NDA 021454/S-029

SUPPLEMENT APPROVAL

Auxilium Pharmaceuticals, LLC
c/o Endo Pharmaceuticals, Inc.
Attention: Erin Abdallah, MS
Associate Director, Regulatory Affairs Liaison
1400 Atwater Drive
Malvern, PA 19355

Dear Ms. Abdallah:

Please refer to your supplemental new drug application (sNDA) dated and received May 20, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Testim® (testosterone gel).

This Prior Approval supplemental new drug application provides for proposed modifications to the approved Testim® risk evaluation and mitigation strategy (REMS). This supplement is in response to our May 10, 2019, REMS Modification Notification letter.

We have completed our review of this supplemental application, as amended. It is approved effective on the date of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Testim® was originally approved on September 18, 2009, and the most recent REMS modification was approved on May 1, 2014. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we

determined that you were required to make the REMS modifications outlined in our REMS Modification Notification letter dated May 10, 2019.

Medication Guide: We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Testim® outweigh its risks. The Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

Therefore, because the Medication Guide is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Testim®.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Meredith Hillig, MS, Safety Regulatory Project Manager, at (301) 796-1218.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, M.D.
Deputy Director for Safety
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CHRISTINE P NGUYEN
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