CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205641Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 19 July 2013

TO: NDA 205641

FROM: Bryan S. Riley, Ph.D.
Team Leader (Acting)
OPS/New Drug Microbiology Staff

THROUGH: Stephen E. Langille, Ph.D.
Senior Review Microbiologist
OPS/New Drug Microbiology Staff

cc: Jessica K. Lee, PharmD
Regulatory Project Manager
OND/DPARP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for ASMANEX HFA [Submission Date: 27 June 2013]

The Microbial Limits specification for ASMANEX HFA (mometasone furoate) is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

ASMANEX HFA is a (b) (4) suspension in a metered dose inhaler for oral inhalation.

The drug product is tested for Microbial Limits at release using a method consistent with USP Chapter <61> (Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests) and <62> (Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms). The Microbial Limits acceptance criteria are consistent with USP Chapter <1111> (Microbiological Examination of Non-sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use).

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Table 1 – Microbial Limits Specification

Test	Acceptance Criteria	Method
Total Aerobic Microbial Count	NMT (b) (4) CFU/g	USP <61>
Total Yeast and Mold Count	NMT (b) (4) CFU/g	USP <61>
Staphylococcus aureus	Absence in (b) (4) g	USP <62>
Pseudomonas aeruginosa	Absence in g	USP <62>
Bile-tolerant gram-negative bacteria	Absence in g	USP <62>

The Microbial Limits test methods were verified to be appropriate for use with the drug product following procedures consistent with those in USP Chapter <61> and <62>.

The drug product will also be tested for Microbial Limits at 0, 24 and 36 months as part of the post-approval stability protocol.

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol.

END

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/s/

BRYAN S RILEY
07/22/2013

STEPHEN E LANGILLE
07/22/2013