DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21330/S-013

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Iris H. Shelton
Associate Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Shelton:

Please refer to your Supplemental New Drug Application (sNDA) dated March 25, 2011, received July 29, 2011, submitted pursuant to section 505(b)(2) 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 14, April 21, August 9, September 7, September 8, 2011, January 31, February 10, March 26, and May 9, 2012.

This "Prior Approval" supplemental new drug application proposes the following:

- Addition of a bullet listing "if you are under 18 years of age, ask a doctor before use. No studies have been done to show if this product will work for you." in the Drug Facts section under the paragraph heading "Directions."
- A new 189 – count Mint flavor "club pack" stock keeping unit to be marketed in 7 x 27-count "Poppac" immediate containers enclosed in a clear plastic blister attached to a backer card.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

This "Prior Approval" supplemental new drug application also reports on the following postmarketing requirement listed in our October 31, 2002 approval letter.

0493-3 For the marketing of Commit™ (nicotine polacrilex lozenge), to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking, we are deferring submission of pediatric studies for patients 10-17 years until October 31, 2007. We are waiving the pediatric study requirement for this application for patients under age 10.

We have reviewed your submission and have determined that you are released from the above requirement. We are waiving the pediatric study requirement for this application because studies are impossible or highly impracticable.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our October 31, 2002 letter.

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 (27-count Mint flavor immediate container "Poppac" vial labels submitted on February 10, 2012, the 72-count Mint, Cherry and Cappuccino carton labels, the 108-count Original carton labels, and the 189-count Mint "club pack" backer cards (front and back panels) submitted on May 9, 2012), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Also include the consumer information leaflet (user guide), the 24-count vial immediate container labels, and 12-count blister card immediate container labels as part of the FPL for this supplement in order to maintain a record of the complete labeling for each stock keeping unit.

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 21330/S-013**." 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 Phong Do, Regulatory Project Manager, at (301) 796-4795.

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

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/

JOEL SCHIFFENBAUER
05/23/2012