NDA 19-813/S-023 and S-030

Alza Corporation
1900 Charleston Road
Mountain View, CA 94039-7210

09 APR 2001

Attention: Janne Wissel
Senior Vice President, Operations

Dear Ms. Wissel:

Please refer to your November 11, 1999 (S-023), and December 8, 2000 (S-030) supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duragesic (fentanyl transdermal system).

We acknowledge receipt of your submission dated March 20, 2001.

Supplement S-023 provides for an update in the CLINICAL PHARMCACOLOGY, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION and HOW SUPPLIED sections of the package insert.

"Changes Being Effected" supplement S-030 provides for the addition of a new subsection, "Post-Marketing Experience" under the ADVERSE REACTIONS section, and a listing of four new adverse reactions.

We note that your submission dated March 20, 2001, contains the changes requested by the Division in the approvable letter for supplement S-023 dated January 12, 2001, as well as proposed changes for supplement S-030.

We have completed the review of supplement S-030 and have concluded that adequate information has been presented to demonstrate that the drug is safe an effective for use as recommended in the final printed labeling submitted on March 20, 2001. Accordingly, the supplemental new drug application S-030 is approved effective on the date of this letter.

We note that your submission for supplement S-023 has been superseded by supplement S-030, approved on the date of this letter. Therefore, supplement S-023 will not be reviewed, but it will be retained in our files.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

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