CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20236/S017

APPROVAL LETTER

DEC 2 4 1998

NDA 20-236/S-017

Glaxo Wellcome Inc.
Five Moore Drive
P.O.Box 13398
Research Triangle Park, North Carolina 27709

Attention: Ramona E. Krailler, Ph.D.
Product Director, Regulatory Affairs

Dear Dr. Krailler:

Please refer to your supplemental new drug application dated July 6, 1998, received July 7, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serevent (salmeterol xinafoate) Inhalation Aerosol.

Reference is also made to your December 21, 1998, telephone conversation with Ms. Parinda Jani of this Division.

We note that the supplement was submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

The supplemental new drug application provides for changes to the Labor and Delivery subsection of the PRECAUTIONS section and to the OVERDOSAGE section. In addition, "Rx only", patent, and copyright statements have been added to the end of the labeling.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

As you agreed, the following changes will be made in the package insert at the next printing or 6 months, whichever occur first.

> The efficacy tables in the Clinical Trials subsection of the CLINICAL PHARMACOLOGY section will be modified to specify which Serevent product is the source of the data.

The changes may be reported in the annual report.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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, contact Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research