CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204977Orig1s000

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: 12 March 2013

TO: NDA 204977

FROM: Bryan S. Riley, Ph.D., Senior Review Microbiologist (OPS/NDMS)

THROUGH: John W. Metcalfe, Ph.D., Senior Review Microbiologist (OPS/NDMS)

cc: Kati Johnson, Project Manager (OND/DMEP)

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for AKR-963 Capsules (omega-3-acid ethyl esters) [Submission Date: 31 January 2013]

The Microbial Limits specification for AKR-963 is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

AKR-963 is a Capsule for oral administration.

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).

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 annually 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.

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END

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/s/

BRYAN S RILEY
03/14/2013

JOHN W METCALFE
03/14/2013
I concur.