DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-903/S-003

Ovation Pharmaceuticals, Inc.
Attention: Ms. Ilze Antons
Four Parkway North
Deerfield, IL 60015

Dear Ms. Antons:

Please refer to your supplemental new drug application dated July 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NeoProfen (ibuprofen lysine) Injection, 10 mg/mL.

We acknowledge receipt of your submission dated June 9, 2008.

This "Changes Being Effected" supplemental new drug application provides for the addition of the following subsection under the **ADVERSE REACTIONS** section:

> **Post-marketing Experience**
> The following adverse reactions have been identified from spontaneous post-marketing reports or published literature: gastrointestinal perforation and necrotizing enterocolitis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency, or establish a causal relationship to drug experience.

We have completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the structured product labeling (SPL) submitted on June 9, 2008.

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, please call Russell Fortney, Regulatory Project Manager, at (301) 796-1068

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director, Division of Cardiovascular and Renal 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/

Norman Stockbridge

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