DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020834/S-014

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 October 28, 2014, received October 28, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Men's Rogaine (5% minoxidil) Topical Solution.

We acknowledge receipt of your amendment dated March 19, 2015.

This Prior Approval sNDA provides for color, graphic and text changes to the one-count 60 mL and three-count 60 mL bottle carton labeling, 60 mL bottle immediate container label, and consumer information booklet 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 agreed-upon labeling text.

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 enclosed labeling (one-count 60 mL bottle carton labeling, three-count 60 mL bottle carton labeling, 60 mL bottle immediate container label, and consumer information booklet labeling) submitted on March 19, 2015, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Although the four-count package size is not currently distributed, we remind you that if you should decide to market the four-count package size in the future with these or other prior approval labeling changes, submit a prior approval labeling supplement.

Submit FPL 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 020834/S-014**." 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.

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}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

KAREN M MAHONEY
04/27/2015