NDA 20-236/S-010

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 propellent-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's for GP
7/17/95

SUPPLEMENTAL NDA APPROVAL

CHEMIST'S REVIEW

1. ORGANIZATION
HFD-155 DPDP

2. NDA NUMBER
20-236

JUL 14 1995

4. AF NUMBER

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.

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

8. SUPPLEMENT PROVIDES FOR:
Revised specifications for analytical methods for determination of propellent-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.)

9. AMENDMENTS DATES
6/7/95 (BC)
6/30/95 (BC)

10. PHARMACOLOGICAL CATEGORY
beta$_2$-adrenoceptor agonist for treatment of bronchospasm

11. HOW DISPENSED
RX X OTC ___

12. RELATED IND/NDA/DMF

13. DOSAGE FORM(S)
inhalation aerosol

14. POTENCY 21 mcg/inhalation

15. CHEMICAL NAME AND STRUCTURE
see USAN 1994

16. RECORDS AND REPORTS
CURRENT YES__NO__
REVIEWED YES__NO__

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: QP 7/14/95
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 Alan C. Schroeder

DATE COMPLETED
7/14/95

DISTRIBUTION ORIGINAL JACKET __ DIVISION FILE __ REVIEWER __ CSO __ SUP. CHEMIST __