NDA 022051/S-027
NDA 205434/S-018

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 June 23, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 022051/S-027: Flonase Sensimist Allergy Relief (fluticasone furoate) nasal spray, 27.5 mcg per spray

- NDA 205434/S-018: Flonase Allergy Relief (fluticasone propionate) nasal spray, 50 mcg per spray

These "Prior Approval" supplemental new drug applications provide for "bonus pack" principal display panel (PDP) "lid" labels and "bonus pack" immediate container labels.

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.

We remind you that research has shown that increased package sizing of products leads to increased usage among consumers.[1,2] Conversely, limiting pack sizes of

[1] Wansink, B. (1996). Can package size accelerate usage volume? Journal of Marketing, 60(3), 1-14.
[2] Chandon, P., & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience–salience framework of postpurchase consumption incidence and quantity. Journal of Marketing Research, 39(3), 321-335.

medication has been shown to reduce episodes of overconsumption by limiting the immediate availability of the drug to the consumer.[3,4]

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.

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.

NDA 022051/S-027: Flonase Sensimist Allergy Relief (fluticasone furoate) nasal spray, 27.5 mcg per spray

Submitted Draft Labeling	Date
Children's 72-spray-count "20% MORE 12 EXTRA SPRAYS" PDP "lid"	12/11/2025
Children's 72-spray-count "20% MORE 12 EXTRA SPRAYS" Immediate container (Front)	06/23/2025
Children's 72-spray-count "20% MORE 12 EXTRA SPRAYS" Immediate container (Back)	08/29/2025

[3] Hawton, K., Bergen, H., 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.

[4] Weiss, S. (2009). Compliance packaging for over-the-counter drug products. Journal of Public Health, 17(2), 155-164.

NDA 205434/S-018: Flonase Allergy Relief (fluticasone propionate) nasal spray, 50 mcg per spray

Submitted Draft Labeling	Date
Children's 90ct "25% MORE 18 EXTRA SPRAYS" PDP "lid"	12/11/2025
Children's 90ct "25% MORE 18 EXTRA SPRAYS" immediate container wraparound label	08/29/2025

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*.[5] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 022051/S-27 and NDA 205434/S-18**." 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.[6] 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

[5] 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.

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

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}

Nushin Todd, MD, PhD
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/

NUSHIN F TODD
12/19/2025 06:25:15 AM