

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 16-126 / S-027

Name: Primatene Mist Inhalation Aerosol

Sponsor: Wyeth Consumer Healthcare

Approval Date: January 25, 2002

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**APPLICATION NUMBER:
NDA 16-126 / S-027**

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APPLICATION NUMBER:
NDA 16-126 / S-027

APPROVAL LETTER



NDA 16-126/SCS-027

Whitehall-Robins Healthcare
5 Giralda Farms
Madison, NJ 07940

Attention: Ken Warner
Director, Regulatory Affairs CMC

Dear Mr. Warner:

Please refer to your supplemental new drug application dated August 17, 2001, received August 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primatene Mist (epinephrine) Inhalation Aerosol.

This "Changes Being Effected" supplemental new drug application provides for mixing of residual _____ CFC-12 propellant in storage tanks with new CFC-12 propellant obtained from _____

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

In addition, we have the following comments:

1. Investigate and _____ when filling the storage tanks with CFC's, and during storage.
2. If the use of a _____ for CFC-12 propellant in the tank is shown to be necessary, submit a proposal for this in a supplement with appropriate data, since S-023 only pertains to _____ CFC-12 and CFC-114 in the manufacturing process. It does not pertain to bulk propellant in the storage tank.

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

Food and Drug Administration
Rockville MD 20857

If you have any questions, call Colette Jackson, Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Guirag Poochikian, Ph.D.
Chemistry Team Leader
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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/s/

Guiragos Poochikian
1/25/02 01:12:02 PM

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APPLICATION NUMBER:
NDA 16-126 / S-027

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-820/570	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	
6. NAME OF DRUG Primatene Mist	7. NONPROPRIETARY NAME epinephrine inhalation aerosol	5. SUPPLEMENT (S) NUMBER(S) DATES(S) SCS-027 (8/17/2001)	
8. SUPPLEMENT PROVIDES FOR: mixing of residual _____ CFC-12 propellant in storage tanks with new CFC-12 propellant obtained from _____ _____ CBE-0 supplement.		9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY bronchodilator	11. HOW DISPENSED RX OTC • SPECIAL DRUG PRODUCT YES NO x	12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) inhalation aerosol	14. POTENCY 0.22 mg epinephrine (base) per inhalation	16. RECORDS AND REPORTS CURRENT YES NO REVIEWED YES <input type="checkbox"/> NO	
15. CHEMICAL NAME AND STRUCTURE see USAN		16. RECORDS AND REPORTS CURRENT YES NO REVIEWED YES <input type="checkbox"/> NO	
17. COMMENTS CC: Orig. NDA #16-126 HFD-570/Div. File HFD-570/GPoochikian HFD-570/SBarnes HFD-560/BMerritt HFD-550/RPuttagunta HFD-550/JSmith R/D Init. by: _____ doc # N16126R1.S027.doc			
18. CONCLUSIONS AND RECOMMENDATIONS This supplement may be approved. The comments at the end of the review should be included in the approval letter.			
19. REVIEWER			
NAME Alan C. Schroeder, Ph.D.		SIGNATURE	DATE COMPLETED 1/03/2002
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16-126/S-027 CHEMISTRY REVIEW

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/s/

Alan Schroeder
1/10/02 11:44:35 AM
CHEMIST
Action letter to be prepared by HFD-570.

Guiragos Poochikian
1/10/02 04:19:27 PM
CHEMIST