
Guidance for Industry

Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products — Chemistry, Manufacturing, and Controls Documentation

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

July 2002

CMC

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GUIDANCE FOR INDUSTRY¹

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I. INTRODUCTION

This document provides guidance for industry on the chemistry, manufacturing, and controls (CMC) documentation that should be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nasal spray and inhalation solution, suspension, and spray drug products intended for local and/or systemic effect. This guidance covers CMC information recommended for inclusion in the application regarding the drug product components, manufacturing process, and associated controls for each of these areas, but does not address the manufacture of drug substances. The guidance also provides recommendations on labeling. This guidance does not address propellant-based inhalation and nasal aerosols (also known as oral and nasal metered-dose inhalers, MDIs), inhalation powders (also known as dry powder inhalers, DPIs), and nasal powders.²

This guidance sets forth information that should be provided to ensure continuing quality and performance characteristics for these drug products. The guidance does not impose mandatory requirements but does suggest approaches that are appropriate for submitting CMC-related regulatory information. The guidance provides recommendations for drug

¹ This guidance has been prepared by the Inhalation Drug Products Working Group of the Chemistry, Manufacturing, and Controls Coordinating Committee (CMCCC) in the Center for Drug Evaluation and Research (CDER) at the FDA.

² In November 1998 (63 FR 64270), the Agency made available a draft guidance document on *Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products — Chemistry, Manufacturing, and Controls Documentation*. When finalized, this guidance will provide CMC recommendations for MDIs and DPIs.

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