This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

<table>
<thead>
<tr>
<th>Active Ingredient:</th>
<th>Voxelotor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage Form; Route:</strong></td>
<td>Tablet, for suspension; Oral</td>
</tr>
<tr>
<td><strong>Recommended Studies:</strong></td>
<td>Two in vivo bioequivalence studies with pharmacokinetic endpoints</td>
</tr>
</tbody>
</table>

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 300 mg  
   **Subjects:** Healthy males and non-pregnant, non-lactating females  
   **Additional comments:** Do not swallow whole, cut, crush, or chew the tablets for oral suspension. Conduct a bioequivalence study according to the reference product labeling. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of voxelotor. Alternatively, a parallel study design may be considered.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 300 mg  
   **Subjects:** Healthy males and non-pregnant, non-lactating females  
   **Additional comments:** See comments above.

**Analyte to measure:** Voxelotor in whole blood  

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

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

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