Initial REMS Approval: 02/2012

Testosterone Gel CIII

Drug Class and Formulation: Testosterone Gel Products

TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

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 testosterone gel.

II. REMS ELEMENTS:

A. Medication Guide

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

B. Timetable for Submission of Assessments

Teva Pharmaceuticals USA will submit REMS assessments to the FDA at 18 months, 3 years, and 7 years from the date of the approval of the 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.

Teva Pharmaceuticals USA will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

AUDREY L GASSMAN
02/14/2012