DOCUMENT INFORMATION PAGE

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Application #(s):	NDA 020941/S-017
Communication Type:	Correspondence
Communication Group:	sNDA Action
Communication Name:	Approval
Communication ID:	COR-SNDAACTION-05
Drafted by:	Suzanne Strayhorn
Clearance History by:	B. J. Freij, 4/13/2026 T. Bell, 4/13/26 H. Mujahid 04/10/2026, P. Ikonomi,04/10/2026 S. Dadiboyena, 4/10/2026 R. Matsouka,4/10/2026 E. Thompson 4/12/2026 M. Blank 4/13/2026
Finalized:	
Filename:	
Signatory Authority:	Division Director or Deputy Division Director. Person who is covering for the signatory authority can sign on their behalf (i.e, the signature block on the letter will not change)
Use Statement:	Use to notify applicant of an approval action for a supplemental application that includes changes to the labels or labeling
Notes:	USE FOR **OTC** APPROVALS ONLY USE COR-SNDAACTION-06 FOR sNDA CMC APPROVALS **For Rx to OTC Switch Applications:** Send approval email within one business day to CDEREXSEC@cder.fda.gov and cc ORP (Linda Jong and Jennifer Forde) **Note:** Remember to check for acceptability of facility **prior to issuing approval letter**.

Version: 08/16/2023

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

NDA 020941/S-017

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Misha Mehta
Senior Associate, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Misha Mehta:

Please refer to your supplemental new drug application (sNDA) dated and received October 16, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abreva (docosanol 10%) cream.

We acknowledge receipt of your amendment dated October 16, 2025, which constituted a complete response to our May 27, 2025, action letter.

This "Prior Approval" supplemental new drug application provides for updates to the graphic designs and claims on the principal display panel and packaging configuration 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 identical to the enclosed labeling as described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
2 g Pump (Beauty) Backer Card	March 19, 2026
2 g Tube (On the Go) Backer Card	March 19, 2026
2 g Tube (Oral Care) Backer Card	March 19, 2026
2 g Tube Round Print Backer Card	March 19, 2026
2 x 2 g Tube Round Print Backer Card	March 19, 2026
2 g Tube (CVS Beauty Pack) Backer Card	March 19, 2026
2 g Pump Round Print Backer Card	March 19, 2026
3 x 2 g Pump (Club pack- BJs) Print Backer Card	March 19, 2026

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 020941/S-017**." Approval of this submission by FDA is not required before the labeling is used.

Remove the "New Look" flag 6 months after marketing.

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, contact Suzanne Strayhorn, Regulatory Project Manager, at suzanne.strayhorn@fda.hhs.gov or (240) 402-4247.

Sincerely,

{See appended electronic signature page}

Melanie Blank, M.D., M.S.
Deputy Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton Labeling