



NDA 022051/S-013

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Linval Francis, M.Sc.
Sr. Manager, US Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Francis:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 2, 2015, 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.

This “Prior Approval” sNDA provides for the use of Flonase Sensimist Allergy Relief (fluticasone furoate nasal spray) for the temporary relief of these symptoms due to hay fever or other upper respiratory allergies in children ages 2 years and older and adults: nasal congestion; runny nose; sneezing; itchy nose; and itchy, water eyes for ages 12 and older.

We have completed our review of this application, as amended. This sNDA, for a full prescription to nonprescription (Rx-to-OTC) switch, is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling.

We have approved package sizes for this product amid concerns that consumers follow instructions that limit duration of use of over-the-counter nasal corticosteroids to no longer than 2 months a year in children. The “Directions” section of the Drug Facts labeling for the product states “Talk to your child’s doctor if your child needs to use the spray for longer than two months a year.”

Research has shown that increased package sizing of products leads to increased usage among consumers.^{1,2} Conversely, limiting pack sizes of medication has been shown to reduce episodes of overconsumption by limiting the immediate availability of the drug to the consumer.^{3,4}

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.

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.

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 Flonase Sensimist Allergy Relief labeling listed below (enclosed labeling), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
60-spray count blister card	7/29/16
120-spray count blister card	7/29/16
Drug Facts peel-back label	7/8/16
2 x 120-spray count blister card	8/1/16
3 x 120-spray count blister card front	8/1/16
3 x 120-spray count blister card back	7/29/16
30-count carton (professional sample)	8/2/16
60-spray count (Children’s) blister card	7/29/16
60-spray count (Children’s) bottle front	7/29/16
30-spray count bottle front	7/29/16
60-spray count bottle front	7/29/16
120-spray count bottle front	7/29/16
30-, 60- and 120-spray count bottle back	8/1/16
Patient Questions and Answers Leaflet	7/8/16
Quick Start Guide	7/8/16
Patient Question and Answer Book	8/1/16

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

The FPL should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).”

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 022051/S-013.**” Approval of this submission by FDA is not required before the labeling is used.

Remove the “NEW” flag from the labels after 6 months of marketing.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT

08/02/2016

Signing on behalf of Dr. Theresa Michele