DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021887/S-006

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, Inc.
Attention: Erin Oliver, M.S., M.B.A., R.A.C.
Head, U.S. Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Ms. Oliver:

Please refer to your Supplemental New Drug Application (sNDA) dated December 12, 2013, received December 13, 2013, 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 December 20, 2013 and February 7, 2014.

This "Changes Being Effected" supplemental new drug application, submitted in response to our November 13, 2013 supplement request letter, provides for the addition of two recommended warnings statements to the Drug Facts Label (DFL) as follows:

Under the "**Ask a doctor or pharmacist before use if you are**" section of the DFL, the bulleted statement is added:

- Taking medicine for seizures

Under the "**Stop use and ask a doctor if**" section of the DFL, the bulleted statement is added:

- You are taking medicine for seizures and your seizures happen more often or get worse

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to: 90-, 120-count immediate container (bottle) label and carton labeling submitted on December 12, 2013, 170-count carton labeling submitted on December 12, 2013, 170-count immediate container (bottle) label submitted on December 20, 2013, and Consumer Information Leaflet (Read Me First brochure) submitted on February 7,

2014. Because the 90-count labeling represents the 150-count immediate container label and carton labeling, any changes approved for the 90-count immediate container label and carton labeling must be incorporated onto the immediate container label and carton labeling of the 150-count labeling. FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL 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-006**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 questions, contact Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton, Container , and Consumer Information Leaflet 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.

/s/

THERESA M MICHELE
06/13/2014