NDA 020516/S-045

SUPPLEMENT APPROVAL

Kenvue Brands LLC
Attention: Margaret Wheler
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Margaret Wheler:

Please refer to your supplemental new drug application (sNDA) dated and received March 3, 2026, and your amendments, submitted under section 505(b) the Federal Food, Drug, and Cosmetic Act (FDCA) for ibuprofen oral suspension.

This "Prior Approval" supplemental new drug application provides for the addition of an 8 fl oz (240 mL) oral suspension with a strength of ibuprofen 200 mg per 10 mL, specifically intended for adult use (i.e., adults and children 12 years and older). This new configuration will be marketed under the proprietary name, "Motrin IB". Motrin IB (ibuprofen 200 mg per 10 mL) is a separate product line from the approved Children's Motrin (ibuprofen 100 mg per 5 mL) oral suspension marketed under this NDA 020516.

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
Motrin IB 8 fl oz (240 mL) carton	May 13, 2026
Motrin IB 8 fl oz (240 mL) immediate container (bottle)	May 13, 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 020516/S-045**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the 'NEW' flag on the carton principal display panel 6 months after introduction to the marketplace.

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. 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.

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.

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}

Ovi Galescu, MD
Deputy 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/

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