**Active Ingredient:** Methsuximide  

**Dosage Form; Route:** Capsule; Oral  

**Recommended Studies:** Two studies  

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 300 mg  
   **Subjects:** Males, and non-pregnant and non-lactating females, general population  
   **Additional comments:** None  

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 300 mg  
   **Subjects:** Males, and non-pregnant and non-lactating females, general population  
   **Additional comments:** None  

**Analytes to measure (in appropriate biological fluid):** Methsuximide and its active metabolite N-desmethylmethsuximide (NDM) in plasma  

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.  

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

**Waiver request of in vivo testing:** 150 mg based on (i) acceptable bioequivalence studies 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 web site, available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](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).