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*Draft – Not for Implementation*

## **Draft Guidance on Tazemetostat Hydrobromide**

**August 2021**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Active Ingredient:** Tazemetostat hydrobromide

**Dosage Form; Route:** Tablet; oral

**Recommended Study:** One study

1. Type of study: Steady state  
Design: Multiple-dose, two-period, two-treatment, crossover in vivo  
Strength: EQ 200 mg Base at the dose of EQ 800 mg Base (4 x EQ 200 mg Base)  
Subjects: Patients who are already receiving tazemetostat in their standard therapy and tolerating a stable dosing regimen of EQ 800 mg Base twice per day  
Additional comments: Ensure the attainment of steady state based on at least three consecutive trough concentrations. Collect blood samples for bioequivalence at appropriate sampling times over a 12-hour period following the attainment of steady state. Females of reproductive potential should use effective non-hormonal contraception during the study and for six months after the last dose. Males with female partners of reproductive potential should use effective contraception during the study and for at least three months after the last dose.

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**Analyte to measure:** Tazemetostat in plasma

**Bioequivalence based on (90% CI):** Tazemetostat

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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