



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-012/S-001

SB Pharmco Puerto Rico Inc. d/b/a GlaxoSmithKline
Attention: Catherine K. Clark
Director, U.S. Regulatory Affairs
One Franklin Plaza
200 N. 16th Street
Philadelphia, PA 19102

Dear Ms. Clark:

Please refer to your supplemental new drug application (NDA) dated January 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coreg CR (carvedilol phosphate) Extended Release 10, 20, 40, and 80 mg Capsules.

This supplemental new drug application provides for deletion of statements from the **PRECAUTIONS** and **DOSAGE AND ADMINISTRATION** sections of the labeling regarding the drug interaction between Coreg CR and alcohol based on the results of study number CRV106904, which evaluated the effects of ethanol administration on the pharmacokinetic properties of Coreg CR.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed electronic labeling (SPL) submitted on January 12, 2007.

Marketing the product with SPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Dan Brum, Pharm.D., MBA, Regulatory Health Project Manager, at (301)796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

**This is a representation of an electronic record that was signed electronically and
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/s/

Norman Stockbridge
7/16/2007 12:45:59 PM