DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22104 / S-008

SUPPLEMENT APPROVAL

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

Dear Mr. Davis:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 22, 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 "Changes Being Effected" supplemental new drug application provides for changes to the labeling with the addition of section 7.14 Drug-Laboratory Test Interactions as follows:

7.14 Drug-Laboratory Test Interactions
False-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported in patients taking venlafaxine. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of venlafaxine therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish venlafaxine from PCP and amphetamine.

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

If you have any questions, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff at Steven.Hardeman@FDA.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

ENCLOSURE: Content of Labeling

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
05/02/2012