NDA 018612/S-083
NDA 020066/S-065

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Mini Nair
Director, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Ms. Nair:

Please refer to your supplemental new drug applications (sNDAs) dated and received on May 14, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA).

We also refer to your General Correspondence dated October 30, 2020 in response to our July 13, 2020 refusal to file letter for Nicorette (nicotine polacrilex) gums, 2 mg and 4 mg.

These "Prior Approval" supplemental new drug applications provide for the following changes:

- Add "N2" imprint to gum piece illustration for all coated 2 mg artwork
- Add "N4" imprint to gum piece illustration for all coated 4 mg artwork
- Change the support program web address on all packaging (i.e., outer cartons, backer cards, and User's Guides) to reflect change from the Committed Quitters behavioral support program and information, including the committedquitters.com website, to the MyQuit behavioral support program and information, including the MyQuit.com website and the MyQuit Software Application.
- Add VALUE PACK banner to 160-count and 170-count cartons

APPROVAL & LABELING

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be must be in the “Drug Facts” format (21 CFR 201.66), where applicable, and identical to the following:

Submitted Labeling for Nicorette Gum, 2 mg **NDA 18612/S-083** *Flavor Variants - Cinnamon Surge (CS), Fruit Chill (FC), White Ice Mint (WIM), Spearmint Burst (SB), Original (Orig)*	**Submission Dates**
20-ct pocket pack bifold backer card (outer carton) -CS, FC, WIM	March 19, 2021
20-ct pocket pack outer carton- CS, FC, WIM	March 19, 2021
100-ct outer carton -CS, FC, WIM, SB	March 19, 2021
110-ct outer carton– Orig	March 19, 2021
160-ct- CS, FC, WIM, SB	March 19, 2021
170-ct- Orig	March 19, 2021
180-ct (160+20-ct)- FC, WIM, SB	March 19, 2021
200-ct club pack outer carton- Orig	March 19, 2021
200-ct club pack outer backer card (Front and Back)- FC, WIM, SB, Orig	March 19, 2021
10-ct pocket pack immediate container- CS, FC, WIM, SB, Orig	March 19, 2021
20-ct pocket pack immediate container- CS, FC, WIM	March 19, 2021
Submitted Labeling for Nicorette Gum, 4 mg **NDA 20066/S-065** *Flavor Variants - Cinnamon Surge (CS), Fruit Chill (FC), White Ice Mint (WIM), Spearmint Burst (SB), Original (Orig)*	**Submission Dates**
20-ct pocket pack bifold backer card (outer carton)- CS, FC, WIM	March 19, 2021
20-ct pocket pack outer carton- CS, FC, WIM	March 19, 2021
100-ct outer carton- CS, FC, WIM, SB	March 19, 2021
110-ct outer carton- Orig	March 19, 2021
160-ct- CS, FC, WIM, SB	March 19, 2021
170-ct- Orig	March 19, 2021
180-ct (160+20-ct)- FC, WIM, SB	March 19, 2021
200-ct club pack outer carton- Orig	March 19, 2021
200-ct club pack outer backer card (Front and Back)- FC, WIM, SB, Orig	March 19, 2021
10-ct pocket pack immediate container- CS, FC, WIM, SB, Orig	March 19, 2021
20-ct pocket pack immediate container- CS, FC, WIM	March 19, 2021

Nicorette Gum, 2 mg NDA 18612/S-083 and Nicorette Gum, 4 mg NDA 20066/S-065 (Consumer Information Leaflet (User's guide) - common to both strengths)	
Consumer Information Leaflet- "Pandora" leaflet (pocket pack)- FC, WIM, SB, Orig	March 19, 2021
Consumer Information Leaflet- "Pandora" leaflet (pocket pack)- CS	March 19, 2021
Consumer information leaflet- User's guide- FC, WIM, SB, Orig	March 19, 2021
Consumer Information Leaflet- User's guide- CS	March 19, 2021

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018612/S-083 and NDA 020066/S-065**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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).

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

If you have any questions, call Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
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