DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-473/S-030

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, North Carolina 27709

Attention: C. Elaine Jones, Ph.D.
Director, Regulatory Affairs

Dear Dr. Jones:

Please refer to your supplemental new drug application dated August 16, 2001, received August 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ventolin (albuterol, USP) Inhalation Aerosol

This "Changes Being Effected" supplemental new drug application provides for the addition of a Geriatric Use subsection to the package insert.

We completed our review of this supplemental new drug application, It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 16, 2001.

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, HF-2
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 Akilah Green, Regulatory Project Manager, at (301) 827-1050.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD., Ph.D.
Director
Division of Pulmonary and Allergy Drug 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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