NDA 215712/S-011

APPROVAL LETTER

Perrigo R&D Company
U.S. Agent for Perrigo Pharma International Designated Activity Company (PPI-DAC)
Attention: Valerie Gallagher
Vice President Regulatory Affairs
515 Eastern Ave
Allegan, MI 49010

Dear Ms. Gallagher:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 19, 2022, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasonex 24HR Allergy (mometasone furoate nasal spray).

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to the carton configurations for the unbranded Mometasone Furoate Nasal Spray (b) (4).

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

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling 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	Dates Submitted
60 Spray- Small Bottle Carton	May 19, 2022
60 Spray- Large Bottle Carton	May 19, 2022
120 Spray- Small Bottle Carton	May 19, 2022
120 Spray- Small Bottle Carton	May 19, 2022
2x120 Spray- Bottle Carton	May 19, 2022

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this

submission "**Final Printed Labeling for approved NDA 215712/S-011.**" Approval of this submission by FDA is not required before the labeling is used.

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

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch 1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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