



ANDA 78-217

Lupin Pharmaceuticals, Inc.
U.S. Agent for: Lupin Limited
Attention: Leslie Sands
 Director, Regulatory Affairs (USA)
Harborplace Tower, 21st Floor
111 South Calvert Street
Baltimore, MD 21202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 16, 2006, 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 your amendments dated August 8, and November 23, 2006; and August 8, and August 31, 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, 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 mg, 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

With respect to the '067 patent, your ANDA contains a paragraph III certification under section 505(j)(2) (A)(vii)(III) of the Act. This certification states that Lupin Pharmaceuticals, Inc. will not market Carvedilol Tablets, 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg under this ANDA prior to the expiration of the '067 patent. The agency recognizes the '067 patent has expired, and that this patent no longer precludes the agency from approving your ANDA.

With respect to the '821 and '069 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 02:44:59 PM
for Gary Buehler