CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215712Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	September 3, 2021
Application Type and Number:	NDA 215712
Product Name and Strength:	Nasonex 24HR Allergy (mometasone furoate monohydrate) nasal spray, 50 mcg per spray
Product Type:	Single Ingredient Product
Rx or OTC:	Over-the-counter (OTC)
Applicant/Sponsor Name:	Perrigo Pharma International DAC (Perrigo)
Panorama or PNR ID #:	2021-1044724016
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Nasonex 24HR Allergy, which was found conditionally acceptable under PIND 142446 on November 7, 2019.[a] Thus, Perrigo submitted the name, Nasonex 24HR Allergy, under NDA 215712 for review on June 10, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

At the initial phase of the review, in response to our initial OSE June 24, 2021 email, the Division of Nonprescription Drug Products 1 (DNPD 1) did not have any concerns related to the proposed proprietary name and determined that Nasonex 24HR Allergy would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with DNPD 1's assessment for Nasonex 24HR Allergy.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we reviewed our previous name assessment taking into consideration any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The July 29, 2021 search of USAN stems did not find any new USAN stems in the proposed proprietary name, Nasonex 24HR Allergy.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the DNPD 1 via email on August 24, 2021. At that time, we also requested additional information or concerns that could inform our review. On August 31, 2021, the DNPD 1 review team communicated that they have no objections with the proposed proprietary name, Nasonex 24HR Allergy; however, DNPD 1 also commented that the name looks and sounds similar to Nasacort Allergy 24HR, but if inadvertent product confusion occurred, generally it would not lead to serious outcomes. We considered and analyzed the name pair Nasonex 24HR Allergy and Nasacort Allergy 24HR in Section 2.3.1.

2.3.1 EVALUATION OF NASONEX 24HR ALLERGY VS. NASACORT ALLERGY 24HR

We note that when Nasonex and Nasacort were marketed as prescription drug products, our postmarketing surveillance did not identify any name confusion medication errors. We further evaluated the name pair with their respective modifiers, 24HR Allergy and Allergy 24HR, and did not determine that the addition of the modifiers would increase the risk for name confusion between the pair. We conclude that the name pair has sufficient orthographic and phonetic differences.

---

[a] Jones, G. Proprietary Name Review for Nasonex 24HR Allergy (PIND 142446). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 NOV 07. Panorama No.: 2019-32179513.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Nasonex 24HR Allergy, is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO PERRIGO PHARMA INTERNATIONAL DAC

We have completed our review of the proposed proprietary name, Nasonex 24HR Allergy, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on June 10, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems) USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

GRACE JONES
09/07/2021 12:30:52 PM

ASHLEIGH V LOWERY
09/07/2021 12:56:57 PM

DANIELLE M HARRIS
09/07/2021 02:24:34 PM
Signed on behalf of Chi-Ming Tu