



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021710/S-011 and S-012

TENTATIVE APPROVAL

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

Dear Dr. Guarino:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 31, 2011, received April 1, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Act for Equetro (carbamazepine) Extended-Release Capsules, 100 mg, 200 mg, and 300 mg.

We acknowledge receipt of your amendments dated April 14, May 24, 26, and 31, August 19, and October 13, 2011, and January 31, February 29, June 6, July 18, and December 5, 2012 for S-011.

We acknowledge receipt of your amendments dated April 13, May 26 and 31, August 19, September 28, and October 13, 2011, and January 31, February 29, June 6, July 18, and December 5, 2012 for S-012.

The June 6, 2012, submissions, received June 7, 2012, constituted a complete response to our February 1, 2012, action letters.

These supplemental new drug applications provide for the use of Equetro (carbamazepine) Extended-Release Capsules for the treatment of trigeminal neuralgia (S-011) and the treatment of partial seizures with complex symptomatology, generalized tonic-clonic seizures, and mixed seizures, respectively (S-012).

We have completed our review of these applications, as amended, and they are tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert and Medication Guide). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product.] This determination is subject to change on the basis of any new information that may come to our attention.

The listed reference drug product upon which you based your application is subject to a period of patent and/or exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act (21 U.S.C. 355(c)(3)) may not be made effective until the period has expired. To obtain final approval of this supplemental application, submit an amendment two or six months prior to the: 1) expiration of the patent(s) protection or 2) date you believe that your supplement will be eligible for final approval, as appropriate. In your cover letter, clearly identify your

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/s/

BOB A RAPPAPORT
12/06/2012

RUSSELL G KATZ
12/06/2012