DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21710/S-013

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Validus Pharmaceuticals
Attention: Richard Guarino, M.D.
Chief Medical Director
119 Cherry Hill Road
Suite 310
Parsippany, NJ 07054

Dear Dr. Guarino:

Please refer to your Supplemental New Drug Application (sNDA) dated October 27, 2011, received October 28, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Equetro (carbamazepine) Extended-Release Capsules 100mg, 200 mg and 300 mg.

This supplemental new drug application proposes to eliminate the requirement for the approved Equetro REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Equetro was originally approved on October 24, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Equetro.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Equetro outweigh its risks.

Therefore, we agree with your proposal, and a REMS for Equetro (carbamazepine) Extended-Release Capsules is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling for Equetro in accordance with 21 CFR 208.

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, email Sharonjit Sagoo, Regulatory Project Manager, at sharonjit.sagoo@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

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

/s/

THOMAS P LAUGHREN
01/27/2012