



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-254/S-003  
NDA 20-692/S-031

GlaxoSmithKline  
P. O. Box 13398  
Five Moore Drive  
Research Triangle Park, NC 27709-3398

Attention: Kevin Fitzgerald, R.Ph.  
Director, Regulatory Affairs

Dear Mr. Fitzgerald

Please refer to your supplemental new drug applications dated June 29, 2007, received June 29, 2007, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Advair HFA (fluticasone propionate and salmeterol xinafoate) Inhalation Aerosol, and Serevent Diskus (salmeterol xinafoate inhalation powder).

We acknowledge receipt of your submissions dated January 10, 18, and 22, 2008.

These supplemental new drug applications propose to add wording to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of the package insert to describe the results of a drug interaction study between Serevent Diskus and Ketoconazole. These supplements also propose to revise the Medication Guide to caution against the concurrent use of long-acting beta-agonists (Symbicort, Perforomist, and Brovana).

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on January 18, 2008 (copy enclosed), for Advair HFA and January 22, 2008, for Serevent Diskus (copy enclosed).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the submitted labeling (package insert patient package insert, and Medication Guide submitted on January 18, 2008, for Advair HFA and January 22, 2008, for Serevent Diskus. Upon receipt, we will transmit those versions to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "SPL for approved NDA 21-254-S-003, and NDA 20-692/S-031.

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If you issue a letter communicating important information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to these NDAs 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 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: Package inserts, Patient Package Inserts, Medication Guides

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/s/

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Badrul Chowdhury  
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