new indications for TAZVERIK (tazemetostat) tablet, 200 mg,¹ also

¹ The indications approved for TAZVERIK (tazemetostat) tablet on June 18, 2020, were approved under a Type 9 NDA, 213400 (Manual of Policies and Procedures 5018.2 NDA Classification Codes). This NDA was administratively closed at approval and the indications and all regulatory requirements were inherited by the parent NDA, 211723. TAZVERIK (tazemetostat) tablets were only marketed with these indications under NDA 211723.

under the accelerated approval pathway pursuant to section 506(c) of the FD&C Act and § 314.510:

- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies.
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

The accelerated approval of TAZVERIK (tazemetostat) tablet, 200 mg, for all three indications was subject to the requirement that Epizyme conduct postmarketing trials to verify and describe the clinical benefit.

On March 6, 2026, Epizyme notified FDA of an increased rate of second primary malignancies in the TAZVERIK (tazemetostat) tablet, 200 mg, arm of SYMPHONY-1 (EZH-302), the clinical trial required to confirm the clinical benefit of the two follicular lymphoma indications. SYMPHONY-1 evaluated TAZVERIK (tazemetostat) tablet, 200 mg, in combination with lenalidomide and rituximab (R²) versus R² plus placebo in patients with relapsed or refractory follicular lymphoma. At the same time, Epizyme notified FDA that it was withdrawing TAZVERIK (tazemetostat) from marketing in the United States. FDA met with Epizyme on April 16, 2026, to discuss their plans for voluntary withdrawal of TAZVERIK (tazemetostat) tablet, 200 mg, from the U.S. market and voluntary withdrawal of approval of the NDA pursuant to 21 CFR 314.150(d). FDA also requested in follow-up correspondence sent on April 20, 2026, that Epizyme waive the expedited withdrawal procedures set forth in section 506(c)(3)(B) of the FD&C Act (21 U.S.C. 356(c)(3)(B)).

On April 30, 2026, Epizyme submitted a letter asking FDA to withdraw approval of NDA 211723 for TAZVERIK (tazemetostat) tablet, 200 mg, under § 314.150(d) and waiving the expedited withdrawal procedures set forth in section 506(c)(3)(B) of the FD&C Act.

For the reasons discussed above, including the increased rate of second primary malignancies in the confirmatory trial, and in accordance with the applicant's request, approval of NDA 211723 for TAZVERIK (tazemetostat) tablet, 200 mg, is withdrawn under § 314.150(d). Distribution of Epizyme's TAZVERIK (tazemetostat) tablet, 200 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections

505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d))).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-12367 Filed 6-18-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

340B Rebate Model Pilot Program Application, Implementation, and Evaluation, Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: HRSA published a 30-day **Federal Register** Notice (FRN) on June 15, 2026, related to the proposed Information Collection Request for the 340B Rebate Model Pilot Program Application, Implementation and Evaluation, which listed 793,080 as the number of total estimated responses. This Notice corrects the number of total responses to 793,091 to reflect inclusion of the 11 manufacturer Pilot Program Plan submissions.

FOR FURTHER INFORMATION CONTACT: Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 15, 2026, FR Doc. 2026-11989, page 35991, correct the total responses in "Table 1: Total Annualized Burden Hours" to 793,091.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026-12442 Filed 6-18-26; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7109-N-10; OMB Control No.: 2577-0295]

60-Day Notice of Proposed Information Collection: Restriction on Assistance to Noncitizens and Authorization To Release Information/Privacy Act

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* August 21, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.regulations.gov. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Eva Fulton, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Eva Fulton, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Eva Fulton at PIH-PRAPublicComments@hud.gov; telephone (202) 402-5847. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Copies of available documents submitted to OMB may be obtained from Eva Fulton.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the