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Draft Guidance on Sapropterin Dihydrochloride

October 2025

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In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Sapropterin dihydrochloride

Dosage Form: Powder

Route: Oral

Strengths: 100 mg/packet, 500 mg/packet

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

To qualify for a waiver of in vivo bioequivalence study requirements under 21 CFR 320.22(b)(3), the generic sapropterin dihydrochloride powder products must contain the same active ingredient in the same concentration and dosage form as the reference product and should not contain an inactive ingredient or other change in formulation from the reference product that may significantly affect absorption of the active ingredient and systemic availability for sapropterin dihydrochloride powder for oral solution.

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: See above

Dissolution test method and sampling times: Not applicable

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