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 Caffe, 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)
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

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

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