CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-051

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-051

GlaxoSmithKline
P. O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Attention: Munir Abdullah, Ph.D.
Director, Regulatory Affairs

Dear Dr. Abdullah:

Please refer to your new drug application (NDA) dated June 28, 2006, received June 29, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Veramyst (fluticasone furoate) Nasal Spray 27.5 mcg.

We acknowledge receipt of your submissions dated July 20, September 13, October 3, 4, 5, 18, and 20, December 13, 14, and 20, 2006, and January 8, 10, 19, 26, and 31, February 5, and 13, March 15, 26, and 27, April 2, 3, 5, 6, 11, 12, 17, 24, 25, and 26, 2007.

This new drug application provides for the use of Veramyst (fluticasone furoate) Nasal Spray 27.5 mcg for treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient information leaflet, submitted on April 26, 2007, and immediate container and carton labels submitted on April 26, 2007). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"FPL for approved NDA 22-051."** Approval of this submission by FDA is not required before the labeling is used.

Within 30 days of the date of this letter, submit the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the labeling text submitted on April 26, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have not fulfilled the requirement for patients less than 2 years of age. We are waiving the requirement for pediatric studies for this application.

We remind you of your postmarketing study commitments in your submission dated April 11, 2007. These commitments are listed below.

1. To conduct a one-year linear growth study in children with fluticasone furoate using a dose that is relevant to the proposed fluticasone furoate nasal spray dose in children. A linear growth study conducted with a formulation other than the nasal formulation may be adequate provided the systemic exposure from that formulation is higher than the systemic exposure from the nasal formulation. Submit a labeling supplement reflecting the results of the study.

   Protocol Submission Date: August 2007
   Study Start Date: November 2007
   Final Report Submission Date: November 2011

2. To conduct a 2-year safety study to assess the long-term effects of fluticasone furoate nasal spray on ocular safety, including cataract formation and the development of elevated intraocular pressure/glaucoma. Submit a labeling supplement reflecting the results of the study.

   Protocol Submission Date: October 2007
   Study Start Date: January 2008
   Final Report Submission Date: February 2011

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Commitment Protocol"**, **"Postmarketing Study Commitment Final Report"**, or **"Postmarketing Study Commitment Correspondence."**

We remind you of the following agreements as listed in your submission dated March 26, 2007. Submit available results and updated progress status with a projected completion date in each annual report to this NDA.

1. To continue drug substance stability studies and submit comparative data to support recent synthetic changes and confirm the ---------- for the drug substance manufactured with a fully representative commercial process. In addition, you agree to provide updated reports on the mass imbalance, formation of --------- ----------, and reevaluation of the current acceptance criteria for drug substance and drug product impurities.

2. To submit release and stability data on six drug product batches (three for each presentation) manufactured with the fully representative commercial process, to support recent device and assembly process changes, and to confirm 24 month expiry period for the drug product manufactured with the fully representative commercial process. In addition, you agree to provide comparative analyses of the dose performance parameters for commercial, stability and clinical batches.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Products, and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Ms. Ladan Jafari, Regulatory Project Manager, at (301) 796-1231.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: PKG Insert, Patient Information Leaflet

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

/s/

Badrul Chowdhury
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