DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21812/S-014

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
Attention: Robert P. Bothwell, PharmD
Associate Director, Regulatory Affairs
199 Grandview Road
Skillman, NJ 08558-9418

Dear Dr. Bothwell:

Please refer to your Supplemental New Drug Application (sNDA) dated December 14, 2018, received December 14, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Women's Rogaine (minoxidil) foam, 5%.

This "Prior Approval" supplemental new drug application provides for revised Directions for Use (DFU), which appear on the side panel of the carton, on the canister, and in the DFU booklet.

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 agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the labeling submitted on May 22, 2019 as described in the table below, with the following caveat:

> Per your cover letter dated May 22, 2019, we agree with your proposal to include the following revised statement under the heading "DIRECTIONS FOR USE":
>
> FROM
> "Information booklet with complete direction on how to use and obtain best results"
>
> TO
> "See information booklet with complete directions on how to use and obtain best results."
>
> Include the above revision when you submit your final printed labeling or in your next annual report, whichever is sooner.

The final printed labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Item	Date
60 g Outer container (carton)	05/22/2019
Two x 60 g Outer container (carton)	05/22/2019
60 g Immediate container (can label)	05/22/2019
Consumer information (booklet)	05/22/2019

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021812/S-014**." Approval of this submission by FDA is not required before the labeling is used.

In addition, given that you market the 6-month supply product, submit the labeling for this product in a future supplement within 2 months.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. 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 Daniel Reed, Regulatory Project Manager, at 301-796-2220.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/

THERESA M MICHELE
06/11/2019 12:45:38 PM