APPLICATION NUMBER:
22-264

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review

04 May 2009

NDA: 22-264/N-000 AZ

Drug Product Name
Proprietary: Invega® Sustenna™
Non-proprietary: paliperidone palmitate

Review Number: 1

Dates of Submission(s) Covered by this Review

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Applicant/Sponsor
Name: Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Address: Johnson & Johnson Pharmaceutical R&D, L.L.C.
1125 Trenton-Harbourton Rd.
PO Box 200
Titusville, NJ 08560

Representative: Dawn Kracht
Telephone: 609-730-3082

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommend approval.
Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Amendment to NDA.

2. **SUBMISSION PROVIDES FOR:** A Complete Response Document which addresses the items provided in the Agency’s Complete Response Letter (25 August 2008). The 03 February 2009 Complete Response Document includes the addition of the applicant’s Cork, Ireland facility for manufacture of the drug substance.

3. **MANUFACTURING SITE:**
   - **Previously Identified DS & DP Manuf Site:** Janssen Pharmaceutica N.V.
     Turnhoutseweg 30
     B-2340 Beerse
     Belgium
   - **Proposed Additional DS Manuf Site:** Janssen Pharmaceutical
     Little Island
     County Cork, Republic of Ireland
     Cork, Ireland

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
   - Suspension for injection in pre-filled plastic syringe.
   - Intramuscular injection.
   - 25, 50, 75, 100 & 150 mg eq.

5. **METHOD(S) OF STERILIZATION:**

6. **PHARMACOLOGICAL CATEGORY:** The subject drug product is indicated for the treatment of schizophrenia and for prevention of recurrence of symptoms of schizophrenia.

B. **SUPPORTING/RELATED DOCUMENTS:**

C. **REMARKS:**
The submission is submitted electronically in the eCTD format.

File Name: N022264AZR1.doc
Executive Summary

I. Recommendations

A. Recommendation on Approvability – NDA 22-264/N-000 AZ is recommended for approval on the basis of microbiological product quality.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – Not applicable.

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The subject drug product is manufactured.

B. Brief Description of Microbiology Deficiencies – There are no microbiology deficiencies identified.

C. Assessment of Risk Due to Microbiology Deficiencies – Not applicable.

III. Administrative

A. Reviewer's Signature _____________________________
   John W. Metcalfe, Ph.D.

B. Endorsement Block _________________________________
   Stephen Langille, Ph.D.

C. CC Block
   N/A

3 pages withheld immediately following this page as (b)(4) CCI/TS.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Metcalfe  
5/4/2009 11:34:50 AM  
MICROBIOLOGIST

Stephen Langille  
5/4/2009 01:42:18 PM  
MICROBIOLOGIST