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

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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: Boehringer 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 (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).

filename: N021747R1.doc
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 (b) (4).

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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/s/

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

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