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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-060

Elan Pharmaceuticals
7475 Lusk Boulevard
San Diego, CA 92121

Attention: Mark Brunswick, PhD
Director, Regulatory Affairs

Dear Dr. Brunswick:

Please refer to your new drug application (NDA) dated December 28, 1999, received December 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prialt (ziconotide intrathecal infusion), 25 mcg/mL in 20 mL fill vials, and 100 mcg/mL in 1, 2, and 5 mL fill vials.

We acknowledge receipt of your presubmission dated October 29, 1999, and your submissions dated January 12, March 10, 22 (2), and 31, April 6, 7, 12, 14, 17, 20, 24, 27, and 28, May 1, 11, 19, 22 (2), and 26, June 23, July 13, 19, and 24, August 7, September 15, 20 (2), and 29, October 13 (2), November 29, and December 28, 2000, and January 26, February 9, 20, and 28, March 13, 20, 23, and 29, April 9, 20, 26, and 27 (2), May 24, and June 1, 13, 19, 21, 25, and 26, July 11 (3) and 17, August 3 and 16, September 17, October 31, November 2, 20, and 29, and December 21, 2001, January 25, March 8, October 7 and 8, and December 3, 2002, January 27 and 31, February 11 and 20, April 3 and 28, May 2, July 25, August 12, and September 8 and 23, 2003, and January 6 and 16, June 25, August 16, October 20 (2) and 26(2), November 1 and 22, and December 2, 6, 8, 9, 14 (2), 20 (2), and 27, 2004.

Your submission of June 25, 2004, constituted a complete response to our July 25, 2001, action letter.

This new drug application provides for the use of Prialt (ziconotide intrathecal) for the management of severe chronic pain in patients for whom intrathecal (IT) therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

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 text for the package insert, immediate container and carton labels submitted December 27, 2004. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidances 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 NDA 21-060.**” 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 are deferring submission of your pediatric studies for ages 0-16 years until December 28, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the management of severe chronic pain in patients for whom intrathecal (IT) therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine in pediatric patients ages 0-16 years.

Final Report Submission: December 28, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated “**Required Pediatric Study Commitments**”.

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

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

NDA 21-060

Page 3

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Sara Stradley, Regulatory Project Manager at (301) 827-7430.

Sincerely,

(See appended electronic signature page)

Robert J. Meyer, MD
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Food and Drug Administration

Enclosure