DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022360/S-006

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Paula T. Markert
Regulatory Associate
1500 Littleton Road
Parsippany, NJ 07054

Dear Ms. Markert:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 30, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette® (nicotine polacrilex) lozenge, 2 mg.

We acknowledge receipt of your amendment dated March 15, 2013.

This "Changes Being Effected" supplemental new drug application provides for increasing the 81-count (ct) mini lozenge 2 mg package size only, consisting of 3 vials each with 27 lozenges (3/27) to a 108-ct mini lozenge package size consisting of 4 vials each with 27 lozenges (4/27). To announce this change, a flag will be added at the top of the carton. The flag will contain the following wording: "Bonus Pack 27 Extra Pieces".

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, identical to the 108 count, 2 mg carton labeling submitted on November 30, 2012, as soon as it is available, but no more than 30 days after it is printed. The final printed labeling (FPL) must be identical to the submitted labeling referenced, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

To maintain a complete record of the labeling being approved as part of this supplemental NDA, please also submit labeling for the 27-count vial (immediate container) and the User's Guides (leaflet and booklet) as approved September 18, 2012 under NDA 022360 / S-004.

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-006**." 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 Doris J. Bates, Ph.D., Senior Regulatory Project Manager, at (301) 796-1040.

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:
Carton Labeling

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
05/23/2013