DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020066/S-038

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Karthik Santhanam
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Santhanam:

Please refer to your Supplemental New Drug Application (sNDA) dated March 28, 2011, received March 28, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) gum, 4 mg.

We acknowledge receipt of your amendments dated April 20, May 11, July 12, July 25, and August 8, 2011.

This Changes Being Effected supplemental new drug application provides for the following changes to the "Cinnamon Surge" stock keeping units:

- Addition of a fourth bullet listing "oral blistering occurs" in the Drug Facts section under the paragraph heading "Some Important Warnings" subheading "Stop use and ask a doctor if."
- Addition of a fourth bullet listing "oral blistering occurs" in the consumer information leaflet (booklet and leaflet format) under the paragraph heading "Some Important Warnings" subheading "Stop use and ask a doctor if."
- Revision of the word "flavor" to read "natural and artificial cinnamon flavors" in the Drug Facts section under the "Inactive ingredients" heading.

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 (consumer information leaflet (booklet and leaflet format) and 20-count immediate container ("pocket pack") label submitted on July 12, 2011 and 20-count carton, 190-count carton (representative of the 100- and 160-count cartons), and 20-count bi-fold backer card ("pocket pack") labels submitted on July 25, 2011) and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Also include the 10-count immediate container (blister card) as part of the FPL for this supplement in order to maintain a record of the complete labeling being approved as part of this supplement.

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 020066/S-038**." Approval of this submission by FDA is not required before the labeling is used. Please note that representative labeling is not acceptable for a FPL submission and that FPL should be submitted in the final to be marketed format.

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
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton Labeling, Container Labeling and Consumer Information Leaflet

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/s/

JOEL SCHIFFENBAUER
09/27/2011