DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-330/S-008 **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 July 6, 2009, received July 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Commit (2 mg and 4 mg, nicotine polacrilex) lozenge.

We acknowledge receipt of your submission dated December 9, 2009.

This "Prior Approval" supplemental new drug application provides for a proprietary name change and associated labeling changes.

We completed our review of this supplemental new drug application, as amended. This supplement 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 (immediate container (blister card) and carton labels for the 108-count 2 mg and 4 mg original flavor lozenge; immediate container (POPPAC vial) and carton labels for the 72-count 2 mg and 4 mg mint, cherry, and cappuccino lozenges, and the consumer information leaflet (user's guide) submitted on July 6, 2009). It 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 (October 2005).* 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 "**FPL for approved supplement NDA 21-330/S-008**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that the flag “Formerly Commit” is to be removed from the label after 6 months.

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosures

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21330	SUPPL-8	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
01/05/2010