DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18612/S-076
NDA 20066/S-057

SUPPLEMENT APPROVAL

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

Dear Mr. Cammarata:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 31, 2015, received March 31, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for

- NDA 18612/S-076 Nicorette (nicotine polacrilex) gum, 2 mg
- NDA 20066/S-057 Nicorette (nicotine polacrilex) gum, 4 mg

We acknowledge receipt of your amendments dated August 31, September 25, 28, and 29, 2015.

These "Prior Approval" sNDAs provide for the addition of a seizure warning to the Drug Facts Label:

Ask a doctor before use if you have

- history of seizures

We have completed our review of these applications, as amended. They are 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 these supplements, submit them with the FPL for complete labeling: 10-count blister card (immediate containers); 20-count pocket pack (immediate container); and 200-ct front cards (ORIG, FM, FC, WIM) that pair with the submitted DFL backer cards (carton for blister cards). The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Flavors	Outer Carton Labeling Nicorette 2 mg and 4 mg	Represents	Date Submitted
Cinnamon Surge (CS)	20-ct (for pocket pack) 20-, 100-, 160-ct (for blister cards)	N/A	9/25/2015
Fresh Mint (FM)	100-ct (for blister cards) 200-ct backer card for club pack (for blister cards)	N/A	9/25/2015
Fruit Chill (FC)	20-ct (for pocket pack) 20-, 100-, 160-, 200-ct (for blister cards) 200-ct backer card for club pack (for blister cards)	N/A	9/25/2015
Mint (MT)	110-, 170-ct (for blister cards)	N/A	9/25/2015
Original (ORIG)	110-,170-, 200-ct (for blister cards) 200-ct backer card for club pack (for blister cards)	N/A	9/25/2015
White Ice Mint (WIM)	20-ct (for pocket pack) 20-, 100-, 160-ct (for blister cards) 200-ct backer card for club pack (for blister cards)	N/A	9/25/2015
FM/FC/MT/ORIG/WIM	Pandora Leaflet and User's Guide	Leaflet and User's Guides are used for all flavor variants except CS.	3/31/2015
Cinnamon Surge	Pandora Leaflet (9/25/2015) and User's Guide (9/29/2015)	Leaflet is specific to CS flavor variant	9/25/2015 9/29/2015

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 18612/S-076 and NDA 20066/S-057**." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge that the approved 10-count cartons (FC/WIM/CS/FM) are not submitted, as you state that the 10-count package has not been marketed. However, the 10-count cartons must be submitted to FDA in a prior approval supplement before marketing in the future, to incorporate this and future changes.

We also acknowledge that the approved 200-ct carton labeling (ORIG, FM, FC, WIM) to hold 25-ct pocket packs are not submitted, as you state this package configuration is no longer marketed and has been replaced by a 200-count (two cartons of 100) included in these supplements. If you choose to resume marketing of the 200-count cartons (8 x 25-count pocket packs), you must submit labeling to FDA in a prior approval supplement before resuming marketing in the future, to incorporate this and future changes.

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/

JANICE ADAMS
09/30/2015

VALERIE S PRATT
09/30/2015