



NDA 020958/S-044

## SUPPLEMENT APPROVAL

Kenvue Brands LLC  
Attention: Maro Ghebryal, PharmD  
Senior Associate, Regulatory Affairs  
7050 Camp Hill Road  
Fort Washington, PA 19034

Dear Maro Ghebryal:

Please refer to your supplemental new drug application (sNDA) dated and received, September 9, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid Complete (famotidine 10 mg, calcium carbonate 800 mg, magnesium hydroxide 165 mg) chewable tablets.

This “Prior Approval” supplement (PAS) was submitted in response to our PAS request sent on June 26, 2025, to address the deviations between the labeling in the Final Printed Labels (FPL), received on May 1, 2025, and the labeling included in the approval letters for supplements -042 and -043. These deviations include removal of the tablet graphic, reformatting of the back panel of the stand-alone immediate containers (bottle), and minor annual reportable changes involving font, distributor information display, and updating the copyright date.

### **APPROVAL & LABELING**

We have completed our review of this application. 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 identical to the following:

| Submitted Labeling                               | Date Submitted    |
|--------------------------------------------------|-------------------|
| 1-count immediate container (pouch)-Berry Flavor | September 9, 2025 |
| 4-count carton (pouch)-Berry Flavor              | September 9, 2025 |

|                                                             |                   |
|-------------------------------------------------------------|-------------------|
| 8-count carton (pouch)-Berry Flavor                         | September 9, 2025 |
| 25-count immediate container (bottle)-Berry Flavor          | September 9, 2025 |
| 50-count immediate container (bottle)-Berry Flavor          | September 9, 2025 |
| 70-count immediate container (bottle)-Berry Flavor          | September 9, 2025 |
| 100-count immediate container (bottle)-Berry Flavor         | September 9, 2025 |
| 25-count immediate container (bottle)-Cool Mint Flavor-alt  | September 9, 2025 |
| 50-count immediate container (bottle)-Cool Mint Flavor-alt  | September 9, 2025 |
| 70-count immediate container (bottle)-Cool Mint Flavor-alt  | September 9, 2025 |
| 25-count immediate container (bottle) Tropical Fruit Flavor | September 9, 2025 |
| 50-count immediate container (bottle) Tropical Fruit Flavor | September 9, 2025 |

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 020958/S-044.**” Approval of this submission by FDA is not required before the labeling is used.

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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>.

## **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 Cynthia Kim, PharmD, Senior Regulatory Project Manager, at 301-796-0879 or [Cynthia.Kim@fda.hhs.gov](mailto:Cynthia.Kim@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Nushin Todd, MD, PhD  
Director  
Division of Nonprescription Drugs I  
Office of Nonprescription Drugs  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Carton and Container Labeling

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<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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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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NUSHIN F TODD  
09/30/2025 02:55:47 PM