DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22007/S-007
NDA 22007/S-008

SUPPLEMENT APPROVAL
ACKNOWLEDGE REMS ASSESSMENT
RELEASE REMS REQUIREMENT

Mylan Specialty L.P.
110 Allen Road, 4th Floor
Basking Ridge, N.J. 07920

Attention: Michael Bailey
Senior Director, Regulatory Affairs

Dear Mr. Bailey:

Please refer to your Supplemental New Drug Applications (sNDA) dated January 31, and September 7, 2012, received January 31, and September 7, 2012, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Perforomist (formoterol fumarate) Inhalation Solution, 20 mcg/2 mL vial.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 31, 2012.

Supplemental new drug application (22007/S-007) proposes to remove the Medication Guide (MG) from the approved REMS for Perforomist (formoterol fumarate) Inhalation Solution.

Supplemental New Drug Application (22007/S-008) proposes to eliminate the requirement for the approved REMS for Perforomist (formoterol fumarate) Inhalation Solution.

We have completed our review of these supplemental applications, as amended. These supplemental applications 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 Perforomist (formoterol fumarate) Inhalation Solution was originally approved on February 1, 2011. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS contained in your submission dated January 31, 2012, consists of eliminating the requirement for the Medication Guide as an element of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Perforomist (formoterol fumarate) Inhalation Solution outweigh the risks.

In your submission dated September 7, 2012, you propose that FDA no longer require a REMS for Perforomist (formoterol fumarate) Inhalation Solution.

Because the assessment demonstrates that the communication plan has been completed and 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 Perforomist (formoterol fumarate) Inhalation Solution is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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.

We remind you that there is a postmarketing commitment listed in the April 27, 2007, approval letter for this application that is still open.

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
09/25/2012