CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20692

Trade Name: SEREVENT DISKUS

Generic Name: SALMETEROL XINAFOATE

Sponsor: GLAXO WELLCOME INC

Approval Date: SEPTEMBER 19, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20692

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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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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-692

SEP 19 1997

Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, North Carolina 27709

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

Dear Dr. Morgan:

Please refer to your pending new drug application dated June 18, 1996, received June 19, 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 June 26, September 20, 23, and 27, October 8, 16, and 21, November 19, 20, and 21, 1996, and January 28, April 1, 17, 21, and 23, May 30, June 18, July 22, and 25, August 22, 24, and 26, and September 15, 16, and 18, 1997. Your submission dated May 30, 1997, extended the user fee due date to September 19, 1997.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for the long-term, twice-daily (morning and evening) administration in the maintenance treatment of asthma and in the prevention of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease, including patients with symptoms of nocturnal asthma, who require regular treatment with inhaled, short-acting $beta_2$-agonists, as recommended in the draft physician labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the mock-up carton and container labels submitted on September 18, 1997, and the enclosed marked-up draft physician labeling and patient package insert. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

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, this submission should be designated "FPL for approved NDA 20-692." Approval of this submission by FDA is not required before the FPL may be used.

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

We remind you of your Phase 4 commitments specified in your submissions dated May 30, August 24, and September 15, 1997. These commitments are listed below.

Redacted 1

page(s) of trade secret and/or confidential commercial information

Protocols, data, and final reports related to the Phase 4 commitments should be submitted to this NDA. For administrative purposes, all submissions, including all supplements, relating to these Phase 4 commitments must be clearly designated as "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any deficiencies that may occur.

Please submit one market package of the drug product when it is available.

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

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

Parinda Jani
Project Manager
(301) 827-1057

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