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Draft Guidance on Risdiplam

May 2022

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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 risdiplam.

Active Ingredient: Risdiplam

Dosage Form; Route: For solution; oral

Recommended Study: Request for waiver of in vivo bioequivalence study requirement

To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of risdiplam for oral solution must contain the same active drug ingredient in the same concentration and dosage form as the reference listed drug and contain no inactive ingredient or other change in formulation from the reference listed drug that may significantly affect systemic availability.

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Additional information:

Device:
The reference listed drug (RLD) is co-packaged with oral dosing syringes that are device constituents used to measure and administer the drug.

FDA recommends that prospective applicants examine the size and shape, and volume markings of the RLD devices when designing the test device.

User Interface Assessment:
An ANDA for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

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[a] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.