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Draft Guidance on Fenfluramine Hydrochloride

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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Active Ingredient: Fenfluramine hydrochloride

Dosage Form: Solution

Route: Oral

Strength: EQ 2.2 mg Base/mL

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 fenfluramine hydrochloride oral solution must contain the same active ingredient in the same concentration and dosage form as the reference listed drug (RLD) and should not contain an inactive ingredient or other change in formulation from the RLD that may significantly affect absorption of the active ingredient or systemic availability of fenfluramine hydrochloride 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

Additional information:

Device:
The RLD is presented in a bottle with a bottle adapter,[1] co-packaged with two oral dosing syringes. The oral dosing syringe is the device constituent part.

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD device when designing the test device including:

- Calibrated volume markings
- Number of co-packaged oral syringes

User interface assessment:
An abbreviated new drug application (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 guidance for industry *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

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Unique Agency Identifier: PSG_212102

[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.

[1] Refer to the most recent version of the guidance for industry *Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products Guidance for Industry*