

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-433

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-570

22 NOVEMBER 2002

NDA: 21-433

Drug Product Name

Proprietary: Flovent HFA Inhalation Aerosol

Non-proprietary: Fluticasone propionate

Drug Product Classification: S

Review Number: 1

Subject of this Review

Submission Date: 26 February 2002

Receipt Date: 27 February 2002

Consult Date: 10 October 2002

Date Assigned for Review: 21 October 2002

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: GlaxoSmithKline

Address: One Franklin Place; PO Box 7929; Philadelphia, PA 19101

Representative: Lorna C. Wilson, Director, Reg. Affairs

Telephone: 919-483-5121

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:** Glaxo Wellcome Production
Zone Industrielle No. 2
23 Rue Lavoisier
BP118
27000 Evreux
France
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Aerosol for Oral Inhalation, 44, 110, and 220 µg/actuation
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of Asthma
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** N/A

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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, inhalation aerosol.
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – The drug product

Therefore, the drug product 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

✓ § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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/s/

Bryan Riley
11/27/02 11:02:30 AM
MICROBIOLOGIST

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