DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-042
NDA 20-066/S-023

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Zinatara A. Manji
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Manji:

Please refer to your supplemental new drug applications dated August 1, 2005, received August 2, 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 submission September 30, 2005.

These supplemental new drug applications propose a new Fruit Chill 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 August 1, 2005.

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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