**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-330/S-003

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

Dear Ms. Shelton:

Please refer to your supplemental new drug application dated April 22, 2005, received April 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Commit® (2 mg & 4 mg nicotine polacrilex) Lozenge.

We acknowledge receipt of your submissions dated September 27, October 14, and October 21, 2005.

This supplemental new drug application proposes a new container/closure system with labeling for this new packaging configuration for the Commit® Mint Lozenge.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the 2 mg and 4 mg POPPAC immediate container labels submitted on April 22, 2005, and the 48 and 72 count POPPAC carton labels and User's Guide, submitted on October 21, 2005.

We remind you of your agreement in response to our October 19, 2005 fax to make the following revisions to the label at the time of next printing or 180 days, whichever comes first:

1. On the vial label and the 48 & 72 count cartons for the 2 mg and 4 mg lozenge, revise the statement under the first vial graphic to read: "To open vial, push in child resistant band on the POPPAC with thumb."

2. Revise sentence 2 in paragraph 2 on the vial label to read: "Discard vial after use." We have used the term "vial" to describe the POPPAC container. However, you have the option of using any appropriate term, e.g. container, vial, POPPAC.

3. On the vial label, revise the first two sentences following the table to read:
"Place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. Do not chew or swallow lozenge. Occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20–30 minutes)."

4. In addition, revise the first bullet under ***Warnings*** to read "a sodium-restricted diet."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laura Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

*{See appended electronic signature page}*

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

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

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/s/

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Andrea Segal

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