DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-105/SLR-070

Ovation Pharmaceuticals, Inc.
Attention: Gary Gordon, M.D., Ph.D.
Vice President, Clinical Affairs
4 Parkway North, Suite 200
Deerfield, IL 60015

Dear Dr. Gordon:

Please refer to your supplemental new drug application dated November 14, 2002, received November 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tranxene® T and SD (clorazepate dipotassium) Tablets.

This supplemental new drug application provides for the addition of a geriatric use subsection to the PRECAUTIONS section of the package insert in accordance with 21 CFR 201.57(f)(10).

We also refer to your February 13, 2003, commitment to revise the storage statement to read: 'Protect from moisture. Keep bottle tightly closed. Store below 77º F (25º C). Dispense in a USP tight, light-resistant container.'

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 submitted draft labeling dated November 14, 2002, and the additional changes to the DOSAGE AND ADMINISTRATION section that you have committed to above. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert) with the agreed upon labeling changes cited above.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-105/S-070" Approval of this submission by FDA is not required before the labeling is used.

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 should have any questions, please call Ms. Anna Marie H. Weikel, R.Ph., Senior Regulatory Health Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
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