DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-360 **NDA APPROVAL**

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Iris H. Shelton
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms Shelton:

Please refer to your new drug application (NDA) dated July 18, 2008, received July 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette (2 mg and 4 mg, nicotine polacrilex) lozenge.

We acknowledge receipt of your submissions dated July 18, September 10, October 3 and 21, November 4, 14 and 17, and December 22, 2008, January 13, February 9, 10, 11, 12 13 (2 submissions), and 19, March 22 and 27, and April 2 and 22, and May 13, 2009.

This new drug application provides for the nonprescription use of Nicorette (2 mg and 4 mg, nicotine polacrilex) mint flavored lozenge, for the reduction of withdrawal symptoms, including nicotine craving associated with quitting smoking.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended 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 (the 2 mg and 4 mg carton labels for the 81-count and the immediate container label of the 27-count on April 22, 2009; the 2 mg and 4 mg carton label for the 24- and 108- count, the immediate container label for the 24-count and the users guide submitted on May 13, 2009). These must be in the "Drug Facts" format (21 CFR 201.66), where applicable. Please note that the only flavor approved is mint flavor.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Application and Related Submissions Using the eCTD Specifications (October 2005).* 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 "**Final Printed Labeling (FPL) for approved NDA 22-360**." Approval of this submission by FDA is not required before the labeling is used.

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.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and 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" flag from the principal display panel after six months of marketing.

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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