



NDA 20-121/S-28

GlaxoSmithKline  
P. O. Box 13398  
Five Moore Drive  
Research Triangle Park, NC 27709

Attention: Roger R. Gaby  
Director, Regulatory Affairs

Dear Mr. Gaby:

Please refer to your supplemental new drug application dated June 28, 2002, received July 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flonase (fluticasone propionate) Nasal Spray, 50 mcg.

We acknowledge receipt of your submissions dated September 10, and 30, 2002, and April 9, and 29, 2003.

This supplemental new drug application provides the results of a long-term longitudinal growth study with Flonase (fluticasone propionate) Nasal Spray, 50 mcg, and proposes to revise the package insert to incorporate pediatric safety information.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted April 29, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement "NDA 20-121/SE8-028." Approval of this submission by FDA is not required before the labeling is used.

FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe use and effective use of this drug in the relevant pediatric populations.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Pulmonary & Allergy Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.

Director

Division of Pulmonary and Allergy Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

Attachment: Approved Labeling

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Badrul Chowdhury  
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