DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021812/S-009

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Companies, Inc.
Attention: Angelina M. Hunt, RAC
Director, Regulatory Affairs
185 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Hunt:

Please refer to your Supplemental New Drug Application (sNDA) dated April 26, 2013, received April 29, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Women's Rogaine (5% minoxidil) Topical Aerosol.

We acknowledge receipt of your amendments dated May 28, June 10, August 1 and 13, September 27, November 11 and 12, December 5 and 18, 2013; and February 7, 21, and 28, 2014.

This sNDA provides for the use of Women's Rogaine (5% minoxidil) Topical Aerosol for the nonprescription treatment of female pattern hair loss/androgenetic alopecia on the top of the scalp.

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.
- Revise statement under "Directions" on the immediate container: "apply half a capful once daily to the scalp in the hair loss area" to "apply half a capful once daily directly to the scalp in the hair loss area" in order to be consistent throughout labeling. All other statements contain the word "directly."
- The term "absorbant" is found in the "Directions For Use" section of the Outer Carton Labels as well as on page 12 of the Consumer Leaflet, which may or may not be the desired alternative spelling of "absorbent."

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

- immediate container label for the 60 g (2.11 oz) canister, Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented
- patient leaflet for Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented
- outer carton for the Two Month Supply, Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented
- outer carton for the Four Month Supply, Women's Rogaine Topical Aerosol Foam (5% minoxidil), unscented

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-009**." 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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Clinical Evaluation
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
02/28/2014