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RESEARCH**

APPLICATION NUMBER:

22-264

CHEMISTRY REVIEW(S)

NDA 22-264

INVEGA® SUSTENNA
(paliperidone palmitate extended release injectable suspension)

Janssen Pharmaceutica N.V.

Review #2

David J. Claffey, Ph.D.
ONDQA

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Chemistry Review Data Sheet

1. NDA 22-264
2. REVIEW #:2
3. REVIEW DATE: 20 JUL 2009
4. REVIEWER: David J. Claffey, PhD

5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
IND 67,356	6 MAY 2003
Original NDA	26 OCT 2007
Amendment (BC)	26 MAY 2008
Amendment (BC)	13 JUN 2008
Amendment (BL)	2 JUL 2008
Amendment (BC)	11 JUL 2008

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Amendment N-0026	3 FEB 2009
Amendment N-0028	24 FEB 2009
Amendment N-0033	22 MAY 2009
Amendment N-0038	16 JUL 2009
Amendment N-0039	17 JUL 2009
Amendment N-0040	20 JUL 2009
Amendment N-0041	20 JUL 2009



CHEMISTRY REVIEW



Chemistry Review Data Sheet

7. NAME & ADDRESS OF APPLICANT:

Janssen, L.P.
Name: Johnson & Johnson Pharmaceutical Research &
Development, LLC
Office 12607, 1125 Trenton-Harbourton Road,
Address: Titusville, NJ 08560

Representative: Kelly Ward (for CMC related issues)

Telephone: 609-730-2056

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: **INVEGA® SUSTENNA**
- b) Non-Proprietary Name (USAN): Paliperidone palmitate
- c) Code Name/# (ONDC only): JNJ16977831; R092670
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 2
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: Antipsychotic

11. DOSAGE FORM: extended release injectable suspension

12. STRENGTH/POTENCY: 39 mg, 78 mg, 117 mg, 156 and 234 mg of paliperidone palmitate (data for (b) (4) strength was provided but applicant is not seeking approval for this strength at this time).

13. ROUTE OF ADMINISTRATION: Intramuscular

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