DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-236/S-028

GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

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

Dear Dr. Jones:

Please refer to your supplemental new drug application dated August 6, 2003, received August 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serevent (salmeterol xinafoate) Inhalation Aerosol.

This supplemental new drug application provides for revision to the package insert to incorporate results of the Serevent Multicenter Asthma Research Trial (SMART) including a boxed warning and revisions to the WARNINGS section and the Information for Patients subsection of the PRECAUTIONS section.

We 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 6, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-236/S-028." Approval of this submission by FDA is not required before the labeling is used.

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 Akylah Green, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

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

Marianne Mann
8/11/03 05:50:32 PM
Signing for Dr. Chowdhury in his absence in my role as Acting Director.