



ANDA 205781

ANDA APPROVAL

Paddock Laboratories, LLC
U.S. Agent for Perrigo UK FINCO Limited Partnership
3940 Quebec Avenue North
Minneapolis, MN 55427
Attention: Maureen Rath
Senior Manager, Regulatory Affairs

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 19, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Testosterone Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet).

Reference is also made to the complete response letter issued by this office on December 23, 2015, and to your amendments received on November 17, 2016; and April 25 and May 22, 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 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 Testosterone Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), AndroGel Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet), of AbbVie Inc. (AbbVie).

The RLD upon which you have based your ANDA, AbbVie's AndroGel Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet), is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
6,503,894 (the '894 patent)	March 2, 2021*
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
9,125,816 (the '816 patent)	March 2, 2021*
9,132,089 (the '089 patent)	March 2, 2021*

* with pediatric exclusivity added

Your ANDA contains paragraph IV certifications to each of the patents¹ under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Testosterone Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet), under this ANDA. You have notified the Agency that Perrigo UK FINCO Limited Partnership (Perrigo) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that litigation was initiated within the statutory 45-day period against Perrigo for infringement of the '894, '136, '137, '138, and '925 patents 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, Perrigo Israel Pharmaceuticals Ltd., and Perrigo UK FINCO Limited Partnership, Civil Action No. 13-0236 (Consolidated)]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Perrigo was the first ANDA applicant for Testosterone Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet), to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Perrigo may be eligible for 180 days of generic drug exclusivity for Testosterone Topical Gel, 1.62%, (20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet). This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Perrigo failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Perrigo's eligibility for 180-day generic drug exclusivity. It will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Perrigo begins commercial marketing of Testosterone Topical Gel, 1.62%,

¹ The Agency notes that the '894, '136, '137, '138, '925, '057, '881, '070, '329, '816 and '089 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

(20.25 mg/1.25 g packet and 40.5 mg/2.5 g packet), or (b) at any time prior to the expiration of the '136, '137, and '138 patents if Perrigo has not begun commercial marketing. 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.

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 the FD&C Act, a drug that is the subject of an ANDA under section 505(j) is subject to certain elements of the REMS required for the applicable listed drug.

Your final proposed REMS submitted on April 25, 2017, and appended to this letter is approved with your application. The REMS consists of a Medication Guide.

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

Prominently identify the 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 205781/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION**

or

**NEW SUPPLEMENT FOR ANDA 205781/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION**

or

**NEW SUPPLEMENT FOR ANDA 205781/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING
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 REVISION FOR ANDA 205781

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format.

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.

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

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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.

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}

For Heidi Lee, PharmD
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

ENCLOSURE: REMS



Priya
Shah

Digitally signed by Priya Shah
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