DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 009170/S-038

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Valeant Pharmaceuticals North America, LLC
Attention: James H. Medley, PhD
Vice President, Regulatory Affairs
700 Route 202/206 North
Bridgewater, New Jersey 08807

Dear Dr. Medley:

Please refer to your Supplemental New Drug Application (sNDA) dated July 5, 2011, received July 6, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mysoline (primidone) Tablets.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated July 25, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Mysoline (primidone) 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 Mysoline (primidone) was originally approved on July 21, 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 Mysoline (primidone).

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 Mysoline (primidone) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Mysoline (primidone) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling 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, call Su-lin Sun, PharmD, Regulatory Project Manager, at (301) 796-0036.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology 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/

RUSSELL G KATZ
08/10/2011