



NDA 022360/S-018

**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 July 22, 2024, 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 & 4 mg.

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

- 1) Introduction of a new formulation of Nicorette mini lozenges, 2 mg and 4 mg, comprising a dual layer lozenge formulation in a new flavor variant (peppermint).
- 2) Inclusion of [REDACTED] <sup>(b) (4)</sup> as the drug product manufacturing, analytical release testing and stability testing site.

**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:

<b>Submitted Labeling</b>	<b>Date Submitted</b>
Nicorette Lozenge - User’s Guide Leaflet	July 22, 2024
20-count immediate container (vial) back label	July 22, 2024
27-count immediate container (vial) back label	July 22, 2024

<b>2 mg Nicorette Mini Lozenges Peppermint flavor</b>	
20 & 27-count immediate container (vial) front label	October 18, 2024
20-count outer container label (Blister card)	November 19, 2024
81-count outer container label (Carton)	November 19, 2024
<b>4 mg Nicorette Mini Lozenges Peppermint flavor</b>	
20 & 27-count immediate container (vial) front label	October 18, 2024
20-count outer container label (Blister card)	November 19, 2024
81-count outer container label (Carton)	November 19, 2024

We recommend that you remove the “New” flag 6 months after market introduction.

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 022360/S-018.**” 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.<sup>2</sup> 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).

<sup>1</sup> 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>.

<sup>2</sup> <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](mailto: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

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  
11/21/2024 11:31:37 AM