*Contains Nonbinding Recommendations*

**Draft Guidance on Vandetanib**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Vandetanib

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

**Recommended Studies:** One study

1. Type of study: Pharmacokinetic, steady-state in thyroid cancer patients.
   Design: Multiple-dose, two treatment, steady state, in vivo study in adult patients. Both crossover and parallel group designs are acceptable, provided that appropriate randomization and balanced comparison of treatments are ensured.
   Strength: 300 mg tablet dosed once daily with or without food.
   Subjects: Symptomatic or progressive medullary thyroid cancer patients with unresectable locally advanced or metastatic disease already receiving a stable dose of vandetanib tablets, 300 mg once daily.
   Additional comments: 1) Attainment of steady state should be based on at least 3 consecutive trough levels, 2) Blood sampling for bioequivalence should consist of appropriate sampling times over a 24hr period following attainment of steady state, 3) Women of child bearing potential should be advised to use an effective method of contraception while using vandetanib and for up to 8 weeks after ending the treatment, 4) Females should not be lactating, 5) The study should be designed around each patient's existing vandetanib regimen, 6) No changes in dose or regimen should be made for the purpose of the bioequivalence study, 7) Appropriate monitoring and precautions should be followed as recommended in the product's label.

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**Analytes to measure (in appropriate biological fluid):** Vandetanib in plasma

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

**Waiver request of in vivo testing:** 100 mg based on (i) acceptable bioequivalence study on the 300 mg strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

**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 (ANDA).