Initial REMS Approval: 2/2012
Most Recent Modification: 07/2015

**Testosterone Gel 1% CIII**

**Drug Class and Formulation: Testosterone Gel Products**

**ANI Pharmaceuticals, Inc.**

**Baudette, MN 56623**

**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 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. One Medication Guide will be available in each carton of testosterone gel 1% to assure that a copy will be available for distribution to patients using the product. Testosterone gel 1% container or package labels will include an instruction alerting the pharmacist to provide the Medication Guide to each person to whom the product is dispensed.

ANI Pharmaceuticals, Inc. will include a Medication Guide with each twin pack carton containing two testosterone gel 1% pumps. Instructions exist on the carton not to separate the twin packs. One Medication Guide will be included in each carton of 30 testosterone gel 1% packets.

### B. Timetable for Submission of Assessments

ANI Pharmaceuticals, Inc. will submit REMS assessments to the FDA 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. ANI Pharmaceuticals, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.