

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22309Orig1s000

MICROBIOLOGY REVIEW(S)

NDA 22-309/SD-029 is a Class 2 resubmission to address the deficiency identified in the Agency's Complete Response Letter of 12 March 2010. The deficiency required the Applicant to perform additional clinical studies. In this submission the results of those studies are presented. There was no CMC Chemistry or Microbiology information submitted for review. My previous review dated 29 October 2009 is remains unchanged. It is noted here that in correspondence to the Agency dated 16 August 2010, the ownership of NDA 22-309 was formally changed from Unimed Pharmaceuticals, LLC., to Abbott Products, Inc.

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/s/

ROBERT J MELLO
11/18/2010

Product Quality Microbiology Review

28 OCTOBER 2009

NDA: 22-309/N-000

Drug Product Name

Proprietary: AndroGel® 1.62%
Non-proprietary: testosterone gel 1.62%

Review Number: 1

Dates of Submission(s) Covered by this Review

<u>Submit</u>	<u>Received</u>	<u>Review Request</u>	<u>Assigned to Reviewer</u>
11 FEBRUARY 2009	12 FEBRUARY 2009	06 APRIL 2009	09 APRIL 2009

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Unimed Pharmaceuticals, LLC
Address: 901 Sawyer Road
Marietta, GA 30062
Representative: Steven Wojtanowski
Telephone: 770-578-2073

Name of Reviewer: Robert J. Mello, Ph. D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint. One COMMENT is to be submitted to the Applicant

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA 505(b)(2)
 - 2. SUBMISSION PROVIDES FOR:** U.S. Marketing Authority
 - 3. MANUFACTURING SITE:**  (b) (4)
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Topical Gel, transdermal (underarm), 1.62%
 - 5. METHOD(S) OF STERILIZATION:**  (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Hormone replacement therapy
- B. SUPPORTING/RELATED DOCUMENTS:**
-  (b) (4)
- C. REMARKS:**
- The ONDQA Initial Quality Assessment was entered into DFS (now DARRTS) on 09 APRIL 2009. A microbiology consult was transmitted to review the applicant's request to delete release and stability testing for microbial limits.
 - The submission is an electronic, technical submission in eCTD format. It was located and reviewed from the Electronic Document Room (EDR) via the Global submit system.
 - **N21-015** (AndroGel[®] (Testosterone, USP) 1% Gel) was approved in 2/2000 for the hormone replacement therapy in hypogonadal adult males. **N21-015/SCP-010** was approved on 9/26/2003 for an alternate container closure system consisting of a multi-pump and canister delivery system in 44 g and 88 g sizes.

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – Recommend Approval
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** - None

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is (b) (4) and is packaged in a pump system. The drug product is formulated using ethyl alcohol to a final, absolute alcohol concentration of (b) (4). Due to the formulation's viscosity (b) (4) the drug product. (b) (4)
 (b) (4) The applicant requests the deletion of microbial limits testing for routine commercial release and stability. Microbial limit testing was performed on three validation demonstration batches and was undetected at an assay limit of < 10CFU/g.
- B. Brief Description of Microbiology Deficiencies** - None
- C. Assessment of Risk Due to Microbiology Deficiencies** – The drug formulation represents a minimal risk to the patient.

III. Administrative

- A. Reviewer's Signature** _____
 Robert J. Mello, Ph. D.
 Microbiology Reviewer
- B. Endorsement Block** _____
 Bryan S. Riley, Ph. D.
 Senior Microbiology Reviewer
- C. CC Block**
 NDA 22-309

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22309	ORIG-1	UNIMED PHARMACEUTICA LS INC	ANDROGEL

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/s/

ROBERT J MELLO
10/29/2009

BRYAN S RILEY
10/29/2009
I concur.