DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16042/S-077 **SUPPLEMENT APPROVAL**

GlaxoSmithKline
Attention: Linda Rebar
Director, Regulatory Affairs
One Franklin Plaza
200 North 16th Street, FP1005
Philadelphia, PA 19102

Dear Ms. Rebar:

Please refer to your supplemental new drug application dated October 26, 2009, submitted under section 505(b)) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dyazide (hydrochlorothiazide/triamterene) Capsules.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the ADVERSE REACTIONS section of the package insert, as we requested in our latter dated June 8, 2009:

1. Under **ADVERSE REACTIONS, Hydrochlorothiazide, *Hypersensitivity***, the phrase, "Stevens-Johnson syndrome" was removed.

2. Under **ADVERSE REACTIONS, Hydrochlorothiazide, *Skin***, the phrase, "Erythema multiforme including Steven-Johnson syndrome, exfoliative dermatitis, including toxic epidermal necrolysis" was added.

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For

instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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:

Michael Monteleone, MS
Regulatory Project Manager
(301) 796-1952

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm. D.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-16042	SUPPL-77	GLAXOSMITHKLINE	DYAZIDE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
02/23/2010