**Draft Guidance on Pretomanid**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

<table>
<thead>
<tr>
<th>Active Ingredient:</th>
<th>Pretomanid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage Form; Route:</strong></td>
<td>Tablet; oral</td>
</tr>
<tr>
<td><strong>Recommended Studies:</strong></td>
<td>Two studies</td>
</tr>
</tbody>
</table>

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 200 mg  
   **Subjects:** Non-pregnant, non-lactating females, general population  
   **Additional comments:** None

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 200 mg  
   **Subjects:** Non-pregnant, non-lactating females, general population  
   **Additional comments:** None

**Analyte to measure:** Pretomanid in plasma

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

**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/](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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*Recommended Nov 2020*