Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Vimseltinib

August 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Capsule

Route: Oral

Strengths: 14 mg | 20 mg | 30 mg

Reference Listed Drug: NDA 219304

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 30 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Safety recommendations:
   - Exclude subjects with abnormal liver function tests.
   - Females of reproductive potential and males with female partners of reproductive potential should use effective contraception during the study and for one month after the last dose.

Study design recommendations:

- A truncated AUC may be used in place of $AUC_{(0\text{-}t)}$ for comparing the extent of absorption due to vimseltinib's long half-life. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of vimseltinib.
- Alternatively, a parallel study design may be considered.

Analyte to measure: Vimseltinib in plasma

Bioequivalence based on (90% CI): Vimseltinib

Bioequivalence of additional strengths: Waiver request of in vivo testing of additional strengths, 14 mg and 20 mg, based on (i) an acceptable bioequivalence study on the 30 mg strength, (ii) acceptable comparative in vitro dissolution studies between the additional strengths and the 30 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations across all strengths

Dissolution: Dissolution test(s) should be included for quality control and to support a waiver request of in vivo testing of additional strengths. For the quality control dissolution method, provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Document History: Recommended August 2026

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm