DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-104/S-002

Osmotica Pharmaceutical Corp.
Attention: Mark S. Aikman
VP Regulatory Affairs & Quality Assurance
1205 Culbreth Drive, Suite 200
Wilmington, NC 28405

Dear Mr. Aikman:

We acknowledge receipt of your supplemental new drug application dated August 25, 2008, received August 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for venlafaxine hydrochloride extended release 37.5 mg, 75 mg, 150mg, and 225 mg tablets.

We additionally acknowledge receipt of your amendment dated October 3, 2008.

This supplemental new drug application provides for unit of use packaging configurations of 15, 30, and 90 tablet counts as well as the correction of Section 2.1 (Social Anxiety Disorder [Social Phobia]) of the prescriber labeling.

We have completed our review of your submission as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

Please note that the attached labeling also includes revisions to labeling which were approved in an Agency letter dated January 30, 2009.

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 Renmeet Grewal, Senior Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: agreed-upon 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 Laughren
2/27/2009 04:46:38 PM