DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18612/S-068
NDA 20066/S-049

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, LP
Attention: Karthik Santhanam, RAC
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Santhanam:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 30, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) Chewing Gum, 2 mg (NDA 18612/S-068) and Nicorette (nicotine polacrilex) Chewing Gum, 4 mg (NDA 20066/S-049).

We acknowledge receipt of your amendments to NDA 20066/S-049 and NDA 18612/S-068 dated June 19, August 30, and October 1, 2013. An additional amendment was submitted on October 8, 2013 to NDA 18612/S-068.

These "Changes Being Effected" sNDAs consist of revised labeling submitted in response to FDA's Notice of Findings, as published in the Federal Register dated April 2, 2013; Docket No. FDA−2013−N−0341: Modifications to Labeling of Nicotine Replacement Therapy Products for Over-The-Counter Human Use (78 FR 19718).

Additional changes include revisions to the trademark statement and call out flags.

We have completed our review of these applications, as amended. Both are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Note that the "NEW DIRECTIONS FOR USE" text added to the PDP must be removed after six months of marketing.

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 following and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Stock Keeping Unit (SKU)	**Flavor**	**Representative of**	**Date Submitted**	**Date Submitted**
			2 mg	**4 mg**
110-ct carton (for 10-ct blistercards)	Original	**170-ct** and **200-ct**	6/19/2013	4/30/2013
200-ct carton, front card for club pack (for 25-ct inner cartons *pocket packs)*	Original	None	6/19/2013	6/19/2013
200-ct carton, back card for club pack (for 25-ct inner cartons *pocket packs*)	Original	None	4/30/2013	4/30/2013
110-ct carton (for 10-ct blistercards)	Mint, uncoated	**170-ct**	6/19/2013	6/19/2013
100-ct carton (for 10-ct blistercards)	Fresh Mint	None	6/19/2013	6/19/2013
200-ct carton, front card for club pack (for 25-ct inner cartons *pocket packs*)	Fresh Mint	None	6/19/2013	6/19/2013
200-ct carton, back card for club pack (for 25-ct inner cartons *pocket packs*)	Fresh Mint	None	4/30/2013	4/30/2013
20-ct carton (for 10-ct blistercards)	Fruit Chill	None	6/19/2013	6/19/2013
20-ct carton, bifold backer card (for 20-ct inner cartons *pocket packs*)	Fruit Chill	None	4/30/2013	4/30/2013
100-ct carton (for 10-ct blistercards)	Fruit Chill	None	6/19/2013	6/19/2013
200-ct carton, front card for club pack (for 25-ct inner cartons *pocket packs*)	Fruit Chill	None	6/19/2013	6/19/2013
200-ct carton, back card for club pack (for 25-ct inner cartons *pocket packs*)	Fruit Chill	None	10/01/2013	10/01/2013

20-ct carton (for 10-ct blistercards)	Cinnamon Surge	None	6/19/2013	6/19/2013
20-ct carton, bifold backer card (for 20-ct inner cartons *pocket packs*)	Cinnamon Surge	None	10/01/2013	4/30/2013
100-ct carton (for 10-ct blistercards)	Cinnamon Surge	**160-ct**	6/19/2013	6/19/2013
Consumer Information Leaflet (User's Guide booklet type used with blistercard cartons)	Cinnamon Surge	Used only with Cinnamon Surge blistercard cartons	4/30/2013	
Consumer Information Leaflet (User's Guide leaflet type for cartons with pocket packs)	Cinnamon Surge	Used only with Cinnamon Surge pocket pack cartons		
20-ct carton (for 10-ct blistercards)	White Ice Mint	None	6/19/2013	6/19/2013
20-ct carton, bifold backer card (for 20-ct inner cartons *pocket packs*)	White Ice Mint	None	10/01/2013	4/30/2013
100-ct carton (for 10-ct blistercards)	White Ice Mint	**160-ct**	6/19/2013	6/19/2013
200-ct carton, front card for club pack (for 25-ct inner cartons *pocket packs*)	White Ice Mint	None	6/19/2013	6/19/2013
200-ct carton, card back for club pack (for 25-ct inner cartons *pocket packs*)	White Ice Mint	None	10/01/2013	4/30/2013
20-ct carton (for 10-ct blistercards)	Spearmint Burst	None	6/19/2013	6/19/2013
20-ct carton, bifold backer card (for 20-ct inner cartons *pocket pack*)	Spearmint Burst	None	4/30/2013	4/30/2013
100-ct carton (for 10-ct blistercards)	Spearmint Burst	None	6/19/2013	6/19/2013
Consumer Information Leaflet (User's Guide booklet-type used with cartons for blistercards)	All except Cinnamon Surge	NA	6/19/2013	6/19/2013

Consumer Information Leaflet (User's Guide leaflet type for cartons with pocket packs)	All except Cinnamon Surge	NA	4/30/2013	4/30/2013

Although no revisions were made to the immediate containers (10-ct blister card and 25-ct pocket pack), submit the immediate container labels for the 10-ct blister card (Original, Mint uncoated, Fresh Mint, Fruit Chill, Cinnamon Surge, White Ice Mint, and Spearmint Burst) and 25-ct pocket pack (Original, Fresh Mint, Fruit Chill, Cinnamon Surge, White Ice Mint, and Spearmint Burst) as part of the final printed labeling (FPL) for these supplements (18612/S-068 and 20066/S-049), in order to maintain a record of the complete labeling.

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 each application. For administrative purposes, designate these submissions "**Final Printed Labeling for approved NDA 18612/S-068"** and **"Final Printed Labeling for approved NDA 20066/S-049**." Approval of these submissions 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.

PREA

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your applications, you are exempt from this requirement.

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 Alina Salvatore, Regulatory Project Manager, at 240-402-0379.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
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
10/30/2013