CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

200533Orig1s000

Trade Name:	Nucynta ER extended-release oral tablets 50, 100, 150, 200, and 250 mg.
Generic Name:	tapentadol
Sponsor:	Janssen Pharmaceuticals, Inc.
Approval Date:	August 25, 2011
Indications:	for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

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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 200533

NDA APPROVAL

Janssen Pharmaceuticals, Inc.
c/o Johnson & Johnson Pharmaceutical
Research & Development, L.L.C.
1125 Trenton-Harbourton Road, P.O. Box 200
Titusville, NJ 08560-0200

Attention: Kathleen F. Dusek, R.Ph., RAC
Associate Director, Regulatory Affairs

Dear Ms. Dusek:

Please refer to your New Drug Application (NDA) dated November 30, 2009, received December 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nucynta ER (tapentadol) extended-release oral tablets 50, 100, 150, 200, and 250 mg.

We acknowledge receipt of your amendments dated December 11, 2009, and March 11, 12, 25, and 30, April 2, 21, 26(2), and 30, May 13 and 21, June 4 and 21, July 23, and August 5 and 19, 2010, and February 28, March 18 and 21, April 28, May 16 and 25, June 15, 20, and 24, July 18, 20, 26, and 29, and August 2, 12, 16, and 23(3), 2011.

The February 28, 2011, submission constituted a complete response to our October 1, 2010, action letter.

This new drug application provides for the use of Nucynta ER (tapentadol) extended-release oral tablets for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

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 and Medication Guide). 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

We acknowledge your August 16, 2011, submission containing final printed carton and container labels.

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 waiving the pediatric study requirement for ages less than 7 years, as the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this group. The very low medical need based upon the very low prevalence of chronic pain conditions in this age category together with the immaturity of the metabolic functions in very young children that may result in unpredictably higher exposures than in other age groups, support the justification that Nucynta ER (tapentadol) extended-release oral tablets does not provide a meaningful therapeutic benefit over existing therapies for very young children.

We are deferring submission of your pediatric study for ages 7 to less than 17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. This required study is listed below.

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