

NDA 022051/S-023
NDA 205434/S-016

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 April 12, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flonase Sensimist Allergy Relief (fluticasone furoate) nasal spray, 27.5 mcg per spray and Flonase Allergy Relief (fluticasone propionate) nasal spray, 50 mcg per metered spray.

These “Prior Approval” supplemental new drug applications provide for the following:

NDA 022051/S-023 Flonase Sensimist Allergy Relief (fluticasone furoate) nasal spray, 27.5 mcg per spray

1. Implement the changes approved in NDA 22051/S-021.

For the Children’s Flonase Sensimist Allergy Relief principal display panel (PDP) “lid”:

2. Add a butterfly graphic to the Children’s Flonase brand logo.
3. Add a graphic of a kid and a pet next to the image of the bottle.

For the Children’s Flonase Sensimist Allergy Relief immediate container label:

4. Add a butterfly graphic to the brand logo.

For the Flonase Sensimist Allergy Relief 72-spray count bonus pack PDP “lid”:

5. Implement the changes approved in NDA 22051/S-021.

NDA 205434/S-016 Flonase Allergy Relief (fluticasone propionate) nasal spray, 50 mcg per metered spray

1. Implement the changes under previously approved NDA 205434/S-015.

For the 72-spray count Children's Flonase Allergy Relief PDP "lid":

2. Add a butterfly graphic to the Children's Flonase brand logo.
3. Add a graphic of a kid and a pet next to the image of the bottle.

For the 72-spray count Children's Flonase Allergy Relief immediate container label:

4. Add a butterfly graphic to the brand logo.

For the 72-spray count Flonase Allergy Relief 72-spray count bonus pack PDP "lid":

5. Implement the changes approved in NDA 205434/S-015.

For the 90-spray count Flonase Allergy Relief 72-spray count bonus pack PDP "lid":

6. Implement the changes approved in NDA 205434/S-015.

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

For NDA 205434/S-016, the Children's 72-spray count immediate container label, there is an asterisk that appears after the Statement of Identity (SOI), but nowhere on the label does it define the meaning of this asterisk. Remove the asterisk and submit the updated label as part of the FPL submission.

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

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Submitted Draft Labeling	Date
72-spray count Children's PDP "lid" (outer container) front	04/12/2024
72-spray count Children's (outer container) back	04/12/2024
72-spray count Children's wraparound label (immediate container)	Pending FPL
72-spray count, bonus pack PDP "lid" (outer container) front	08/09/2024
72-spray count, bonus pack (outer container) back	08/09/2024
72-spray count, bonus pack wraparound label (immediate container)	09/10/2024
90-spray count, bonus pack PDP "lid" (outer container) front	08/09/2024
90-spray count, bonus pack (outer container) back	08/09/2024
90-spray count, bonus pack wraparound label (immediate container)	09/10/2024

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Submitted Draft Labeling	Date
60-spray count Children's PDP "lid" (outer container)	08/09/2024
60-spray count Children's (outer container) back	08/09/2024
60-spray count Children's (immediate container) front	08/09/2024
60-spray count Children's (immediate container) back	09/10/2024
72-spray count bonus pack PDP "lid" (outer container) front	08/09/2024
72-spray count bonus pack (outer container) back	08/09/2024
72-spray count bonus pack (immediate container) front	08/05/2024
72-spray count bonus pack (immediate container) back	09/10/2024

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-23 and NDA 205434/S-16.**" Approval of this submission by FDA is not required before the labeling is used.

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>.

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 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).

² <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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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):

- 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/

MARTHA K LENHART
10/24/2024 01:59:12 PM