



ANDA 204571

**ANDA APPROVAL**

Actavis Laboratories UT, Inc.  
577 Chipeta Way  
Salt Lake City, UT 84108  
Attention: Cherri Petrie  
Executive Director, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 13, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD& CAct), for Testosterone Topical Gel, 10 mg per pump actuation.

Reference is made to the tentative approval letter issued by this office on February 24, 2015, and to your amendments dated May 22, May 27, and July 7, 2015.

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, 10 mg per pump actuation, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Fortesta Gel of Endo Pharmaceuticals, Inc. (Endo).

The RLD upon which you have based your ANDA, Endo's Fortesta Gel, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,319,913 (the '913 patent) and 6,579,865 (the '865 patent) are both scheduled to expire on November 9, 2018.

Your ANDA contains paragraph IV certifications to each of the patents 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, 10 mg per pump actuation, under this ANDA. You have notified the agency that Actavis Laboratories UT, Inc. (Actavis) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Actavis for infringement of the '913 and '865 patents within the statutory 45-day period in the United States District Court for the Eastern District of Texas, Marshall Division [Endo Pharmaceuticals Inc. and Strakan International S.á r.l. v. Watson Pharmaceuticals, Inc., et al., Civil Action No. 2:13-cv-192]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Actavis was the first ANDA application for Testosterone Topical Gel, 10 mg per pump actuation, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Actavis may be eligible for 180 days of generic drug exclusivity for Testosterone Topical Gel, 10 mg per pump actuation. This exclusivity, which is provided for under section 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 Actavis failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Actavis' 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 Actavis begins commercial marketing of Testosterone Topical Gel, 10 mg per pump actuation, or (b) at any time prior to the expiration of the '913 and '865 patents if Actavis has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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 the 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 7, 2015, and appended to this letter, is approved. 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 of goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

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 204571/S-000/  
CHANGES BEING EFFECTED IN 30 DAYS  
PROPOSED MINOR REMS MODIFICATION**

*or*

**NEW SUPPLEMENT FOR ANDA 204571/S-000  
PRIOR APPROVAL SUPPLEMENT  
PROPOSED MAJOR REMS MODIFICATION**

*or*

**NEW SUPPLEMENT FOR ANDA 204571/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 204571**

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,  
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Date: 2015.08.05 16:05:42 -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