DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-050
NDA 20-066/S-031

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Marissa M. Fletcher, Ph.D.
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Dr. Fletcher:

Please refer to your supplemental new drug applications for NDA 18-612 dated February 13, 2008, received February 13, 2008, and NDA 20-066 dated February 14, 2008 received February 14, 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for:

NDA Number	Name	Dosage Form
18-612/S-050	Nicorette	2 mg, nicotine polacrilex gum
20-066/S-031	Nicorette	4 mg, nicotine polacrilex gum

We also acknowledge receipt of your submissions dated March 21, and June 10, 2008 to both NDAs.

This supplemental new drug application provides for the nonprescription marketing of a new White Ice Mint flavor of 2 mg and 4 mg gum with associated packaging and labeling.

We have completed our review of these applications. These applications are 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 (10-count blister card, 20-, 100- and 160-count carton labels and users guide for the 2 and 4 mg strengths), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

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-050 and NDA 20-066/S-031**." Approval of these submissions by FDA is not required before the labeling is used.

We remind you that the word “New” must be removed from the label and labeling, wherever it appears, after the first six months of marketing.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

In addition, we remind you that the statement of identity phrase “STOP SMOKING AID” on the principal display panel should be capitalized at the time of next printing of the label or within 180 days, whichever is sooner.

Please submit one market package of the drug product when it is available.

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 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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