DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21929/S-33

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

AstraZeneca LP
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Attention: Matthew E. Arnold
Associate Director, Regulatory Affairs

Dear Mr. Arnold:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 29, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Symbicort (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol.

We also acknowledge your risk evaluation and mitigation strategy (REMS) assessment dated February 10, 2012.

This supplemental new drug application proposes to eliminate the requirement for the approved Symbicort (budesonide and formoterol fumarate dihydrate) REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Symbicort was originally approved on February 27, 2009, and the most recent REMS modification was approved on August 18, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA eliminate the requirement for the REMS for Symbicort.

The REMS assessment received on February 10, 2012 demonstrates that the communication plan, and therefore the REMS, has met its goals. Therefore, 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 Symbicort is 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 product.

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
07/23/2012