NDA 020958/S-043

SUPPLEMENT APPROVAL

Kenvue, LLC
Attention: Felicia Mohammed
Manager, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Felicia Mohammed:

Please refer to your supplemental new drug application (sNDA) dated and received, September 27, 2024, 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" sNDA provides for the introduction of a 70-count package for the mint and berry formulations.

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 identical to the following:

Submitted Labeling	Date Submitted
70-count immediate container (bottle) Berry Flavor – *Value Size*	January 6, 2025
70-count immediate container (bottle) Cool Mint Flavor (alt) – *Value Size*	January 6, 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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020958/S-043**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we have the following additional comment:

> As recommended in the approval letter for S-042 on January 17, 2025, in FPL, ensure the statement "*may contain mineral oil" is left-justified at the end of the **Inactive ingredients** section per the Guidance for Industry: Labeling OTC Human Drug Products (May 2009) section IV (E).

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 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).

[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

If you have any questions, call Cynthia Kim, PharmD, Senior Regulatory Project Manager, at 301-796-0879 or 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:

- 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
02/11/2025 10:27:58 AM