



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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 mg¹, also 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)).

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.

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.
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