DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018612/S-061
NDA 020066/S-042

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 Applications (sNDAs) dated August 15, 2011, received August 15, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) gum, 2 mg and 4 mg.

We acknowledge receipt of your amendments dated January 19 and February 2, 2012.

These "Changes Being Effected" supplemental new drug applications provide for addition of the statement "you have symptoms of an allergic reaction (such as difficulty breathing or rash)" to the "Stop use and ask a doctor if" section of the "Drug Facts" label and to the "Stop use and ask a doctor if" subheading under "Some Important Warnings" in the consumer information leaflet (booklet and leaflet format).

(b) (4)

We have completed our review of these applications, 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 (110-count uncoated Original flavor carton (representative of the 170-count carton); 110-count uncoated Mint flavor carton (representative of the 170-count carton); 100-count Fresh Mint flavor carton (representative of the 40-count and 190-count carton); 100-count Fruit Chill flavor carton (representative of the 40-count and 190-count carton); 100-count Cinnamon Surge flavor carton (representative of the 20-count, 160-count and 190-count carton); 100-count White Ice Mint flavor carton (representative of the 20-count, 160-count and 190-count carton); 100-count

Spearmint Burst flavor carton (representative of the 20-count, 160-count, 190-count and 200-count carton); 20-count Cinnamon Surge, Fruit Chill, Spearmint Burst, Fresh Mint and White Ice Mint bi-fold backer card (for the "pocket pack" immediate containers) labels; and consumer information leaflets (booklet and leaflet format) submitted on January 17, 2012), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Also include the immediate container (blister card and pocket pack) 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 018612/S-061 and NDA 20066/S-042**." 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

ENCLOSURE(S):
Carton Labels and Consumer Information Leaflets

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
02/15/2012