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 __________ 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.

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 initiated by: Peter Cooney, Ph.D.

filename: C:\Data\Data\Word\NDA\21253.doc
10 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable
/s/                      
Bryan Riley
2/16/01 10:25:39 AM
MICROBIOLOGIST

Peter Cooney
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MICROBIOLOGIST