

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**20-919**

**Microbiology Review(s)**

REVIEW TO HFD-120  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST REVIEW OF AN NDA  
October 15, 1998

A. NDA 20-919

PRODUCT NAME: Ziprasidone Mesylate For Injection  
Zeldox IM

APPLICANT: Pfizer, Inc.  
Central Research  
Eastern Point Road  
Groton, Connecticut 06340

MANUFACTURING SITE: [ ] [ ]

DOSAGE FORM: For IM Injection, 20 mg/vial; 20 mg/mL (when  
reconstituted according to label instructions)

METHOD OF STERILIZATION: [ ] [ ]

PHARMACOLOGICAL CATEGORY: Antipsychotic Agent

B. INITIAL APPLICATION DATE: December 17, 1997  
ASSIGNED FOR REVIEW: June 9, 1998

C. REMARKS: A consult was requested to review CMC section for product quality  
microbiology considerations.

D. CONCLUSIONS: The NDA 20-919 which provides for Ziprasidone Mesylate  
for Injection is recommended for approval from the standpoint of product quality  
microbiology. The applicant should be reminded that [ ] [ ] should not  
be used to produce the marketed product until the commitment made by [ ]  
[ ] to validate [ ] [ ] is completed. Please  
see section E for Review Notes.

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Patricia F. Hughes, Ph. D.  
Review Microbiologist

cc.: Original NDA 21-919  
HFD-160 /Consult File  
HFD-805/PFHughes  
HFD-120/Hardeman  
HFD-120/Division File  
Drafted by PFHughes. 10/15/98  
R/D Initialed by PHCooney

*printed from DFS system*  
*11/20/98*  


**ENVIRONMENTAL ASSESSMENT**

**Ziprasidone Mesylate Trihydrate**

**Claim for Categorical Exclusion According to 21 CFR Part 25.15 (a),(d)**

Pfizer Inc claims a categorical exclusion to the environmental analysis requirements in accordance with categorical exclusion criteria 21 CFR Part 25.31 (b): the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. Pfizer Inc claims that to the best of our knowledge no extraordinary circumstances exist.

**Preparers:**

Jon F. Ericson, Senior Research Scientist, Environmental Sciences, Process Research and Development Department, Pfizer Central Research. Analytical Chemist with M.S. and eleven years experience in drug metabolism and environmental science.

James Spavins, Group Director, Analytical Research and Development Department, Pfizer Central Research. Chemical Engineer with M.S. in Chemistry and seventeen years experience with Pfizer's Production and Process Research and Development.

The undersigned official states that the information presented is true, accurate, and complete to the best of Pfizer Inc's knowledge.

Name: Mr. James Spavins

Title: Group Director, Analytical  
Research and Development

Department:  
Process Research and Development

Pfizer Central Research  
Groton, CT 06340

  
Signature

12-4-97  
Date