DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-642

DEC 22 2005

Apotex Corp.
Attention: Kalpesh Shroff
Project Leader, Regulatory Affairs
U.S. Agent for: Apotex Inc.
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 27, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Zonisamide Capsules, 25 mg, 50 mg and 100 mg.

Reference is also made to your amendments dated July 29, September 1, September 22, October 20, October 31, and December 16, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Zonisamide Capsules, 25 mg, 50 mg, and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zonegran Capsules, 25 mg, 50 mg, and 100 mg, of Dainippon Pharmaceutical USA Corp.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these

submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research