NDA 021812/S-015

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 August 2, 2019, received August 2, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Women's Rogaine (minoxidil) topical aerosol, 5%.

This Prior Approval supplemental new drug application provides for revised labeling for the 6-month supply product (three x 60g containers) outer container (carton) labeling.

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 Women's Rogaine (minoxidil) topical aerosol, 5%, 6-month supply product (three x 60g containers) outer container (carton) labeling submitted on January 10, 2020 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. Although the immediate container labeling and consumer information leaflet labeling are identical to the labeling approved for the 2-month and 4-month supply products, submit these as part of the FPL for this supplement to maintain a record of the complete labeling being approved as part of this supplement.

We remind you to update the statement on the Rogaine website's Frequently Asked Questions #35 "How soon can I expect results?" (https://www.rogaine.com/faq.html#q35) in accordance with the teleconference discussion with FDA that took place on January 28, 2020 and your confirmation received by FDA on January 29, 2020 (dated January 31, 2020).

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-015**." 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.[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 CDR Trang Tran, Regulatory Project Manager, at (240) 402-7945.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Acting Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs I
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton Labeling

[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

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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.

/s/

THERESA M MICHELE
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