DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022360/S-009

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 October 10, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) mini lozenge 2 mg and 4 mg.

We acknowledge receipt of your amendment dated November 24, 2014.

This sNDA provides for the following revisions:

- Addition of a new allergy warning
- Modification of the Directions in the Drug Facts to update the Pediatric Research Equity Act (PREA) language
- Addition of the GSK brand logo to the front page of the User's Guide and the principal display panel
- Minor editorial changes.

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 enclosed labeling, listed in the following table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling to each NDA for the 2 mg and 4mg *mini* lozenges	Submission Date(s)
20-ct vial outer carton	October 10, 2014
81-ct, outer carton, (3 vials x 27-ct immediate container [vials], Mint	October 10, 2014

108-ct, outer carton, (4 vials x 27-ct immediate container [vials]) (with Bonus flag-27 extra pieces) , Mint	November 24, 2014
135-ct, outer Card (front and back), (5 vials x 27-ct immediate container [vials], Mint	October 10, 2014
Consumer User's Guide-Leaflet	October 10, 2014
Consumer User's Guide-Booklet	October 10, 2014

Although no modifications were made to the 20-ct, 24-ct and 27-ct immediate container (vial) labeling as part of this supplement, submit the 20-ct, 24-ct and 27-ct immediate container (vial) labeling as part of the FPL for this supplement to maintain a record of the complete labeling approved as part of supplement-009.

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 022360/S-009**." 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 and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
04/16/2015