*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

# Draft Guidance on Fluticasone Propionate

**May 2021**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

In September 2015, FDA issued a draft product-specific guidance for industry on generic fluticasone propionate. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

**Active Ingredient:** Fluticasone propionate

**Dosage Form; Route:** Spray, metered; nasal

**Prescribing Information:** Over-the-counter (OTC)

**Recommended Studies:** In vitro and in vivo studies

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The draft product-specific guidance (PSG) for *Fluticasone Propionate Metered Nasal Spray* (NDA 020121) provides recommendations on in vitro and in vivo studies to establish bioequivalence (BE) of the test (T) to reference (R) fluticasone propionate metered nasal spray, for the configuration with the highest number of labeled actuations.

**Bioequivalence for Other OTC Configurations:**
Prospective applicants intending to market additional OTC configurations with a lower number of labeled actuations than the configuration used in the recommended BE studies described above may establish BE for these additional OTC configurations based on (1) acceptable BE studies on the configuration with the highest number labeled actuations, (2) same formulation composition across all configurations, and (3) same container and closure components critical to the product performance across all configurations.

**Bioequivalence for an OTC Configuration Following Approval of a T Prescription Use Product:**
Prospective applicants with an approved T fluticasone propionate metered nasal spray for prescription use (i.e., 120 actuation configuration) may establish BE for a T OTC configuration with the same number of labeled actuations (i.e., 120 actuations) based on (1) same manufacturing facility, process and release specifications to the approved T product for prescription use, (2) same formulation composition to the approved T product for prescription use, and (3) same container and closure components critical to the product performance to the approved T product for prescription use.

**Additional comments:**
The draft PSG for *Fluticasone Propionate Metered Nasal Spray* (NDA 020121) provides recommendations on formulation and device.

**Revision History:** Recommended September 2015; Revised May 2021

**Unique Agency Identifier:** PSG_205434