

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
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MEDICAL REVIEW(S)

CLINICAL REVIEW

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Reviewer Name(s) Jing Zhang, MD, PhD
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Established Name Paliperidone Palmitate
(Proposed) Trade Name Invega[®] Sustenna[™]
Therapeutic Class Atypical Antipsychotic
Applicant Johnson & Johnson

Formulation(s) Long-Acting Injection
Dosing Regimen Injection Every 4 Weeks
Indication(s) Acute Treatment of
Schizophrenia
Intended Population(s) Adults

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