



NDA 021887/S-004

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
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 August 12, 2010, received August 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Alli (orlistat) capsules, 60mg.

We acknowledge receipt of your amendment dated October 27, 2010.

This "Changes Being Effected" supplemental new drug application provides for 21-count professional and retail SKUs to implement a new liver warning statement to the Alli Drug Facts Label and the addition of a manufacturer's coupon on the inner carton.

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 labeling (21-count professional sample carton, 21-count retail carton, and immediate container (bottle) labels submitted on August 12, 2010, and the five dollar and ten dollar inner carton coupon configurations submitted on October 27, 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" as part of this supplement, we request that you submit the "Read Me First Brochure" as part of the FPL for this supplement to maintain a record of the complete labeling (count sizes and packaging configurations) 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-004.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that the "new size" flag is to be removed from the label after 6 months.

MARKET PACKAGE

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

Please send to:

LCDR Jessica M. Diaz
Food and Drug Administration
Center for Drug Evaluation and
Research
White Oak Building 22, Room: 5483
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

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.

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 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 Jessica M. Diaz, Regulatory Project Manager, at (301) 796-4908.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

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/

JOEL SCHIFFENBAUER
02/04/2011