CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

020503/S-047

Trade Name: Proventil® HFA (albuterol sulfate) Inhalation Aerosol

Generic Name: albuterol sulfate

Sponsor: 3M Drug Delivery Systems Division

Approval Date: 02/25/2013

Indication: Proventil® HFA (albuterol sulfate) Inhalation Aerosol is indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20503/S-047

APPROVAL LETTER

3M Drug Delivery Systems Division
Attention: Dina Clementson
Senior Regulatory Affairs Associate
3M Center, Bldg. 275-3E-02
St. Paul, MN 55144

Dear Ms. Clementson:

Please refer to your Supplemental New Drug Application (sNDA) dated November 30, 2012, received December 4, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Proventil® HFA (albuterol sulfate) Inhalation Aerosol.

This "Prior Approval" supplemental new drug application proposes addition of new (b) (4) test method.

We have completed our review of this supplemental new drug application. This supplement 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, call Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

RAMESH RAGHAVACHARI
02/25/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

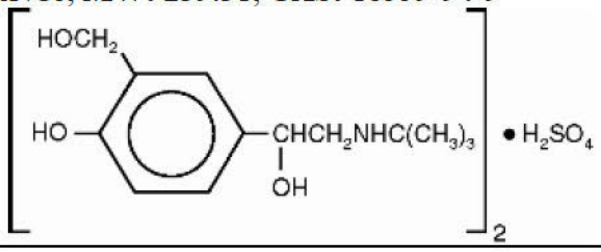
020503/S-047

CHEMISTRY REVIEW(S)

Chemistry Review:# 1	**1. Division:** HFD-570	**2. NDA Number: 20-503**	
3. Name and Address of Applicant: 3M Drug Delivery System Division 3M Center, Bldg. 0275-03-E-02 St. Paul, MN 55144-1000		**4. Supplement(s):** PA **Number:** S-047 **Date(s):** 04-DEC-2012	
5. Name of Drug: Proventil® HFA (Albuterol Sulfate) Inhalation Aerosol		**6. Nonproprietary name:** Albuterol Sulfate	
7. Supplement Provides for: the addition of a new [redacted] (b) (4) test method for diaphragms, seals & O-rings and a [redacted] (b) (4) for the [redacted] (b) (4) test method.			**8. Amendment(s):**
9. Pharmacological Category: Bronchodilator		**10. How Dispensed:** R_x	**11. Related Documents:** DMF 12952
12. Dosage Form: Inhalation Aerosol		**13. Potency:** 108 mcg per actuation	

14. Chemical Name and Structure: (RS)-4-[2-(tert-butylamino)-1-hydroxyethyl]-2 (hydroxymethyl) phenol

Molecular Formula: $C_{13}H_{21}NO_3$; **MW:** 239.31; **CAS:** 18559-94-9



15. Comments:

- In this PAS, the Applicant is updating the NDA to reflect the cross-referenced DMF 12952 (Title: Container Closure System for Non-CFC Inhalation Aerosols, DMF Holder: 3M) changes: addition of the new [redacted] (b) (4) test method for diaphragms, seals & O-rings and [redacted] (b) (4) for the [redacted] (b) (4) test method.
- There is no information provided in the supplement besides the Letter of Authorization for DMF 12952.
- DMF 12952 was reviewed and deemed Adequate (reviewed by Dr. D. Lakhani, 22-FEB-2013)

16. Conclusion: Recommend Approval from CMC perspective.

17. Name:	**Signature:**	**Date:**
Deepika Arora Lakhani, Ph.D., Chemist		**02/22/2013**
18. Concurrence:	**Signature:**	**Date:**
Jim Vidra, Ph.D., Branch Chief, Div., IX, ONDQA		**02/22/2013**

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/s/

DEEPIKA LAKHANI
02/25/2013
Recommend Approval from CMC perspective.

RAMESH RAGHAVACHARI
02/25/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20503/S-047 **PRIOR APPROVAL SUPPLEMENT**

3M Drug Delivery Systems Division
Attention: Dina M. Clementson
Sr. Reg. Associate
3M Center, Bldg. 275-3E-02
St. Paul, MN 55144

Dear Ms. Clementson:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA NUMBER: 20503

SUPPLEMENT NUMBER: S-047

PRODUCT NAME: Proventil® HFA (albuterol sulfate) Inhalation Aerosol

DATE OF SUBMISSION: November 30, 2012

DATE OF RECEIPT: December 4, 2012

This supplemental application provides for addition of new (b) (4) test method.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on February 2, 2013 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be April 4, 2012.

Please cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy, and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have questions, please call me at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Youbang Liu
Regulatory Project Manager
Division III of New Drug Quality Assessment
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

YOUBANG LIU
12/31/2012