DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-330/S-004

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 July 22, 2005, received July 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Commit® (2mg and 4mg nicotine polacrilex) Lozenge.

We also acknowledge receipt of your submission dated November 2, 2005.

This supplemental new drug application proposes a new cherry flavor.

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) submitted on July 22, 2005.

In addition, we remind you to make the following agreed upon labeling changes at the time of next printing or in 180 days, which ever comes first:

1. In the "Inactive ingredients" section, correct the spelling of the ingredient listed as "palm kernal oil" to "palm kernel oil."

2. Please be reminded that FDA recommended the following label revisions after review of SCP-003 (BL) for Commit Mint Lozenge, submitted 10/21/05:

    a. On vial labels and carton labels, revise the statement under the first vial graphic to read: "To open vial, push in child resistant band on the POPPAC with thumb."

    b. Revise sentence 2 in paragraph 2 on vial labels to read: "Discard vial after use."

    c. On vial labels, 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)."

    d. Revise the first bullet under "Ask a doctor before use if you have" to read "a sodium-restricted diet."

We remind you to remove the word “New” from the label after 6 months of OTC marketing.

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 Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

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