DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-042/S-074

GlaxoSmithKline
Attention: Linda Rebar
200 N. 16th St.
Philadelphia, PA 19102

Dear Ms. Rebar:

Please refer to your supplemental new drug applications dated December 7, 2006, received December 8, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dyazide (hydrochlorothiazide/triamterene) Capsules.

We also acknowledge receipt of your submission dated May 9, 2007.

This "Changes Being Effected" supplemental new drug application provides for adding text specifying adverse events to the ADVERSE REACTIONS section; additional changes were made in the DESCRIPTION and HOW SUPPLIED sections..

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 labeling text and with the minor editorial revisions listed below.

1. Under "**PRESCRIBING INFORMATION**" remove the following from the title:

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The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted December 7, 2006).

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA.

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 Mr. John David, Regulatory Project Manager at (301) 796-1059.

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 this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

5/18/2007 12:01:44 PM