DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-330/S-002

GlaxoSmithKline Consumer Healthcare
Attention: David Schifkovitz
Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Schifkovitz:

Please refer to your supplemental new drug application dated March 12, 2003, received March 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Commit® (nicotine polacrilex) Lozenge.

We acknowledge receipt of your submission dated October 15, 2003.

Your submission of October 15, 2003, constituted a complete response to our July 14, 2003, Approvable letter.

This supplemental new drug application provided for a new spearmint flavored Commit® Spearmint (nicotine polacrilex) Lozenge.

We 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 March 12, 2003.

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 CDR Laura E. Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
Director
Division of Over the Counter Drug Products
Office of Drug Evaluation V
Center for Drug Development 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/

Charles Ganley
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