Contains Nonbinding Recommendations

Draft Guidance on Revefenacin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Revefenacin

Dosage Form; Route: Solution; inhalation

Strength: 175 mcg/3 mL

Waiver

A. To qualify for a waiver of evidence of in vivo bioavailability (BA) or bioequivalence (BE) study requirement under 21 CFR 320.22(b)(3), generic versions of revefenacin (175 mcg/3 mL) inhalation solution should contain the same active drug ingredient in the same concentration and dosage form as the Reference Listed Drug (RLD) product and contain no inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability.

B. For an inhalation solution drug product for nebulization that differs from the RLD in inactive ingredients [as permitted by the chemistry, manufacturing and controls regulations for Abbreviated New Drug Applications (ANDAs), 21 CFR 314.94(a)(9)(v)], the regulation specifies that the prospective applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

Additional Comments:

In general, evidence to demonstrate that the formulation of the test product should not alter the systemic or local availability of revefenacin, compared to that of the RLD product, may be based upon a comparison of the formulation composition as well as relevant quality and performance attributes of the test and RLD products.

If the test and RLD products are not qualitatively (Q1) and quantitatively (Q2) the same as defined in the guidance for industry, *ANDA Submissions – Refuse-to-Receive Standards* (December 2016, Revision 2), relevant quality and performance attributes should include appearance, pH, osmolality and any other potentially relevant physical and chemical properties, characterized for a minimum of three batches of the test and three batches (as available) of the RLD product.

Analytes to measure (in appropriate biological fluid): Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: Not applicable