NDA 020589/S-043

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Alberto Jose Garzon
Regulatory Affairs Senior Manager
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Alberto Jose Garzon:

Please refer to your supplemental new drug application (sNDA) dated and received December 23, 2025, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Advil (ibuprofen) oral suspension, 100 mg per 5 mL.

This "Prior Approval" supplemental new drug application provides for revisions to the carton and bottle labeling (artwork and text) for the grape, white grape, and sugar-free/dye-free/berry flavor stock-keeping units of the Children's Advil 4 fl oz oral suspension.

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 must be identical to the following labeling:

Submitted Labeling	Date Submitted
Children's Advil 4 fl oz carton (Grape flavor)	March 3, 2026
Children's Advil 4 fl oz bottle label (Grape flavor)	March 3, 2026
Children's Advil 4 fl oz carton (White Grape flavor)	March 3, 2026
Children's Advil 4 fl oz bottle label (White Grape flavor)	March 3, 2026
Children's Advil 4 fl oz carton (Sugar-Free Dye-Free Berry flavor)	March 3, 2026
Children's Advil 4 fl oz bottle label (Sugar-Free Dye-Free Berry flavor)	March 3, 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 020589/S-043**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to submit a prior approval labeling supplement if you plan to reintroduce the discontinued stock-keeping units (i.e., the fruit, bubble gum, and dye-free blue raspberry flavors) to the U.S. market.

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

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, contact Myla Dellupac, Regulatory Project Manager, at Myla.Dellupac@fda.hhs.gov or 301-837-7461.

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/

NUSHIN F TODD
05/01/2026 08:59:09 AM