*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Telotristat Etiprate**

**October 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

---

**Active Ingredient:** Telotristat etiprate

**Dosage Form:** Tablet

**Route:** Oral

**Strength:** EQ 250 mg Base

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 250 mg Base, as telotristat ethyl
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Potential applicants may consider using 500 mg dose (2 x 250 mg tablets) for measurement of telotristat ethyl plasma concentrations in the bioequivalence study.

**Analytes to measure:** Telotristat ethyl and telotristat in plasma

**Bioequivalence based on (90% CI):** Telotristat ethyl

Submit the metabolite data as supportive evidence of comparative therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and $C_{max}$.

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

---

**Document History**: Recommended October 2017; Revised October 2024

**Unique Agency Identifier:** PSG_208794

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.