Contains Nonbinding Recommendations

Draft Guidance on Erdafitinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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: 5 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: 1) Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of erdafitinib. Alternatively, a parallel study design may be considered. 2) Females of reproductive potential and males with female partners of reproductive potential should use effective contraception during the study and for at least 1 month after the last dose of erdafitinib.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 5 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above

Analyte to measure: Erdafitinib in plasma

Bioequivalence based on (90% CI): Erdafitinib

Waiver request of in vivo testing: 3 mg and 4 mg strengths based on (i) acceptable bioequivalence studies on the 5 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths

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