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.

APPEARS THIS WAY
ON ORIGINAL

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.

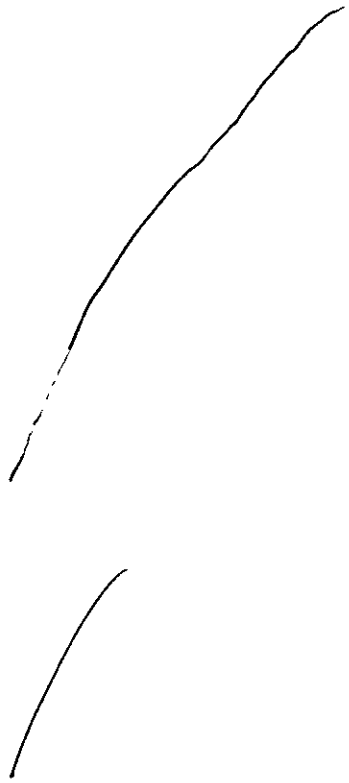
B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable

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

17 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling