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RESEARCH**

*APPLICATION NUMBER:*

**204275Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

20 November 2012

**NDA:** 204-275/N-000

**Drug Product Name**

**Proprietary:** BREO Elliptal

**Non-proprietary:** fluticasone furoate/vilanterol

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

<b>Submit</b>	<b>Received</b>	<b>Review Request</b>	<b>Assigned to Reviewer</b>
11 July 2012	12 July 2012	21 September 2012	26 September 2012

**Submission History (for amendments only):** Not applicable

**Applicant/Sponsor**

**Name:** GlaxoSmithKline

**Address:** Glaxo Wellcome House  
Berkley Avenue  
Greenfield Middlesex  
UB6 0NN UK

**Representative:** Patrick D. Wire, Pharm. D

**Telephone:** 919-483-7650

**Name of Reviewer:** Stephen E. Langille, Ph.D.

**Conclusion:** Recommended for approval

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## Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original Submission
  - 2. SUBMISSION PROVIDES FOR:** An oral inhaled powder
  - 3. MANUFACTURING SITE:** Glaxo Operations UK Ltd  
Priory St.  
Ware  
Hertfordshire SG12 0DJ  
UK
  - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - Dry powder in blister strips
    - Inhalant
    - 100 ug fluticasone furoate/25 ug vilanterol
  - 5. METHOD(S) OF STERILIZATION:** Not applicable
  - 6. PHARMACOLOGICAL CATEGORY:** Treatment for chronic obstruction pulmonary disease (COPD).
- B. SUPPORTING/RELATED DOCUMENTS:** None
- C. REMARKS:** The submission was provided in eCTD format

**filename:** N204275r1.doc

## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability -**  
NDA 204-275/N-000 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**  
Not applicable

### **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 dry powder inhalant that is processed using a (b) (4) packaging procedure.
- B. Brief Description of Microbiology Deficiencies -**  
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**  
Not applicable.

### **III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Stephen E. Langille, Ph.D.  
Senior Microbiology Reviewer
- B. Endorsement Block** \_\_\_\_\_  
Stephen E. Langille, Ph.D.  
Senior Microbiology Reviewer
- C. CC Block**  
N/A

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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STEPHEN E LANGILLE  
11/27/2012

JOHN W METCALFE  
11/27/2012  
I concur.