DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-306

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 18, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Verapamil Hydrochloride Extended-release Capsules (PM), 100 mg, 200 mg, and 300 mg.

Reference is also made to your amendments dated April 13, May 24, and June 28, 2007.

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 Verapamil Hydrochloride Extended-release Capsules (PM), 100 mg, 200 mg, and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Verelan PM Extended-release Capsules, 100 mg, 200 mg and 300 mg, respectively, of Elan Drug Delivery Inc.

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 with the following "interim" method and specifications:

Method:	0.1 N HCl at 37 degrees Celsius
Volume:	900 mL
USP Apparatus:	II (Paddle) at 100 rpm

The drug product should meet the following "interim" specifications:

Time (hours)	Percent Dissolved
2	-----------
4	----------
8	----------
24	-----------

The "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 when 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.

Sincerely yours,

{See appended electronic signature page}

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