DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21887/S-008

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Michael Cammarata
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 87054

Dear Mr. Cammarata:

Please refer to your Supplemental New Drug Application (sNDA) received November 25, 2015**,** and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for alli™ (orlistat) capsules, 60 mg.

This supplemental new drug application provides for the addition of a potential drug-drug interaction between orlistat and amiodarone as requested by the Agency in its CBE Supplement Request letter dated September 3, 2015. This supplement also provides for the following:

- Updates tamper evident statements
- Changes to *questions/comments* in DFL
- Adds graphics
- Updates distributor information, trademarks and copyright
- Updates 60-count carton design from supplement 002
- Introduces 170-count backer card
- Removes 21- and 150-count labeling from NDA

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 the enclosed and dated labeling identified below. The labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

FPL submitted on November 25, 2015:

- 120-count immediate container (bottle)
- 120-count *Refill Pack* carton (bottle)
- 170-count immediate container (bottle)

- 170-count *Refill Pack* carton (bottle)
- 170-count backer card

FPL submitted on January 21, 2016:

- 60-count *Starter Pack* carton (bottle)
- 90-count *Starter Pack* carton (bottle)
- *Read Me First* brochure

FPL submitted on February 10, 2016:

- 60-count immediate container (bottle)
- 90-count immediate container (bottle)

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 21887/S-008**." 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.

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 Janice Adams-King, Safety Regulatory Project Manager, at (301)796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

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

/s/

VALERIE S PRATT
05/25/2016