ANDA 204570

ANDA APPROVAL

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

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 27, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Testosterone Gel, 1.62% (20.25 mg/1.25 g pump actuation).

Reference is also made to the tentative approval letter issued by this office on August 30, 2017, the complete response letter issued by this office on December 27, 2018, and to any amendments thereafter.

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 Gel, 1.62% (20.25 mg/1.25 g pump actuation), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), AndroGel, 1.62%, of Abbvie Inc. (Abbvie).

The RLD upon which you have based your ANDA, Abbvie's AndroGel, 1.62%, 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.S. Patent Number	Expiration Date
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 patents[1] 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 Gel, 1.62% (20.25 mg/1.25 g 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. Litigation was initiated within the statutory 45-day period against Actavis for infringement of the '894 patent in the United States District Court for the District of Delaware [Unimed Pharmaceuticals, LLC, Besins Healthcare Inc., and Besins Healthcare Luxembourg SARL v. Watson Laboratories, Inc., Civil Action No. 13-00236 (consolidated)]. You have also notified the Agency that this case was dismissed.

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, 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 May 1, 2017, is approved; and will be posted on the FDA REMS website: http://www.fda.gov/rems

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 204570/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 204570/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 204570 /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 204570

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

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

In addition to submitting the proposed REMS as described above, you can also submit the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, include the SPL file with your proposed REMS submission.

For more information on submitting REMS in SPL format, please email REMSWebsite@fda.hhs.gov

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

POSTMARKETING COMMITMENT UNDER SECTION 505(j)(10)

We remind you of your post marketing commitment:

FDA approved a revision to the RLD's labeling within 60 days of the expiration of the 180-day exclusivity period under section 505(j)(5)(B)(iv) of the FD&C Act. This revision to the RLD's labeling does not include a change to the "Warnings" section, and the Agency has determined that the continued presence of the labeling in effect before the revision will not adversely impact the safe use of the drug. The Agency has also determined that your ANDA meets the applicable standards for approval under section 505(j) of the FD&C Act, and was otherwise eligible for approval but for expiration of the 180-day exclusivity period under section 505(j)(5)(B)(iv) of the FD&C Act.

Therefore under section 505(j)(10) of the FD&C Act, your ANDA is eligible for approval with labeling that differs from that of the RLD. You are hereby notified that you are required to change the labeling of your product to contain the revision that was approved on February 25, 2019, for AbbVie's Androgel, 1.62%. Acceptance of this letter constitutes your agreement to submit a "Supplement-Changes Being Effected" containing such revised labeling no later than 60 days after the date of the notification, March 26, 2019.

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[2] 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.

Sincerely yours,

{See appended electronic signature page}

For Vincent Sansone, PharmD
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] The Agency notes that the '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.

[2] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Catherine Poole

Digitally signed by Catherine Poole
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