DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 5-378/S-024

Ovation Pharmaceuticals, Inc.
Attention: Timothy Cunniff, Pharm.D.
Vice President, Regulatory Affairs
Four Parkway North, Suite 200
Deerfield, IL 60015

Dear Dr. Cunniff:

Please refer to your supplemental new drug application dated November 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desoxyn (methamphetamine HCl) 5 mg Tablets.

We acknowledge receipt of your submission dated February 19, 2003.

Your submission of February 19, 2003, constituted a complete response to our February 10, 2003 action letter.

This supplement provides for the following revisions to labeling:

1. The addition of a *Geriatric Use* subsection under the **PRECAUTIONS** section to comply with 21 CFR 201.57(f)(10).
2. The revision of the storage statement in the **HOW SUPPLIED** section as requested by the Agency in a letter dated February 10, 2003.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in your labeling dated February 19, 2003.

The final printed labeling (FPL) must be identical to your submitted labeling (package insert submitted February 19, 2003).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 5-378/S-024**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Susan Player, MS, APRN, BC, 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

Enclosure

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
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