Contains Nonbinding Recommendations

Draft Guidance on Flibanserin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Healthy nonpregnant females, general population
   Additional comments: 1. The study design (e.g., inclusion/exclusion criteria), procedures (e.g., safety monitoring), and concomitant medications (drug interactions) should address all of the elements related to subject safety specified in the RLD label. 2. The Addyi® (Flibanserin) tablet was approved with a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU). All pertinent elements of the REMS must be incorporated into the protocol and informed consent.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 100 mg
   Subjects: Healthy nonpregnant females, general population
   Additional comments: See comments above

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

Bioequivalence based on (90% CI): Flibanserin

Waiver request of in vivo testing: N/A

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).