CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205488Orig1s000

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: 1 May 2013

TO: NDA 205488

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

THROUGH: Stephen E. Langille, Ph.D.
Senior Review Microbiologist (OPS/NDMS)

cc: Jeannie Roule
RPM (OND/DRUP)

SUBJECT: Product Quality Microbiology assessment of Microbial Quality for Testosterone Nasal Gel [Submission Date: 29 APRIL 2013]

The Microbial Limits specification for Testosterone Nasal Gel is acceptable from a Product Quality Microbiology perspective and the drug product meets the acceptance criteria for Antimicrobial Effectiveness Testing. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Testosterone Nasal Gel is packaged in a multi-dose applicator pump. The drug product formulation does not contain a preservative but it is non-aqueous (Castor Oil base).

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 also be tested for Microbial Limits annually as part of the post-approval stability protocol.

Table 1: Microbial Limits Acceptance Criteria

	Release	Stability
Total Aerobic Microbial Count Total Combined Yeast and Mold Count	(b) (4)	
P. aeruginosa	Absent in 1 g	Absent in 1 g
S. aureus	Absent in 1 g	Absent in 1 g

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 was also tested for antimicrobial effectiveness using USP <51> and met the acceptance criteria for a Category 2 (non-sterile nasal) product.

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol and the drug product formulation is acceptable for a multi-dose container.

END

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/s/

BRYAN S RILEY
05/13/2013

STEPHEN E LANGILLE
05/13/2013