Initial REMS Approval: 06/2014
Most Recent Modification: 05/2015

NDA 204399

VOGELXO (testosterone) gel CIII
and Authorized Generic (testosterone gel) CIII

Class of Drug: Androgen

UPSHER-SMITH LABORATORIES, INC.
6701 Evenstad Drive
Maple Grove, MN 55369
763-315-2000

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 prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS.

B. Timetable for Submission of Assessments

Upsher-Smith Laboratories, Inc. (USL) will submit REMS Assessments to the FDA for testosterone gel at 18 months, 3 years and 7 years from the date of initial approval of the VOGELXO (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. USL will submit each assessment so that it will be received by the FDA on or before the due date.