DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 208092

ANDA APPROVAL

Watson Laboratories, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054
Attention: Joann Stavole
Senior Director, Regulatory Affairs

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 30, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Minoxidil Topical Aerosol, 5% (for Men) and Minoxidil Topical Aerosol, 5% (for Women).

Reference is also made to the letter issued by this office on February 17, 2017, granting approval to your Minoxidil Topical Aerosol, 5% (for Men), and granting tentative approval to your Minoxidil Topical Aerosol, 5% (for Women). We also refer to your amendments received on March 23 and May 10, 2017.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Minoxidil Topical Aerosol, 5% (for Women), to be bioequivalent to the reference listed drug (RLD), Women's Rogaine Topical Aerosol, 5%, of Johnson and Johnson Consumer Group Inc. (Johnson and Johnson).

The RLD upon which you have based your ANDA, Johnson and Johnson's Women's Rogaine Topical Aerosol, 5%, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
6,946,120 (the '120 patent)	April 20, 2019

Your ANDA contains a paragraph IV certification to the '120 patent[1] under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Minoxidil Topical Aerosol, 5% (for Women), under this ANDA. You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Watson for infringement of the '120 patent within the statutory 45-day period in the United States District Court District of New Jersey [McNeil-PPC, Inc. and Stiefel Research Australia Pty. Ltd. v. Watson Laboratories, Inc., Civil Action No. 2:15-cv-02197-MCA-JBC]. You have also notified the agency that the action has been dismissed.

With respect to 180-day generic drug exclusivity, we note that Watson was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Minoxidil Topical Aerosol, 5% (for Women). Therefore, with this approval, Watson is eligible for 180 days of generic drug exclusivity for Minoxidil Topical Aerosol, 5% (for Women). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Under section 506A of FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

[1] The Agency notes that the '120 patent for the Women's product was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent for the Women's product would not create a statutory stay of approval.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

Sincerely yours,

{See appended electronic signature page}

Priya Shah, PharmD
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Priya Shah

Digitally signed by Priya Shah
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