



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Food and Drug Administration  
Rockville, MD 20857

ANDA 76-373

TEVA Pharmaceuticals USA  
Attention: Philip Erickson, R.Ph.  
Senior Director, Regulatory Affairs  
1090 Horsham Road  
P.O. Box 1090  
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 6, 2002, 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 June 9, 2004, and to your amendments dated July 25, and December 16, 2005; and July 5, July 9, and August 28, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been provided 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, and 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 reference 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 (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>U.S. Patent Number</u>	<u>Expiration Date</u>
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

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Robert L. West  
9/5/2007 02:41:03 PM  
for Gary Buehler