

# Risk Evaluation and Mitigation Strategy (REMS) Document

## DSUVIA™ (sufentanil) REMS Program

### I. Administrative Information

Application Number: NDA 209128  
Application Holder: AcclRx Pharmaceuticals, Inc.  
Initial REMS Approval: 11/2018

### II. REMS Goal

The goal of the DSUVIA REMS is to mitigate the risk of respiratory depression resulting from accidental exposure by:

- Ensuring that DSUVIA is dispensed only to patients in certified medically supervised healthcare settings.

### III. REMS Requirements

**AcclRx Pharmaceuticals, Inc. must ensure that healthcare settings and wholesalers-distributors comply with the following requirements:**

---

#### 1. Healthcare settings that dispense DSUVIA must:

- 
- |                                 |  |
|---------------------------------|--|
| To become certified to dispense | <ol style="list-style-type: none"><li>1. Be able to manage acute opioid overdose, including respiratory depression.</li><li>2. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.</li><li>3. Have the authorized representative enroll in the REMS Program by completing the <a href="#">Healthcare Setting Enrollment Form</a> and submitting it to the REMS Program.</li><li>4. Train all relevant staff that DSUVIA must not be dispensed for use outside of the certified healthcare setting.</li><li>5. Train all relevant staff involved in administration of DSUVIA to refer to the Directions for Use prior to administration.</li><li>6. Establish processes and procedures to verify that DSUVIA is not dispensed for use outside of the certified healthcare setting.</li></ol> |
|---------------------------------|--|

To maintain certification to dispense	7. Have a new authorized representative enroll in the REMS Program by completing the <a href="#">Healthcare Setting Enrollment Form</a> if the authorized representative changes.
At all times	8. Not dispense DSUVIA for use outside the certified healthcare setting. 9. Not distribute, transfer, loan or sell DSUVIA. 10. Maintain records of staff training. 11. Maintain records of all processes and procedures including compliance with those processes and procedures. 12. Comply with audits by AcelRx Pharmaceuticals, Inc. or a third party acting on behalf of AcelRx Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

---

**2. Wholesalers-distributors that distribute DSUVIA must:**

To be able to distribute	1. Establish processes and procedures to ensure that DSUVIA is distributed only to certified healthcare settings. 2. Train all relevant staff involved in distributing DSUVIA on the processes and procedures to verify the healthcare settings are certified.
At all times	3. Distribute only to certified healthcare settings. 4. Maintain and submit records of all shipments of DSUVIA to AcelRx Pharmaceuticals, Inc. 5. Comply with audits carried out by AcelRx Pharmaceuticals, Inc. or a third party acting on behalf of AcelRx Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

---

**To support REMS Program operations, AcelRx Pharmaceuticals, Inc. must:**

1. Establish and maintain a REMS Program website, [www.DSUVIAREMS.com](http://www.DSUVIAREMS.com). The REMS Program website must include the capability to complete healthcare setting certification online and, the option to print the Prescribing Information, Directions for Use, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website.
2. Make the REMS Program website fully operational and all REMS materials available through website and call center by the date DSUVIA is first commercially distributed.
3. Establish and maintain a REMS Program call center for REMS participants at 1-855-925-8476.

4. Establish and maintain a validated, secure database of all REMS participants who are certified in the DSUVIA REMS.
5. Ensure healthcare settings are able to enroll by fax, mail, and online.
6. Provide [Healthcare Setting Enrollment Form](#) and the Prescribing Information to healthcare settings that (1) attempt to order DSUVIA and are not yet certified or (2) inquire about how to become certified.
7. Notify healthcare settings, confirming certification, within 7 calendar days after they become certified in the REMS Program.
8. Provide wholesalers-distributors access to the database of certified healthcare settings.

**To ensure REMS participants' compliance with the REMS Program, AcelRx Pharmaceuticals, Inc. must:**

9. Verify annually that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the healthcare setting. If different, the healthcare setting must be required to re-certify with a new authorized representative.
10. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: DSUVIA distribution; certification of healthcare settings; and audits of REMS participants.
11. Establish a plan for addressing noncompliance with REMS Program requirements.
12. Monitor healthcare settings and wholesaler-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
13. Audit all certified healthcare settings at 6 months and 12 months from the date the drug is first commercially distributed, and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. To be audited, healthcare settings must have received at least one shipment of DSUVIA in the past 6 months.
14. Audit wholesalers-distributors no later than 90 calendar days after they become authorized to distribute the drug or from the date DSUVIA is first commercially distributed (whichever is later) to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
15. Take reasonable steps to improve operation of and compliance with the requirements in the DSUVIA REMS Program based on monitoring and evaluation of the DSUVIA REMS Program.

## **IV. REMS Assessment Timetable**

AcelRx Pharmaceuticals, Inc. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (11/02/2018). 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. AcelRx Pharmaceuticals, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

## **V. REMS Materials**

The following materials are part of the DSUVIA REMS:

### **Enrollment Forms**

Healthcare Setting:

1. [Healthcare Setting Enrollment Form](#)

### **Other Materials**

2. [REMS Program Website](#)