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APPLICATION NUMBER:

21-813

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

11-October-2006

NDA: 21-813
21-813-BI

Drug Product Name
Proprietary: Bio-E-Gel™
Non-proprietary: estradiol gel
Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

Submission	Letter	Stamp	Consult Sent	Assigned to Reviewer
NDA 21-813	2/17/06	2/21/06	7/24/06	7/25/06
NDA 21-813-BI	9/28/06	9/9/06	9/29/06	Not applicable

Submission History (for amendments only): Not applicable

Applicant/Sponsor
Name: Biosante Pharmaceuicals
Address: 111 Barclay Blvd.
Lincolnshire, IL 60069
Representative: Joanne Zborowski
Telephone: 847-478-0500

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original Application

2. SUBMISSION PROVIDES FOR: Preservative effectiveness and microbial limits testing for a topical gel drug product.

3. MANUFACTURING SITE: DPT Laboratories, Ltd.
307 E. Josephine St.
San Antonio, TX 78215

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Gel
- Topical
- 0.06% 17-β-estradiol w/w

5. METHOD(S) OF STERILIZATION: Non-sterile drug product

6. PHARMACOLOGICAL CATEGORY: Hormone

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS: An information request was e-mailed to Ms. Joanne Zborowski in the Biosante Pharmaceuticals Inc. regulatory affairs department on September 20, 2006. Ms. Zborowski mailed a response to the agency on 9/28/06.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 21-813 is recommended for approval from the standpoint of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -
Not applicable

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 topical gel containing [ ]% ethanol. The results of preservative effectiveness testing and microbial limits specifications were provided in the application.

B. Brief Description of Microbiology Deficiencies -
No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -
Not applicable.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
James McVey, Team Leader

C. CC Block
N/A

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Microbiology Review

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/s/

Stephen Langille
10/11/2006 03:26:55 PM
MICROBIOLOGIST

James McVey
10/12/2006 09:19:09 AM
MICROBIOLOGIST