DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021330/S-018

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Geet Mankad, MS, MBA, RAC
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Mankad:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 17, 2015, 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 amendments dated February 25 and March 4, 2015.

This "Prior Approval" sNDA provides for the following:

- adds a soya allergy statement under the Warnings section of the drug facts labeling for the mint flavor lozenges only
- adds a new 144-count carton package size and associated carton labeling for the mint flavor lozenges
- adds a GlaxoSmithKline Consumer Healthcare, L.P. (GSK) logo to the principal display panel of the carton labeling.

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), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the submitted enclosed labeling, listed in the following table, including the 24-count carton labeling, and must be in the drug facts labeling format (21 CFR 201.66), where applicable.

Also, submit the 24-count and 27-count immediate container (vial) labels as part of the FPL for this supplement to maintain a record of the complete labeling approved as part of supplement 018.

Submitted Labeling	Representative of the following stock-keeping units	Submission Date
72-ct, Carton, (3 x 24- count immediate container ["Poppac" vial]), Mint	24-ct, Carton, (1 x 24-ct immediate container ["Poppac" vial]), Mint	December 17, 2014
81-ct, Carton, (3 x 27-ct immediate container ["Poppac" vials]-2 flags bonus pack, 9 extra pieces), Mint	None	February 25, 2015
189-ct, Carton, (Front and Back Cards), (7 x 27-ct immediate container ["Poppac" vials]), Mint	None	February 25, 2015
Consumer Information Leaflet (User's Guide – vials)	None	February 25, 2015
144-ct, Carton,(6 x 24- count immediate container ["Poppac" vial]), Mint	None	March 4, 2015

The FPL 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, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021330/S-018**." 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

ENCLOSURES:
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
05/18/2015