DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 10841/S-023

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Lundbeck Inc.
Attention: Kathyrn B. Patterson
Associate Director, Post-approval Regulatory Affairs
Four Parkway North, Suite 200
Deerfield, IL 60015

Dear Ms. Patterson:

Please refer to your Supplemental New Drug Application (sNDA) dated March 16, 2011, received March 17, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Peganone (ethotoin) tablets.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated March 17, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved 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 Peganone (ethotoin) was originally approved on June 7, 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 Peganone (ethotoin).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate 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, and a REMS is no longer necessary to ensure that the benefits of Peganone (ethotoin) outweigh its risks. Therefore, we agree with your proposal and a REMS for Peganone (ethotoin) 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, please call Jacqueline H. Ware, PharmD, Senior Regulatory Project Manager, at (301) 796-1160.

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
05/31/2011