# Draft Guidance on Mometasone Furoate

**November 2022**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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**Active Ingredient:** Mometasone furoate

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

**Strength:** 0.05 mg/spray

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

**Recommended Study:** In vitro and in vivo bioequivalence studies

The Product-Specific Guidance (PSG) for *Mometasone Furoate Metered Nasal Spray* (NDA 020762)[a] provides recommendations on in vitro and in vivo studies to establish bioequivalence of the test (T) to reference (R) mometasone furoate 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 bioequivalence studies described above may establish bioequivalence for these additional OTC configurations based on (1) acceptable bioequivalence 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 mometasone furoate metered nasal spray for prescription use (i.e., 120 actuation configuration) may establish bioequivalence 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 information:**

The draft PSG for *Mometasone Furoate Metered Nasal Spray* (NDA 020762)[a] provides recommendations on formulation.

Device:
The Reference Listed Drug (RLD) is presented in a nasal pump dispenser that is a device constituent.

FDA recommends that prospective applicants examine the size and shape, external critical design attributes, and external operating principles of the RLD device when designing the test device including the following characteristics:

- Multi-dose design
- Metered spray
- Priming and cleaning processes

User interface assessment:
An Abbreviated New Drug Application (ANDA) for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.*[b]

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**Unique Agency Identifier:** PSG_215712

[a] For the most recent version of a product-specific guidance, check the FDA product-specific guidance web page at https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm.
[b] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.