



NDA 020944/S-017

**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 (FDCA) for Junior Strength Advil (ibuprofen) chewable tablets, 100 mg.

This “Prior Approval” supplemental new drug application provides for revisions (artwork and text) to the carton and bottle labeling for the 24-count product.

**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:

<b>Submitted Labeling</b>	<b>Date Submitted</b>
Junior Strength Advil 24-count carton	March 3, 2026
Piggy-back label (for 24-count carton)	March 3, 2026
Junior Strength Advil 24-count bottle label	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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 020944/S-017.**” 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).

If you have any questions, contact Myla Dellupac, Regulatory Project Manager, at [Myla.Dellupac@fda.hhs.gov](mailto: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

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<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>

ENCLOSURE(S):

- Carton and Container Labeling

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**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.**  
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/s/  
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