DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021330/S-021

SUPPLEMENT APPROVAL

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

Dear Ms. Kim:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 22, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) lozenges, 2 mg and 4 mg.

We acknowledge receipt of your major amendment dated June 5, 2018, which extended the goal date by two months.

This "Prior Approval" sNDA provides for a new mint flavor coated lozenge which will be referred to as "Coated Ice Mint".

We have completed our review of this application, as amended. It is 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 labels and labeling listed in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date(s) Submitted
20-ct, 2 mg Immediate container "Flip-Pack" (front)	February 22, 2018
20-ct, 4 mg Immediate container "Flip Pack" (front)	February 22, 2018
20-ct, 2 mg and 4 mg Immediate container "Flip-Pack" (back)	February 22, 2018
20-ct, 2 mg outer carton container backer card (back)	February 22, 2018

20-ct, 2 mg outer carton container backer card (front)	June 25, 2018
20-ct, 4 mg outer carton container backer card (back)	February 22, 2018
20-ct, 4 mg outer carton container backer card (front)	June 25, 2018
80-ct (4x20 pack), 2 mg outer carton container backer card (back)	February 22, 2018
80-ct (4x20 pack), 2 mg outer carton container backer card (front)	June 25, 2018
80-ct (4x20 pack), 4 mg outer carton container backer card (back)	February 22, 2018
80-ct (4x20 pack), 4 mg outer carton container backer card (front)	June 25, 2018
120-ct (6x20 pack), 2 mg Club pack outer carton container backer card (front and back)	June 25, 2018
120-ct (6x20 pack), 4 mg Club pack outer carton container backer card (front and back)	June 25, 2018
Consumer Information leaflet (User's Guide leaflet)	February 22, 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 NDA 21330/S-021**." 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.

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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
08/10/2018