NDA 018612/S-084
NDA 020066/S-066

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Neha Jadhav
Director, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Neha Jadhav:

Please refer to your supplemental new drug application (sNDA) dated and received July 21, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) gum, 2 mg and 4 mg.

This "Prior Approval" supplemental new drug application provides for visual brand language (VBL) and labeling changes.

APPROVAL & LABELING

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 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 in the "Drug Facts" format (21 CFR 201.66), where applicable and identical to the following:

Submitted Labeling	Date Submitted
2 mg	
20-count Carton–Fruit Chill	December 20, 2023
20-count Print Card–Fruit Chill	July 21, 2023
100-count Carton–Fruit Chill	December 20, 2023
160-count Carton–Fruit Chill	December 20, 2023
20-count Carton–White Ice Mint	December 20, 2023
20-count Print Card–White Ice Mint	July 21, 2023
100-count Carton–White Ice Mint	December 20, 2023
160-count Carton–White Ice Mint	December 20, 2023
100-count Carton–Cinnamon Surge	December 20, 2023

Submitted Labeling	Date Submitted
2 mg	
160-count Carton–Cinnamon Surge	December 20, 2023
100-count Carton–Spearmint Burst	December 20, 2023
160-count Carton–Spearmint Burst	December 20, 2023
110-count Carton–Original	December 20, 2023
170-count Carton–Original	December 20, 2023
200-count Carton–Original	December 20, 2023
170-count Carton–Mint	December 20, 2023
4 mg	
20-count Carton–Fruit Chill	December 20, 2023
20-count Print Card–Fruit Chill	July 21, 2023
100-count Carton–Fruit Chill	December 20, 2023
160-count Carton–Fruit Chill	December 20, 2023
20-count Carton–White Ice Mint	December 20, 2023
20-count Print Card–White Ice Mint	July 21, 2023
100-count Carton–White Ice Mint	December 20, 2023
160-count Carton–White Ice Mint	December 20, 2023
20-count Carton–Cinnamon Surge	December 20, 2023
20-count Print Card–Cinnamon Surge	July 21, 2023
100-count Carton–Cinnamon Surge	December 20, 2023
160-count Carton–Cinnamon Surge	December 20, 2023
100-count Carton–Spearmint Burst	December 20, 2023
160-count Carton–Spearmint Burst	December 20, 2023
110-count Carton–Original	December 20, 2023
170-count Carton–Original	December 20, 2023
200-count Carton–Original	December 20, 2023
170-count Carton–Mint	December 20, 2023

In addition, on September 22, 2023, you formally requested to remove the following stock-keeping units (SKUs) from their NDA(s):

NDA 018612 (2 mg gum)

- 20-count pocket pack print card Cinnamon Surge flavored
- 20-count carton Cinnamon Surge flavored
- 180-count (160 + 20-count) carton Fruit Chill, White Ice Mint, & Spearmint Burst flavored
- 200-count club pack outer carton (front and back) Fruit Chill, White Ice Mint, Spearmint Burst, & Original flavored

NDA 020066 (4 mg gum)

- 180-count (160 + 20-count) carton Fruit Chill, White Ice Mint, & Spearmint Burst flavored

- 200-count club pack outer carton (front and back) Fruit Chill, White Ice Mint, Spearmint Burst, & Original flavored

As a reminder, if you wish to reintroduce these discontinued SKUs in the future, submit a prior approval supplement(s) to the appropriate NDA(s).

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(s) "**Final Printed Labeling for approved NDA 018612/S-084 and NDA 020066/S-066."** 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, PharmD, Senior 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
Office of New 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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