DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-066/S-017

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 December 23, 2003, received December 24, 2003, 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 12, March 25, May 14, and June 16, 2004.

This supplemental new drug application proposes modifications to current labeling for Nicorette® gum.

We have 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 User's Guide submitted March 12, 2004, with the revisions listed below), in accordance with the requirements of 21 CFR 201.66. In addition we remind you to add the following agreed upon revisions in the FPL:

- User's Guide revision submitted May 14, 2004: Add the statement "To request a free audio CD containing tips to help make quitting easier, call the toll free number listed above. (ONE CD PER CUSTOMER)."

- Carton label revision submitted June 16, 2004: Add the statement "Free Audio CD upon request."

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}

Cutis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over the Counter Drug Products
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/

Curtis Rosebraugh
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