DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-710 / S-005

Validus Pharmaceuticals
Attention: Pauliana Hall, RAC
US Agent and Regulatory Consultant
119 Cherry Hill Road, Suite 310
Parsippany, NJ 07054

Dear Ms. Hall:

Please refer to your supplemental new drug application dated December 10, 2007, received December 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Equetro (carbamazepine) Extended-Release Capsules.

We also acknowledge receipt of your electronic mail messages dated December 10 and 11, 2007.

This supplemental new drug application provides for the addition of new safety-related information regarding Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis to the package insert.

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 appended agreed-upon labeling text.

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

We note that SPL has not been submitted representing the content of your proposed labeling. By regulation [21 CFR 314.50(l), 314.94(d), and 601.14(b); Guidance for Industry: *Providing Regulatory Submissions in Electronic Format — Content of Labeling* (April 2005); http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s-0251-m000032-vol1.pdf], you are required to submit to FDA prescribing and product information (i.e., the package insert or label) in SPL format. Please submit SPL within 30 days of your implementation of this labeling. You may also use the following URLs to obtain information on format and content of SPL: http://www.fda.gov/cder/guidance/7074fnl.htm and http://www.fda.gov/oc/datacouncil/spl.html .

We have also received the agreed-upon draft text for your 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 to the following address when it is disseminated:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Doris J. Bates, Ph.D, Regulatory Project Manager, at (301) 796-2260.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures:
Full text of approved labeling
Full text of DHP letter
CC: Herb Harris, M.D., Ph.D.,
Chief Medical Officer, Validus Pharmaceuticals, Inc.

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

/s/

Thomas Laughren
12/19/2007 02:50:18 PM