DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019813/S-068

SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
c/o Janssen Research & Development, LLC
1400 Mckean Rd
Spring House, PA 19477

Attention: Kelly Rudnick, MSPH
Manager, Global Regulatory Affairs

Dear Ms. Rudnick:

Please refer to your Supplemental New Drug Application (sNDA), submitted and received on February 24, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Duragesic (fentanyl transdermal system).

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. This information pertains to the risk of accidental pediatric exposures to fentanyl transdermal systems.

This Prior Approval supplemental new drug application provides for addition of a graphic design to the printing on the backing membrane of the Duragesic system in order to improve product visibility, responsive to our January 14, 2013, letter.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

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 Kimberly Compton, Senior Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Director
Division of Anesthesia, Analgesia, and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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
02/10/2017