

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205641Orig1s000

Trade Name: Asmanex HFA 100 mcg and 200 mcg

Generic Name: mometasone furoate inhalation aerosol

Sponsor: Merck Sharp & Dohme Corp.

Approval Date: April 25, 2014

Indications: Asmanex HFA is a corticosteroid indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

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APPROVAL LETTER



NDA 205641

NDA APPROVAL

Merck Sharp & Dohme Corp.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889

Attention: Scott Hambaugh
Director, Regulatory Liaison
Global Regulatory Affairs

Dear Mr. Hambaugh:

Please refer to your New Drug Application (NDA) dated June 27, 2013, received June 27, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Asmanex HFA (mometasone furoate) Inhalation Aerosol 100 mcg and 200 mcg.

We acknowledge receipt of your amendments dated September 4, 12, and 19, October 22, 2013, and January 28, April 4, and 17 (2), 18, and 22, 2014.

This new drug application provides for the use of Asmanex HFA for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

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

EXPIRATION DATING PERIOD

A 36-month expiry dating period is granted for Asmanex HFA (mometasone furoate) when stored at controlled room temperature between 20°C and 25°C (68°F and 77°F) with excursions permitted from 15°C and 30°C (59°F and 86°F).

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, Instructions for Use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 4, 2014, submission containing final printed carton and 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.

We are waiving the pediatric studies requirement for ages 0 through 4 years of age because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group.

We are deferring submission of your pediatric studies for ages 5 through 11 years of age for this application because this product is ready for approval for use in adults and the pediatric study have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act/FDCA. These required studies are listed below.

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.
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Study Completion:	04/2015
Final Report Submission:	09/2015

2149-2 A 12-week, double-blind, active-controlled, efficacy and safety study of two doses of mometasone furoate/formoterol fumarate combination MDI compared with the corresponding doses of mometasone furoate monotherapy MDI in the treatment of children ages 5-11 with persistent asthma.

Final Protocol Submission: 10/2015
Study Completion: 09/2018
Final Report Submission: 02/2019

2149-3 A 6-month safety study, with a 6-month extension of two doses of mometasone furoate/formoterol fumarate combination MDI compared to fluticasone/salmeterol combination DPI in children 5-11 years of age with persistent asthma.

Final Protocol Submission: 10/2015
Study Completion: 09/2018
Final Report Submission: 02/2019

Submit the protocols to your INDs 70,283 and 112,669, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

We note that you have fulfilled the pediatric studies requirement for ages 12 to 18 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Jessica Lee, Regulatory Project Manager, at (301) 796-3769.

Sincerely,

{See appended electronic signature page}

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

Enclosure(s):

Content of Labeling
Carton and Container Labeling

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

/s/

LYDIA I GILBERT MCCLAIN
04/25/2014