

Initial REMS Approval: 08/2015

Most Recent Modification: 10/2019

NDA 22526 Addyi® (flibanserin)

Serotonin 1A receptor agonist and a Serotonin 2A receptor antagonist

Sprout Pharmaceuticals, Inc.
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

To inform patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

II. ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each Addyi prescription in accordance with 21 C.F.R. 208.24.

The Medication Guide is part of the REMS.

B. Timetable for Submission of Assessments

Sprout Pharmaceuticals must submit REMS assessments 6 months from 10/9/2019, 18 months, 3 years and 7 years thereafter. 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 calendar days before the submission date for that assessment. Sprout must submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

CHRISTINE P NGUYEN
10/09/2019 10:00:29 PM