DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-813/S-039

Alza Corporation
1900 Charleston Road
Mountain View, CA 94043

Attention: Susan P. Rinne, M.S.
Vice President, Regulatory Affairs

Dear Ms. Rinne:

Please refer to your supplemental new drug application dated April 5, 2004, received April 6, 2004, 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 July 9 and 29, and November 24, 2004, and January 24, February 1 and 3, 2005.

We also acknowledge receipt of your September 10, 2004, submission for Supplement S-031 in response to our June 10, 2003, Approvable Letter for that supplement. The labeling for S-031 is now superceded by the labeling approved with this supplement.

This supplemental new drug application provides for the use of Duragesic® (Fentanyl Transdermal System) 12 mcg/h patch for the management of persistent, moderate to severe chronic pain that: requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and the patient package insert and submitted labeling (immediate container and carton labels submitted November 24, 2004).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* and *Providing Regulatory Submissions in Electronic Format-Content of Labeling*. Alternatively, except for the content of labeling, which must be submitted electronically in PDF format, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-813/S-039**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application for patients 2 years of age and over. We are waiving the requirement for patients from birth to 2 years of age.

We remind you of your agreement to lower the limits (b)(4)----------

We also remind you of your agreement during our February 4, 2005 teleconference to continue discussions with the Agency regarding establishment of a risk management program for this product.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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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