*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Desonide**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Aerosol, foam; topical

**Recommended Studies:** Two studies

1. Type of study: Pilot vasoconstrictor study
   Design: A pilot dose duration-response study using the reference product
   Strength: 0.05%
   Subjects: Males and nonpregnant, nonlactating females, general population
   Additional comments: Refer to the guidance for industry *Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.*

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2. Type of study: Pivotal vasoconstrictor study
   Design: A pivotal bioequivalence study
   Strength: 0.05%
   Subjects: Males and nonpregnant, nonlactating females, general population
   Additional comments: See comments above.

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**Analyte to measure:** Not applicable

**Bioequivalence based on (90% CI):** Pivotal vasoconstrictor study

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

**Dissolution test method and sampling times:** Not applicable

Applicants intending to propose an alternative approach by which to demonstrate bioequivalence should refer to the guidance for industry *Controlled Correspondence Related to Generic Drug Development* and the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* for additional information describing the procedures on how to clarify regulatory expectations regarding your individual drug development program.