

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

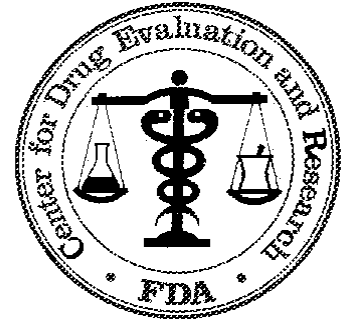
APPLICATION NUMBER:

203794Orig1s000

CHEMISTRY REVIEW(S)

**MEMORANDUM: DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC
HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

DATE: 19-SEP-2012
TO: N203794 File
FROM: Craig M. Bertha, Ph.D.
Chemistry Reviewer
ONDQA, Division III, Branch VIII
THROUGH: Prasad Peri, Ph.D.
Branch Chief
ONDQA, Division III, Branch VIII



SUBJECT: ACCEPTABLE recommendation from the Office of Compliance for application of 18-SEP-2012; Final CMC recommendation

SUMMARY: The Office of Compliance has placed an overall recommendation of ACCEPTABLE into the EES on 18-SEP-2012. The CMC team can now recommend that the application be **approved**.

RECOMMENDATION: The application is recommended for **approval**.

Craig M. Bertha, Ph.D.
Chemist

cc:
OND/DAAAP/DChiapperino
ONDQA/DIV 1/CBertha/19-SEP-2012
ONDQA/DIV 1/PPeri_____
ONDQA/DIV1/DChristodoulou
OND/DAAAP/EFields
ONDQA/LRivera

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/s/

CRAIG M BERTHA
09/19/2012

PRASAD PERI
09/20/2012
I concur

NDA 203794

Nucynta® (tapentadol) Oral Solution

Janssen Pharmaceuticals, Inc.

**Craig M. Bertha, Ph.D.
Office of New Drug Quality Assessment
Division III/Branch VIII**

for

Division of Anesthesia, Analgesia, and Addiction Products

Table of Contents

Table of Contents	2
Chemistry Review Data Sheet.....	3
The Executive Summary	7
I. Recommendations.....	7
A. Recommendation and Conclusion on Approvability.....	7
B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable.....	7
II. Summary of Chemistry Assessments.....	7
A. Description of the Drug Product(s) and Drug Substance(s)	7
B. Description of How the Drug Product is Intended to be Used.....	8
C. Basis for Approvability or Not-Approval Recommendation.....	8
III. Administrative.....	8
A. Reviewer's Signature.....	8
B. Endorsement Block.....	8
C. CC Block.....	8
Chemistry Assessment	9

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