



NDA 022244/S-006

SUPPLEMENT APPROVAL

Eisai Inc.
300 Tice Boulevard
Woodcliff Lake, NJ 07677

Attention: Jacqueline M. Kline, Ph.D.
Senior Director, Regulatory Affairs

Dear Dr. Kline:

Please refer to your supplemental new drug application dated November 4, 2009, received November 5, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LUSEDRA™ (fospropofol disodium) Injection.

This “Changes Being Effected” supplement is submitted to reflect the scheduling of LUSEDRA™ Injection as C-IV under the Controlled Substance Act.

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 enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format submitted on November 4, 2009.

CONTENT OF LABELING

We note that your November 4, 2009, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia,
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-22244	----- SUPPL-6	----- EISAI INC	----- LUSEDRA INJECTION

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BOB A RAPPAPORT
01/21/2010