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*Draft – Not for Implementation*

**Draft Guidance on Lemborexant**

**October 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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<b>Active Ingredient:</b>	Lemborexant
<b>Dosage Form:</b>	Tablet
<b>Route:</b>	Oral
<b>Strengths:</b>	5 mg, 10 mg
<b>Recommended Study:</b>	One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period, crossover in vivo  
Strength: 10 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Exclude subjects with narcolepsy. Exclude subjects with compromised respiratory conditions (e.g., chronic obstructive pulmonary disease and obstructive sleep apnea). Subjects should be instructed not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery until they have completely returned to their level of baseline cognitive functioning after taking lemborexant.

**Analyte to measure:** Lemborexant in plasma

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

**Waiver request of in vivo testing:** 5 mg strength based on (i) acceptable bioequivalence study on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, (iii) proportional similarity of the formulations between both strengths

**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 for each of both strengths of the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended November 2021; Revised October 2024

**Unique Agency Identifier:** PSG\_212028

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<sup>1</sup> If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.