CENTER FOR DRUG EVALUATION AND RESEARCH

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

Letter	Stamp	Review Request	Assigned to Reviewer
03 FEB 2009	03 FEB 2009	03 MAR 2009	12 MAR 2009

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:	Proposed Additional DS Manuf Site:
Janssen Pharmaceutica N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	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: (b) (4).

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:

- Microbiology Review of Type II DMF 20902; Paliperidone Palmitate (R092670) Drug Substance. Johnson & Johnson Pharmaceutical R & D, L.L.C (dated 18 June 2008).
- Microbiology Review of Type II DMF 20902; Paliperidone Palmitate (R092670) Drug Substance. Johnson & Johnson Pharmaceutical R & D, L.L.C (dated 20 April 2009).

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 (b) (4) 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