### Draft Guidance on Nebivolol Hydrochloride and Valsartan

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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

**Recommended Studies:** Two studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** EQ 5 mg base/80 mg  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study. Drugs, including BYVALSON, that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** EQ 5 mg base/80 mg  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** See comments above

**Analytes to measure (in appropriate biological fluid):** Racemic nebivolol and valsartan in plasma

**Bioequivalence based on (90% CI):** Nebivolol and valsartan

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

*Recommended Jul 2018*