DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022518/S-019
NDA 205641/S-005

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

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

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

Dear Dr. Flicker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received September 24, 2015, and your amendments submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dulera (mometasone furoate and formoterol fumarate dihydrate) Inhalation Aerosol 100/5 and 200/5 micrograms and Asmanex HFA (mometasone furoate) Inhalation Aerosol 100/5, and 200/5 micrograms.

These Prior Approval supplemental new drug applications include results of a dose ranging study with mometasone furoate MDI in children 5 through 11 years of age and provide for incorporation of information to the labeling to be consistent with the Pregnancy and Lactation Labeling Rule (PLLR).

APPROVAL & LABELING

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

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 Medication Guide for Dulera), and (text for the package insert, text for the patient information leaflet for Asmanex) 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 supplemental application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated July 2, 2015, containing the final report for the following postmarketing requirements listed in the June 22, 2010, and April 25, 2014, approval letters for Dulera Inhalation Aerosol and Asmanex HFA Inhalation Aerosol, respectively.

Dulera Inhalation Aerosol

1658-4 Deferred pediatric trial under PREA to evaluate the safety and efficacy of multiple doses of mometasone MDI in children 5 to 11 years of age with asthma.

Asmanex HFA Inhalation Aerosol

2149-1 A 12-week, randomized, placebo-controlled, dose-ranging efficacy and safety study of mometasone furoate metered dose inhaler (MDI) in the

treatment of children ages 5-11 years with persistent asthma.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the June 22, 2010, and April 25, 2014, approval letters for Dulera Inhalation Aerosol and Asmanex HFA Inhalation Aerosol, respectively, that are 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 LeAnn Brodhead, Regulatory Project Manager, at (240) 402-2605.

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(S):
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
07/12/2016