

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

215712Orig1s000

Trade Name: Nasonex 24HR Allergy nasal spray, 50 mcg/spray, metered

Generic or Proper Name: mometasone furoate

Sponsor: Perrigo Pharma International Designated Activity Company

Approval Date: March 17, 2022

Indication: Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose

CENTER FOR DRUG EVALUATION AND RESEARCH

215712Orig1s000

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	X
REMS	
Officer/Employee List	X
Integrated Review(s)	X
Product Quality Review(s)	X
Other Reviews	X
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	X
Administrative/Correspondence Document(s)	X

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

215712Orig1s000

APPROVAL LETTER



NDA 215712

NDA APPROVAL

Perrigo Pharma International Designated Activity Company
c/o Perrigo R&D Company
Attention: Valerie Gallagher
Vice President Regulatory Affairs
515 Eastern Avenue
Allegan, MI 49010

Dear Ms. Gallagher:

Please refer to your new drug application (NDA) dated and received on May 17, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasonex 24HR Allergy (mometasone furoate) nasal spray, 50 mcg/spray, metered.

This new drug application provides for the use of Nasonex 24HR Allergy for the following indication(s):

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose

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 agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
120 spray count blister card (secondary packaging)	2/7/2022
120 spray count container label	2/7/2022
60 spray count blister card (secondary packaging)	2/7/2022
60 spray count container label	2/7/2022
30 spray count blister card (secondary packaging)	2/7/2022
30 spray count container label	2/7/2022
Consumer Information Leaflet (Package Insert for all Nasonex 24HR Allergy SKUs)	2/7/2022

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.¹ For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 215712.**” Approval of this submission by FDA is not required before the labeling is used.

Additional Comments

We have approved package sizes for this product amid concerns that consumers follow instructions that limit duration of use of over-the-counter nasal corticosteroids to no longer than 2 months a year in children. The “Directions” section of the Drug Facts labeling for the product states “Talk to your child’s doctor if your child needs to use the spray for longer than two months a year.”

Research has shown that increased package sizing of products leads to increased usage among consumers.^{2,3} Conversely, limiting pack sizes of medication has been shown to reduce episodes of overconsumption by limiting the immediate availability of the drug to the consumer.^{4,5}

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

² Wansink B, 1996, Can Package Size Accelerate Usage Volume? *J Mark*, 60(3): 1-14.

³ Chandon P, B Wansink, 2002, When are Stockpiled Products Consumed Faster? A Convenience-salience

Framework of Postpurchase Consumption Incidence and Quantity, *J Mark Res*, 39(3): 321-335.

⁴ Hawton K, H Bergen, S Simkin, S Dodd, P Pocock, W Bernal, et al., 2013, Long Term Effect of Reduced Pack

Sizes of Paracetamol on Poisoning Deaths and Liver Transplant Activity in England and Wales: Interrupted Time

Series Analyses, *BMJ*, 346: f403 (doi: 10.1136/bmj.f403).

⁵ Weiss S, 2009, Compliance Packaging for Over-the-counter Drug Products, *J Public Health*, 17(2): 155-164.

U.S. Food and Drug Administration

Silver Spring, MD 20993

www.fda.gov

If you are interested in marketing a package configuration that would extend use beyond 2 months in children, we advise you to request a meeting with us to discuss the safety and efficacy implications, consumer use patterns, and data needed to support a prior approval supplement submission.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.⁶ Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 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.

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 Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

{See appended electronic signature page}

⁶ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Nushin Todd, MD, PhD
Acting Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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/

NUSHIN F TODD
03/17/2022 11:49:28 AM