DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203794/S-002, S-003

SUPPLEMENT APPROVAL

Janssen Research and Development, LLC
on behalf of Janssen Pharmaceuticals Inc.
920 Route 202 South, P.O. Box 300
Raritan, NJ 08869-0602

Attention: Tania Hillmer, MS, RAC
Associate Director, Regulatory Affairs

Dear Ms. Hillmer:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received July 30, 2013 (S-002), and dated and received September 24, 2013 (S-003), submitted under section 505(b)) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nucynta (tapentadol) oral solution.

Supplement S-002 proposes revisions to the package insert intended to harmonize the Nucynta oral solution label to the updated labels of other tapentadol products, Nucynta immediate release tablets (NDA 022304) and Nucynta ER extended-release tablets (NDA 200533).

Supplement S-003 provides for revisions to the **ADVERSE REACTIONS: Post-marketing Experience** section of the package insert. Adverse events, anaphylactic shock and panic attack, are added.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dominic Chiapperino, PhD, Senior Regulatory Health Project Manager, at (301) 796-1183.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Acting Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SHARON H HERTZ
11/17/2014