DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021330/S-015

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Dan Keravich, RPh, MSc, MBA, RAC
Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Keravich:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 15, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette® (nicotine polacrilex) lozenge, 2 mg and 4 mg.

We acknowledge receipt of your amendments dated April 30, 2013 and June 17, 2013.

This prior approval supplemental new drug application provides for the following changes:

- Packaging change to allow for the retail sale of a 24-count single Poppac® container
- Labeling modifications related to the change in packaging
- Coupon flag
- Addition of images to the principal display panel (PDP)
- Addition of previously approved Pediatric Research Equity Act language to the Directions for Use
- Product description changed to Nicorette Lozenge
- Change in trademark symbol

Your April 30, 2013 amendment included revisions to the labeling submitted on February 15, 2013, to comply with the Agency's Notice of Findings, issued April 2, 2013, regarding Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter (OTC) Human Use (78 FR 19718). Your June 17, 2013 amendment included revisions to the proposed flag in the principal display panel.

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 attached labeling text.

LABELING

Submit final printed labeling, identical to:

- the 24-count mint, 2 mg/4 mg, and 24-count cherry, 2 mg/4 mg carton labels submitted on June 17, 2013
- the 5 Dollar Coupon inner carton (as submitted on February 15, 2013)

- the User's Guide (24 count) for the 2 mg /4mg mint/cherry Nicorette lozenge (as submitted on April 30, 2013)

Even though no revisions were made to the immediate container (vial) labels for the 24-count mint, 2 mg/4 mg or the 24-count cherry 2 mg/4 mg, we request that you also submit these labels as part of the Final Printed Labeling for this supplement to maintain a complete record of the labeling (count sizes and packaging configurations) being approved as part of this supplement.

Please also note that the new callout flag on the carton PDP is to be deleted 6 months after initiation of OTC marketing.

We remind you that use of a new or different callout flag in labeling requires prior approval.

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 021330/S-015**." 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 Doris J. Bates, Ph.D., Senior Regulatory Project Manager, at (301) 796-1040.

Sincerely,

{See appended electronic signature page}

Shaw T. Chen, M.D., Ph.D.
Director (Acting)
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Approved Labeling (Carton, Inner Carton, User's Guide)

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

/s/

SHAW T CHEN
08/07/2013