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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-462

Microbiology Review(s)

Product Quality Microbiology Review
Review for HFD-150
29 October 2003

NDA: NDA 21-462

Drug Product Name

Proprietary: Alimta

Non-proprietary: pemetrexed disodium

Drug Product Classification: anti-cancer

Review Number: 1

Subject of this Review

Submission Date: 29 September 2003

Receipt Date: 30 September 2003

Consult Date: 10 October 2003

Date Assigned for Review: 20 October 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s):

Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: Eli Lilly and Company

Address: Lilly Corporate Center, Indianapolis, IN 46285

Representative: Jeffery Ferguson

Telephone: (317)433-5615

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** Not Applicable
 2. **SUPPLEMENT PROVIDES FOR:** Not Applicable
 3. **MANUFACTURING SITE:** Fegersheim, France
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 500 mg sterile lyophilized powder per vial
 5. **METHOD(S) OF STERILIZATION:** —
 6. **PHARMACOLOGICAL CATEGORY:** Anticancer
- B. **SUPPORTING/RELATED DOCUMENTS:**
- C. **REMARKS:** This — submission of the — NDA adds the Lilly facility at Fegersheim, France as an additional manufacturing site for the vial configuration of the product. The submission references Type V DMF — for the Fegersheim facility. The DMF review has been previously completed by this reviewer and found adequate to support approval of this application. See Microbiologist's Review of Type V DMF — 7 dated 19 March 2003.

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – The submission is recommended for approval on the basis of sterility assurance.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
- B. Brief Description of Microbiology Deficiencies -**
- C. Assessment of Risk Due to Microbiology Deficiencies -**

III. Administrative

- A. Reviewer's Signature** _____ 
- B. Endorsement Block**
Paul Stinavage
Peter H. Cooney
- C. CC Block**
cc: P. Garvey
Original NDA 21-462
HFD-150/Division File/NDA 21-462

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/s/

Paul Stinavage
11/7/03 12:55:23 PM
MICROBIOLOGIST
Product manufacture at Fegersheim facility.

Peter Cooney
11/7/03 01:48:23 PM
MICROBIOLOGIST