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 (R^2) versus R^2 plus placebo in patients with relapsed or refractory follicular lymphoma. At the same time, Epizyme notified FDA that it was withdrawing TAZVERIK (tazmetostat) 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and in accordance with the applicant's request, approval of NDA 211723 for TAZVERIK (tazemetostat) tablet, 200 mg, is withdrawn under § 314.150(d).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]

BILLING CODE 4165–15–P

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