Contains Nonbinding Recommendations

Draft Guidance on Telotristat Etiprate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

Active Ingredient: Telotristat etiprate

Dosage Form; Route: Tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 250 mg BASE, as telotristat ethyl
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: You may consider using 500 mg dose (2 x 250 mg tablets) for measurement of telotristat ethyl plasma concentrations in the bioequivalence studies.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 250 mg BASE, as telotristat ethyl
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See above

Analytes to measure (in appropriate biological fluid): Telotristat ethyl and telotristat in plasma

Bioequivalence based on (90% CI): Telotristat ethyl

Submit the metabolite data (telotristat) 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 Cmax.

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and

reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).