NDA 021812/S-016

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
Attention: Robert P. Bothwell, PharmD
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Mail Stop 111
Fort Washington, PA 19034

Dear Dr. Bothwell:

Please refer to your supplemental new drug application (sNDA) dated and received July 7, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Men's Rogaine (minoxidil) topical aerosol, 5%.

This "Prior Approval" supplemental new drug application provides for revised container (can) label, consumer information (booklet) labeling, and outer container (carton) labeling for the 1-month, 3-month, and 4-month supply products to align with the previously approved labeling for Women's Rogaine (minoxidil) topical aerosol, 5%, in supplements 014 and 015.

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 identical to the can label, booklet labeling, and carton labeling for the 1-month, 3-month, and 4-month supply products submitted on December 8, 2020, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

We remind you to ensure that the carton labeling on the product website is consistent with the FPL.

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 021812/S-016**." Approval of this submission by FDA is not required before the labeling is used.

If you are interested in including any unapproved efficacy claim(s) on your website, an efficacy supplement that includes data to adequately support such claim(s) must be submitted. We encourage you to contact us about the content and format of such a supplement prior to submission.

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 CDR Trang Tran, Regulatory Project Manager, at (240) 402-7945.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Can Label, Booklet and Carton 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
12/29/2020 10:42:52 AM