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Draft – Not for Implementation

Draft Guidance on Istradefylline

March 2021

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This guidance, which interprets the Agency’s regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic istradefylline.

Active Ingredient: Istradefylline

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 40 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: Advise females of reproductive potential to use contraception during treatment. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of istradefylline. Alternatively, a parallel study design may be considered.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 40 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: See comments above.
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Analyte to measure: Istradefylline in plasma

Bioequivalence based on (90% CI): Istradefylline

Waiver request of in vivo testing: 20 mg based on (i) acceptable bioequivalence studies on the 40 mg strength, (ii) proportional similarity of the formulations between both strengths, and (iii) acceptable in vitro dissolution testing of both strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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