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RESEARCH**

APPLICATION NUMBER:
021463Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-580

7 NOVEMBER 2002

NDA: 21-463

Drug Product Name

Proprietary: Tostrex

Non-proprietary: Testosterone gel

Drug Product Classification: S

Review Number: 1

Subject of this Review

Submission Date: 31 May 2002

Receipt Date: 3 June 2002

Consult Date: 21 August 2002

Date Assigned for Review: 23 August 2002

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Cellegy Pharmaceuticals

**Address: 349 Oyster Point Blvd. Suite 200; South San Francisco, CA
94080**

Representative: William Schary, Ph.D., RAC

Telephone: 650-606-2200

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUPPLEMENT:** N/A
2. **SUPPLEMENT PROVIDES FOR:** N/A
3. **MANUFACTURING SITE:** (b) (4)
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Non-sterile, topical, gel, 2% w/w
5. **METHOD(S) OF STERILIZATION:** N/A
6. **PHARMACOLOGICAL CATEGORY:** Androgen
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** N/A

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is a non-sterile gel.
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – The drug product meets the acceptance criteria for Antimicrobial Effectiveness (USP <51>) the composition is unlikely to support microbial growth. Therefore, the drug product presents a minimal risk from the standpoint of product quality microbiology.

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. CC Block**
N/A

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**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Bryan Riley
11/8/02 10:23:28 AM
MICROBIOLOGIST

Peter Cooney
11/8/02 11:39:09 AM
MICROBIOLOGIST