NDA 219962

NDA APPROVAL

Kenvue Brands LLC
Attention: Vahini Manivannan
Manager, Regulatory Affairs
1 Kenvue Way
Summit, NJ 07901

Dear Vahini Manivannan:

Please refer to your new drug application (NDA) dated and received September 26, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tylenol with Naproxen (acetaminophen 325 mg and naproxen sodium 110 mg) tablet.

This new drug application provides for the nonprescription use of Tylenol with Naproxen (acetaminophen 325 mg and naproxen 110 mg) tablet for the temporary relief of minor aches and pains due to headache, backache, muscular aches, toothache, menstrual cramps, and minor pain of arthritis, in adults and children 12 years and older.

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 agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
20-count carton	July 9, 2026
20-count bottle	July 9, 2026
20-count carton (for hospital/government use only)	July 9, 2026
20-count bottle (for hospital/government use only)	July 9, 2026
40-count carton	July 9, 2026
40-count bottle	July 9, 2026
80-count carton	July 9, 2026
80-count bottle	July 9, 2026
90-count carton	July 9, 2026
90-count bottle	July 9, 2026
140-count carton	July 9, 2026

140-count bottle	July 9, 2026
200-count carton (club)	July 9, 2026
200-count bottle (club)	July 9, 2026
220-count carton	July 9, 2026
220-count bottle	July 9, 2026

The final printed labeling 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 219962**." 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 labeling six months after the date of initial 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, 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 & 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for patients from birth to less than 6 months of age because the product would be unsafe in this age group.

[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

We are waiving the pediatric study requirement for patients 6 months to less than 6 years of age because the product would not represent a meaningful therapeutic benefit over existing therapies and is unlikely to be used in a substantial number of patients in this age group.

This product is appropriately labeled for use in ages 12 to 17 years of age for this indication. Therefore, no additional studies are needed in this pediatric group. We note that you have fulfilled the pediatric study requirement for ages 12 to 17 years of age for this application.

We are deferring submission of your pediatric studies for patients 6 years to less than 12 years of age for this application because this product is ready for approval for use in adults and pediatric studies in this age group have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

5021-1

Pharmacokinetic study in children 6 years to less than 12 years of age with acute pain suitable for treatment with a nonprescription analgesic to evaluate the pharmacokinetic profile and tolerability of acetaminophen/naproxen sodium fixed-dose combination.

a. Final Protocol Submission: 02/2027
b. Study Completion: 02/2028
c. Final Report Submission: 08/2028

5021-2

Consumer behavior program in support of a fixed dose combination of acetaminophen/naproxen sodium for children 6 years to less than 12 years of age to assess parent or caregiver understanding of the indication and ingredients (acetaminophen and naproxen sodium) of this drug product.

a. Final Protocol Submission: 03/2028
b. Study Completion: 09/2028
c. Final Report Submission: 11/2028

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial. See the guidance for industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act.*

Submit the protocol(s) to your IND 145058, with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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 or 301-837-7461.

Sincerely,

{See appended electronic signature page}

Dorothy Chang, MD
Deputy Director for Safety
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/

DOROTHY CHANG
07/24/2026 09:08:47 AM