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.

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