

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
021747Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

22 JUNE 2009

NDA: 21-747

Drug Product Name

Proprietary: COMBIVENT RESPIMAT

Non-proprietary: ipratropium bromide and albuterol sulfate

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
7 October 2008	8 October 2008	13 November 2008	20 November 2008

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Boehringer Ingelheim Pharmaceuticals, Inc.

Address: 900 Riodgebury Road, Ridgefield, CT 06877

Representative: Amy Van Andel

Telephone: 203-798-5452

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** New Drug Application 505(b)(2)
 2. **SUBMISSION PROVIDES FOR:** Inhalation spray drug product
 3. **MANUFACTURING SITE:** Boehring Ingelheim Pharma GmbH
Binger Strasse 173
55216 Ingelheim/Rhein
Germany
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile preserved aqueous solution for oral inhalation in a cartridge, 20 µg ipratropium bromide and 100 µg albuterol sulfate per actuation. The cartridge will be used with the Respimat metered dose inhaler.
 5. **METHOD(S) OF STERILIZATION:** (b) (4)
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of bronchospasms
- B. **SUPPORTING/RELATED DOCUMENTS:** Product quality microbiology review of DMF (b) (4) (review dated 22 June 2009)
- C. **REMARKS:** This was a paper submission in the CTD format. This drug product was developed as a propellant-free version of the approved COMBIVENT inhalation aerosol (CFC-MDI).

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is [REDACTED]^{(b) (4)} [REDACTED].
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
Senior Review Microbiologist OPS/NDMS
- B. Endorsement Block** _____
James L. McVey
Team Leader OPS/NDMS
- C. CC Block**
N/A

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this page is the manifestation of the electronic signature.**

/s/

Bryan Riley
6/24/2009 12:32:47 PM
MICROBIOLOGIST

James McVey
6/24/2009 12:51:34 PM
MICROBIOLOGIST
I concur.