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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 selinexor.

**Active Ingredient:** Selinexor

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

**Recommended Study:** One study

1. Type of study: Steady-state
   Design: Multiple-dose, two-period, two-treatment, crossover
   Strength: 20 mg
   Subjects: Patients with multiple myeloma or diffuse large B-cell lymphoma already receiving selinexor in a stable regimen
   Additional comments: Blood sampling for bioequivalence should consist of appropriate sampling times following the dose on day three. Due to risk of embryo-fetal toxicity, females of reproductive potential and males with a female partner of reproductive potential should be advised of the potential risk to a fetus and to use of effective contraception during the study and for one week after the last dose. Design the study
around each patient’s existing selinexor regimen and do not change the dose or regimen for the purpose of conducting the bioequivalence study.

Analyte to measure: Selinexor in plasma

Bioequivalence based on (90% CI): Selinexor

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 of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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