

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-658

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD-000

19 MARCH 2004

NDA: 21-658

Drug Product Name

Proprietary: ALVESCO MDI

Non-proprietary: ciclesonide

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 22 December 2003

Receipt Date: 24 December 2003

Consult Date: 26 January 2004

Date Assigned for Review: 19 February 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Aventis Pharmaceutical

**Address: 200 Crossing Blvd., Route 202-206; PO Box 6890;
Bridgewater, NJ 08807-0890**

Representative: Steve Caffè, MD, VP Regulatory Affairs

Telephone: 908-231-5863

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
 2. SUPPLEMENT PROVIDES FOR: N/A
 3. MANUFACTURING SITE:
 b(4)
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Metered Dose Inhaler for oral inhalation, _____ 80 mcg and 160 mcg
 5. METHOD(S) OF STERILIZATION: N/A
 6. PHARMACOLOGICAL CATEGORY: Treatment of Asthma
- B. SUPPORTING/RELATED DOCUMENTS: N/A
- C. REMARKS: This review covers the microbiological challenge study performed on the drug product to demonstrate the inability of the drug product to support microbial growth. This was an electronic submission.

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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 a non-sterile MDI.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product composition is hostile to vegetative microorganisms and therefore presents a minimal risk from the standpoint of product quality microbiology.

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. **CC Block**
N/A

3 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)



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/s/

Bryan Riley
4/2/04 10:29:14 AM
MICROBIOLOGIST

Peter Cooney
4/2/04 10:46:07 AM
MICROBIOLOGIST

