DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021330/S-016

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, LP
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 May 2, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette® (nicotine polacrilex) lozenge, 2 mg and 4 mg.

We acknowledge receipt of your amendments dated June 17, October 8, and October 11, 2013.

This "Changes Being Effected" supplemental new drug application consists of revised labeling submitted in response to FDA's Notice of Findings, as published in the Federal Register dated April 2, 2013; Docket No. FDA−2013−N−0341: Modifications to Labeling of Nicotine Replacement Therapy Products for Over-The-Counter Human Use (78 FR 19718).

Additional changes include revisions to the trademark statement and call out flags.

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.

Note that the "NEW DIRECTIONS FOR USE" text added to the PDP must be removed after six months of marketing.

LABELING

Submit final printed labeling, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the following and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling (2 mg and 4 mg)	Date Submitted, 2 mg	Date Submitted, 4 mg
72-ct, carton, mint	June 17, 2013	Oct 08, 2013
72-ct, carton, cherry	Oct 08, 2013	Oct 08, 2013
81-ct, carton, mint	May 02, 2013	May 02, 2013
81-ct, carton, cherry	May 02, 2013	May 02, 2013
108-ct, carton, original	June 17, 2013	Oct 08, 2013
132-ct, carton, original	May 02, 2013	May 02, 2013
189-ct, carton, mint (front card)	June 17, 2013	Oct 11, 2013
189-ct, carton, mint (back card)	May 02, 2013	October 08, 2013
	Date Submitted	
Consumer Information Leaflet (User's Guide Vials)	May 02, 2013	
Consumer Information Leaflet (User's Guide Booklet)	May 02, 2013	

Even though no revisions were made to the immediate container (24-count vial "Poppac") label for the 72-ct carton, the immediate container (27-count vial "Poppac") label for 81-ct and 189-ct cartons, and the immediate container (12-count blistercards) label for 108-ct and 132-ct cartons as part of this supplement, submit these labels as part of the final printed labeling (FPL) for this supplement (S-016), in order to maintain a record of the complete labeling.

The final printed labeling 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-016**." 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.

PREA

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}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
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/

JOEL SCHIFFENBAUER
10/28/2013