

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**21-253**

**MICROBIOLOGY REVIEW**

**REVIEW TO HFD-120  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF/HFD-805  
MICROBIOLOGY REVIEW #1 OF NDA**

31 January 2001

- A.
1. NDA: 21-253
  2. TYPE OF SUPPLEMENT: N/A
  3. SUPPLEMENT PROVIDES FOR: N/A
  4. APPLICANT/SPONSOR: Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285
  5. MANUFACTURING SITES: Same as above (Central File # \_\_\_\_\_, and
  6. DRUG PRODUCT NAME:  
Proprietary: Zyprexa® —  
Nonproprietary: Olanzapine for Injection  
Drug Priority Classification: S
  7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND  
STRENGTH/POTENCY: Sterile Lyophilized Powder for IM injection in a  
glass vial, 10 mg, C
  8. METHOD(S) OF STERILIZATION: The Drug Product is \_\_\_\_\_  
J, sterilized C J
  9. PHARMACOLOGICAL CATEGORY: Anti-Psychotic
- B.
1. DOCUMENT/LETTER DATE: June 15, 2000
  2. RECEIPT DATE: June 16, 2000
  3. CONSULT DATE: June 23, 2000
  4. DATE OF AMENDMENT: N/A
  5. ASSIGNED FOR REVIEW: July 20, 2000
  6. SUPPORTING/RELATED DOCUMENTS: NDA 20-592
- C. REMARKS: This review covers the manufacture of — the lyophilized drug  
product L 1

- D. CONCLUSIONS: This submission is approvable pending resolution of microbiology deficiencies. Please see "Microbiologist's List of Deficiencies" at the end of this review.

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Bryan S. Riley, Ph.D.  
Microbiology Reviewer

cc.: Original NDA 21-253  
HFD 120/Division File  
HFD 120/Project Manager  
HFD 120/Chemist  
HFD 805/Consult File  
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.  
R/D initialed by: Peter Cooney, Ph.D.

filename: C:\Data\Data\Word\NDA\21253.doc

10 page(s) have been  
removed because it  
contains  
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and/or  
confidential information  
that is not disclosable

/s/

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Bryan Riley  
2/16/01 10:25:39 AM  
MICROBIOLOGIST

Peter Cooney  
2/16/01 01:19:59 PM.  
MICROBIOLOGIST