

PART I: PROPOSED RISK EVALUATION AND MITIGATION STRATEGY
(REMS)

1. GOAL

The goal of this REMS is to communicate the risks of Savella.

2. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each Savella prescription. Savella is packaged as a unit of use. In addition, PDFs of the medication guide will be made available for pharmacists to dispense, as well as for other healthcare providers and patients (e.g. on the Savella website).

Because the Medication Guide is included as part of the Package Insert for Savella, Cypress Bioscience, Inc. and Forest Laboratories, Inc. have met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

B. Communication Plan

The REMS for Savella does not include a Communication Plan.

C. Elements To Assure Safe Use

There are no specific serious risks requiring additional elements to assure safe use.

D. Implementation System

Because this REMS for Savella does not include elements to assure safe use, an implementation system is not required.

3. ASSESSMENT of REMS

The Timetable for Assessments is as follows:

- 1st FDAAA assessment: April 2010 (18 months from approval)
- 2nd FDAAA assessment: October 2011 (3 years from approval)
- 3rd FDAAA assessment: October 2015 (7 years from approval).

The sponsor will submit the assessments within 60 days of the close of the intervals as noted above.