DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21812/S-010

SUPPLEMENT APPROVAL

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

Dear Ms. Hunt:

Please refer to your Supplemental New Drug Application (sNDA) Prior Approval Labeling Supplement dated June 14, 2013, received June 17, 2013, for Men's Rogaine® (minoxidil topical aerosol), 5%.

We acknowledge receipt of your amendments dated November 1, 12, and 27, 2013.

This labeling supplement provides for the addition of two graphic icons to the product labeling to improve consumer use of the product. The graphic icons are inserted before the "Directions" section of the immediate container (canister) label.

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, for the 1-count (60 g) immediate container (canister). The final printed labeling (FPL) must be identical to the 1-count (60 g) immediate container (canister) enclosed labeling submitted on November 27, 2013 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Although not submitted to this supplement, you should submit the confirmed outer carton labeling for the 1-count, 60 g canister (1-month supply) , 2-count, 60 g canister (2 months' supply), 3-count, 60 g canister (3-months' supply), and 4-count, 60 g canister (4 months' supply), and the consumer information leaflet label identical to that submitted with your March 18, 2013 annual report, in order to maintain a complete record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement. It must be in the "Drug Facts" format (21 CFR 201.66) where applicable.

The final printed labeling 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 21812/S-010**" 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.

PREA

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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): Container Label

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
12/13/2013