CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205625Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

18 June 2014

NDA: 205625

Drug Product Name
Proprietary: Not applicable
Non-proprietary: fluticasone furoate inhalation powder

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
22 October 2013	22 October 2013	24 October 2013	25 October 2013

Applicant/Sponsor
Name: GlaxoSmithKline
Address: 980 Great West Road
Brentford, Middlesex, UK UB6 0NN

Representative: Christopher J. Stotka
Telephone: 919-483-4411

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

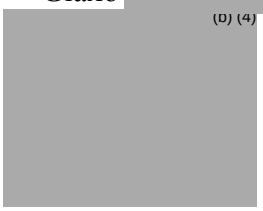
Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: A new non-sterile inhalation product.

3. MANUFACTURING SITE: Glaxo (b) (4)



4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Non-sterile powder
- Inhalation
- 100 ug or 200 ug per dose

5. METHOD(S) OF STERILIZATION: Not applicable

6. PHARMACOLOGICAL CATEGORY: Treatment for asthma

B. SUPPORTING/RELATED DOCUMENTS: Not applicable

C. REMARKS: The application was submitted in eCTD format.

filename: N205625r1.doc.

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended for Approval

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 dry blended powder for inhalation. The applicant proposes a two tiered microbial limits testing regimen involving the bulk drug product and product packaged in the blister packs.

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

D. Contains Potential Precedent Decision(s)- ☐ **Yes** ☒ **No**

III. Administrative

A. Reviewer's Signature _____
Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer

B. Endorsement Block _____
Bryan Riley, Ph.D.
Acting Team Leader

C. CC Block
N/A

8 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

---

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

/s/

STEPHEN E LANGILLE
06/20/2014

BRYAN S RILEY
06/20/2014
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 205625 **Applicant:** GlaxoSmithKline **Letter Date:** 22 OCT 2013

Drug Name: fluticasone furoate inhalation powder **NDA Type:** Standard **Stamp Date:** 22 OCT 2013

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Section 3.2.P.3.3
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Section 3.2.P.3.5
4	Are any study reports published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?		X	The drug product is a non-sterile (b) (4) powder.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Section 3.2.P.5.1
7	Has the applicant submitted the results of analytical method verification studies?	X		Section 3.2.P.5.3
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?		X	No such studies were requested by the NDMS.
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The applicant proposes the use of a two-tiered approach to microbial limits testing similar to that approved in NDA 204-275.

Reviewing Microbiologist 28 OCT 2013
Stephen E. Langille, Ph.D.

Microbiology Secondary Reviewer/Team Leader 28 OCT 2013
John Metcalfe, Ph.D.

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

/s/

STEPHEN E LANGILLE
10/29/2013

JOHN W METCALFE
10/30/2013
I concur.