

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 16-126 / S-024

Name: Primatene Mist Inhalation Aerosol

Sponsor: Wyeth Consumer Healthcare

Approval Date: November 24, 1999

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**APPLICATION NUMBER:
NDA 16-126 / S-024**

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Reviews / Information Included in this Review
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APPLICATION NUMBER:
NDA 16-126 / S-024

APPROVAL LETTER

NDA 16-126/S-024

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 30, 1999, received August 4, 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 transfer of the chlorofluorocarbon supply from the _____ to the _____ manufacturing facility in _____.

We have completed the review of this supplemental application and it is approved.

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

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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/11-24-99

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

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

Filename: c:\my_documents\N16126\S024\99-11-24.apltr.doc

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 16-126 / S-024

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. AF NUMBER	
		5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
6. NAME OF DRUG Primatene Mist	7. NONPROPRIETARY NAME epinephrine inhalation aerosol	SCS-024 7/30/99	
8. SUPPLEMENT PROVIDES FOR: Transfer of CFC stockpiling from _____ facility to _____ facility (drug product manufacturing site).		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/11-23 -99 HFD-570/GPoochikian HFD-570/CSO PJani HFD-570/SJohnson HFD-560/BMerritt R/D Init. by: _____ F/T by: ACSchroeder/11-23 -99 doc #N16126R1 S24.doc			
18. CONCLUSIONS AND RECOMMENDATIONS This supplement may be approved. Project manager should prepare an AP letter.			
19. REVIEWER			
NAME Alan C. Schroeder, Ph.D.	SIGNATURE		DATE COMPLETED 11/23/1999
DISTRIBUTION	ORIGINAL JACKET	DIVISION FILE	REVIEWER
CSO	SUP. CHEMIST		

Redacted 2 page(s)

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information from

16-126/S-024 CHEMISTRY REVIEW