



NDA 21-433/S-006

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

Attention: Dawn Watson
Director, Regulatory Affairs

Dear Ms. Watson:

Please refer to your supplemental new drug application dated June 23, 2006, received June 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent HFA (fluticasone propionate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated July 14, and October 20, 2006.

This supplemental new drug application provides for the addition of a dose counter mechanism to Flovent HFA Inhalation Aerosol.

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 on October 20, 2006, and immediate container and carton labels submitted on July 14, 2006).

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-433/S-006.**" Approval of this submission by FDA is not required before the labeling is used.

Within 30 days of the date of this letter, submit the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the labeling text submitted on October 5, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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) 796-1231.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Pkg Insert

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

Badrul Chowdhury
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