DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022544/S-003

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Depomed, Inc.
1360 O'Brien Drive
Menlo Park, CA 94025-1436

Attention: Hayley Welton, RAC
Director, Regulatory Affairs

Dear Ms. Welton:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 13, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gralise™ (gabapentin) Tablets, 300 mg and 600 mg.

This supplemental new drug application provides for proposed elimination of the requirement of the approved REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Gralise (gabapentin) Tablets was originally approved on January 28, 2011. 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 Gralise (gabapentin) Tablets.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Gralise (gabapentin) Tablets outweigh its risks. Therefore, we agree with your proposal and a REMS for Gralise (gabapentin) Tablets 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 Allison Meyer, Regulatory Project Manager, at (301)796-1258.

Sincerely,

{See appended electronic signature page}

Laura Governale, Pharm.D., M.B.A.
Acting Deputy Director for Safety
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

LAURA A GOVERNALE
04/28/2011