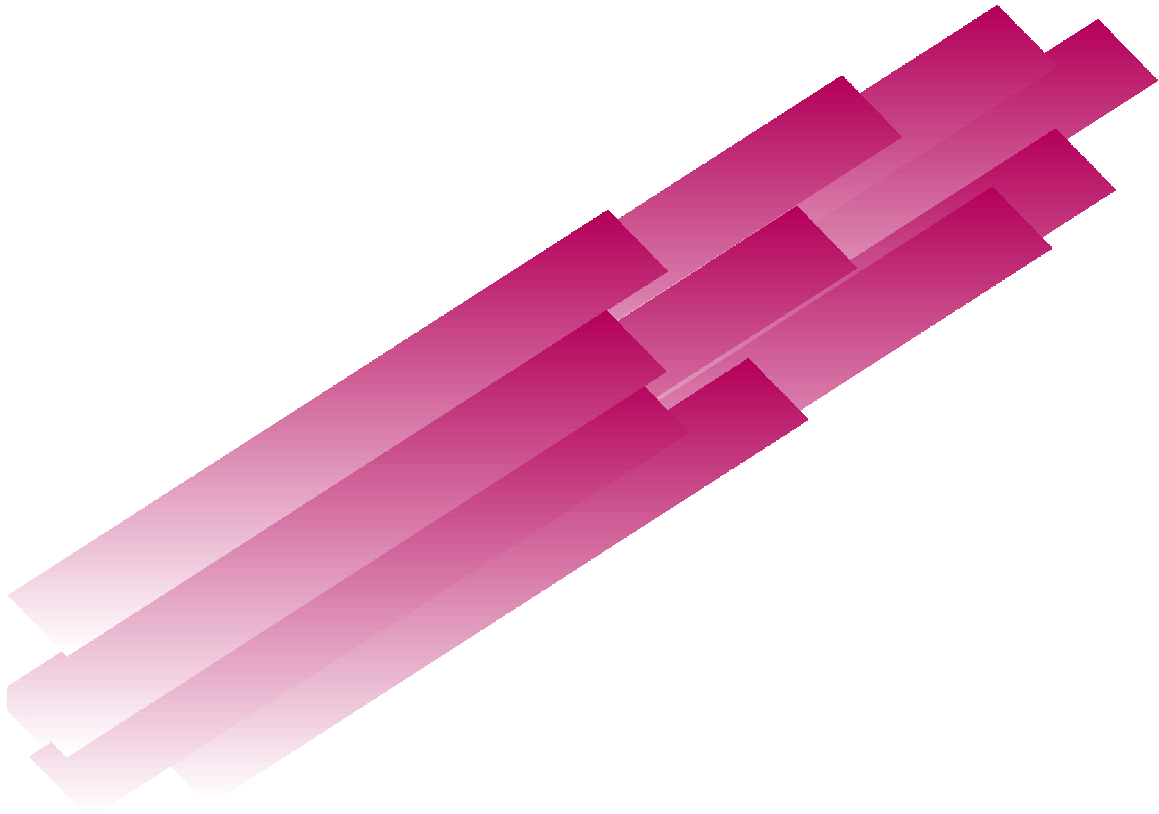


Guidance for Industry

Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
December 1997
DDMAC 1**

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Additional copies are available from:
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GUIDANCE FOR INDUSTRY¹

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I. INTRODUCTION

Aerosol steroid products (i.e., inhaled corticosteroid drug products) may be used after a course of therapy with systemic steroids. Labeling for all aerosol steroid products contains a prominent *boxed warning* that describes the importance of switching carefully from systemic to inhaled steroids to prevent the life-threatening occurrence of adrenal insufficiency.

II. PRECAUTIONARY STATEMENT IN ADVERTISEMENTS AND LABELING

Certain precautionary information addressing the life-threatening occurrence of adrenal insufficiency when patients switch from systemic to aerosol steroid products should be included in advertising and promotional labeling for the aerosol steroid products. Advertisements and promotional labeling that only contain a notice referring to the brief summary or full prescribing information for this precautionary information would not meet the fair balance requirements under § 202.1, “True Statement” of information (21 CFR 202.1(e)(5)).

Therefore, all advertisements and labeling for aerosol steroid products should contain within the body of the advertisement or labeling piece a prominent note similar to the following:

**CAUTION: ADRENAL INSUFFICIENCY MAY OCCUR WHEN
TRANSFERRING PATIENTS FROM SYSTEMIC STEROIDS (SEE
WARNINGS)**

¹This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance document represents the Agency’s current thinking on aerosol steroid safety information in prescription drug advertising and labeling. 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. Additional copies of this draft guidance document are available from the Drug Information Branch, Division of Communications Management, HFD-210, 5600 Fishers Lane, Rockville, MD 20857, (Tel) 301-827-4573.