**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

# NDA 020762/S-050

***Trade Name:*** NASONEX®

***Generic Name:*** mometasone furoate monohydrate

***Sponsor:*** Merck Sharp Dohme

***Approval Date:*** 10/24/2014

***Indication:*** NASONEX® is a corticosteroid indicated for: 1) treatment of nasal symptoms of allergic rhinitis in patients ≥ 2 years of age; 2) treatment of nasal congestion associated with seasonal allergic rhinitis in patients ≥ 2 years of age; 3) prophylaxis of seasonal allergic rhinitis in patients ≥ 12 years of age; 4) treatment of nasal polyps in patients ≥ 18 years of age.

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***APPLICATION NUMBER:***

# NDA 020762/S-050

# APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20762/S-050

**APPROVAL LETTER**

Merck Sharp & Dohme Corp
Attention: Wendy Sikorski
Senior Specialist, Global CMC Regulatory Affairs
2000 Galloping Hill Road, Mailstop K-6-1, 1620
Kenilworth, NJ 07033

Dear Ms. Sikorski:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 12, 2014, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex® (mometasone furoate monohydrate) Nasal Spray.

This "Changes being effected" supplemental application provides for a new analytical method for determining (b) (4) in the (b) (4) of the Nasonex® nasal spray pump.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely,

Ramesh Raghavachari -S

Digitally signed by Ramesh Raghavachari -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1100211793, cn=Ramesh Raghavachari -S
Date: 2014.10.24 12:20:51 -04'00'

Ramesh Raghavachari, Ph.D.
Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

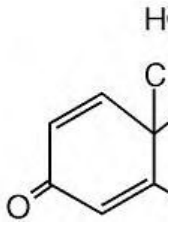
# NDA 020762/S-050

# CHEMISTRY REVIEW(S)

| ***Chemistry Review:# 1*** | 1. **Division:** ONDQA-DPARP | **2. NDA Number:** 20-762 |
|---|---|---|
| **3. Name and Address of Applicant:**<br>Merck Sharp and Dohme Corp.<br>2000 Galloping Hill Road<br>Mailstop K23/Q50<br>Kenliworth, NJ, 07033-1310 | | **4. Supplement(s):** CBE-0<br>**Number:** 50<br>**Date(s):** 05/12/2014 |
| **5. Name of Drug:** Nasonex nasal spray | | **6. Nonproprietary name:** Mometasone furoate |
| **7. Supplement Provides for**: a new analytical method for determining (b) (4) in the (b) (4) of the Nasonex® nasal spray pump. | | **8. Amendment(s):** |
| **9. Pharmacological Category:** corticosteroid | **10. How Dispensed:** $R_x$ | **11. Related Documents:** |
| **12. Dosage Form:** Nasal metered spray | **13. Potency:** 50 mcg/actuation | |

**14. Chemical Name and Structure:** 21-Dichloro-11b, 17-dihydroxy-16a-methylpregna-1, 4-diene-3, 20-dione 17-(2 furoate monohydrate); $C_{27}H_{30}Cl_2O_6 \bullet H_2O$: MW = 539.45

APPEARS THIS WAY ON ORIGINAL




**15. Comments:**

- An LOA was provided by (b) (4) for DMF (b) (4) on 11/8/2013
- DMF (b) (4) was last reviewed by Erika Englund, Ph.D. on 10/30/2013 and the new method to analyze (b) (4) extractables was found adequate
- (b) (4) was informed on November 5, 2013 by the FDA to instruct their clients to submit a CBE-0 CMC supplement for the changed method
- Stability data on the marketed product will be reported in subsequent annual reports.

**16. Conclusion:** This supplement is recommended for approval from CMC perspective

**17. Name:** Erika Englund, Ph.D., Chemist **Signature:** **Date:**

**18. Concurrence:** Ramesh Raghavachari, Ph.D., Branch Chief, Br., IX, ONDQA **Signature:** **Date:**

**Drug Product Information**

1. NDA 20-762 was approved October 1, 1997
2. Nasonex is indicated for:
    a. Treatment of Nasal Symptoms of Allergic Rhinitis in patients ≥2 years of age
    b. Treatment of Nasal Congestion Associated with Seasonal Allergic Rhinitis in patients ≥2 years of age
    c. Prophylaxis of Seasonal Allergic Rhinitis in patients ≥12 years of age;
    d. Treatment of Nasal Polyps in patients ≥18 years of age
3. The maximum recommended dosage is 2 sprays in each nostril twice daily
4. Nasal Spray contains 50 mcg of mometasone furoate in each 100 µL spray
5. NASONEX is a metered-dose, manual pump unit containing an aqueous suspension of mometasone furoate monohydrate (equivalent to 0.05% w/w mometasone furoate calculated on the anhydrous basis).
6. Each bottle of NASONEX provides 120 sprays.
7. Mometasone furoate is practically insoluble in water; slightly soluble in methanol, ethanol, and isopropanol; soluble in acetone and chloroform; and freely soluble in tetrahydrofuran
8. Mometasone furoate is in an aqueous medium containing glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, sodium citrate, citric acid, benzalkonium chloride, and polysorbate 80. The pH is between 4.3 and 4.9.
9. NASONEX (mometasone furoate monohydrate) is supplied in a white, high-density, polyethylene bottle fitted with a white metered-dose, manual spray pump, and blue cap. It contains 17 g of product formulation. Each bottle contains 120 sprays.
10. It is stored at 25 °C.

**Chemistry Review**

The new method to analyze (b) (4) extractables in DMF (b) (4) was reviewed on 10/30/2013 by Erika E. Englund, Ph.D. and found adequate. There have been no changes to this method since that review. (b) (4) informed their clients to submit this change as a CBE-0 CMC supplement following the e-mail recommendation from Youbang Liu, Ph.D. on November 5, 2013.

An LOA (NOV-18-2013) from (b) (4) for DMF (b) (4) was submitted with this supplement. There are no other changes to the drug product described.

**Overall Evaluation:** Adequate

DMF (b) (4) was last found adequate on 10/30/2013 by Erika E. Englund, Ph.D. There are no other changes to the drug product described in this supplement. This supplement is recommended for approval from CMC perspective.

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/s/

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ERIKA E ENGLUND
05/20/2014

RAMESH RAGHAVACHARI
05/20/2014

# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# NDA 020762/S-050

# ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20762/S-050

**CBE SUPPLEMENT – ACKNOWLEDGEMENT**

Merck Sharp & Dohme Corp
Attention: Wendy Sikorski
Senior Specialist, Global CMC Regulatory Affairs
2000 Galloping Hill Road, Mailstop K-6-1, 1620
Kenilworth, NJ 07033

Dear Ms. Sikorski

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

**NDA Number:** 20762

**Supplement number:** S-050

**Name of Drug Product:** Nasonex® (mometasone furoate monohydrate) Nasal Spray

**Date of supplement:** May 12, 2014

**Date of receipt:** May 12, 2014

This supplemental application, submitted as a "Changes Being Effected in 30 days" supplement, proposes a new analytical method for determining (b) (4) in the (b) (4) of the Nasonex® nasal spray pump.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on July 11, 2014, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 12, 2014.

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have questions, call me, at (301) 796-1926.

Sincerely,

*{See appended electronic signature page}*

Youbang Liu
Regulatory Project Manager
Division III of New Drug Quality Assessment
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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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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YOUBANG LIU
06/06/2014