DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22104/S-007

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Osmotica Pharmaceutical
Attention: Tim Davis
Manager, Regulatory Affairs
1205 Culbreth Drive Suite 200
Wilmington, NC 28405

Dear Mr. Davis:

Please refer to your Supplemental New Drug Application (sNDA) dated March 21, 2012, received March 21, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Venlafaxine HCl Extended Release Tablets 37.5 mg, 75 mg, 150 mg, and 225 mg.

This supplemental new drug application proposes to eliminate the requirement for the approved Venlafaxine Extended Release 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 Venlafaxine ER was originally approved on May 20, 2008. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA release you from the seventh year assessment of the REMS.

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 Venlafaxine ER outweigh its risks.

Therefore, we agree with your proposal, and a REMS for Venlafaxine HCl Extended Release Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling for Venlafaxine HCl Extended Release Tablets 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, contact CDR Kofi Ansah, Pharm.D. Senior Regulatory Project Manager, at (301) 796-4158 or email: Kofi.Ansah@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
07/31/2012