Contains Nonbinding Recommendations

**Draft Guidance on Tafenoquine Succinate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Active Ingredient:** Tafenoquine succinate

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

**Recommended Studies:** Two studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, randomized, parallel in vivo  
   **Strength:** EQ 100 mg Base  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** Due to the risk of hemolytic anemia, conduct a Glucose-6-Phosphate Dehydrogenase (G6PD) testing and exclude subjects with G6PD deficiency. Females of reproductive potential should use effective contraception during the study and three months after the study.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, randomized, parallel in vivo  
   **Strength:** EQ 100 mg Base  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** See comments above

**Analyte to measure:** Tafenoquine in plasma

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

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

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](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.