



NDA 020066/S-062  
NDA 018612/S-081

**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 May 14, 2018, and your amendment, 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 bonus package containing a total of 180-count (pieces of gum) for your 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.

<b>Submitted Labeling for Nicorette® Gum, 2 mg NDA 18-612/S-081</b>	<b>Submission Date(s)</b>
10-ct immediate container (blister card), Spearmint Burst	May 24, 2018
180-ct (160+20-ct) outer carton, Spearmint Burst	May 14, 2018
10-ct immediate container (blister card), White Ice Mint	May 24, 2018
180-ct (160+20-ct) outer carton, White Ice Mint	May 14, 2018
10-ct immediate container (blister card), Fruit Chill	May 24, 2018
180-ct (160+20-ct) outer carton, Fruit Chill	May 14, 2018

<b>Submitted Labeling for Nicorette® Gum, 4 mg NDA 20-066/S-062</b>	
10-ct immediate container (blister card), Spearmint Burst	May 24, 2018
180-ct (160+20-ct) outer carton, Spearmint Burst	May 14, 2018
10-ct immediate container (blister card), White Ice Mint	May 24, 2018
180-ct (160+20-ct) outer carton, White Ice Mint	May 14, 2018
10-ct immediate container (blister card), Fruit Chill	May 24, 2018
180-ct (160+20-ct) outer carton, Fruit Chill	May 14, 2018
Consumer information leaflet (same one used for all flavor variants – Spearmint Burst, White Ice Mint, and Fruit Chill)	May 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-081 and 020066/S-062**”. 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.

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## **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

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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THERESA M MICHELE  
11/14/2018