DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018612/S-072 and S-073
NDA 020066/S-053 and S-054

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Michael Cammarata
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Cammarata:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER	SUPP NUMBER	PRODUCT NAME/ STRENGTH and FLAVORS	DATE OF SUBMISSION	DATE OF RECEIPT
020066	053	Nicorette® (nicotine polacrilex) Gum, 4 mg (Fruit Chill, White Ice Mint)	12/10/13	12/11/13
018612	072	Nicorette® (nicotine polacrilex) Gum, 2 mg (Fruit Chill, White Ice Mint)	12/11/13	12/11/13
020066	054	Nicorette® (nicotine polacrilex) Gum, 4 mg (Cinnamon Surge, Fresh Mint0	01/31/14	01/31/14
018612	073	Nicorette® (nicotine polacrilex) Gum, 2 mg (Cinnamon Surge, Fresh Mint)	01/31/14	01/31/14

We acknowledge receipt of your amendments dated March 19 and 20, and May 30, 2014 for each supplement listed above.

These "Prior Approval" sNDAs provide for:

- the addition of a 10-count blister pack for the Fruit Chill, White Ice Mint, Cinnamon Surge and Fresh Mint flavors
- the addition of prominent flag at the top of the Principal Display Panel to alert consumers that the 10-ct package size may not be a full day's supply; it is intended to start or continue a quit attempt

- changes to the package labeling to include the addition of three coupons located inside of the outer carton container
- minor editorial changes to the package labeling (e.g., relocation of labeling text regarding distributor information, lot and expiration numbers, and illustration of steps for removal of pieces of gum from blister packs).
- relocation of the following text from the right side panel to the left side panel of the outer carton:

  Increase Your Success In Quitting: 1. You must be motivated to quit. 2. **Use Enough** - Chew **at least 9 pieces** of Nicorette gum per day during the first six weeks. 3. **Use Long Enough** - Use Nicorette gum for the full 12 weeks. 4. **Use with a support program** as directed in the enclosed User's Guide.

  For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.
  ***Free Audio CD upon request. See inside*.**

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

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling listed in the following table.

NDA	Date Submitted	Labeling
18612/s053 (2 mg) 20066/s072 (4 mg) (Fruit Chill, White Ice Mint)	December 11, 2013 December 10. 2013 May 30, 2014	$ 0.50 Coupon $ 1.00 Coupon $ 5.00 Coupon Drug Facts 10-count Cartons
18612/s054 (2 mg) 20066/s073 (4 mg) (Cinnamon Surge, Fresh Mint)	January 31, 2014 May 30, 2014	$ 0.50 Coupon $ 1.00 Coupon $ 5.00 Coupon Drug Facts 10-count Cartons

Although not submitted in these supplements, please also submit the immediate container labels (10-count blister cards) and Consumer Information Leaflets as part of the FPL. Labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL for each supplement 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, for each supplemental NDA, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**Final Printed Labeling for approved NDA 018612/S-072**", "**Final Printed Labeling for approved NDA 018612/S-073"**, "**Final Printed Labeling for approved NDA 020066/S-053"**, and "**Final Printed Labeling for approved NDA 020066/S-054".** Approval of these FPL submissions by FDA is not required before the labeling approved under each of these sNDAs 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 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.

REQUIRED PEDIATRIC ASSESSMENTS

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 application, 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}

Theresa Michele, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton Labeling, Drug Facts Labeling, and Coupon Labeling

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

/s/

THERESA M MICHELE
06/11/2014