

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 16-126 / S-023

Name: Primatene Mist Inhalation Aerosol

Sponsor: Wyeth Consumer Healthcare

Approval Date: November 24, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:
NDA 16-126 / S-023**

CONTENTS

Reviews / Information Included in this Review
--

Approval Letter	X
Approvable Letter(s)	
Approved Labeling	
Labeling Review(s)	
Medical Review(s)	
Chemistry Review(s)	X
Statistical Review(s)	
Microbiology Review(s)	
Administrative Document(s)	
Correspondence	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 16-126 / S-023

APPROVAL LETTER

NDA 16-126/S-023

Whitehall-Robins
Five Giralda Farms
Madison, NJ 07940-0871

Attention: Ken Warner
Director, Regulatory Affairs CMC

Dear Mr. Warner:

Please refer to your supplemental new drug application dated July 27, 1999, received July 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primatene Mist (epinephrine) Inhalation Aerosol.

This supplemental new drug application provides for CFC blending operations carried out at the _____.

We have completed the review of this supplemental application and it is approved, with the understanding that the submitted _____ manufacturing batch record is owned by, and currently used by, _____ at their _____ facility.

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,

Guirag Poochikian, Ph.D.
Chemistry Team Leader for
Division of Pulmonary and Allergy Drug Products (HFD-570)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

NDA 16-126/S-023

Page 2

cc:

Archival NDA 16-126

HFD-570/Div. Files

HFD-570/Jani

HFD-570/Schroeder/11-24-99

HFD-570/Poochikian/11-24-99

HFD-560/Merritt

HFD-560/Ganley

HFD-095/DDMS-IMT

HFD-820/DNDC Division Director

DISTRICT OFFICE

Drafted by: HFD-570/Hilfiker/November 24, 1999

Initialed by: HFD-570/Barnes/11-24-99

Final: HFD-570/Hilfiker/11-24-99

Filename: c:\my_documents\N16126\S023\99-11-24.apltr.doc

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 16-126 / S-023

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-820	2. NDA NUMBER 16-126
3. NAME AND ADDRESS OF APPLICANT (City and State) Whitehall-Robins, Five Giralda Farms, Madison, NJ 07940-0871		4. AP NUMBER	
		5. SUPPLEMENT (S) NUMBER (S) DATES (S)	
6. NAME OF DRUG Primatene Mist	7. NONPROPRIETARY NAME epinephrine inhalation aerosol	SCS-023 7/27/99	
8. SUPPLEMENT PROVIDES FOR: CFC blending operations at _____ facility in _____ (drug product manufacturing site, formerly _____).		9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY bronchodilator	11. HOW DISPENSED RX _____ OTC _____ X	12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) metered dose inhaler	14. POTENCY 0.22 mg epinephrine (base) per inhalation		
15. CHEMICAL NAME AND STRUCTURE See USP		16. RECORDS AND REPORTS CURRENT YES _____ NO _____ REVIEWED YES _____ NO _____	
17. COMMENTS cc: Orig. NDA #16-126 HFD-560/Div. File HFD-570/ACSchroeder/11-22-99 HFD-570/GPoochikian HFD-570/CSO PJani HFD-570/SJohnson HFD-560/BMerritt R/D Init. by: _____ F/T by: ACSchroeder/11-22-99 doc #N16126R1 S23.doc			
18. CONCLUSIONS AND RECOMMENDATIONS This supplement may be approved. The comment at the end of this review should be included in the approval letter.			
19. REVIEWER			
NAME Alan C. Schroeder, Ph.D.	SIGNATURE		DATE COMPLETED 11/22/1999
DISTRIBUTION	ORIGINAL JACKET _____	DIVISION FILE _____	REVIEWER _____ CSO _____ SUP. CHEMIST _____

Redacted 7 page(s)

of trade secret and/or

confidential commercial

information from

16-126/S-023

CHEMISTRY REVIEW.