DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-789/S-005

Dainippon Pharmaceutical USA Corporation
c/o Elan Pharmaceuticals, Inc.
Attention: Barbara Black, RAC
Director, Regulatory Affairs
7475 Lusk Boulevard
San Diego, CA 92121

Dear Ms. Black:

Please refer to your supplemental new drug application dated January 25, 2002, received January 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zonegran (zonisamide) Capsules, 100mg.

We also acknowledge receipt of your submissions dated May 23, 2002 and May 31, 2002.

This "Changes Being Effected" supplemental new drug application provides for revisions to labeling in the "Oligohydrosis and Hyperthermia in Pediatric Patients" subsection of WARNINGS. Specifically, the subsection has been revised to include a bolded warning and updated safety information for this pediatric adverse event.

We have completed the review of this supplemental application, as amended. Accordingly, this supplemental application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-789/S-005." Approval of this submission by FDA is not required before the labeling is used.

We note that a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) was issued in June 2002 to physicians and others responsible for patient care. We request that you submit a paper 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 Jacqueline H. Ware, Pharm.D., Regulatory Project Manager, at (301) 594-5533.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz

10/7/02 04:06:06 PM