DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-060/S-003

Elan Pharmaceuticals, Inc
7475 Lusk Boulevard
San Diego, CA 92121

Attention: Mark Brunswick, Ph.D.
Senior Director, Regulatory Affairs

Dear Dr. Brunswick:

Please refer to your supplemental new drug application dated October 18, 2006, received October 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prialt (ziconotide intrathecal infusion).

We acknowledge receipt of your submissions dated October 27, 2006, and April 5, 2007.

This supplemental new drug application provides for two changes; an increase in the refill interval for undiluted Prialt Medtronic pumps fron 60 to 84 days, and the recoding of safety information from COSTART to MEDRA.

We have completed our review of this application 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, submitted April 5, 2007.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission **"Content of Labeling for approved NDA 21-060/S-003."** Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
WO22, Room 4447
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

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 Matt Sullivan, Regulatory Project Manager, at 301-796-1245.

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

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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