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JUL 19 1995

Glaxo Inc.
Five Moore Drive
P.O. Box 13358
Research Triangle Park, NC 27709

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

Dear Dr. Morgan:

Reference is made to your supplemental new drug application dated April 28, 1995 submitted pursuant to section 505(b) of the Federal Food, Drug and Cosmetic Act for the product Serevent (salmeterol xinafoate) Inhalation Aerosol.

We acknowledge receipt of your amendments dated June 7 and 30, 1995.

The supplemental application provides for revised specifications for the propellants analytical methods for determination of propellant-related impurity levels, and a test method for non-volatile matter.

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

We have the following additional comments.

1. It is recommended that, where possible, concentrations of individual impurities in the impurity standard should be close to the specification limits.
2. Please clarify that a GC analysis is performed for every batch of impurity standard mixture to ensure that the appropriate concentrations are present.

3. You are reminded of your commitment in the amendment dated June 7, 1995 to provide any assistance which the Agency might require in performing methods validation.

We remind you that you must comply with the requirements for an approved NDA as set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

Guirag Poochikian, Ph.D.
Supervisory Chemist
Division of ~~Oncology~~ and
Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:

Orig. NDA 20-236

HFD-155/Division File

HFD-155/ACSchroeder/7-14-95

HFD-155/GPoochikian

HFD-156/CSO PJani

HFD-155/JJenkins

HFC-130/JAllen (District Office Copy)

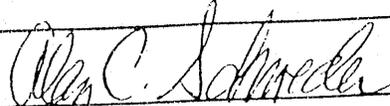
R/D Init. by: GPoochikian 7/14/95

F/T by: RMcCree

doc. #N20236L1.S10

*AC & for GP
7/17/95*

SUPPLEMENTAL NDA APPROVAL

CHEMIST'S REVIEW		1. ORGANIZATION HFD-155 DPDP	2. NDA NUMBER 20-236	JUL 14 1995
3. NAME AND ADDRESS OF APPLICANT (City and State) Glaxo Inc./P.O. Box 13358/Research Triangle Park, NC 27709.....ATTN. John W. Morgan, Ph.D.			4. AF NUMBER	5. SUPPLEMENT(S) NUMBER(S) DATES(S) SCS-010 (4/28/95)
6. NAME OF DRUG Serevent Inhalation Aerosol	7. NONPROPRIETARY NAME salmeterol xinafoate inhalation aerosol		9. AMENDMENTS DATES 6/7/95 (BC) 6/30/95 (BC)	
8. SUPPLEMENT PROVIDES FOR: Revised specifications for analytical methods for determination of propellant-related impurity levels, and a test method for non-volatile matter. (This supplement will allow the use of any supplier for these CFCs, provided that the propellants from other suppliers conform to the proposed specifications. Changes in suppliers may be reported in the next annual report.)			12. RELATED IND/NDA/DMF	
10. PHARMACOLOGICAL CATEGORY beta ₂ -adrenoceptor agonist for treatment of bronchospasm	11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		16. RECORDS AND REPORTS CURRENT YES ___ NO ___ REVIEWED YES ___ NO ___	
13. DOSAGE FORM(S) inhalation aerosol	14. POTENCY 21 mcg/inhalation			
15. CHEMICAL NAME AND STRUCTURE see USAN 1994				
17. COMMENTS see page 2 CC: Orig. NDA #20-236 HFD-155/Div. File HFD-155/ACSchroeder/7-14-95 HFD-155/GPoochikian HFD-156/CSO PJani HFD-155/RNicklas R/D Init. by: <u>RP 7/14/95</u> F/T by: ACSchroeder/7-14-95 doc # n20236r1.s10				
18. CONCLUSIONS AND RECOMMENDATIONS It is recommended that this supplement be approved. See attached draft letter, with comments that should be included in the approval letter.				
19. REVIEWER NAME Alan C. Schroeder, Ph.D.			SIGNATURE 	
DISTRIBUTION ORIGINAL JACKET <input type="checkbox"/> DIVISION FILE <input type="checkbox"/>			DATE COMPLETED 7/14/95	
REVIEWER <input type="checkbox"/> CSO <input type="checkbox"/> SUP. CHEMIST <input type="checkbox"/>				