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 Food and Drug Administration
 5630 Fishers Lane, Rm 1061
 Rockville, MD 20857

December 27, 2001

To: David Hilfiker or Whom It May Concern,

This memo is a suggestion regarding the draft Guidance for Industry on the Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children (J:/!Guidance/3787dft.doc – 11/01/01.

1. Lines 80-82 in the draft state that “Sponsors of both intranasal and inhaled corticosteroid products that contain the same active moiety may be able to use pharmacokinetic data to bridge the growth findings associated with one formulation to a second formulation.”

• Suggestion:

Because there may be different effects and different absorption routes and rates due to the different routes of administration, we believe that data from intranasal and inhaled corticosteroids should not be used interchangeably to bridge growth findings. Growth findings should be proven separately for intranasal and inhaled corticosteroid products. Studies should also look at growth effects from using a combination of intranasal and inhaled products.

2. I am concerned that the draft guidance does not state any lower age limit for participants in these studies. While we want data for all ages, it would probably be safer to exclude the very youngest children until growth data proves to be within safe limits.

Sincerely,

Patricia G. Goldman
 Executive Director

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