

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-051

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** Nasal Spray
 3. **MANUFACTURING SITE:**
Glaxo Operations UK
Hamire Rd
Branard Castle
County Durham
DL12 8DT
United Kingdom
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Non sterile nasal spray in an amber glass bottle with atomizing spray pump, 27.5 mcg/actuation. — or 120 actuations/bottle
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of seasonal and perennial allergic rhinitis.
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This review addresses the microbial quality of the drug product and the use of a rapid microbiology method for release testing of the drug product.

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Product Quality Microbiology Review

24 OCTOBER 2006

NDA: 22-051

Drug Product Name

Proprietary: N/A

Non-proprietary: fluticasone furoate nasal spray

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
6/28/2006	6/29/2006	8/29/2006	8/31/2006

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: GlaxoSmithKline

Address: One Franklin Plaza, PO Box 7929, Philadelphia, PA 19101

Representative: Munir Abdullah, Ph.D.

Telephone: 919-483-9318

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

Conclusion: Recommended for Approval

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 nasal spray with a microbial limits specification.
- 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.

- B. Endorsement Block** _____
James L. McVey
(Microbiology Team Leader)

- C. CC Block**
N/A

5 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Bryan Riley
10/25/2006 01:49:34 PM
MICROBIOLOGIST

James McVey
10/25/2006 02:06:40 PM
MICROBIOLOGIST