



ANDA 78-790

Lupin Pharmaceuticals, Inc.  
Attention: Leslie Sands  
Director, Regulatory Affairs (USA)  
U.S. Agent for: Lupin Limited  
Harborplace Tower  
111 South Calvert St, 21<sup>st</sup> Floor  
Baltimore, MD 21202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 31, 2006, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act (the Act), for Divalproex Sodium Delayed-release Tablets USP, 125 mg, 250 mg and 500 mg (Valproic Acid Activity).

Reference is also made to your amendments dated August 16, and October 3, 2007; January 7, January 24, February 18, March 7, May 29, June 6, and July 10, 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 the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Divalproex Sodium Delayed-release Tablets USP, 125 mg, 250 mg and 500 mg (Valproic Acid Activity) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Depakote Delayed-release Tablets, 125 mg, 250 mg and 500 mg, respectively, of Abbott Laboratories. 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, certain 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 FDA 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

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Robert L. West  
7/29/2008 12:25:11 PM  
Deputy Director, for Gary Buehler