DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-043
NDA 20-066/S-024

GlaxoSmithKline Consumer Healthcare
Attention: Zinatara A. Manji, MS, PharmD
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Dr. Manji:

Please refer to your supplemental new drug applications dated November 3, 2005, received November 4, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette® (2 mg and 4 mg nicotine polacrilex) gum.

We also acknowledge receipt of your submissions dated April 7, 2006.

These "Changes Being Effected" supplemental new drug applications provide for a new 20 count package size.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 7, 2006.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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}

Charles Ganley, MD
Director
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/

Charles Ganley
5/4/2006 02:38:20 PM