

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0432]

DMB

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**Draft Guidance for Industry on the Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children." The Division of Pulmonary and Allergy Drug Products is providing guidance to industry regarding the design, conduct, and evaluation of clinical trials to evaluate the effects of orally inhaled and intranasal corticosteroids on growth in children. This action is important because of recently implemented class labeling of these products with regard to their impact on growth in children. An assessment of the available data supporting the class labeling action has led to recommendations that all drug products of this class be tested by means of a "growth study." The recommendations in this document can provide adequate and well-controlled data that is consistent among drug products and can be included in product labeling.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance

to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sandy Barnes, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1050.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children." This draft guidance has been developed by the Division of Pulmonary and Allergy Drug Products, in consultation with the Division of Metabolic and Endocrine Drug Products, to provide guidance in the design, conduct, and evaluation of clinical studies to assess the effects of orally inhaled and intranasal corticosteroids on linear growth.

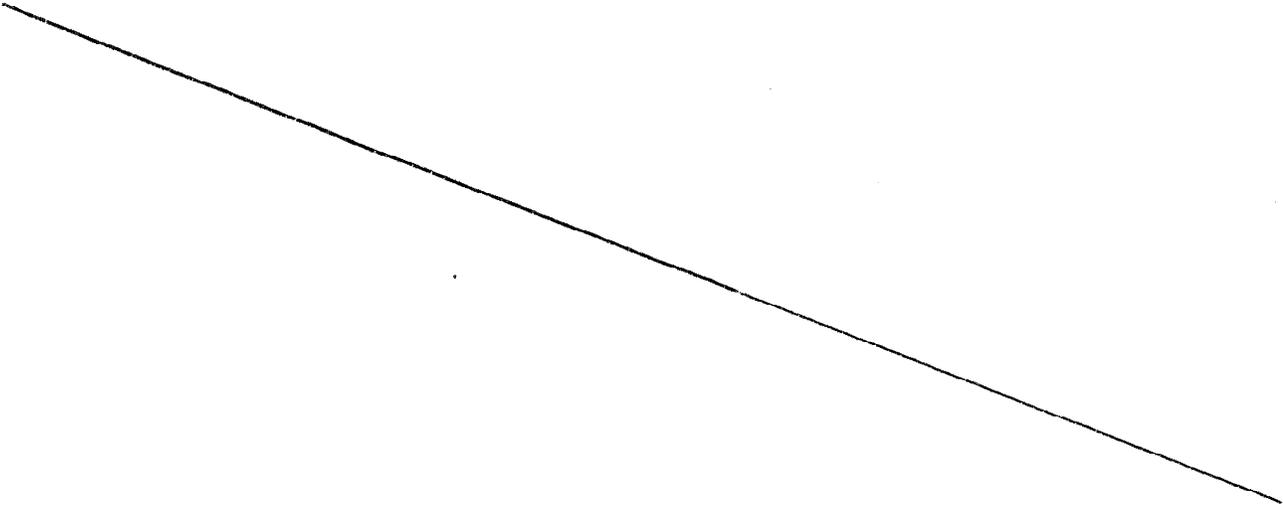
On July 30 and 31, 1998, the Pulmonary and Allergy Drugs Advisory Committee and the Metabolic and Endocrine Drugs Advisory Committee were jointly convened to discuss the implications of findings in previous clinical studies that indicated that inhaled corticosteroids may, as a class of compounds, affect linear growth in pediatric patients. The joint committees agreed that data were sufficient to justify inclusion of a precautionary statement in the labeling for this class of compounds, but the data were inadequate to precisely determine the decrement in growth velocity resulting from the use of these drug products. Members of the joint committees recommended that companies filing new drug applications for all newly approved corticosteroid products conduct further studies, as post-approval phase 4 commitments, to assess the effects of nasally and orally inhaled corticosteroids on growth velocity in prepubertal children.

The draft guidance provides general recommendations for the design and conduct of a “growth study.” The Division of Pulmonary and Allergy Drug Products endorses these recommendations to encourage the collection of other evidence that will consistently and accurately describe the effects of intranasal and orally inhaled corticosteroids on growth velocity in children.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on evaluating the effects of orally inhaled and intranasal corticosteroids on growth in children. 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 statutes and regulations.

## **II. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

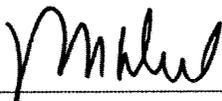


### III. Electronic Access

Persons with access to the Internet can obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 10/26/01

October 26, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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