DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-052
NDA 20-066/S-033

GlaxoSmithKline Consumer Healthcare
Attention: David Schifkovitz
Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Schifkovitz:

Please refer to your supplemental new drug application dated July 8, 2009, received July 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette (2 mg and 4 mg, nicotine polacrilex) gum.

We acknowledge receipt of your submissions dated July 8, October 6 and 13, 2008, February 9, April 6, 7 and 17, 2009.

These supplemental new drug applications provide for new dosing instructions regarding appropriate dose selection of gum strength from cigarettes per day (CPD) to time to first cigarette (TTFC) and labeling for the following:

		20 count	**40 count**	**100 count**	**110 count**	**160 count**	**170 count**	**190 count**	**200 count**
Coated	**White Ice Mint**	2mg/4mg	2mg/4mg	2mg/4mg		2mg/4mg		2mg/4mg	
Coated	**Fruit Chill**		2mg/4mg	2mg/4mg				2mg/4mg	
Coated	**Cinnamon Surge**	2mg/4mg		2mg/4mg		2mg/4mg		2mg/4mg	
Coated	**Fresh Mint**		2mg/4mg	2mg/4mg				2mg/4mg	
Uncoated	**Mint**				2mg/4mg		2mg/4mg		
Uncoated	**Original**				2mg/4mg		2mg/4mg		2mg/4mg

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended for the above referenced SKUs in the agreed upon labeling text.

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling immediate container and carton labels for the 20- (white ice mint and cinnamon surge flavors), 40- (White ice mint, fruit chill, and freshmint flavors), 100- (white ice mint, fruit chill, cinnamon surge and fresh mint flavors), 110- (mint and original flavors), 160- (white ice mint and cinnamon surge flavors), 170- (mint and original flavors), 190- (white ice mint, fruit chill, cinnamon surge and fresh mint flavors, and 200-count sizes (original flavor) submitted on April 6 and 7, 2009; and to the User Guide for all of the above referenced SKUs submitted on in the July 8, 2008. These must be formatted in accordance with the requirements of 21 CFR 201.66 where applicable. Please note that you did not propose any changes to your blister card and therefore we expect that they will remain identical to the most recent approved versions.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 18-612/S-052 and NDA 20-066/S-033**." Approval of these submissions by FDA is not required before the labeling is used.

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
Suite 12B05
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).

We remind you to remove the "New—See new dosing instructions" flag from the principal display panel after six months of marketing.

Additional Comment:

(b) (4)

If you have any questions, call Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
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/

Joel Schiffenbauer

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