DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017105/S-077

SUPPLEMENTAL APPROVAL
RELEASE REMS REQUIREMENT

Lundbeck, Inc.
Attn: Kathryn Patterson
Associate Director Post-approval Regulatory Affairs
Four Parkway North
Deerfield, IL 60015

Dear Ms. Patterson:

Please refer to your Supplemental New Drug Application (sNDA) dated March 16, 2011 (S-077), submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tranxene T-Tab Tablets (clorazepate dipotassium tablets) 3.75mg, 7.5mg, and 15mg.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated March 16, 2011, in which you indicated there are currently no ongoing post-approval studies or clinical trials to investigate safety issues for Traxene T-Tab Tablets (clorazepate dipotassium tablets).

This supplement (S-077) proposes to eliminate the requirement for the approved REMS for Tranxene T-Tab Tablets (clorazepate dipotassium tablets).

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 Tranxene T-Tab Tablets (clorazepate dipotassium tablets) 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 Tranxene T-Tab Tablets (clorazepate dipotassium tablets).

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 Tranxene T-Tab Tablets (clorazepate dipotassium tablets) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Tranxene T-Tab 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, please email CDR Sonny Saini, Senior Regulatory Project Manager, at sonny.saini@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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
07/19/2011