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Draft Guidance on Triheptanoin

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Triheptanoin

Dosage Form; Route: Liquid; oral

Recommended Study: Request for waiver of in vivo bioequivalence study requirement and in vitro feeding tube studies

Triheptanoin is a liquid active pharmaceutical ingredient with no inactive ingredients. In vivo bioequivalence of this product is self-evident and satisfies the requirements for establishing bioequivalence under 21 CFR 320.24(b)(6). Therefore, no in vivo bioequivalence studies are necessary to establish bioequivalence of triheptanoin liquid.

In vitro feeding tube studies

The approved labeling for the reference product states that the product may be administered via enteral feeding tubes. Refer to the most recent version of the FDA guidance for industry on *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling*

Recommendations[a] for conducting the in vitro feeding tube studies including comparative recovery testing and in-use stability in designated dispersion media (i.e., formula).

1. Testing tube: Gastrostomy (G) tube (12 French) including
    a. 3 types of tube configurations including different materials (silicone or polyurethane) and/or different designs
        - At least one G tube should be tested with an inflated balloon design
    b. Holding times of 0 and 15 minutes
    c. Repeated administration
2. In-use stability in designated dispersion media (i.e., formula)

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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.