DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022360/S-004

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Alice Welenc
Regulatory Affairs Manager
1500 Littleton Road,
Parsippany, NJ 07054

Dear Ms. Welenc:

Please refer to your Supplemental New Drug Application (sNDA) dated March 23, 2012, received March 23, 2012, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) lozenges, 2 mg and 4 mg.

We acknowledge receipt of your amendments dated April 4, August 13, and August 29, 2012.

This "Prior Approval" supplemental new drug application proposes removal of all references to oral dissolution time from the Drug Facts label.

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.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (consumer information leaflet (booklet and leaflet formats), 24-count carton, 81-count carton, 135-count backer card (front side) and 162-count backer card (front side) submitted on March 23, 2012 and 20-count immediate container, "regular blister card," (for backer card configuration), 20-count immediate container, "skinny blister card," (for backer card configuration), 135-count backer card (back side) and 162-count backer card (back side) submitted on August 29, 2012), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Also include the 20-count, 24-count, and 27-count vial immediate containers as part of the FPL for this supplement in order to maintain a record of the complete labeling for each stock keeping unit.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 022360/S-004**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Phong Do, Regulatory Project Manager, at (301) 796-4795.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Backer Card with "Drug Facts", Consumer Information Leaflet, and Carton Labeling

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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
09/18/2012