CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 20-692 S001/002

Trade Name: Serevent Diskus

Generic Name: Salmeterol Xinafoate Inhalation Powder

Sponsor: Glaxo Wellcome

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APPLICATION NUMBER: 20-692 S001/002

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)			X	
EA/FONSI			X	
Pharmacology Review(s)	X			

Statistical Review(s)	X
Microbiology Review(s)	X
Clinical Pharmacology Biopharmaceutics Review(s)	X
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APPLICATION NUMBER: 20-692 S001/002

APPROVAL LETTER

NDA 20-692/S-001, S-002

Glaxo Wellcome Inc.
Five Moore Drive
P.O.Box 13358
Research Triangle Park, North Carolina 27709

Attention: John W. Morgan, Ph.D.
Associate Director, Regulatory Affairs

Dear Dr. Morgan:

Please refer to your supplemental new drug applications dated September 24, 1997, received September 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serevent Diskus (salmeterol xinafoate inhalation powder).

We acknowledge receipt of your submissions dated December 18, 1997, January 15, August 12, and September 4 and 24, 1998 (S-001) and November 4, 1997, January 15, April 16, August 12, and September 1 and 24, 1998 (S-002). The user fee goal date for these applications is September 26, 1998.

Supplement S-001 provides for the use of Serevent Diskus for the treatment of exercise-induced bronchospasm in adults and children 4 years of age and older with reversible obstructive airway disease.

Supplement S-002 provides pediatric labeling for children 4 to 11 years of age for the maintenance treatment of asthma and prevention of bronchospasm.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL

for approved supplement NDA 20-692/S-001, S-002." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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 Ms. Parinda Jani, Project Manager, at (301) 827-1050.

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

Enclosure