DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020066/S-060
NDA 018612/S-079

SUPPLEMENT APPROVAL

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

Dear Ms. Nair:

Please refer to your Supplemental New Drug Applications dated and received June 21, 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 "Changes Being Effected" supplemental new drug applications provide for a Spearmint Burst Gum Club Pack that will contain two 100-count cartons (2x100-ct).

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 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 18612/S-079	**Submission Date(s)**
200-ct outer carton (2x100-ct) front backer card for clam shell outer carton, Spearmint Burst	August 29, 2017
200-ct outer carton (2x100-ct) back backer card for clam shell outer carton, Spearmint Burst	June 21, 2017
100-count outer carton, Spearmint Burst	September 19, 2017
10-ct immediate container (blister card), Spearmint Burst	August 29, 2017

Submitted Labeling for Nicorette Gum, 4 mg NDA 20066/S-060	
200-ct outer carton (2x100-ct) front backer card for clam shell outer carton, Spearmint Burst	August 29, 2017
200-ct outer carton (2x100-ct) back backer card for clam shell outer carton, Spearmint Burst	June 21, 2017
100-count outer carton, Spearmint Burst	September 20, 2017
10-ct immediate container (blister card), Spearmint Burst	August 29, 2017

Even though no revisions were made to the consumer information leaflet (User's Guide), submit the consumer information leaflet (User's Guide) as part of the FPL for this supplement to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

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-079 and 020066/S-060**". 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
12/11/2017