*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Oteseconazole**

**August 2023**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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**Active Ingredient:** Oteseconazole

**Dosage Form:** Capsule

**Route:** Oral

**Strength:** 150 mg

**Recommended Studies:** Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, parallel in vivo
   Strength: 150 mg
   Subjects: Healthy females not of reproductive potential
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, parallel in vivo
   Strength: 150 mg
   Subjects: Healthy females not of reproductive potential
   Additional comments: None

**Analyte to measure:** Oteseconazole in plasma

**Bioequivalence based on (90% CI):** Oteseconazole

**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 each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended August 2023

**Unique Agency Identifier:** PSG_215888