NDA 019501 / S-036
NDA 020834 / S-021
NDA 021812 / S-020

SUPPLEMENT APPROVALS

Kenvue Brands LLC
Attention: Soujanya Rajagopal
Senior Associate, Regulatory Affairs
1 Kenvue Way
Summit, NJ 07901

Dear Soujanya Rajagopal:

Please refer to your supplemental new drug applications (sNDAs) dated and received July 17, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 019501 / S-036: Women's Rogaine (minoxidil) topical solution, 2%
NDA 020834 / S-021: Men's Rogaine Extra Strength (minoxidil) topical solution, 5%
NDA 021812 / S-020: Men's Rogaine (minoxidil) topical aerosol, 5%
Women's Rogaine (minoxidil) topical aerosol, 5%

These "Prior Approval" supplemental new drug applications provide for revised labeling on the outer cartons, immediate containers, and consumer information booklets, to include statements to keep out of reach of pets and to avoid contact between children and minoxidil application sites.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 identical to the enclosed labeling described in the tables below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The patent website provided on the outer carton (www.kenvuepats.com) must be up-to-date and include the UPCs for the products in these supplements.

NDA 019501/S-036:

Submitted Draft Labeling	Date
Women's ROGAINE Topical Solution 1-month supply Outer Carton	12/10/2025
Women's ROGAINE Topical Solution 3-month supply Outer Carton	12/10/2025
Women's ROGAINE Topical Solution Immediate Container	12/10/2025
Women's ROGAINE Topical Solution Consumer Information Booklet	07/17/2025

NDA 020834/S-021:

Submitted Draft Labeling	Date
Men's ROGAINE Extra Strength Topical Solution 1-month supply Outer Carton	12/10/2025
Men's ROGAINE Extra Strength Topical Solution 3-month supply Outer Carton	12/10/2025
Men's ROGAINE Extra Strength Topical Solution Immediate Container	12/10/2025
Men's ROGAINE Extra Strength Topical Solution Consumer Information Booklet	07/17/2025

NDA 021812/S-020:

Submitted Draft Labeling	Date
Men's ROGAINE Topical Aerosol Immediate Container	12/10/2025
Men's ROGAINE Topical Aerosol 1-month supply Outer Carton	12/10/2025
Men's ROGAINE Topical Aerosol 3-month supply Outer Carton	12/10/2025
Men's ROGAINE Topical Aerosol Consumer Information Booklet	07/17/2025
Women's ROGAINE Topical Aerosol Immediate Container	12/10/2025
Women's ROGAINE Topical Aerosol 2-month supply Outer Carton	12/10/2025
Women's ROGAINE Topical Aerosol 4-month supply Outer Carton	12/10/2025
Women's ROGAINE Topical Aerosol Consumer Information Booklet	07/17/2025

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 these submissions "**Final Printed Labeling for approved NDA 019501/S-036, NDA 020834/S-021, and NDA 021812/S-020**." Approval of these submissions by FDA are 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.[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, please contact Shannon Liu, DPT, Regulatory Project Manager, at (240) 402-2484, or email shannon.liu@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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/

NUSHIN F TODD
01/14/2026 02:23:45 PM