



NDA 22051/S-005

**SUPPLEMENT APPROVAL**

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 (sNDA) dated March 1, 2011, received, March 1, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Veramyst (fluticasone furoate) Nasal Spray 27.5 mcg.

We acknowledge receipt of your amendment dated, August 24, 2011.

This “Changes Being Effected” supplemental new drug application provides for the following changes:

Package Insert

1. Deletion of the Recent Major Changes from the Highlights along with the change bars alongside the associated text in the Full Prescribing Information.
2. Miscellaneous editorial changes.

Patient Information Leaflet

3. Moving the statements regarding possibly allergy to ingredients from the heading “**What should I tell my healthcare provider before taking VERAMYST Nasal Spray?**” to a new heading “**Who should not use VERAMYST Nasal Spray?**” and deleted reference to “other nasal corticosteroid” in this text.
4. Revision of the section under the heading “**What are the possible side effects of VERAMYST Nasal Spray?**” to be consistent with the package insert.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient information leaflet), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **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 Carol F. Hill, Senior Regulatory Health Project Manager, at (301) 796-1226

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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LYDIA I GILBERT MCCLAIN  
09/01/2011  
Acting Division Director