DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018612/S-074
NDA 020066/S-055

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	055	Nicorette® (nicotine polacrilex) Gum, 4 mg (Fruit Chill, White Ice Mint, and Fresh Mint flavors)	05/23/14	05/23/14
018612	074	Nicorette® (nicotine polacrilex) Gum, 2 mg (Fruit Chill, White Ice Mint, and Fresh Mint flavors)	05/23/14	05/23/14

We acknowledge receipt of your amendments dated July 10 and September 12, 2014 for each supplement listed above.

These "Changes Being Effected" sNDAs provide for:

- The reintroduction of blister pack format for 200-count (two 100-count blister packs enclosed in a plastic shell) for sale in club stores.
- The addition of statement "Now in Original Blister Pack" to the upper right corner of principal display panel (PDP).

We have completed our review of these applications, as amended. Both applications 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.

Submitted Labeling Gum, 2mg (NDA 18612/S-074) Gum, 4 mg (NDA 20066/S-055)	**Submission Dates**
Front Card (PDP): Fruit Chill, White Ice Mint and Fresh Mint	May 23, 2014
Back Card with Drug Facts Label: Fruit Chill, White Ice Mint and Fresh Mint	May 23, 2014
Back Card Panel: Fruit Chill, White Ice Mint and Fresh Mint	July 10, 2014

Although no revisions were made to the immediate containers (10-ct blister card), 100-ct outer cartons or consumer user guide, submit the immediate container labels for the 10-ct blister card, 100-ct outer carton (Fruit Chill, White Ice Mint and Fresh Mint) and consumer guide as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) approved as part of these supplements (NDA 18612/S-074 and NDA 20066/S-055). Labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable. We remind you of your September 12, 2014 commitment to submit revised labeling incorporating the grammatical revision to the declaration of net quantity of contents in the next annual report covering January 13, 2014 through January 12, 2015.

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 sNDA, 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-074**" and "**Final Printed Labeling for approved NDA 020066/S-055".** Approval of these FPL submissions by FDA is not required before the labeling approved under these sNDAs are 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 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}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
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
10/30/2014