

NDA 020485 / S-021

## SUPPLEMENT APPROVAL

Kenvue Brands LLC  
Attention: Robert Bothwell, PharmD  
Associate Director, Regulatory Affairs  
7050 Camp Hill Road  
Mail Stop 111  
Fort Washington, PA 19034

Dear Robert Bothwell:

Please refer to your supplemental new drug application (sNDA) dated and received on June 27, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Visine (naphazoline hydrochloride 0.025% and pheniramine maleate 0.3%) ophthalmic solution.

This Prior Approval supplemental new drug application provides for the following Chemistry, Manufacturing and Controls (CMC) and labeling changes:

- **Change in Back Label Format:** Transition from a 2-ply back label to a 1-ply back label on the immediate container (b) (4)
- (b) (4)
- **Change to Labeling:** Change to the product information on the primary label on the back of the bottle going from a 2-ply label to a 1-ply label. Additionally, inclusion of a statement on the outer carton instructing consumers to keep carton for important information.
- **Change to Legal Entity and Address:** Change to legal entity and address on the primary label and secondary label (carton) from Johnson & Johnson Consumer Inc. to Kenvue Brands LLC.

### **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 with minor editorial revisions listed below.

- For the immediate container bottle (front) labeling, revise the net contents statement from: “1/2 fl oz (15 ml)” to: “1/2 fl oz (15 mL)” to comply with 21 CFR 201.62.

## **LABELING**

Submit final printed labeling (FPL), with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling (except for the minor revision), as described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Labeling</b>	<b>Date of Submission</b>
Outer Carton	September 4, 2025
Outer Carton Twin Pack	September 4, 2025
Immediate Container - Front	September 4, 2025
Immediate Container - Back	October 3, 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 020485/S-021.**” 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 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.

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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>.

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

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.<sup>3</sup>

If you have any questions, contact Suzanne Strayhorn, Sr. Regulatory Project Manager, at (240) 402-4247 or via email at [suzanne.strayhorn@fda.hhs.gov](mailto:suzanne.strayhorn@fda.hhs.gov)

Sincerely,

*{See appended electronic signature page}*

Pamela Horn, M.D.  
Division Director  
Division of Nonprescription Drugs II  
Office of Nonprescription Drugs  
Office of New Drugs  
Center for Drug Evaluation and Research

### ENCLOSURES:

- Carton and Container Labeling

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<sup>3</sup> <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

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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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PAMELA J HORN  
10/22/2025 12:17:19 PM