

**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. Manbiar, Ph.D.

**Telephone:** (508) 357-7457

**Name of Reviewer:** James L. McVey

**Conclusion:** The applicant has a \_\_\_\_\_ established for  
the drug substance but covers himself with a \_\_\_\_\_ for the drug  
product. Because the specifications indicate the \_\_\_\_\_ requirement to be  
below \_\_\_\_\_, growth in the product is not likely.

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**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.

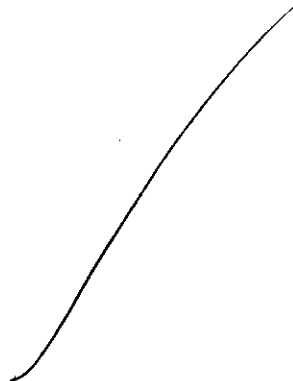
7.d) Provide justification of the microbial specifications (  
even though the release and stability data show the value to be



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

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/s/

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

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