Contains Nonbinding Recommendations

Draft Guidance on Suvorexant

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 20 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments:
   1) Females should practice abstinence or contraception during the study.
   2) Study subjects should be advised not to drive if they are experiencing drowsiness and/or dizziness at the end of the study.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 20 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Same as comments above

Analytes to measure (in appropriate biological fluid): Suvorexant in plasma

Bioequivalence based on (90% CI): Suvorexant

Waiver request of in vivo testing: 5 mg, 10 mg, and 15 mg strengths based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) proportionally similar formulation across all strengths, and (iii) acceptable in vitro dissolution testing of 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/. 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).