DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-170/S-033

Pharmaceuticals International
Attention: Arthur L. Rosenthal, R.A.C.
Senior Director, Corporate Regulatory Affairs
One Enterprise
Aliso Viejo, CA 92656

Dear Mr. Rosenthal:

Please refer to your supplemental new drug application dated July 28, 2008, received July 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mysoline (primidone) Tablets, 50 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for **(b) (4)** **(b) (4)** as an alternate site for repackaging the drug product.

We completed our review of this supplemental new drug application and it is approved.

IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Container Labels for approved NDA 09-170**." Approval of this submission by FDA is not required before the labeling is used.

PACKAGE INSERT

The submitted package insert in paper format has not been reviewed for this supplement. Only changes to the package insert associated with the new alternate repackaging site are approved in this supplement.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Jim Vidra

1/29/2009 05:00:51 PM