*Contains Nonbinding Recommendations*

**Guidance on Divalproex Sodium**

This guidance represents 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:** Divalproex Sodium

**Form/Route:** Delayed-Release Pellets Capsule/Oral

**Recommended studies:** 3 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 125 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Normal liver function test should be required prior to dosing with divalproex sodium in bioequivalence studies. Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 125 mg
   Subjects: Normal healthy males and females, general population.
   Additional comments: Please see comment above.

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3. Type of study: Fasting sprinkle-in-applesauce
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 125 mg
   Subjects: Normal healthy males and females, general population.
   Additional comments: Please see comment above.

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**Analytes to measure:** Valproic acid in plasma. It is not necessary to measure plasma concentrations of the metabolites.

**Bioequivalence based on (90% CI):** Valproic acid

**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.fda.gov/cder/ogd/index.htm. 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.