DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-567

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 8, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Divalproex Sodium Extended-release Tablets, 250 mg and 500 mg.

Reference is also made to our tentative approval letter issued on March 6, 2007, and to your amendments dated July 1, 2005; and September 1, 2006; and November 16, 2007; May 8, and July 29, 2008; and January 2, and 8, 2009.

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 Extended-release Tablets, 250 mg and 500 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Depakote ER Tablets, 250 mg and 500 mg, of Abbott Laboratories (Abbott). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Abbott's Depakote ER Tablets, is subject to periods of patent protection. The following unexpired patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic

Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
6,419,953*(the '953 patent)	June 18, 2019
6,511,678 (the '678 patent)	June 18, 2019
6,528,090 (the '090 patent)	June 18, 2019
6,528,091*(the '091 patent)	June 18, 2019
6,713,086 (the '086 patent)	June 18, 2019
6,720,004 (the '004 patent)	June 18, 2019

*Listed for the 500 mg strength only.

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Divalproex Sodium Extended-release Tablets, 250 mg and 500 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Mylan Pharmaceuticals, Inc. (Mylan) for infringement of one or more of the patents that were the subject of the paragraph IV certifications. You notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act, and no litigation for infringement of the patents listed above was brought against Mylan within the statutory 45-day period.[1]

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA for Divalproex Sodium Extended-release Tablets, 500 mg, with paragraph IV certifications to the patents listed above. Therefore, with this approval, Mylan is eligible for 180-days of generic drug exclusivity for Divalproex Sodium Extended-release Tablets, 500 mg. (This exclusivity does not apply to the 250 mg product; you submitted an amendment for this strength that was received by the agency on March 23, 2006.) This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

[1] The agency is aware that litigation was initiated against Mylan with respect to two other patents that have since expired. The pediatric exclusivity attached to each of these patents also has expired. The agency further notes the expiration of the 30-month period, identified in section 505(j)(5)(B)(iii) of the Act, that had been associated with this litigation.

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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For

administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 77-567".***

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
1/29/2009 02:33:22 PM
Deputy Director, for Gary Buehler