DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22360/S-010

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Geet Mankad, MS, MBA, RAC
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Mankad:

Please refer to your Supplemental New Drug Application (sNDA) dated March 31, 2015, received March 31, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) *mini* lozenge, 2 mg and 4 mg.

We acknowledge receipt of your amendments dated June 15, August 28, and September 21, 2015.

This "Prior Approval" supplemental new drug application provides for the addition of a seizure warning on the Drug Facts Label:

Ask a doctor before use if you have

- history of seizures

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 (FPL), as identified in the table below as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the approved labeling identified in the table below. Even though the following pieces of labeling were not revised as part of this supplement, submit them with the FPL for complete labeling: immediate containers (i.e., 20-ct, 24-ct and 27-ct "Poppac" vial). The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Flavor	Date Submitted
20-ct Outer Carton (with bi-fold backer card), 2 mg and 4 mg	Mint	September 21, 2015
81-ct Outer Carton (for 27-ct "Poppac" container-vial), 2 mg and 4mg	Mint	September 21, 2015
108-ct Outer Carton (for 27-ct "Poppac" container-vial: 1 flag bonus pack, 27 extra pieces), 2 mg and 4 mg	Mint	September 21, 2015
135-ct Outer Carton (for 27-ct "Poppac" container-vial) Back and Front Cards, 2 mg and 4 mg	Mint	September 21, 2015
Consumer Information Leaflet (User's Guide Booklet), 2 mg and 4 mg		September 21, 2015
Consumer Information Leaflet (User's Guide Leaflet), 2 mg and 4 mg		September 21, 2015

Submit the FPL 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, 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 22360/S-10**." Approval of this submission by FDA is not required before the labeling is used.

In addition, a prior approval supplement must be submitted before marketing the 24-ct outer carton physician sample, with updated labeling information. Distribution of this particular stock keeping unit (SKU) will be contingent upon approval of the prior approval supplement.

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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Acting Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
09/30/2015