DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-182

Upsher-Smith Laboratories, Inc.
Attention: Cynthia G. Farner
Director, Regulatory Affairs
6701 Evenstad Drive
Maple Grove, MN 55369

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 23, 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 the Tentative Approval letter issued by this office on April 11, 2007, and your amendments dated November 22, 2006; July 13, and October 29, 2007; and February 25, March 21, May 30, May 31, June 12, July 9, and July 15, 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

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
7/29/2008 12:25:55 PM
Deputy Director, for Gary Buehler