



NDA 5-378/S-026

Ovation Pharmaceuticals, Inc.  
Attention: Kathryn B. Patterson  
Associate Director, Global Regulatory Affairs  
Four Parkway North, Suite 200  
Deerfield, IL 60015

Dear Ms. Patterson:

Please refer to your supplemental new drug application (NDA) dated November 16, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Desoxyn (methamphetamine hydrochloride) 5 mg tablets.

Reference is also made to Agency letters dated December 18, 2006, and February 21, 2007.

We acknowledge receipt of your submission dated April 5, 2006. Your April 5, 2006 submission constituted a complete response to our December 18, 2006, and February 21, 2007 letters.

This supplement, submitted under "Changes Being Effected", provides for the following revisions to labeling:

1. The addition of the subsections **Serious Cardiovascular Events, Psychiatric Adverse Events, Long Term Suppression of Growth, Seizures, and Visual Disturbances** to the **WARNINGS** section of labeling.
2. An update to the boxed **WARNING** at the beginning of the label.
3. Revisions to the **PRECAUTIONS-Information for Patients** section regarding the Medication Guide.
4. Revisions to the **PRECAUTIONS-Usage in Nursing Mothers** section.
5. Revisions to the container labeling to denote that Desoxyn has a Medication Guide.
6. The addition of a Medication Guide.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, this application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LT Felecia Curtis, Regulatory Project Manager, at 301-796-1074.

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

Attachment

-----  
**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  
5/11/2007 01:40:47 PM