NDA 215712/S-008

SUPPLEMENT APPROVAL

Perrigo Pharma International Designated Activity Company
c/o Perrigo R&D Company
Attention: Derick Winkle
Sr. Manager Regulatory Affairs
515 Eastern Avenue
Allegan, MI 49010

Dear Mr. Winkle:

Please refer to your supplemental new drug application (sNDA) dated and received on March 29, 2022, 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.

This "Prior Approval" supplemental new drug application provides for the addition of alternative labeling with an added descriptor "Children's", in 30, 60 and 2 x 60 spray count sizes.

APPROVAL & LABELING

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

LABELING

Per the commitment provided in your correspondence received on August 24, 2022, remove the discard statement from the blister card and leaflet 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 tablet below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. We remind you to remove the "NEW!" flag from the labeling six months after the marketing start date.

Submitted Draft Labeling	Date(s) Submitted
30 spray count blister card	09/08/2022
30 spray count bottle	09/08/2022
60 spray count blister card	09/08/2022
60 spray count bottle	09/08/2022
Twin pack 60 count spray blister card	09/08/2022

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/S-008**." Approval of this submission by FDA is not required before the labeling is used.

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.[2] 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*. 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.

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}

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

ENCLOSURE(S):

- Carton and Container Labeling

[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] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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
09/20/2022 01:27:29 PM