

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**207071Orig1s000**

**MICROBIOLOGY / VIROLOGY REVIEW(S)**

MEMORANDUM



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

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**DATE:** 02 April 2015

**TO:** NDA 207071

**FROM:** Jessica G. Cole, PhD  
Review Microbiologist  
CDER/OPS/New Drug Microbiology Staff  
(301) 796-5148

**THROUGH:** Stephen Langille, PhD  
Microbiology Branch Chief  
CDER/OPQ/OPF/Division of Microbiology Assessment

**cc:** Omolara Laiyemo, OND/ODEIII/DDDP

**SUBJECT:** Product Quality Microbiology assessment of Microbial Limits for Finacea Foam (Azelaic acid (b) (4) 15%) [Submission Date: 30 September 2014]

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The Microbial Limits specification for Finacea Foam (Azelaic acid (b) (4) 15%) is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Finacea Foam (Azelaic acid (b) (4) 15%) is an emulsion aerosol foam for topical use to treat (b) (4) rosacea. The drug product is (b) (4)

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 drug product will have (b) (4)

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## MEMORANDUM

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> . Three batches

(b) (4)



**ADEQUATE**

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

**END**

MEMORANDUM

Jessica Cole -S

Digitally signed by Jessica Cole -S  
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ou=FDA, ou=People, cn=Jessica Cole -S,  
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Stephen E.  
Langille -A

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