

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-479

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-120

10 DECEMBER 2002

NDA: 21-479

Drug Product Name

Proprietary: Zelapar

Non-proprietary: selegiline hydrochloride

Drug Product Classification: S

Review Number: 1

Subject of this Review

Submission Date: 29 March 2002

Receipt Date: 8 April 2002

Consult Date: 16 September 2002

Date Assigned for Review: 27 September 2002

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Elan Pharmaceuticals

Address: 7475 Lusk Blvd.; San Diego, CA 92121

Representative: Donald G. Grilley, Director, Reg. Affairs

Telephone: 858-457-7457

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUPPLEMENT: N/A
2. SUPPLEMENT PROVIDES FOR: N/A
3. MANUFACTURING SITE: [] b(4)
4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Tablet for Oral Administration, 1.25 mg
5. METHOD(S) OF STERILIZATION: N/A
6. PHARMACOLOGICAL CATEGORY: Treatment of Parkinson's Disease
- B. SUPPORTING/RELATED DOCUMENTS: N/A
- C. REMARKS:

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Executive Summary**I. Recommendations**

- A. **Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- 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** – The drug product is a non-sterile solid oral dosage form.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product is a non-sterile solid oral dosage that has been demonstrated to be inhospitable for microorganisms as a bulk aqueous solution. The drug product also has appropriate microbial limit specifications for this type of dosage form. Therefore, the drug product presents a minimal risk from the standpoint of product quality microbiology.

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. **CC Block**
N/A

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Draft Labeling (b4)

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/s/

Bryan Riley
1/13/03 08:31:48 AM
MICROBIOLOGIST

Peter Cooney
1/13/03 09:28:44 AM
MICROBIOLOGIST

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