

NDA 022360/S-019

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 on November 21, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicorette (nicotine polacrilex) mini lozenges, 2 mg & 4 mg.

This “Prior Approval” supplemental new drug application provides for the addition of a new flavor variant, Cherry Peppermint, to your Nicorette lozenge with the “mini” descriptor.

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
Nicorette Lozenge - User’s Guide Leaflet	November 21, 2024
20-count immediate container (vial) back label	November 21, 2024
27-count immediate container (vial) back label	November 21, 2024
2 mg Nicorette Mini Lozenges Cherry Peppermint flavor	
20 & 27-count immediate container (vial) front label	November 21, 2024
20-count outer container label (Blister card)	January 8, 2025
81-count outer container label (Carton)	January 8, 2025
4 mg Nicorette Mini Lozenges Cherry Peppermint flavor	
20 & 27-count immediate container (vial) front label	November 21, 2024
20-count outer container label (Blister card)	January 8, 2025
81-count outer container label (Carton)	January 8, 2025

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-019.**” Approval of this submission by FDA is not required before the labeling is used.

In addition, we remind you to remove the “New” flag 6 months after market introduction.

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 or Cynthia.Kim@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Martha Lenhart, MD, PhD
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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/

MARTHA K LENHART
03/17/2025 02:09:57 PM