DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-066/S-019

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

Dear Ms. Manji:

Please refer to your supplemental new drug application dated February 18, 2004, received February 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette® (4 mg nicotine polacrilex) gum.

We acknowledge receipt of your submissions dated March 1, March 12, May 4, and June 4, 2004.

This supplemental new drug application proposes a new mint flavored coated gum.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the approved draft labeling (carton label and Users Guide submitted May 4, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

We remind you to remove the word "**New**" from the carton label within 6 months of 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely yours,

{See appended electronic signature page}

Jonca Bull, MD
Director
Office of Drug Evaluation V
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/

Jonca Bull

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