DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-330/S-007

GlaxoSmithKline Consumer Healthcare
Attention: Iris H. Shelton
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Shelton:

Please refer to your supplemental new drug application dated January 24, 2008 received January 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Commit (2 mg and 4 mg, nicotine polacrilex) lozenge.

We also acknowledge receipt of your submissions dated April 17, 2008, providing confirmatory six month stability data, and May 22, 2008, providing a revised 48-count POPPAC container label.

This supplemental new drug application provides for the nonprescription marketing of a new Cappuccino flavor of the 2 mg and 4 mg lozenge with associated packaging and labeling.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels for the 72-count 2 mg and 4 mg Cappuccino lozenge and the immediate container labels for the 48-count 2 mg and 4 mg Cappuccino lozenge submitted on January 24, 2008, and the carton labels for the 48-count 2 mg and 4 mg Cappuccino lozenge submitted on May 22, 2008). This must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-330/S-007".** Approval of this submission by FDA is not required before the labeling is used.

We remind you that the word "New" must be removed from the label and labeling, wherever it appears, after the first six months of marketing.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit one market package of the drug product when it is available.

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, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Andrea Segal

5/23/2008 10:58:09 AM