Initial REMS Approval: 09/18/2009
Most Recent Modification: 11/2011

NDA 21-454 TESTIM® 1% (testosterone gel)

Class of Product: Androgen

Auxilium Pharmaceuticals, Inc.
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of TESTIM® 1% (testosterone gel).

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each TESTIM® 1% (testosterone gel) prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Auxilium Pharmaceuticals will submit REMS Assessment to FDA by 18 months, 3 years, and 7 years from the date of initial approval (09/18/2009) of the TESTIM® 1% (testosterone gel) REMS.

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Auxilium Pharmaceuticals will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

CHRISTINE P NGUYEN
11/22/2011