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Draft Guidance on Terbinafine Hydrochloride

May 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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: Terbinafine hydrochloride

Dosage Forms: Solution, Spray

Route: Topical

Strength: 1%

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

To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of terbinafine hydrochloride topical solution and spray, 1% should contain the same active ingredient in the same concentration and dosage form as the reference standard (RS) and contain no difference in inactive ingredients or in other aspects of the formulation relative to the RS that may significantly affect the local or systemic availability of the active ingredient.

For a topical solution or spray drug product that differs from the RS in inactive ingredients [as permitted by the chemistry, manufacturing, and controls regulations for abbreviated new drug applications, 21 CFR 314.94(a)(9)(v)], the regulation specifies that the applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

Applicants intending to propose an alternative approach by which to demonstrate bioequivalence should refer to the most recent version of the FDA guidance for industry on *Formal Meetings between FDA and ANDA Applicants of Complex Products Under GDUFA*[a] for additional information describing the procedures on how to clarify regulatory expectations regarding your individual drug development program.

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