RISK EVALUATION AND MITIGATION STRATEGY (REMS)

ANDA 76737
Testosterone Gel 1%
Class of Drug: Androgen
Actavis Laboratories UT, Inc.
577 Chipeta Way
Salt Lake City, Utah UT 85108
TEL: (801) 588-6633 FAX: (951) 493-4581

I. Goal
The goal of this REMS is to inform patients about the serious risks associated with the use of Testosterone Gel 1%.

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.

The Medication Guide is part of the REMS and is appended.