APPLICATION NUMBER:
22-173

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review

14-February-2008

NDA: 22-173

Drug Product Name
Proprietary: Zyprexa® Adhera
Non-proprietary: olanzapine long-acting injection
Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

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<th>Letter Stamp</th>
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<td>6/28/07</td>
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Submission History (for amendments only): Not applicable

Applicant/Sponsor
Name: Eli Lilly and Company
Address: Lilly Corporate Center
Representative: Indianapolis, IN 46285
Telephone: (317) 276-2000

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval
Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: Sterility assurance package for a terminally sterilized injectable

3. MANUFACTURING SITE: Eli Lilly and Company Lilly Technology Center Indianapolis, IN 46285 U.S.A.

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
   • Sterile injection
   • Intramuscular
   • 210 mg, 300 mg and 405 mg/vial
   • Separate 5 mL vials of drug product depot and vehicle

5. METHOD(S) OF STERILIZATION: 

6. PHARMACOLOGICAL CATEGORY: Treatment of schizophrenia

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS: NDA 22-173 is an electronic submission in CTD format. An IQA recommending a microbiology consult was entered into DFS on July 19, 2007. The drug product consists of a dry powder and an aqueous vehicle packaged in separate vials. The drug product is reconstituted with the vehicle immediately prior to intramuscular administration. A product quality microbiology information request was sent to the applicant on January 29, 2008. Responses to this request were received by e-mail on February 8 and 12, 2008.

filename: N022173R1.doc
Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 22-173 is recommended for approval from the standpoint of product quality microbiology.

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 will be supplied in two parts. The lyophilized depot for injection will be (b) (4)
(b) (4) The liquid “vehicle”, which will be used to re-constitute the drug product, is packaged separately (b) (4)
(b) (4)

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
   James McVey – Team Leader

C. CC Block
   N/A

12 pages of microbiology review has been withheld in full immediately following this page as B4 CCI/TS
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
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Stephen Langille  
4/8/2008 01:32:20 PM  
MICROBIOLOGIST  

Recommended for approval

James McVey  
4/9/2008 08:16:43 AM  
MICROBIOLOGIST