DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021887/S-002

**SUPPLEMENT APPROVAL**

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

Dear Ms. Oliver:

Please refer to your Supplemental New Drug Application (sNDA) dated March 22, 2010, received March 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Alli (orlistat) capsules, 60 mg.

We acknowledge receipt of your amendments dated June 28, August 11, and September 9, 2010.

This “Prior Approval” supplemental new drug application provides for the addition of the warning statement “Stop use and ask a doctor if [bullet] you develop itching, yellow eyes or skin, dark urine or loss of appetite. There have been rare reports of liver injury in people taking orlistat.” to the Drug Facts label.

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.

**LABELING**

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to enclosed labeling (60-count carton (starter pack) back panel with Drug Facts label, and 120-count carton (refill) label submitted on August 11, 2010, and the 60-, 90-, and 120-count immediate container (bottle) labels and 90-count carton (starter pack) back panel with Drug Facts label submitted on June 28, 2010), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Even though no revisions were made to the “Read Me First” brochure, and the 60- and 90-count carton (starter pack) front panel labels, we request that you submit the “Read Me First” brochure, and the 60- and 90-count carton (starter pack) front panel labels as part of the FPL for this supplement to maintain a record of the complete labeling for this NDA.

The final printed labeling should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 021887/S-002**.” Approval of this submission by FDA is not required before the labeling is used.

## POSTMARKETING COMMITMENT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment in your submission dated June 28, 2010. This commitment is listed below.

1683-1 Conduct a label comprehension study of the Alli Drug Facts label to evaluate how consumers understand and interpret the new warning statement related to potential liver injury.

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| Final Protocol Submission: | October 2010 |
| Study/Trial Completion: | April 2011 |
| Final Report Submission: | July 2011 |

Submit clinical protocols to your IND 62758 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol**,” “**Postmarketing Commitment Final Report**,” or “**Postmarketing Commitment Correspondence**.”

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

**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, call Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

*{See appended electronic signature page}*

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S): Labeling

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

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/s/

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JOEL SCHIFFENBAUER
09/22/2010