DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21077/ S-049
NDA 21254/ S-019
NDA 20692/ S-042

SUPPLEMENT APPROVAL
ACKNOWLEDGE REMS ASSESSMENT
RELEASE REMS REQUIREMENT

GlaxoSmithKline
P.O. Box 13998
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 and received July 18, 2012, 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 acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment, dated November 16, 2011, and your amendments dated March 14, April 5, and May 18, 2012.

These supplements propose to eliminate the requirement for the approved 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) REMS, respectively.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

In addition, we have found the REMS assessment to be complete.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS 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) were originally approved on April 30,

2008, July 31, 2008, and November 18, 2010, respectively. The most recent REMS modification for all three products was approved on June 27, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS 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).

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS 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) are no longer required.

OTHER

We encourage you to maintain your educational materials on your product website to provide a resource for patients and practitioners about the risks and benefits of your products.

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 Wayne Amchin, Senior Regulatory Health Project Manager for Safety, at (301) 796-0421.

Sincerely,

{See appended electronic signature page}

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

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
08/09/2012