

NDA 020589/S-044

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Francis Barbone, PhD
Senior Director Regulatory Affairs
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Dr. Barbone:

Please refer to your supplemental new drug application (sNDA) dated and received February 27, 2026, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ibuprofen oral suspension, 100 mg per 5 mL.

This “Prior Approval” supplemental new drug application provides for labeling and chemistry, manufacturing, and controls (CMC) updates to Advil Liquid (ibuprofen) oral suspension, 200 mg per 10 mL, indicated for adults and children 12 years of age and older in two flavor variants (White Grape and Sugar-Free Dye-Free (SFDF) Berry).

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, described in the table below, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
Adult SFDF Berry 4 oz carton	June 17, 2026
Adult SFDF Berry 4 oz label	June 17, 2026
Adult White Grape 4 oz carton	June 17, 2026
Adult White Grape 4 oz label	June 17, 2026
Adult White Grape 8 oz carton	June 17, 2026
Adult White Grape 8 oz label	June 17, 2026

The FPL should be submitted electronically according to 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-044.**” Approval of this submission by FDA is not required before the labeling is used.

- We remind you to remove the “NEW” flag featured on your product labels six months from the date of initial marketing.
- We recommend moving the tamper-evident safety feature statement from the principal display panel on your immediate container (bottle) labels to a position that is comparable to your outer container (carton) labels. This revision could reduce visual crowding and clutter, improving the readability of the information presented on the panel.
- We recommend removing the bold font applied to the flavor descriptors (i.e., white grape flavor and sugar-free berry flavor) on all labeling (carton and bottle) to avoid creating an impression of value greater than their true functional role in the formulation per 21 CFR 201.10(c). This revision could also reduce the information crowding and clutter on the immediate container (bottle) label.

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 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.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the

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>

supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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, call Odongerel Pount, PharmD, Regulatory Project Manager at (240) 402-7144, or email Odongerel.Pount@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
U.S. Food and Drug Administration

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
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