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Draft Guidance on Mometasone Furoate

February 2026

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Active Ingredient:	Mometasone furoate
Dosage Form:	Implant
Route:	Implantation
Strength:	1.35 mg
Recommended Studies:	In vitro characterization studies

The Agency's current thinking is that bioequivalence of a generic mometasone furoate sinus implant product may be established using an in vitro characterization-based approach. The proposed in vitro bioequivalence approach should address the following three aspects:

1. **Compositional similarity**
The test product should demonstrate no major difference in formulation composition compared to the reference listed drug (RLD).
2. **In vitro drug release**
Comparable drug release rates should be demonstrated using a properly developed and validated in vitro release test method that can discriminate meaningful differences in critical formulation and manufacturing parameters.
3. **Physicochemical and mechanical properties**
The test product and RLD should have comparable physicochemical and mechanical properties, including:
 - Total sinus implant weight and dimensions
 - Drug content
 - Radial strength

- Polymer degradation rate under conditions taking physiological factors into consideration
- Three-dimensional configuration and mechanical properties throughout the intended use period (suggested time points: 0, 1, 2, and 3 months) as feasible

The Agency encourages prospective applicants to develop appropriate methodologies and discuss detailed proposals with the Agency via a pre-ANDA product development meeting.

Additional information:

Device:

The RLD is presented in a kit containing the drug-eluting sinus implant pre-loaded into a crimper and a disposable delivery system. The sinus implant, crimper, and delivery system constitute the device constituent parts of the product.

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

- Three-dimensional configuration/geometry of the sinus implant
- Sinus implant flexibility
- Mechanical properties of the sinus implant
- Comparative appearance, external characteristics, and operation of the delivery system

User interface assessment:

An abbreviated new drug application 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 guidance for industry *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.^a

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^a For the most recent version of a guidance, refer to the FDA guidance website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.