DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-316

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 October 7, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Carvedilol Tablets, 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg.

Reference is also made to the tentative approval letter issued by this office on February 22, 2006, and to your amendments dated January 27, and March 9, 2005; and June 20, July 20, and August 27, 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 Carvedilol Tablets, 3.125 mg, 6.25 mg, 12.5 mg, 25 mg, to be bioequivalent and therefore, therapeutically equivalent to the reference listed drug, Coreg Tablets, 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg, respectively, of SmithKlineBeecham Corp. 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 application, Coreg Tablets, 3.125 mg, 6.25, 12.5 mg and 25 mg of SmithKlineBeecham Corp., is subject to periods of patent protection. The following patents with their expiration dates (with pediatric exclusivity extension 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
4,503,067 (the '067 patent)	September 5, 2007
5,760,069 (the '069 patent)	December 7, 2015
5,902,821 (the '821 patent)	August 7, 2016

We note that the '067 patent has expired.

With respect to the '069 and '821 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents, and that their associated uses (U-233 and U-313) are not claimed in any of the indications for which you are seeking approval under this ANDA.

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

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
9/5/2007 02:45:58 PM
for Gary Buehler