



NDA 022051/S-024
NDA 205434/S-017

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Lydia Wen
Regulatory Affairs Manager
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Lydia Wen:

Please refer to your supplemental new drug applications (sNDA) dated and received on May 7, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for

- NDA 022051/S-024: Flonase Sensimist Allergy Relief (fluticasone furoate) nasal spray, 27.5 mcg per spray
- NDA 205434/S-017: Flonase Allergy Relief (fluticasone propionate) nasal spray, 50 mcg per spray

These "Prior Approval" supplemental new drug applications provide for 3-bottle presentations

(b) (4)

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 tables below with an exception for NDA 022051/S-024: update the tamper-evident statement to include an adjective before the term "container" (e.g., paper, cardboard, etc.) to distinguish which container is being referred to or change the term to reflect that it is a paper package. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

NDA 022051/S-024 (Flonase Sensimist Allergy Relief)

Submitted Draft Labeling	Date
3 x 120 Spray-count front PDP (outer container)	09/09/2024
Backer card (includes DFL) (outer container)	11/22/2024

NDA 205434/S-017 (Flonase Allergy Relief)

Submitted Draft Labeling	Date
3 x 144 Spray count front PDP (outer container)	09/09/2024
Backer card (includes DFL) (outer container)	11/22/2024

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 022051/S-24 and NDA 205434/S-17.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the “NEW LOOK” flag from the labeling six months after the marketing start date.

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.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the

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>

Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53 (d)(2)(ii)(B) and 314.53(f)(2)(iv).

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, contact Tam Dinh, PharmD, Regulatory Project Manager, at 240-402-6284 or Tam.Dinh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Martha Lenhart, MD, Ph.D
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Outer 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/

MARTHA K LENHART
01/10/2025 01:39:10 PM