

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **Draft Guidance on Azelastine Hydrochloride**

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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

This is a new draft product-specific guidance for industry on generic azelastine hydrochloride.

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<b>Active Ingredient:</b>	Azelastine hydrochloride
<b>Dosage Form; Route:</b>	Spray, metered; nasal
<b>Strength:</b>	0.2055 mg/spray
<b>Prescribing Information:</b>	Over-the-counter (OTC)
<b>Recommended Studies:</b>	In vitro bioequivalence studies

The draft product-specific guidance (PSG) for *Azelastine Hydrochloride Metered Nasal Spray* (NDA 022203)<sup>a</sup> provides recommendations on in vitro studies to establish bioequivalence of the test (T) to reference (R) azelastine hydrochloride 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 azelastine hydrochloride metered nasal spray for prescription use (i.e., 200 actuation configuration) may establish bioequivalence for a T OTC configuration with the same number of labeled actuations (i.e., 200 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 *Azelastine Hydrochloride Metered Nasal Spray* (NDA 022203)<sup>a</sup> provides recommendations on formulation.

Device:

The reference listed drug (RLD) product 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:

- Metered, multi-dose format of RLD device
- Number of doses

User Interface Assessment:

An 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*.<sup>b</sup>

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<sup>a</sup> 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>.

<sup>b</sup> 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>.