DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205434

NDA APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Erin Oliver
Head US Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Ms. Oliver:

Please refer to your New Drug Application (NDA) dated September 21, 2013, received September 23, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flonase Allergy Relief (fluticasone propionate) Metered Spray, 50 mcg per spray.

We acknowledge receipt of your amendments dated October 9, 2013, November 7, 15 (2), 2013, January 6, 17 (2), April 4, May 13, 23, 27, June 19 (2), and July 22, 2014.

This NDA provides for the use of Flonase Allergy Relief (fluticasone propionate) Metered Spray for the temporary relief of symptoms due to hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose, and itchy, watery eyes.

We have completed our review of this application, as amended. This NDA, for a partial 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 text.

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 following labeling submitted via email on July 22, 2014 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

- 60- and 120-spray count immediate containers
- 60- and 120-spray count principal display panels (PDPs)
- 3 x 120-spray count club pack carton
- Drug Facts (peel-back label attached to back of all clamshell packs)
- Question & Answer Book
- Quick Start Guide

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 205434**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

If sending via USPS, please send to:

Jung Lee, RPh
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5487
10903 New Hampshire Avenue
Silver Spring, Maryland **20993**

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Jung Lee, RPh
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5487
10903 New Hampshire Avenue
Silver Spring, Maryland **20903**

ADDITIONAL COMMENTS

The submitted data do not support the proposed over-the-counter (OTC) use of Flonase Allergy Relief (fluticasone propionate) Metered Spray for the (b) (4) due to

(b) (4)

(b) (4)

To support your proposed OTC labeling [redacted] (b) (4), we recommend that you:

1. [redacted] (b) (4)
2. [redacted]

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 Jung Lee, Regulatory Project Manager, at (301) 796-3599.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling
Question & Answer Book
Quick Start Guide

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
07/23/2014