DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22518/S-007
NDA 22518/S-010

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGEMENT

Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
K-15-3 1375
Kenilworth NJ 07033

Attention: Michael Belman
Director and Liaison, Global Regulatory Affairs

Dear Mr. Belman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on November 7, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dulera (mometasone and formoterol) Inhalation Aerosol.

We also acknowledge your risk evaluation and mitigation strategy (REMS) assessment dated June 18, 2012. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we have found the REMS assessment to be complete.

This supplemental new drug application proposes to eliminate the requirement for the approved Dulera (mometasone and formoterol) Inhalation Aerosol 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 Dulera (mometasone and formoterol) Inhalation Aerosol was originally approved on June 22, 2010, and the most recent REMS modification to remove the Medication Guide from the REMS was approved on August 18, 2011. The currently approved REMS consists of a communication plan and a timetable for submission of assessment of the REMS.

You propose that FDA eliminate the requirement for the REMS for Dulera (mometasone and formoterol) Inhalation Aerosol.

The REMS assessment received on June 18, 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 Dulera (mometasone and formoterol) Inhalation Aerosol 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
Office of Drug Evaluation II
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
11/27/2012