



NDA 021077/S-046
NDA 021254S-015
NDA 020692/S-038

SUPPLEMENT APPROVAL

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

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

Dear Mr. Fitzgerald:

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 6, 2011, received April 6, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder), Advair HFA (fluticasone propionate and salmeterol xinafoate) Inhalation Aerosol, and Serevent Diskus (salmeterol xinafoate inhalation powder).

We also refer to your risk evaluation and mitigation strategy (REMS) assessments dated April 6, 2011 for the three products listed above.

These Prior Approval supplemental new drug applications propose modifications to the approved REMS to synchronize the timelines for the submission of the REMS assessments for Advair Diskus, Advair HFA, and Serevent Diskus, such that the assessments are due and submitted on the same date.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder) was originally approved on April 30, 2008, and a REMS modification was approved on January 4, 2011. The REMS for Advair HFA (fluticasone propionate and salmeterol xinafoate) Inhalation Aerosol was originally approved on July 31, 2008, and a REMS modification was approved on January 4, 2011. The REMS for Serevent Diskus (salmeterol xinafoate inhalation powder) was originally approved on November 18, 2010. The REMS for all three products consists of a Medication Guide, a communication plan, and a timetable for submission of

assessments of the REMS. Your proposed modification to the REMS consists of synchronized timetable for the submission of the REMS assessments for all three products.

Your proposed modified REMS for Advair Diskus, Advair HFA, and Serevent Diskus, submitted on April 6, 2011, and appended to this letter, are approved.

There are no changes to the REMS assessment plan described in our November 18, 2010, letter for Serevent Diskus, and January 4, 2011, letter for Advair Diskus and Advair HFA.

We remind you that assessments of an approved REMS must also include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

If you currently distribute or plan to distribute an authorized generic product under this NDA, you must submit a complete proposed REMS that relates only to the authorized generic product. Submit a proposed REMS, REMS supporting document, and any required appended documents as a prior approval supplement. Approval of the proposed REMS is required before you may market your authorized generic product.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 021077 REMS ASSESSMENT
NDA 021254 REMS ASSESSMENT
NDA 020692 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 021077
NEW SUPPLEMENT FOR NDA 021254
NEW SUPPLEMENT FOR NDA 020692

**PROPOSED REMS MODIFICATION
REMS ASSESSMENT**

**NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 021077
FOR NDA 021254
FOR NDA 020692
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)**

If you do not submit electronically, please send 5 copies of REMS-related submissions.

REPORTING REQUIREMENTS

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 Carol Hill, Regulatory Project Manager, at (301) 796-2006.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
05/10/2011