



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-066/S-016

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 November 26, 2003, received December 2, 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 February 5, 2004, March 1, 2004, March 12, and April 6, 2004.

The April 6, 2004, submission constituted a complete response to our April 2, 2004, action letter.

This supplemental new drug application proposes a new mint flavored uncoated 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 enclosed labeling (carton label submitted April 6, 2004, and Users Guide submitted March 12, 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 after 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}

Charles Ganley, MD
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/

Charles Ganley

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