DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-389/S-027

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 supplemental new drug application dated April 26, 2005, received April 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Beconase AQ (beclomethasone dipropionate monohydrate) Nasal Spray 42 mcg.

This "Changes Being Effected" supplemental new drug application proposes to add "anaphylactoid/anaphylactic reactions" to the following paragraph in the ADVERSE REACTIONS section of the package insert.

> Rare cases of immediate and delayed hypersensitivity reactions, including anaphylactoid/anaphylactic reactions, urticaria, angioedema, rash, and bronchospasm, have been reported following the oral and intranasal inhalation of beclomethasone dipropionate.

We completed our review of this supplemental new drug application. It is are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 26, 2005.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 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 Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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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