



March 6, 2026

Iilun Murphy, M.D.
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

**RESPONSE TO PREA NON-
COMPLIANCE LETTER**

**DEFERRAL EXTENSION
REQUESTED**

NDA # 216774, Sequence # 0054
Eltrombopag Choline Tablets, Eq. to 9 mg, 18 mg, 36 mg, and 54 mg of Eltrombopag

Dear Dr. Murphy:

Teva Pharmaceuticals, Inc. (Teva) herewith submits a response to [FDA's Notification of Non-Compliance with PREA Letter dated February 6, 2026](#) (provided in **Section 1.11.1**) for the above-referenced, New Drug Application (NDA). Additionally, reference is made to our IND # 139539 for Eltrombopag Choline Tablets, 9 mg, 18 mg, 36 mg, and 54 mg.

In compliance with Pediatric Research Equity Act (PREA), Teva committed to the Agency on September 23, 2022 (**Sequence 0013**) as a Post Marketing Requirement (PMR) to develop an appropriate formulation for Alvaiz (eltrombopag choline) that can be used to directly and accurately administer Alvaiz (eltrombopag choline) to pediatric patients less than 6 years of age, and conduct any necessary human factors studies to evaluate the ability of healthcare providers and/or caregivers to measure and administer the appropriate doses.

Teva is amending the PREA PMR to provide the reasons for the delayed pediatric assessment, and we are additionally providing the dates by which we expect to submit the assessment in **Section 1.17.2** of this submission. Teva has been actively developing an appropriate formulation for Alvaiz (eltrombopag choline) to administer to pediatric patients less than 6 years of age. We submitted an IND update with the pilot study protocol # ACT-23014 on May 24, 2024. However, we received a nonclinical information request from the Agency, to which we responded on August 5, 2024, in which updates were proposed to the drug product specification, drug product analytical test method, and formulation composition. Due to formulation challenges as described below, we were unable to proceed with the pilot study as initially planned by end of 2024. Consequently, we have rescheduled the pilot study to begin in (b) (4). Currently, we are working on updating our pilot study protocol, and the IND will be updated with the final revised pilot protocol by (b) (4).

The Eltrombopag (b) (4) formulation process has faced several hurdles, including (b) (4). These issues necessitated further investigation, (b) (4) to the formulation and manufacturing process. To resolve these challenges, (b) (4).

(b) (4)

Given the complexity of these formulation issues, it's necessary to conduct a pilot study to ensure that the revised formulation and manufacturing process are robust and reliable. The pilot study will help us identify any remaining issues and allow us to make necessary adjustments before proceeding with the pivotal study. This step is vital to ensure the safety and efficacy of the final product.

Based on the reasons provided above and the timeline included in **Section 1.17.2**, Teva is kindly requesting a deferral extension for this PMR 4554-1, until May 31, 2028.

The proposed pediatric specific formulation for Eltrombopag Choline (b) (4) along with new study protocols, IRB approval, and any amendments, will be provided in our above-referenced IND # 139539, in accordance with MAPP 6030.9 *Good Review Practice: Good Review Management Principles and Practices for Effective IND Development and Review*.

This submission has been prepared in eCTD format and is being submitted through the Electronic Submissions Gateway. The contents of this submission are verified to be virus free using Trellix Endpoint Security, Version 10.7.0.5162, on the date of this letter. If there are any technical questions regarding this submission, please contact Ryan Hernandez via email ryan.hernandez01@tevapharm.com or 484-753-6467.

If additional information is required, please do not hesitate to contact the undersigned at RegulatoryAffairsUS@tevapharm.com, or (954) 358-6109 (direct dial).

Sincerely,

Frida M. Navarro
Associate Director, Regulatory Affairs *for*

Alberto Rivalta
Senior Director, Regulatory Affairs