



ANDA 76-314

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

Sent by Facsimile and U.S. Mail

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 26, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Topiramate Tablets, 25 mg, 100 mg, and 200 mg.

As you know, an order was entered on March 20, 2007, in the United States District Court for the District of New Jersey, in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., et al.* (Civil Action Nos. 04-1689, 06-757 and 06-5166 Consolidated Cases). Mylan requested stays of this order in both the district court and the Court of Appeals for the Federal Circuit; both requests were denied. Therefore, we are writing to inform you that, in light of this court order, the Agency hereby converts the final approval of ANDA 76-314 issued on September 11, 2006, to a tentative approval and regards ANDA 76-314 as tentatively approved, including all amendments and approved supplements thereto. Any pending or unapproved supplements are hereby considered to be withdrawn and should be resubmitted as amendments.

Your ANDA was approved because the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, had expired. (The September 11, 2006 approval pertained to the 25 mg, 100 mg, and 200 mg strengths only; the letter of September 11, 2006, tentatively approved the 50 mg strength.) The Act anticipates that in some cases an ANDA may be approved before litigation concerning the listed patents is completed. (See section 505(j)(5)(b)(iii) of

the Act.) This leaves open the possibility that, as happened with these products, the approved drug products will later be found to infringe a listed patent.

The court ordered "pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the generic topiramate tablets

-----  
shall not be earlier than the expiration date of the '006 patent, September 26, 2008..." (-----  
-----,  
-----)

Therefore, your ANDA 76-314 is now tentatively approved. Based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. This determination is based upon information available to the Agency at this time, i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug products, and is subject to change on the basis of new information that may come to our attention. Final approval cannot be granted earlier than September 26, 2008.

Because the Agency is granting a tentative approval for this ANDA, when you believe that your ANDA may be considered for final approval, you must amend your ANDA to notify the Agency regarding whether circumstances have or have not arisen that may affect the effective date of final approval. To reactivate your ANDA, please submit an amendment at least 60 days (but not more than 90 days) prior to the date your ANDA will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. Please note that this amendment should be submitted even if none of these changes were made. The amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above. Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the ANDA will be made.

The drug products that are the subject of this ANDA may not be marketed without final Agency approval under section 505 of the

Act. The introduction or delivery or introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 301(d) of the Act. Also, until the Agency issues the final approval letter, these drug products will not be listed in the "Orange Book."

For further information regarding this issue, please contact Cecelia Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs, at (240) 276-9310.

Sincerely yours,

*{See appended electronic signature page}*

Gary J. 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/

-----  
Gary Buehler

7/27/2007 01:05:30 PM