NDA 22360/S-017

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Neha Jadhav
Senior Associate, 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 November 8, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) mini lozenges, 2 mg and 4 mg.

This "Prior Approval" supplemental new drug application provides for the following labeling changes:

- Updated Nicorette brand logo and trademark information.
- Addition of new vial image and opening instructions on top panel.
- Active ingredient concentration (2 mg and 4 mg) made conspicuous and prominent on the Principal Display Panel (PDP) for easier consumer differentiation.
- Text "Actual Size" added on PDP depicting the actual size of the product.

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
20-count & 27-count immediate container (Vial) back label	January 10, 2024
Nicorette Mini Lozenge – User's Guide leaflet	January 10, 2024
2 mg Nicorette Mini Lozenges – *Mint flavor*	
20-count & 27-count immediate container (Vial) front label	January 10, 2024
20-count outer container (Blister card)	April 29, 2024
81-count outer container (Carton)	April 29, 2024
4 mg Nicorette Mini Lozenges – *Mint flavor*	
20-count & 27-count immediate container (Vial) front label	January 10, 2024
20-count outer container (Blister card)	April 29, 2024
81-count outer container (Carton)	April 29, 2024

We recommend that you remove the "New" flag 6 months after market introduction. Your subsequent annual report may reflect this change.

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 022360/S-017**." 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.

[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

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 Cynthia Kim, PharmD, BCPS, 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

ENCLOSURE(S):

- 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/

CYNTHIA N KIM
04/30/2024 03:02:36 PM

NUSHIN F TODD
04/30/2024 03:48:04 PM