DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021812/S-011

SUPPLEMENT APPROVAL

Johnson & Johnson Healthcare Products
Attention: Angelina M. Hunt, RAC
Director, Regulatory Affairs
199 Grandview Road
Skillman, NJ 08558

Dear Ms. Hunt:

Please refer to your Supplemental New Drug Application (sNDA) dated September 12, 2014, received September 15, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Women's Rogaine (5% minoxidil) Topical Aerosol.

This Changes Being Effected sNDA provides for minor graphic and labeling changes and addition of a 3-count club store package (6-month supply).

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 and with the minor editorial revisions listed below:

- Remove the comma in the statement "This product is for once, daily use" from the bulleted section on the Left Side Panel of the Outer Carton. (3-count size only).
- Revise the text size used in the statement of identity so that it appears in a size reasonably related to the most prominent printed matter as required in 21 CFR 201.61(c). We recommend that the text size should be one-half the size of the most prominent printed matter.

LABELING

Submit final printed labeling (FPL), with the revisions 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

- information booklet for Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented
- outer carton label for the Two Month Supply, Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented – One 60 g can
- outer carton label for the Four Month Supply, Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented – Two 60 g cans
- outer carton label for the Six Month Supply, Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented – Three 60 g cans

and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021812/S-011**." 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 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable; there is no prevalence of female pattern hair loss (FPHL)/Androgenetic Alopecia (AA) of the scalp in female pediatric patients.

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 Lara Akinsanya, Regulatory Project Manager, at (301) 796-9634.

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 and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
02/10/2015