Guidance for Industry

Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action

DRAFT GUIDANCE

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For questions regarding this draft document contact Wallace P. Adams (301) 594-5651 (CDER).

U.S. Department of Health and Human Services
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Center for Drug Evaluation and Research (CDER)
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Draft - Not for Implementation

GUIDANCE FOR INDUSTRY[1]

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I. INTRODUCTION

This guidance is intended to provide recommendations to applicants who are planning product quality studies to measure bioavailability (BA) and/or establish (BE) in support of new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for locally acting drugs in nasal aerosols (metered-dose inhalers (MDIs)) and nasal sprays (metered-dose spray pumps). Product quality includes chemistry, manufacturing, and controls (CMC), microbiology, certain BA information, and BE information (i.e., information that pertains to the identity, strength, quality, purity, and potency of a drug product). Product quality BA and BE are reflective of potency, in that release of the drug substance from the drug product should be assessed and controlled to achieve a reproducibly potent product. BA studies can address many questions, but this guidance discusses studies that focus on product performance (i.e., release of drug substance from drug product). A BE study is normally used to compare a test product (T) to a precursor product (R) — the to-be-marketed product is compared to a pivotal clinical trial material; a generic product is compared to a reference listed drug .

Product quality approaches should be similar for all nasal aerosols and nasal sprays where the active ingredient/active moiety is intended for local action, regardless of drug or drug class. This guidance should be used with other, more general CMC and BA and BE guidances available from CDER (Internet, http://www.fda.gov/cder/guidance/index.htm). Product quality information is different from, yet complementary to, the clinical safety and efficacy information that supports approval of an NDA. For information about the type of safety and efficacy information that may be needed for a new active ingredient/active moiety intended for local action in the nose, or for a new product such as a nasal aerosol that may include an active ingredient/active moiety previously approved in a nasal spray, appropriate CDER review staff should be consulted.

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[1] This guidance has been prepared by the Oral Inhalation and Nasal Drug Products Technical Committee, Locally Acting Drug Products Steering Committee, Biopharmaceutics Coordinating Committee, with contributions from the Inhalation Drug Products Working Group, the Chemistry, Manufacturing, and Controls Coordinating Committee, in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance represents the Agency's current thinking on product quality information related to inhalation aerosols and metered dose spray pumps for nasal delivery. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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