CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 16-126 / S-028

Name:	Primatene Mist Inhalation Aerosol
Sponsor:	Wyeth Consumer Healthcare
Approval Date:	January 13, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-028

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	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-028

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-126/S-028

Wyeth Consumer Healthcare
Attention: Susan Beavis
Director, Regulatory Affairs CMC
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Beavis:

Please refer to your supplemental new drug application dated July 15, 2003, received July 16, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primatene Mist® (epinephrine inhalation aerosol, USP), 5.5 mg/mL.

This supplemental new drug application provides for a ———— for individual CFCs (CFC 12 or CFC 114).

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 827-2276.

Sincerely,

{See appended electronic signature page}

John Smith, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Smith
1/13/04 08:49:13 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-028

CHEMISTRY REVIEW(S)

Chemistry Review # 1	**1. Division** HFD-560	**2. NDA Number** 16-126

3. Name and Address of Applicant
Wyeth Consumer Healthcare
Attention: Susan Beavis, Director, Regulatory Affairs CMC
5 Giralda Farms
Madison, NJ 07940
Phone: 973-660-5068

4. Supplement
Number: SCS-028
Letter Date: 7/15/03
Stamp Date: 7/16/03
PDUFA Due Date: 1/16/04

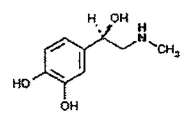
5.Name of Drug Primatene Mist	**6. Nonproprietary Name** Epinephrine Inhalation Aerosol, USP

7. Supplement Provides for:
A [redacted] for individual CFCs (CFC 12 or CFC 114)

8. Amendment(s)
N/A

9.Pharmacological Category Bronchodilator	**10. How Dispensed** OTC	**11. Related Documents** N/A
12. Dosage Form Aerosol	**13. Potency(ies)** 5.5 mg/mL	

14. Chemical Name and Structure
(-)-3,4-Dihydroxy-a-[(methylamino)methyl]benzyl alcohol,
$C_9H_{13}NO_2$, mol. wt. 183.20



15. Comment **Changes Being Effected**

This supplement provides for [redacted] individual CFCs (CFC 12 or CFC 114). It was stated that the proposed procedure is the same as the one that was approved for [redacted] CFC 12/114 blend (NDA 16-126/SCS-023, approved 11/24/99).

The same type of [redacted].) and [redacted] are used for the individual and blended CFCs. It was proposed that the [redacted] be used if the [redacted] is [redacted]. The same criterion for the [redacted] was used for the blended CFCs (S-023).

[redacted]

16. Conclusions and Recommendations
This supplement is recommended for approval.

17. Name **Date**
Rao Puttagunta, Ph.D., Reviewer 1/12/04

18. Concurrence
John Smith, Ph.D., Chemistry Team Leader

Doc. ID: N16126 SCS-028

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rao Puttagunta
1/13/04 07:20:16 AM
CHEMIST

John Smith
1/13/04 08:08:26 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-028

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-126/S-028

CBE-0 SUPPLEMENT

Wyeth Consumer Healthcare
Attention: Susan Beavis
Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Beavis:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Primatene® Mist (5.5 mg/mL epinephrine) Inhalation Aerosol

NDA Number: 16-126

Supplement Number: S-028

Date of Supplement: July 15, 2003

Date of Receipt: July 16, 2003

This supplemental application, submitted as a "Supplement - Changes Being Effected" supplement, provides a procedure for the —— of individual CFCs.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on September 14, 2003, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be January 16, 2004.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Division Document Room
HFD-560
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Division Document Room
HFD-560
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

David Hilfiker
Chief, Project Management Staff
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Hilfiker
8/22/03 09:14:35 AM