DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-813/S-033

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
(c/o) ALZA Corporation
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Attention: Michael H. Kaufman
Director, Regulatory Affairs

Dear Mr. Kaufman:

Please refer to your supplemental new drug application dated January 12, 2001, received January 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duragesic (fentanyl transdermal system).

We acknowledge receipt of your submissions dated February 11, 2002, September 9, 2005, June 22, and December 14, 2007.

Your submission of September 9, 2005 constituted a complete response to our September 26, 2001 action letter.

This "Changes Being Effected" supplemental new drug application originally provided for changes only to the Pouchstock. Supplement S-043, submitted March 19, 2007, provides for changes to the Package Insert, Medication Guide, Carton, Pouchstock, and the Risk Management Plan. In the final stages of labeling negotiations, the Package Insert, Carton, Information for Use, and Medication Guide were also submitted to Supplement S-033. The Risk Management Plan is currently under review as part of Supplement S-043.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on December 14, 2007, and with the following editorial revision to the Medication Guide as agreed upon in an email exchange with Michael Kaufman of Johnson and Johnson on January 15, 2008.

What are the possible side effects of DURAGESIC®?

"Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088."

CONTENT OF LABELING

We will transmit the content of labeling in SPL format, as amended, to the National Library of Medicine for public dissemination.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 14, 2007 electronic submission containing the representative mock-up of the 50mcg/hr printed Carton and Pouchstock labels.

Submit final printed carton and container labels that are identical to the enclosed Carton and Pouchstock labels for all strengths 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 (October 2005)*. 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 19-813/S-033**." Approval of this submission by FDA is not required before the labeling is used.

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Kathleen Davies, Regulatory Project Manager, at (301) 796-2205.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology 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/

Bob Rappaport

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