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: Selegiline Transdermal System
Drug Product Classification:

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/cm², 30 mg/cm², and 40 mg/cm²
    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/20cm² 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 cm² and 40 mg/40 cm². 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.

filename: c:\reviews\21-336r1.doc
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 cm², 30 cm² and 40 cm² 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

√ Trade Secret / Confidential

Draft Labeling

Deliberative Process
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

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

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