DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021330/S-009

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Iris H. Shelton
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Ms. Shelton:

Please refer to your Supplemental New Drug Application (sNDA) dated March 2, 2010, received March 2, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) lozenge, 2 mg and 4 mg.

This "Changes Being Effected" supplemental new drug application provides for a change in the flag from "Formerly Commit" to "Previously Commit" and updating the labeling website reference.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit final printed labeling 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 enclosed labeling (12-ct immediate container (blister card) and carton labels for the 108-count 2 mg and 4 mg original flavor lozenge; 24-ct immediate container (POPPAC vial) and carton labels for the 24-count and 72-count 2 mg and 4 mg mint, cherry, and cappuccino lozenges, and the consumer information leaflet (user's guide) submitted on March 2, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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-009**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that the flag "Previously Commit" is to be removed from the label after 6 months.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Phong Do, Regulatory Project Manager, at (301) 796-4795.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton, Container Labeling, and Consumer Information Leaflet

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21330	SUPPL-9	GLAXOSMITHKLINE CONSUMER HEALTHCARE	COMMIT (NICOTINE POLACRILEX)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANDREA LEONARD SEGAL
08/27/2010