



NDA 204683/S-003

**SUPPLEMENT APPROVAL**

Osmotica Pharmaceutical US, LLC  
Attention: Mark Aikman, PharmD  
Vice President, Regulatory Sciences  
1205 Culbreth Drive, Suite 200  
Wilmington, NC 28405

Dear Dr. Aikman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 9, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Khedezla (desvenlafaxine) 50 mg and 100 mg extended-release tablets.

We also refer you to our Safety Labeling Change Notification letter dated June 08, 2016, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Khedezla (desvenlafaxine). This information pertains to the risk of acute pancreatitis.

This supplemental new drug application provides for the addition of “*Gastrointestinal Disorders – Pancreatitis acute*” to the **Postmarketing Experience** subsection (6.2) consistent with our June 8, 2016 letter.

**APPROVAL & LABELING**

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

We note that your August 9, 2016, submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

**WAIVER OF HIGHLIGHTS SECTION**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **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 contact Bill Bender, Senior Regulatory Project Manager, at [william.bender2@fda.hhs.gov](mailto:william.bender2@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell Mathis, M.D.  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MITCHELL V Mathis  
09/06/2016