



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville, MD 20857

ANDA 090788

Mylan Pharmaceuticals Inc.  
U.S. Agent for : Matrix Laboratories Limited  
Attention: Keith Giunta  
Associate Director, Regulatory Affairs  
781 Chestnut Ridge Road  
PO Box 4310  
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 5, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Didanosine Delayed-release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg.

Reference is also made to your amendments dated November 17, and November 25, 2008; January 21, May 15, July 24, August 19, September 25, and October 13, 2009; and January 21, and March 15, 2010.

This ANDA was reviewed under the expedited review provisions of the President's Emergency Plan for AIDS Relief (PEPFAR).

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 Didanosine Delayed-release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Videx EC Delayed-release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg, respectively, of Bristol Myers Squibb Company. 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:

Dissolution Testing should be conducted in 1000 mL of 0.1N HCl (Acid Stage): 0.1N HCl followed by 0.1 N HCl:0.2M Tribasic Sodium Phosphate (3:1), pH 6.8 (Buffer Stage) at 37°C ± 0.5°C using USP Apparatus I (basket) at 100 rpm. The test product should meet the following "interim" specifications:

Acid Stage: NMT (b)(4) dissolved in 120 min;  
Buffer stage: NL (b)(4) dissolved in 45 min.

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if 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 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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, 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 090788**".

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.  
Deputy Director  
Office of Pharmaceutical Science  
Center for Drug Evaluation and Research