This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 150 mg  
   **Subjects:** Males and females, general population  
   **Additional comments:** Exclude females of reproductive potential and subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Monitor subjects during the study for electrocardiogram changes. Based on the potential for genotoxicity, males with female partners of reproductive potential should be advised to use effective contraception during the study and for 3 months following completion of the study. Subjects should be evaluated before enrollment to ensure normal transaminase (ALT, AST), alkaline phosphatase, and total bilirubin levels. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of ceritinib. Alternatively, a parallel study design may be considered.

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2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 150 mg  
   **Subjects:** Males, and females of non-reproductive potential, general population  
   **Additional comments:** See comments above.

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**Analyte to measure:** Ceritinib in plasma

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

**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/](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.