

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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

Letter	Stamp	Review Request	Assigned to Reviewer
4/30/07	4/30/07	6/28/07	7/2/07

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:** (b) (4)
(b) (4)
 - 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.

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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/

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

Recommended for approval

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