DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-887

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Erin Oliver
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Oliver:

Please refer to your new drug application (NDA) dated June 6, 2005, received June 7, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alli (60 mg orlistat) capsules.

We acknowledge receipt of your submissions dated August 4, and 25, and November 8, 2006, and January 12, and 17, and February 1, 2007.

The August 4, 2006, submission constituted a complete response to our April 6, 2006, action letter.

This new drug application provides for the nonprescription use of Alli (60 mg orlistat) capsules for weight loss in overweight adults, 18 years and older, when used along with a reduced-calorie, low-fat diet, and exercise program.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (starter pack carton labels and bottle labels for the 60, 90, and 120 count package size, refill carton label and bottle label for the 120 count package size, and Read Me First (Keys to successful weight loss) brochure submitted on February 1, 2007)., and must be in the "Drug Facts" format (21 CFR 201.66) where applicable. Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-887**." Approval of this submission by FDA is not required before the labeling is used.

At the time of next printing, we recommend that you darken the gray print on the starter pack (principal display panel (PDP) and top panel), refill carton (PDP and side panel), and bottle labels (60, 90, and 120 count sizes). Also, in the Read Me First brochure, under "Eat Right", under "Choose

foods low in fat; reduce calories and portion sizes," change the part of the phrase that reads "on **MyAlli.com**" to "at **MyAlli.com**".

The only materials that we are considering as part of the labeling are the starter pack and refill carton and ***Drug Facts*** label, the bottle label, and the Read Me First/Keys to successful weight loss brochure. The other supporting materials (Companion Guide, Daily Journal, QuickFacts Card, Healthy Eating Guide, Calorie & Fat Counter, and Welcome Guide) will not be considered as part of the approved labeling. You may choose to disseminate these supporting materials by including them in the box or via telephone or website with a number or address on the box.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, we request that you submit to the Division of Nonprescription Clinical Evaluation one copy of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print.

Please submit one market package of the drug product when it is available.

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, call LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosures

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

/s/

Curtis Rosebraugh
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Charles Ganley
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