NDA 021140/S-039

SUPPLEMENT APPROVAL

Kenvue Brands LLC
Attention: Felicia Mohammed
Manager, Regulatory Affairs
7050 Camp Hill Road
Mail Stop 111
Fort Washington, PA 19034

Dear Felicia Mohammed:

Please refer to your supplemental new drug application (sNDA) dated and received August 11, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imodium Multi-Symptom Relief (loperamide hydrochloride 2 mg, simethicone 125 mg) tablets.

We acknowledge receipt of your amendment dated December 23, 2025, which constituted a complete response to our December 11, 2025, action letter.

This "Prior Approval" supplemental new drug application provides for labeling updates and associated manufacturing changes related to the new blister packaging.

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
12-count carton (blister) [CR]	February 13, 2026
18-count carton (blister) [CR]	February 13, 2026
6-count immediate container (blister) [CR]	November 26, 2025
24-count carton (blister) [NCR]	February 13, 2026
6-count immediate container (blister) [NCR]	November 26, 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 021140/S-039**." 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 are 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).

If you have any questions, call Cynthia Kim, PharmD, BCPS, Senior Regulatory Project Manager, at 301-796-0879 or Cynthia.Kim@fda.hhs.gov.

[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

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.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

ENCLOSURES:

- 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/

NUSHIN F TODD
03/02/2026 02:35:51 PM