CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-788

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD-580

9 March 2005

NDA:	21-788
Drug Product Name	
Proprietary:	Cenetstin Vaginal Cream
Non-proprietary:	NA
Drug Product Classification:	S1
Review Number:	1
Subject of this Review	
Submission Date:	June 25, 2004
Receipt Date:	Electronic submission
Consult Date:	October 28, 2004
Date Assigned for Review:	November 11, 2004

Submission History (for amendments only)
Date(s) of Previous Submission(s): NA
Date(s) of Previous Micro Review(s): NA

Applicant/Sponsor	
Name:	Duramed Pharmaceuticals Inc
Address:	4040 Broadway, San Antonio, TX
Representative:	Patricia Thomas, c/o Barr Research
Telephone:	609-897-0809 ext 2169
Name of Reviewer:	Vinayak B. Pawar
Conclusion:	The application is recommended for approval from microbiological standpoint.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** New NDA

2. **SUPPLEMENT PROVIDES FOR:** NA

3. **MANUFACTURING SITE:** San Antonio, TX 78215

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 0.625 mg/g Vaginal Cream

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

6. **PHARMACOLOGICAL CATEGORY:** Conjugated Estrogen Treatment

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** The consult requests review of NDA 21-788 for drug product Cenestin vaginal cream 0.625 mg/g. The application for a non-sterile product was an electronic submission which included no microbiology summary but did include data for Microbial Limits Tests and Antimicrobial Effectiveness Testing in the CMC section.

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APPEARS THIS WAY
ON ORIGINAL

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval based on the microbiology product quality review for a non-sterile product.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The final form of the drug substance is prepared

b(4)

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies - NA

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Vinayak B. Pawar, Ph.D.
David Hussong, Ph.D., Microbiology Supervisor

C. CC Block
cc:
Original NDA 21-788
HFD- 580/Division File/George Lyght

4 Page(s) Withheld

X Trade Secret / Confidential (b4)

X Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

Vinayak Pawar
3/18/05 01:13:07 PM
MICROBIOLOGIST

Recommended for approval from microbiological standpoint

David Hussong
3/18/05 04:33:31 PM
MICROBIOLOGIST