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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 dated 19 March 2003.
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 [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
Redacted 6

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/s/

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

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