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

<table>
<thead>
<tr>
<th>Submit</th>
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<th>Review Request</th>
<th>Assigned to Reviewer</th>
</tr>
</thead>
</table>

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

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

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

STEPHEN E LANGILLE
10/29/2013

JOHN W METCALFE
10/30/2013
I concur.