CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

203794Orig1s000

Trade Name:	Nucynta oral solution, 20 mg/mL.
Generic Name:	tapentadol
Sponsor:	Janssen Research & Development, L.L.C. on behalf of Janssen Pharmaceuticals, Inc.
Approval Date:	October 15, 2012
Indications:	Provides for the use of Nucynta (tapentadol) oral solution for the management of moderate to severe acute pain in adults.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 203794

NDA APPROVAL

Janssen Research & Development, L.L.C.
on behalf of Janssen Pharmaceuticals, Inc.
920 Route 202 PO Box 300
Raritan, New Jersey 08869

Attention: Peggy Ferrone
Manager, Regulatory Affairs

Dear Ms. Ferrone:

Please refer to your New Drug Application (NDA) dated and received December 15, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Nucynta (tapentadol) oral solution, 20 mg/mL.

We acknowledge receipt of your amendments dated February 7, March 13, April 3 and 10, May 7 (2), June 13 and 18, July 12, August 3, 10, and 29, and October 15, 2012.

This new drug application provides for the use of Nucynta (tapentadol) oral solution for the management of moderate to severe acute pain in adults.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide, and Instructions for Use). Information on submitting SPL files using eLIST may be

found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and carton and immediate container labels submitted on August 3, 2012, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 203794**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies in accordance with study report submission dates below because this product is ready for approval for use in adults and the pediatric studies have not been completed. We acknowledge that your pediatric program for PREA requirements under NDA 022304 for Nucynta (tapentadol) immediate-release tablets is ongoing and those studies are intended to also fulfill the PREA requirements for Nucynta oral solution specified below.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. The required studies are listed below.

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