

NDA 22-195/S-002 MORPHINE SULFATE Oral Solution

10 mg/5 mL, 20 mg/5 mL, 100 mg/5 mL

(Opioid Analgesic)

Roxane Laboratories, Inc.

1809 Wilson Road

Columbus, OH 43228

614-272-4785

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 MORPHINE SULFATE oral solution.

II. REMS ELEMENTS:

A. Medication Guide

In accordance with 21 CFR 208.4 (b), Roxane Laboratories Inc. will make the Medication Guide available for distribution to patients or caregivers to be dispensed with each MORPHINE SULFATE oral solution prescription. The Medication Guide will be provided in sufficient numbers to meet the dispenser obligations under 21 CFR 208.24(e).

Under 21 CFR 208.24(d), Roxane Laboratories will ensure that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide the Medication Guide to each patient to whom the drug is dispensed and state how the Medication Guide is provided.

A Medication Guide will be dispensed with each MORPHINE SULFATE oral solution prescription as follows:

- 10 mg/5 mL: Bottles of 100 mL- one (1) medication guide
Bottles of 500 mL- five (5) medication guides
- 20 mg/5 mL: Bottles of 100 mL- one (1) medication guide
Bottles of 500 mL- five (5) medication guides
- 100 mg/5 mL: Bottles of 120 mL- one (1) medication guide
Bottles of 30 mL- one (1) medication guide

The Medication Guide will also be available on the company website at (www.roxane.com) and through our toll-free technical product assistance telephone number (800-962-8364).

B. Timetable for Submission of Assessments

Roxane Laboratories, Inc. will submit REMS assessments to the FDA at a minimum by 18 months, 3 years, and in the 7th year after the REMS is initially approved. 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. Roxane Laboratories Inc. will submit each assessment so that it will be received by the FDA on or before the due date.