DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022051/S-017

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Michael Cammarata
Manager, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Mr. Cammarata:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 23, 2017, 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 "Changes Being Effected" supplemental new drug application provides for correction of an error in the labeling regarding the fill volume statement.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below.

Remove the "NEW" flag on the upper left side of the front blister cards and front panel as this product line has been marketed for over 6 months.

LABELING

Submit final printed labeling, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to submitted labeling described in the table below, with the removal of the "NEW" flag referenced above, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
30-spray count carton (professional sample)	February 23, 2017
30-spray count bottle front	February 23, 2017
60-spray count blister card	February 23, 2017
60-spray count bottle front	February 23, 2017

120-spray count blister card	February 23, 2017
120-spray count bottle front	February 23, 2017
2 x 120-spray count blister card	February 23, 2017
3 x 120-spray count blister card front	February 23, 2017
60-spray count (Children's) blister card	February 23, 2017
60-spray count (Children's) bottle front	February 23, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 022051/S-017**." 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 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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

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

ENCLOSURES:
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/

THERESA M MICHELE
08/23/2017