



NDA 20-297/S-021

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Ms. Catherine K. Clark
One Franklin Plaza
200 N. 16th Street
Philadelphia, PA 19102

Dear Ms. Clark:

Please refer to your supplemental new drug application dated June 23, 2006 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 27, December 5, and 14, 2006.

This supplemental new drug application provides for language to incorporate the secondary endpoints from the COMET trial in the **CLINICAL TRIALS** section of the package insert.

We have 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 labeling text and with the minor editorial revisions listed below.

1. In the second paragraph of the **CLINICAL TRIALS/The COMET Trial** section, the following sentence was added as the third to last sentence:

The effect on mortality was primarily due to a reduction in cardiovascular deaths.

This sentence should read:

The effect on mortality was primarily due to a reduction in cardiovascular death.

2. In the second sentence of the eighth paragraph of the **PRECAUTIONS/General** section, a space is missing before the phrase “ α - and β -blocking pharmacologic activities.”
3. In the first sentence of the **PRECAUTIONS/Drug Interactions/Clonidine** section, a space is missing before the phrase “ β -blocking properties.”
4. In what is now referred to as “**Table 4. Adverse Events in US Placebo-Controlled Hypertension Trials Incidence $\geq 1\%$, Regardless of Causality***”, the following heading is indented “Metabolic.”

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the submitted labeling dated December 14, 2006 with the minor editorial revisions listed above. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in SPL format to include the changes approved in this application.

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 this division and two copies of both the promotional materials and the 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 20705-1266

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) 796-1138

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

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

Norman Stockbridge
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