



ANDA 78-979

Dr. Reddy's Laboratories Inc.
US Agent for: Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
3600 Arco Corporate Drive, Suite 310
Charlotte, NC 28273

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 3, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Divalproex Sodium Delayed Release Capsules, 125 mg.

Reference is also made to your amendments dated October 30, 2007; January 14, January 31, February 12, March 25, March 25, May 19, June 24, July 30, September 17, October 20, October 23, and December 26, 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 Capsules, 125 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Depakote Sprinkle Capsules, 125 mg, of Abbott Laboratories.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

- 500 mL of 0.05M Phosphate Buffer, pH 7.5 at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ using USP apparatus II (paddle) [REDACTED] (b)(4) at 50 rpm.

Specifications:

- NLT [REDACTED] in 2 hours
- NLT [REDACTED] in 4 hours
- NLT (b) [REDACTED] in 6 hours

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement - Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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(s) 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

**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
1/23/2009 12:03:21 PM
Deputy Director, for Gary Buehler