DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-710 / S-003

Shire Development, Inc.
Attention: Linda Mota, Associate Manager, Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087-7362

Dear Ms. Mota:

Please refer to your supplemental new drug application dated November 18, 2005, received November 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Equetro (carbamazepine) extended-release capsules.

We acknowledge receipt of your submissions dated January 11, 2006 and October 20, 2006.

This supplemental new drug application provides for revised labeling as follows:

- Under the **PRECAUTIONS** section, **Agents with Decreased Levels in the Presence of Carbamazepine due to Induction of Cytochrome P450 Enzymes** subsection, "trazodone" was added to the list of agents and the following paragraph was added per the Agency's request of October 8, 2005:

  Following co-administration of carbamazepine 400 mg/day with trazodone 100 mg to 300 mg daily, carbamazepine reduced the plasma concentration of trazodone (as well as meta-chlorophenylpiperazine [mCPP]) by 76 and 60% respectively, compared to pre-carbamazepine values.

- Under the **HOW SUPPLIED** section, the statement "PROTECT FROM LIGHT" was amended to read, "PROTECT FROM LIGHT AND MOISTURE."

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 agreed-upon labeling text.

Within 21 days of the date of this letter, please submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 21-710/S-003**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a 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 a copy to the following address:

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, email Doris Bates, Ph.D., Senior Regulatory Project Manager, at Doris.Bates@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

Enclosure (labeling)

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
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