

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Piflufolastat F-18

May 2023

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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: Piflufolastat F-18

Dosage Form; Route: Solution; Intravenous

Strength: 50 mL (1-80 mCi/mL)

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

In vivo bioequivalence study may be waived on the basis that bioequivalence is self-evident under 21 CFR 320.22(b), for a generic piflufolastat F-18 injection product that is qualitatively (Q1)¹ and quantitatively (Q2)² the same as the reference listed drug (RLD).

An applicant may seek approval of a test product that differs from the RLD in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the test product.³

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¹ Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference listed drug.

² Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the reference listed drug.

³ 21 CFR 314.94(a)(9)(iii)