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

NDA 21-015 ANDROGEL® (testosterone gel) 1% CIII

Drug Class and Formulation: Testosterone Drug Products

Abbott Laboratories

200 Abbott Park Road

Abbott Park, IL 60064-3500

1-800-241-1643

# RISK EVALUATION AND MITIGATION STRATEGY (REMS)

## I. GOAL(S)

To inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1%.

## II. REMS ELEMENTS:

### A. Medication Guide

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

### B. Timetable for Submission of Assessments

Abbott Laboratories will submit REMS assessments to FDA by 18 months, 3 years and 7 years from the date of initial approval (September 18, 2009) of the AndroGel (testosterone gel) 1% 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 the assessment. Abbott Laboratories will submit each assessment so that it will be received by FDA on or before the due date.

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CHRISTINE P NGUYEN
11/30/2011