CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 16-126 / S-029

Name:	Primatene Mist Inhalation Aerosol
Sponsor:	Wyeth Consumer Healthcare
Approval Date:	January 15, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-029

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Correspondence	X

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APPLICATION NUMBER:

NDA 16-126 / S-029

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 16-126/S-029

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 30, 2003, received August 1, 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 an alternate supplier of 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

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/s/

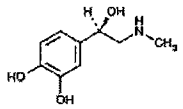
John Smith
1/15/04 08:05:14 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-029

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: 973-660-5139		4. Supplement **Number:** SCM-029 **Letter Date:** 7/30/03 **Stamp Date:** 8/01/03 **PDUFA Due Date:** 2/01/04
5.Name of Drug Primatene Mist	6. Nonproprietary Name Epinephrine Inhalation Aerosol, USP	
7. Supplement Provides for: An alternate supplier of CFC 114 [redacted]		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 an alternate supplier of CFC 114 [redacted]

The proposed supplier was approved for CFC 12 (NDA 16-126/SCS-027, approved 1/25/02). It was stated that the initial shipment form the proposed supplier would be mixed with residual [redacted] (current supplier) CFC 114 in the storage tank. The initial mixing of the CFCs from these suppliers was found acceptable by Dr. Alan Schroeder, HFD-570, in S-027 (see Dr. Schroeder's review in DFS for details).

The "General Process and Testing Requirements for Introduction of Additional CFCs ("Replenishment") of Storage Tanks" listed in the submission (Attachment 1) are the same as those in the approved supplement.

[redacted]

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

17. Name	Date
Rao Puttagunta, Ph.D., Reviewer	1/14/04

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

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/s/

Rao Puttagunta
1/15/04 07:49:30 AM
CHEMIST

John Smith
1/15/04 08:01:17 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 16-126 / S-029

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-126/S-029

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-029

Date of Supplement: July 30, 2003

Date of Receipt: August 1, 2003

This supplemental application, submitted as a "Supplement - Changes Being Effected" supplement, provides for an alternate supplier for CFC 114.

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 30, 2003, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be February 1, 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
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
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

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/s/

David Hilfiker
8/27/03 01:28:16 PM