CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-346

MICROBIOLOGY REVIEW
Product Quality Microbiology Review
Consult review for HFD-120

09 APRIL 2002

ANDA/NDA: NDA 21-346
Name of Drug: RISPERDAL CONSTA
Review Number: 1
Submission Date: AUGUST 31, 2001
Applicant: JANSSEN RESEARCH FOUNDATION
Name of Reviewer: Vinayak Pawar

Conclusion: The application is recommended for approval from the microbiological standpoint of
Product Quality Microbiology Data Sheet

A. 1. NDA: 21-346
   2. REVIEW NUMBER: 1
   3. REVIEW DATE: 09 APRIL 2002
   4. TYPE OF SUPPLEMENT: NA
   5. SUPPLEMENT PROVIDES FOR: NA
   6. APPLICANT/SPONSOR: JANSSEN RESEARCH FOUNDATION
      1125 Trenton-Harbourton Road
      Titusville, New Jersey 08560-0200

      Name: Division of Janssen Pharmaceutica, Inc.
      Representative: Jorge Cruz
      Telephone: 609-730-3080

   7. MANUFACTURING SITE: Wilmington, Ohio
   8. DRUG PRODUCT NAME:
      Proprietary: Risperdal CONSTA™
      Non-proprietary: Risperidone
      Drug Priority Classification: Standard

   9. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
      STRENGTH/POTENCY: 25, 37.5, and 50 mg dosage injected
      intramuscularly.

   10. METHOD (S) OF STERILIZATION: ——

   11. PHARMACOLOGICAL CATEGORY: Schizophrenic treatment

B. 1. DOCUMENT/LETTER DATE: August 31, 2001
   2. RECEIPT DATE: August 31, 2001
   3. CONSULT DATE: October 04, 2001
   4. DATE OF AMENDMENTS: NA
   5. ASSIGNED FOR REVIEW: October 10, 2001
   6. SUPPORTING/RELATED DOCUMENTS: DMF ——
C. **REMARKS**: The consult requests review of NDA 21-346 in support of drug product RISPERDAL CONSTA™ as extended release form of risperidone, microencapsulated in biological polymers for treatment of Schizophrenia. The NDA was submitted as an electronic submission. The NDA makes reference to an amendment to Type II DMF —— which includes specifications and Methods for Parenteral Applications. This microbiology review is for the product and its diluent.
Executive Summary

I. Recommendations

A. Recommendation on Approvability —
This application is submitted as an original New Drug Application for RISPERDAL CONSTA™ long-acting injection. The final product and the diluent manufacture as demonstrated by the sterilization process validation and __________ is adequate from microbiological aspects of __________. The application is therefore recommended for approval from the standpoint of Product Quality Microbiology.

B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable
NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology

1. Product:
B. Brief Description of Microbiology Deficiencies
   None

C. Assessment of Risk Due to Microbiology Deficiencies
   None

III. Administrative

A. Reviewer's Signature ___________________________________________________________________

B. Endorsement Block
   Vinayak Pawar/09 April, 2002
   Peter H. Cooney/

C. CC Block
   cc:
   Original NDA 21-346
   HFD-120/Division File/S. Hardeman

APPEARS THIS WAY ON ORIGINAL
17 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

☐ § 552(b)(5) Deliberative Process

☐ § 552(b)(5) Draft Labeling