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## Draft Guidance on Vosoritide

February 2023

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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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<b>Active Ingredient:</b>	Vosoritide
<b>Dosage Form; Route:</b>	Powder; subcutaneous
<b>Strengths:</b>	0.4 mg/vial; 0.56 mg/vial; 1.2 mg/vial
<b>Recommended Study:</b>	Request for waiver of in vivo bioequivalence study requirements

To qualify from submitting an in vivo bioequivalence study on the basis that bioequivalence is self-evident under 21 CFR 320.22(b), a generic vosoritide subcutaneous powder product should be qualitatively (Q1)<sup>1</sup> and quantitatively (Q2)<sup>2</sup> the same as the Reference Listed Drug (RLD).

An applicant may seek approval of a drug product that differs from the RLD in preservative, buffer, or antioxidant if the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.<sup>3</sup>

Recommendations and principles outlined in the most recent version of the FDA guidance for industry on *ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin*<sup>a</sup> are applicable to this product.

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<sup>1</sup> Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the RLD product.

<sup>2</sup> Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the RLD product.

<sup>3</sup> 21 CFR 314.94(a)(9)(iii)

**Additional information:**

## Device:

The RLD is presented in a “co-pack” that consists of: (1) a vial with powdered drug, (2) a prefilled syringe of diluent (sterile water), (3) a 23-gauge diluent needle with needle retraction safety device, and (4) the injection syringe with attached 30-gauge needle with needle retraction safety device. The device constituent parts of this product are: the prefilled diluent syringe, the diluent needle with needle guard system, and the injection syringe with attached needle and needle retraction safety device.

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

- Single-use, pre-filled syringe of diluent
- Needle for drug reconstitution with needle guard system
- Injection syringe with attached needle with retraction safety device
- Needle gauge and length

## 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*.<sup>a</sup>

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<sup>a</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>.