DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021330/S-017

SUPPLEMENT APPROVAL

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

Dear Mr. Mankad:

Please refer to your Supplemental New Drug Application (sNDA), dated and received February 18, 2014, 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 amendment dated April 11, 2014.

This "Changes Being Effected" sNDA provides for the addition of an allergy statement to the "Stop use and ask a doctor if" section in the "Drug Facts" labeling, and to the "Important Warnings" under the "Stop use and ask a doctor if" section of the consumer information leaflet (User's Guide).

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 (2 mg and 4	Flavors	Date Submitted
24-ct outer containers, carton	Mint, Cherry	February 18, 2014
72-ct (for 24-ct "Poppac" containers-vials), carton	Mint, Cherry	February 18, 2014
81-ct (for 24-ct "Poppac" containers-vials), carton	Mint, Cherry	February 18, 2014
108-ct (for 12-ct blister cards)	Original	February 18, 2014
132-ct (for 12-ct blister cards)	Original	February 18, 2014
189-ct (for 27-ct "Poppac" containers-vials), carton with Front and Back Cards	Mint	February 18, 2014
12-ct blister cards, immediate container	Original	April 11, 2014
24-ct "Poppac" immediate containers-vials	Mint, Cherry	April 11, 2014
27-ct "Poppac" immediate containers-vials	Mint, Cherry	April 11, 2014
Consumer Information Leaflet (User's Guide Blister)		February 18, 2014
Consumer Information Leaflet (User's Guide Vial)		February 18, 2014
Consumer Information Leaflet (User's Guide Booklet)		April 11, 2014

Even though no revisions were made to the 48-ct carton labeling (contains 24-ct x 2 "Poppac" immediate containers), for the Mint and Cherry flavors, submit these as part of the FPL for this supplement to maintain a record of the complete labeling approved as part of S-017.

For the delisted Cappuccino flavor of Nicorette lozenges, we remind you to submit the updated proposed labeling under a future new prior approval labeling supplement if the flavor is reintroduced to the market.

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-017**." 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 application, 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 Clinical Evaluation
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
08/14/2014