



NDA 21-077/S-008

GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park NC 27709

Attention: Lorna Wilson
Director, Regulatory Affairs

Dear Ms Wilson:

Please refer to your supplemental new drug application dated February 8, 2002, received February 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advair Diskus (fluticasone propionate/salmeterol) Inhalation Powder.

This supplemental new drug application provides for the removal of the black box surrounding the warning about the risk of hypothalamic-pituitary-adrenal (HPA) axis suppression when patients are switched from systemic corticosteroids to inhaled corticosteroids in the package insert.

We completed our review of this application. 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 submitted labeling (package insert submitted February 8, 2002).

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 21-077/S-008." Approval of this submission by FDA is not required before the labeling is used.

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 Mrs. Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

Badrul Chowdhury, M.D.
Acting Director
Division of Pulmonary and Allergy Drug Product
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

Badrul Chowdhury
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