DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 10-841/S-013/S-014

Ovation Pharmaceuticals, Inc.
Attention: Timothy M. 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 applications dated July 31, 1991 (S-013) and July 2, 1997 (S-014), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Peganone (ethotoin) 250 mg Tablets.

We acknowledge receipt of your amendments dated March 26, and September 22, 2003. Your amendment dated March 26, 2003, constituted a complete response to our September 25, 2001 action letter.

These "Prior Approval" supplemental new drug applications propose the following revisions to product labeling:

1. The term "Stevens-Johnson syndrome" was placed in the "rarely" or "occasionally" section of labeling under the **Adverse Reactions** section.

2. Change to Pregnancy Category D with appropriate language placed in the **WARNINGS** and **PRECAUTIONS-Pregnancy** sections.

3. Replace the subsection heading entitled **Carcinogenesis** with **Carcinogenesis, Mutagenesis, Impairment of Fertility**.

4. The addition of a **Norteratogenic Effects** subsection under the **PRECAUTIONS** section with a reference to the **WARNINGS** section.

5. Changes to the **Dosage and Administration** section revising the phenacamide warning because it is outdated and deleting the warning about trimethadione since trimethadione is no longer marketed.

6. The addition of a new storage statement under the **HOW SUPPLIED** section.

We have completed the review of these supplemental applications, 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 labeling. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert) submitted on September 22, 2003. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 10-841/S-013/S-014." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

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

9/26/03 04:51:24 PM