



NDA 22051/S-002

APPROVAL LETTER

GlaxoSmithKline
5 Moore Drive
Research Triangle Park, NC 27709

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

Dear Dr. Abdullah:

Please refer to your supplemental new drug application dated January 28, 2009, received January 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Veramyst (fluticasone furoate) Nasal Spray.

We acknowledge receipt of your submission dated, July 9, 2009.

This supplemental new drug application provides for the addition of hypersensitivity to the CONTRAINDICATIONS sections of the Highlights and Full Prescribing Information (FPI) and hypersensitivity reactions including anaphylaxis, angioedema, rash and urticaria to Section 6.2 (Postmarketing Experience) of the label. These revisions are the terms of the approval of this application.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the revisions indicated in the enclosed labeling.

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the submitted attached labeling text for the package insert and patient package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission **“SPL for approved NDA 22051/S-002.”**

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 Carol Hill, Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

BADRUL A CHOWDHURY
07/28/2009