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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-297/S-009

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-297/S-009

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Ms. Catherine K. Clark
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Ms. Clark:

Please refer to your supplemental new drug application dated September 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coreg (carvedilol) 3.125, 6.25, 12.5 and 25 mg Tablets.

We acknowledge receipt of your submissions dated October 21 and 30 (two), November 4 and 25, 2002; February 3 (two) and March 11, 17 and 25, 2003.

This supplemental new drug application provides for the use of Coreg (carvedilol) 3.125, 6.25, 12.5 and 25 mg Tablets for the treatment of patients with left ventricular dysfunction following myocardial infarction.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon draft labeling text.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 25, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-297/S-009" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardio-Renal Drug products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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:

Ms. Melissa Robb
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

/S/

Robert Temple, M.D.
Director
Office of Drug Evaluation I
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 Temple
3/27/03 11:57:39 AM