

## Draft Guidance on Gefitinib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 250 mg  
Subjects: Normal healthy males, general population.  
Additional Comments: Due to the risk of teratogenicity of gefitinib, the study should be conducted in healthy male volunteers.
  
2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 250 mg  
Subjects: Normal healthy males, general population.  
Additional Comments: Same as Study 1 above

**Analytes to measure (in appropriate biological fluid):** Gefitinib

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

**Waiver request of in vivo testing:** N/A

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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.