DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019813/S-060

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals
c/o Janssen Research & Development LLC
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

Attention: Mary Mulligan
Manager Global Regulatory Affairs

Dear Ms. Mulligan:

Please refer to your Supplemental New Drug Application (sNDA) dated and received, February 12, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Duragesic (fentanyl transdermal system).

We also refer to our approval letter dated September 23, 2013, which contained the following error:

> An incorrect version of the Package Insert was attached to the approval letter. The labeling submitted on June 5, 2013, which has updates to the **DOSAGE FORMS AND STRENGTHS, DESCRIPTION**, and **HOW SUPPLIED/STORAGE AND HANDLING** sections of the Package Insert, is the version that should have been attached.

This replacement approval letter incorporates the correction of the error.

The effective approval date will remain September 23, 2013, the date of the original approval letter.

We acknowledge receipt of your amendments dated April 12, May 17, and June 5, 2013.

We also refer to our letter dated January 14, 2013, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Duragesic (fentanyl transdermal system). This information pertains to the risk of accidental pediatric exposure to fentanyl transdermal systems.

This supplemental new drug application provides for revisions to the labeling for Duragesic (fentanyl transdermal system). The agreed-upon changes to the labeling based on our January

14, 2013, letter are related to changing the printing on the back of all patch strengths from their current color to a new darker green to improve the visibility of all patch strengths.

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

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), 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed immediate container (i.e., backing membrane) labels that are identical to the enclosed labels submitted on May 17, 2013, as soon as they are available, but no more than 30 days after they are printed.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, contact Katherine Won, Pharm.D., Safety Regulatory Project Manager, at (301) 796-7568 or Katherine.won@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Judith A. Racoosin, M.D., M.P.H.
Deputy Director for Safety
Division of Anesthesia, Analgesia, and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

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

/s/

JUDITH A RACOOSIN
09/23/2013