DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22518/S-022

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Merck Sharpe & Dohme Corp.
126 E. Lincoln Avenue
P.O. Box 2000
RY34-B188
Rahway, NJ 07065-0900

Attention: Michele R. Flicker, MD
Executive Director, Global Regulatory Affairs

Dear Dr. Flicker:

Please refer to your Supplemental New Drug Application (sNDA) dated July 31, 2017 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, 200 mcg/5 mcg and 100 mcg/5 mcg.

This Prior Approval supplemental new drug application provides for updated labeling for the prescribing information to incorporate the results of the required safety study with Dulera and revised class labeling for inhaled corticosteroid/long-acting beta agonist combination products, including removal of the Boxed Warning for asthma-related death and removal of the Medication Guide to be replaced with a Patient Information Leaflet.

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.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, text for the patient information leaflet, and for the instructions for use, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 application, you are exempt from this requirement.

FULFULLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated July 13, 2017, containing the final report for the following postmarketing requirement listed in the April 14, 2011 postapproval postmarketing requirement letter.

1751-1 A randomized, double-blind, 26-week, active-controlled clinical trial comparing Dulera (mometasone furoate and formoterol fumarate) Inhalation Aerosol with

mometasone furoate to evaluate the risk of serious asthma outcomes (hospitalizations, intubation, death) in 11,700 adult and adolescent patients 12 years of age and older with persistent asthma.

Final Protocol Submission:	May 2011
Trial Completion:	February 2017
Final Report Submission:	June 2017

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes your postmarketing requirement acknowledged in our April 14, 2011, letter.

We remind you that there is a postmarketing requirement listed in the January 7, 2015 postapproval postmarketing requirement letter 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 Carol F. Hill, Senior Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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
12/20/2017