CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-476

Microbiology Review(s)
Product Quality Microbiology Review
Review for HFD-120

22 November 2004

NDA: 21-476

Drug Product Name
   Proprietary: Estorra
   Non-proprietary: eszopiclone
   Drug Product Classification: nonbenzodiazepine hypnotic

Review Number: 1

Subject of this Review
   Submission Date: 02/06/04
   Receipt Date:
   Consult Date: 11/01/04
   Date Assigned for Review: 11/09/04

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

Applicant/Sponsor
   Name: Sepracor Inc.
   Address: 84 Waterford Drive
             Marlborough, MA 01752-7010
   Representative: P. Manbhar, Ph.D.
   Telephone: (508) 357-7457

Name of Reviewer: James L. McVey

Conclusion: The applicant has established for the drug substance but covers himself with a requirement to be below , growth in the product is not likely.
Summary

I. Recommendations

A. Recommendation on Approvability – Recommended for approval.

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 – Review of applicants response to questions 7.d and 24 in the Feb. 6, 2004 amendment were requested.

Question 7 is in regard to the drug substance eszopiclone.

7.d) Provide justification of the microbial specifications ( )

even though the release and stability data show the value to be

Acceptable

Question 24 is regarding the drug product; Estorra Tablets.

Comment 24: Microbial Specifications Provide justification for the microbial specifications ( ) for the drug product even though the release and stability data show the value to be
Acceptable

B. Brief Description of Microbiology Deficiencies – None.

C. Assessment of Risk Due to Microbiology Deficiencies – N. A.

III. Administrative

A. Reviewer's Signature ____________________________

B. Endorsement Block
   Microbiologist: James L. McVey
   Microbiology Supervisor: David Hussong

C. CC Block
   cc: DFS
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
---------------------
James McVey
11/23/04 02:12:56 PM
MICROBIOLOGIST

David Hussong
11/23/04 02:14:24 PM
MICROBIOLOGIST
Microbiology recommendation - APPROVE