ANDA 40-866

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-8474

FAX TRANSMISSION COVER SHEET

DATE: 4/23/08

TO: APPLICANT: Amneal Pharmaceuticals TEL: 973-357-0222

ATTN: Alpesh Patel FAX: 973-357-0230

FROM Lisa Kwok PROJECT MANAGER: 240-276-8494

TOTAL NUMBER OF PAGES: 3
(EXCLUDING COVER SHEET)

Special Instructions:

Congratulations! Your application has been approved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 40-866

Amneal Pharmaceuticals
Attention: Alpesh Patel
Associate Director, Regulatory Affairs
209 McLean Blvd.
Paterson, NJ 07504

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 19, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Primidone Tablets USP, 50 mg **and 250 mg.**

Reference is also made to your amendments dated November 6, and December 14, 2007; and March 7, 2008.

We have completed the review of this **ANDA** and have concluded that adequate information has been presented to demonstrate that the **drug** is safe and effective for use **as** recommended in tha submitted labeling. Accordingly the **ANDA is approved,** effective on the date of this letter. The Division of Bioequivalence has determined **youx** Primidone Tablets USP', 50 mg and 250 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Mysoline Tablets, 50 mg and 250 mg, respectively, of Valeant Pharmaceuticals International. Your **dissolution** testing should **be** incorporated into the stability and quality **control program** using **the same** method proposed in your application.

Under section 506A of the Act, cextain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this **ANDA** are set forth in 21 CFR 314.80-81 **and 314.98.** The ***Office*** of Generic Drugs should be advised of any Change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form PDA 2253 at the time of their initial use.

Sincerely *yours*,

{see appended electronic signature page)

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
4/23/2008 02:04:04 PM
Deputy Director, for Gary Buehler