CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-336/21-708

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD 120
22-October-2003

NDA:	21-336-AZ
Drug Product Name:	EMSAM
Non-proprietary Drug Product Classification:	Selegiline Transdermal System
Review Number:	1
Subject of this Review	
Submission Date:	July 31, 2003
Receipt Date:	August 1, 2003
Consult Date:	August 29, 2003
Date Assigned for Review:	September 25, 2003
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	
Date(s) of Previous Micro Review(s):	
Applicant/Sponsor	
Name:	Somerset Pharmaceuticals Inc.
Address:	2202 N. West Shore Blvd., Suite 450 Tampa, Florida 33607
Representative:	Melissa L. Goodhead
Telephone:	(813) 288-0040
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Original NDA amendment

2. **SUPPLEMENT PROVIDES FOR:** Not applicable

3. **MANUFACTURING SITE:** Mylan Technologies Inc.
10 Lake St.
St. Albans, VT

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

- Transdermal patch
- 20 mg/cm^2, 30 mg/cm^2, and 40 mg/cm^2

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

6. **PHARMACOLOGICAL CATEGORY:** treatment for depression

B. **SUPPORTING/RELATED DOCUMENTS:** NDA 21-336

C. **REMARKS:** The Applicant did not establish a requirement for microbial limits testing in NDA 21-336 (20 mg/20cm^2 Selegiline Transdermal System patch). A microbiology consult was not requested for the original NDA. NDA 21-336-AZ is an amendment to the original application and seeks to add 2 new dosage strengths: 30 mg/30 cm^2 and 40 mg/40 cm^2. A microbiology consult has been requested for NDA 21-336-AZ to evaluate the Applicant's request to waive microbial limits testing for all 3 dosage strengths.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 21-336-AZ is recommended for approval from the standpoint of microbial product quality.

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 consists of a non-sterile transdermal patch cut into 20 cm^2, 30 cm^2 and 40 cm^2 sizes. The applicant did not establish a requirement for microbial limits testing.

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
Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block
In DFS

3 Page(s) Withheld

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/s/

Stephen Langille
11/12/03 08:44:41 AM
MICROBIOLOGIST

Peter Cooney
11/12/03 02:23:04 PM
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