DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018612/S-060
NDA 020066/S-041

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 1, 2011, received August 1, 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 August 9, 2011, January 23 and 27, 2012.

These "Prior Approval" supplemental new drug applications propose the statement "Sample-Not for Sale" on the principal display panel for the 20-count "Fresh Mint", "Fruit Chill", "Cinnamon Surge", "White Ice Mint", and "Spearmint Burst" samples that are intended for distribution to healthcare professionals, but are not intended for retail sale.

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 and with the provision listed below.

Reference is made to the GlaxoSmithKline Consumer Healthcare (GSKCH) amendment dated January 27, 2012 in which GSKCH clarified and agreed that the statements "Sample – Not for Sale" and "Sample" will be printed directly onto the PDP and side panel of sample carton labels, respectively and will not be incorporated on the carton labels by the use of any stickers.

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 (20-count Spearmint Burst, Fresh Mint, Fruit Chill, Cinnamon Surge flavors, and White Ice Mint carton labels submitted on January 23, 2012 with all text printed on the label as per the January 27, 2012 submission), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Also include the 10-count immediate container (blister card) and consumer information leaflet as part of the FPL for these supplements 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 018612/S-060 and NDA 20066/S-041**." 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}

Andrea Leonard-Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton Labeling

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

/s/

ANDREA LEONARD SEGAL
02/01/2012