DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020066/S-061
NDA 018612/S-080

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Julia Kim
Manager, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Ms. Kim:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received December 8, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) gums, 2 mg and 4 mg.

These "Prior Approval" sNDAs provide for the addition of a new package size configuration, 120-ct bonus pack, for the approved flavor variants, Spearmint Burst, White Ice Mint and Fruit Chill.

We have completed our review of these applications, as amended. They 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 following labeling listed in the table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling for Nicorette Gum, 2 mg NDA 18-612/S-080	Submission Date(s)
10-ct immediate container (blister card), Spearmint Burst	January 24, 2018
120-ct (100+20-ct) outer carton, Spearmint Burst	December 8, 2017
10-ct immediate container (blister card), White Ice Mint	January 24, 2018
120-ct (100+20-ct) outer carton, White Ice Mint	December 8, 2017
10-ct immediate container (blister card), Fruit Chill	January 24, 2018
120 (100+20-ct) outer carton, Fruit Chill	December 8, 2017

Submitted Labeling for Nicorette Gum, 4 mg NDA 20-066/S-061	
10-ct immediate container (blister card), Spearmint Burst	January 24, 2018
120-ct (100+20-ct) outer carton, Spearmint Burst	December 8, 2017
10-ct immediate container (blister card), White Ice Mint	January 24, 2018
120-ct (100+20-ct) outer carton, White Ice Mint	December 8, 2017
10-ct immediate container (blister card), Fruit Chill	January 24, 2018
120-ct (100+20-ct) outer carton, Fruit Chill	December 8, 2017
Consumer information leaflet	January 24, 2018

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDAs 018612/S-080 and 020066/S-061**". 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.

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 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/

THERESA M MICHELE
06/05/2018