

MYLAN PHARMACEUTICALS INC.

**AMLODIPINE BESYLATE TABLETS, 2.5MG, 5MG AND 10MG**

**ATTACHMENT A**

**APPROVAL LETTER DATED OCTOBER 3, 2005**



DEPARTMENT OF HEALTH & HUMAN SERVICES

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ANDA 76-418



Food and Drug Administration  
Rockville MD 20857

OCT 3 2005

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 May 22, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act (Act), for Amlodipine Besylate Tablets, 2.5 mg (base), 5 mg (base) and 10 mg (base).

Reference is also made to your amendments dated October 2, 2002; and January 6, April 1, August 1, and August 4, 2005.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Amlodipine Besylate Tablets 2.5 mg (base), 5 mg (base), and 10 mg (base), to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Norvasc Tablets 2.5 mg (base), 5 mg (base), and 10 mg (base), respectively, of Pfizer, Inc. (Pfizer). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your ANDA, Pfizer's Norvasc® Tablets, is subject to periods of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,572,909 (the '909 patent) and 4,879,303 (the '303 patent) are scheduled to expire (with pediatric exclusivity added) on January 31, 2007, and September 25, 2007, respectively.

Your ANDA contains patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that both these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Amlodipine Besylate Tablets, 2.5 mg (base), 5 mg (base) and 10 mg (base), 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 either of the patents that were the subject of the paragraph IV certifications. This action must have been brought against Mylan prior to the expiration of 45 days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '909 patent or the '303 patent was brought against Mylan within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).<sup>1</sup>

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Amlodipine Besylate Tablets, 2.5 mg (base), 5 mg (base) and 10 mg (base). Therefore, with this approval, Mylan is eligible for 180-days of market exclusivity. This exclusivity, which is provided for under section 505(j)(5)(8)(iv) of the Act,<sup>2</sup> will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to the ANDA informing the agency of the date the exclusivity begins to run.

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.

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<sup>1</sup> Because information on the '909 and '303 patents was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) of the Act is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3). The Agency is aware that Pfizer initiated patent litigation against Mylan shortly after expiration of the statutory 45-day period.

<sup>2</sup> Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

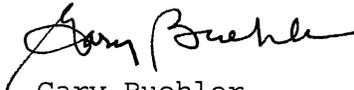
Post-marketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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 Amundson Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research