CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203975Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

03 April 2013

NDA: 203975

Drug Product Name
Proprietary: ANORO Ellipta™
Non-proprietary: umeclidinium and vilanterol

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
19 DEC 2012	19 DEC 2012	15 FEB 2013	22 FEB 2013

Applicant/Sponsor
Name: Glaxo Group Limited, England d/b/a GlaxoSmithKline
Address: Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UK
Representative: Mary Sides (Authorized US Agent)
Telephone: 919-483-6464

Name of Reviewer: Erika Pfeiler, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: 505(b)(1)

2. SUBMISSION PROVIDES FOR: Initial marketing of a drug product

3. MANUFACTURING SITE:
Glaxo Operations UK Ltd
Priory Street
Ware
Hertfordshire SG12 0DJ, UK

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
Oral powder for inhalation in blister packs
62.5/25 µg and 125/25 µg umeclidinium/vilanterol

5. METHOD(S) OF STERILIZATION: N/A, drug product is nonsterile

6. PHARMACOLOGICAL CATEGORY: Treatment of airflow obstruction in patients with COPD

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: This document was submitted in the eCTD format.

filename: N203975R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended for Approval

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 – Drug product is subjected to a two-tiered microbiological quality release testing scheme.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

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

Water activity testing to replace microbial limits testing for release of dry oral inhalation products

21 CFR 211.165(a) and (b) requires appropriate laboratory testing of each batch of drug product for release. For nonsterile dry oral inhalation products, testing of drug product water activity may be sufficient to forgo microbial limits testing at release if adequate microbiological control is demonstrated during manufacturing. A product-specific risk assessment should be included in the application identifying potential routes of microbial contamination and the steps taken to mitigate the risk of adulteration.

More information can be seen on pages 4-6 of this review.

III. Administrative

A. Reviewer's Signature _____
Erika Pfeiler, Ph.D.

B. Endorsement Block_____
Stephen Langille, Ph.D.
Senior Microbiology Reviewer

C. CC Block
N/A

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/s/

ERIKA A PFEILER
04/03/2013

STEPHEN E LANGILLE
04/03/2013