DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 204268

ANDA APPROVAL

Perrigo Company
U.S. Agent for: Perrigo Israel Pharmaceuticals Ltd.
Attention: Valerie Gallagher
Senior Director, Regulatory Affairs
515 Eastern Avenue
Allegan, MI 49010

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 6, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Testosterone Topical Gel, 1.62%.

Reference is made to your amendments dated June 30, August 15, and September 8, 2014; January 13, January 26, June 16, and July 8, 2015. Reference is also made to the complete response letter issued by this office on April 24, 2014. Your amendment dated August 15, 2014 represented a complete response to our April 24, 2014 action letter.

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 use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Testosterone Topical Gel, 1.62%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Androgel of AbbVie Inc. (AbbVie).

The RLD upon which you have based your ANDA, AbbVie's Androgel, is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
6,503,894 (the '894 patent)	August 30, 2020
8,466,136 (the '136 patent)	October 12, 2026
8,466,137 (the '137 patent)	October 12, 2026
8,466,138 (the '138 patent)	October 12, 2026
8,486,925 (the '925 patent)	October 12, 2026
8,729,057 (the '057 patent)	October 12, 2026
8,741,881 (the '881 patent)	October 12, 2026

8,754,070 (the '070 patent)	October 12, 2026
8,759,329 (the '329 patent)	October 12, 2026

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Testosterone Topical Gel, 1.62%, under this ANDA.[1] You have notified the agency that Perrigo Israel Pharmaceuticals Ltd. (Perrigo) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Perrigo for infringement of the '894, '136, '137, '138, and '925, patents within the statutory 45-day period in the United States District Court for the District of Delaware [Unimed Pharmaceuticals, LLC, Besins Healthcare Inc., and Besins Healthcare Luxembourg SARL v. Perrigo Company and Perrigo Israel Pharmaceuticals Ltd., Civil Action No. 13-236 (RGA)]. You have notified the agency that the case was dismissed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Perrigo was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Testosterone Topical Gel, 1.62%. Therefore, with this approval, Perrigo is eligible for 180 days of generic drug exclusivity for Testosterone Topical Gel, 1.62%. 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 the exclusivity begins to run.

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

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

Section 505-1 of the FD&C Act authorizes FDA to require the submission of a risk evaluation and mitigation strategy (REMS) if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks [section 505-1(a)]. In accordance with section 505-1(i) of FD&C Act, an ANDA is required to have a REMS if the applicable listed drug has an approved REMS.

In accordance with section 505-1 of the FD&C Act, we have determined that a REMS is necessary for topical products containing testosterone, including Testosterone Topical Gel, to ensure the benefits of the drug outweigh the risk of secondary exposure of children to testosterone due to drug transfer from adult men using the drug.

Your proposed REMS, submitted on July 8, 2015, and appended to this letter, is approved. The REMS consists of a Medication Guide.

[1] The agency notes that the ‘136, ‘137, ‘138, ‘925, ‘057, ‘881, ‘070 and ‘329 patents were not listed in the Orange Book when the Office of Generic Drugs received your ANDA and your paragraph PIV certifications were submitted in amendments to your ANDA.

We remind you that you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any of goal or element of the REMS, as described in section 505-1(g)(4) of the FD&C Act.

Prominently identify any submission containing proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NEW SUPPLEMENT FOR ANDA 204268/S-000/
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 204268/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 204268/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABEL CHANGES
SUBMITTED IN SUPPLEMENT XXX

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR ANDA 204268

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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.

PROMOTIONAL MATERIALS

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

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 1 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.

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.

Sincerely yours,

Carol A. Holquist -S

Digitally signed by Carol A. Holquist -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052464, cn=Carol A. Holquist -S
Date: 2015.08.04 17:27:14 -04'00'

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

ENCLOSURE: REMS
MEDICATION GUIDE