



NDA 021330/S-026

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Neha Jadhav
Senior 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 April 2, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) lozenges, 2 mg and 4 mg.

This “Prior Approval” supplemental new drug application provides for the following changes:

- Updated the Nicorette brand logo and trademark information.
- Increased the font size of the Statement of Identity (SOI) to match the text “Lozenge”.
- Increased the prominence of the active ingredient concentrations (2 mg and 4 mg) on the Principal Display Panel (PDP).
- Added the text “Actual Size” depicting the actual size of the product on the PDP.
- Added a new claim, “Sugar Free”, on the PDP.
- Included an additional reference to the Quit Support Program on the 20-count and 80-count print cards.

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-ct immediate container (Flip-pack) back label	May 23, 2024
Nicorette Lozenge – User’s Guide leaflet	May 23, 2024
2 mg Nicorette Lozenges Coated Ice Mint	
20-ct immediate container (Flip-pack) front label	May 23, 2024
20-ct outer container (Backer card) back	May 23, 2024
20-ct outer container (Backer card) front	August 15, 2024
80-ct (4 x 20) outer container (Backer card) back	May 23, 2024
80-ct (4 x 20) outer container (Backer card) front	August 15, 2024
4 mg Nicorette Lozenges Coated Ice Mint	
20-ct immediate container (Flip-pack) front label	May 23, 2024
20-ct outer container (Backer card) back	May 23, 2024
20-ct outer container (Backer card) front	August 15, 2024
80-ct (4 x 20) outer container (Backer card) back	May 23, 2024
80-ct (4 x 20) outer container (Backer card) front	August 15, 2024

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 021330/S-026.**” 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, Senior Regulatory Project Manager, at 301-796-0879 or Cynthia.Kim@fda.hhs.gov.

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):

- Container and User's Guide leaflet 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
09/06/2024 02:07:26 PM