DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22518/S-018

**SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp.
351 North Sumneytown Pike
P.O. Box 1000, UG2C-26
North Wales, PA 19454-2505

Attention: Scott Hambaugh
Director, Regulatory Liaison, Global Regulatory Affairs

Dear Mr. Hambaugh:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 26, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dulera (mometasone furoate/formoterol fumarate) Inhalation Aerosol.

We also refer to our approval letter dated December 24, 2015, which contained the following error: faces of carton and container labels were blank.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain December 24, 2015, the date of the original approval letter.

This "Changes Being Effected" supplemental new drug application provides for canister and actuator label changes, specifically to enhance identification of the product strength and add a truncated version of the NDC barcode to the trade actuator labels.

## APPROVAL & LABELING

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

## CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 26 and July 28, 2015, submissions containing final printed container labels.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

**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 Christine Ford, Regulatory Project Manager, at (301) 796-3420.

Sincerely,

*{See appended electronic signature page}*

Lydia Gilbert-McClain, M.D.
Deputy Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Container Labeling

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

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/s/

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LYDIA I GILBERT MCCLAIN
12/24/2015