*Contains Nonbinding Recommendations*

**Draft Guidance on Lapatinib Ditosylate**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 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:** Lapatinib Ditosylate

**Form/Route:** Tablets/Oral

**Recommended studies:** 1 study

Type of study: Fasting
Design: Steady state, two-way, crossover *in-vivo*
Strength: 250 mg (Dose 5 x 250 mg base)
Subjects: Patients with advanced or metastatic breast cancer for whom the drug is indicated.
Additional Comments:
1. Patients with rapidly progressing disease, especially with visceral organ involvement, should not be entered into the study.
2. Women of childbearing potential and nursing mothers should be excluded from study given the potential for embryo-fetal toxicity and secretion of the drug into the milk.
3. Males and their female partners need to practice adequate contraception for at least 1 week after the last lapatinib dose.
4. The usual inclusions/exclusions regarding acceptable hepatic function and limiting of concomitant medications that could result in metabolic drug interactions are recommended.
5. Due to the impact of co-administration of capecitabine on pharmacokinetics of lapatinib, the $AUC_{tau}$ and $C_{max}$ of lapatinib may be determined at the steady state during the period when capecitabine is not co-administered (3-5 lapatinib elimination half-lives after the last dose of capecitabine in that cycle of treatment).

---

**Analytes to measure (in appropriate biological fluids):** Lapatinib in plasma

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

**Waiver request of in-vivo testing:** Not Applicable

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.