DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-780

Taro Pharmaceuticals U.S.A., Inc.
U.S. Agent for: Taro Pharmaceutical Industries, Ltd.
Attention: Srinivasa Rao
Director, Regulatory Affairs
3 Skyline Drive
Hawthorne, NY 10532

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 30, 2005, 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 our Tentative Approval letter dated April 21, 2006 and to your amendments dated December 8, 2005; June 8, and August 30, 2007.

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 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 of GlaxoSmithKline. 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 GlaxoSmithKline, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

| 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 |

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 that do not claim any of the indications for which you are seeking approval.

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(s) 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 02:43:47 PM
for Gary Buehler