

## **Draft Guidance on Fluticasone Propionate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

|                                 |                              |
|---------------------------------|------------------------------|
| <b>Active Ingredient:</b>       | Fluticasone propionate       |
| <b>Dosage Form; Route:</b>      | Metered, spray; nasal        |
| <b>Prescribing Information:</b> | Over-the-counter (OTC)       |
| <b>Recommended Studies:</b>     | In vitro and in vivo studies |

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The draft product-specific recommendations for fluticasone propionate metered nasal spray<sup>1</sup> provides recommendations on in vitro and in vivo studies to establish bioequivalence of the test (T) to reference (R) nasal spray, for configuration with the highest number of labeled actuations.

### **Bioequivalence for Other Configurations:**

**(A)** Configuration with same number of labeled actuations as an approved T fluticasone propionate metered nasal spray product for prescription use (i.e., 120 actuations) based on (i) same manufacturing facility, process and release specifications to the approved T product for prescription use, (ii) same formulation composition to the approved T product for prescription use, and (iii) same container and closure components critical to the product performance to the approved T product for prescription use.

**(B)** Configurations with lower number of labeled actuations based on (i) acceptable bioequivalence studies on configuration with highest number of labeled actuations, (ii) same formulation composition across all configurations, and (iii) same container and closure components critical to the product performance across all configurations.

### **Additional comments:**

The draft product-specific recommendations for fluticasone propionate metered nasal spray<sup>1</sup> provides recommendations on number of reserved samples, formulation, and device.

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<sup>1</sup> <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm>