Risk Evaluation and Mitigation Strategy (REMS) Document
Adasuve (loxapine) REMS Program

I. Administrative Information
Application Number: NDA 022549
Application Holder: Alexza Pharmaceuticals, Inc.
Initial REMS Approval: 12/2012
Most Recent REMS Update: 01/2022

II. REMS Goal
The goal of the ADASUVE REMS is to mitigate the risk of negative outcomes (respiratory distress or respiratory arrest) associated with ADASUVE induced bronchospasm by:

1) Ensuring that ADASUVE is dispensed only in certified healthcare setting that have:
   a) Immediate access on site to supplies and healthcare professionals competent in the management of acute bronchospasm and access to emergency assistance for symptoms that require immediate medical attention. Healthcare settings must have a short-acting bronchodilator (e.g., albuterol), for the immediate treatment of bronchospasm; this short-acting bronchodilator can be delivered by inhaler (with spacer) or nebulizer.
   b) Processes and procedures to ensure that patients are screened for conditions for which Adasuve is contraindicated and monitored for signs of bronchospasms.

III. REMS Requirements
Alexza Pharmaceuticals, Inc. must ensure that healthcare settings, patients, and wholesalers-distributors comply with the following requirements
1. **Healthcare settings that dispense ADASUVE must:**

| To become certified to dispense                                                                 | 1. Have immediate access to supplies and personnel onsite competent in the management of acute bronchospasm including: a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer, and access to emergency assistance for symptoms that require immediate medical attention. |
|                                                                                                 | 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. |
|                                                                                                 | 3. Have the authorized representative review the Education Program for Healthcare Settings. |
|                                                                                                 | 4. Have the authorized representative enroll in the REMS Program by completing the Healthcare Settings Enrollment Form and submitting it to the REMS Program. |
|                                                                                                 | 5. Establish processes and procedures to verify (1) the patient is assessed for respiratory abnormalities before administration (by medical history, medication history, and chest auscultation), (2) the patient is assessed for a minimum of 1 hour after administration for bronchospasm, (3) no more than a single dose of ADASUVE is administered within a 24-hour period, (4) ADASUVE is not dispensed outside of the certified healthcare setting. |

| Before administering                                                                 | 6. Assess the patient’s health status for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD) or other lung disease associated with bronchospasm, acute respiratory signs/symptoms (e.g. wheezing), and current use of medications to treat airway disease such as asthma or COPD. |
|                                                                                     | 7. Assess the patient’s health status for respiratory abnormalities by chest auscultation. |

| After administering, for a minimum of 1 hour                                      | 8. Assess the patient’s health status for signs and symptoms of bronchospasm. |
|                                                                                     | 9. Dispense no more than a single dose per patient. |

| During treatment, within a 24-hour period                                           | 10. Have any new Authorized Representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form and submitting to the REMS Program. |

| To maintain certification to dispense                                               | 11. Not dispense ADASUVE for use outside of the certified healthcare setting. |
|                                                                                     | 12. Report any adverse events of bronchospasm that occur following ADASUVE treatment to the REMS Program. |
|                                                                                     | 13. Not distribute, transfer, loan or sell ADASUVE. |
|                                                                                     | 14. Maintain appropriate documentation that all processes and procedures are being followed for the Adasuve REMS Program. |
|                                                                                     | 15. Comply with audits by Alexza Pharmaceuticals, Inc., or a third party acting on behalf of Alexza Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed. |

| At all times                                                                         | 11. Not dispense ADASUVE for use outside of the certified healthcare setting. |

Reference ID: 4928289
2. Patients who are prescribed ADASUVE:

Before treatment initiation

1. Be monitored for signs and symptoms of breathing problems.
2. Complete a medical history and medication history with the prescriber.

During treatment; for at least 1 hour

3. Be monitored for signs and symptoms of bronchospasm.

3. Wholesalers-distributors that distribute ADASUVE must:

To be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings.
2. Train all relevant staff involved in distributing ADASUVE.

At all times

3. Distribute only to certified healthcare settings.
4. Maintain records of distribution including all shipments of ADASUVE.
5. Comply with audits by Alexza Pharmaceuticals, Inc., or a third party acting on behalf of Alexza Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and being followed.

Alexza Pharmaceuticals, Inc. must provide training to healthcare settings that dispense ADASUVE

The training includes the following educational materials: Education Program for Healthcare Settings. The training must be available online and in print format.

To support REMS Program operations, Alexza Pharmaceuticals, Inc. must:

1. Establish and maintain a REMS Program website, www.adasuverems.com. The REMS Program website must include the option to print the Prescribing Information, Medication Guide, 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(s).
2. Make the REMS Program website fully operational and all REMS materials available through the website or ADASUVE REMS Program Call Center within 60 calendar days of REMS modification (01/27/2022).
3. Establish and maintain a REMS Program call center for REMS participants at 855-755-0492.
4. Establish and maintain a validated and secure database of all REMS participants who are enrolled and/or certified in the ADASUVE REMS Program.
5. Ensure healthcare settings are able to enroll online, by email and fax.
6. Provide authorized wholesalers-distributors access to the database of certified healthcare settings.
7. Provide Education Program for Healthcare Settings, Healthcare Setting Enrollment Form, and the Prescribing Information to healthcare settings who (1) attempt to order ADASUVE and are not yet certified or (2) inquire about how to become certified.
8. Notify healthcare settings within 2 business days after they become certified in the REMS Program.
To ensure REMS participants’ compliance with the REMS Program, Alexza 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 ADASUVE distribution; certification of healthcare settings; and audits of REMS participants. These records must be readily available for FDA inspections.

11. Establish a plan for addressing noncompliance with REMS Program requirements.

12. Monitor healthcare settings and wholesalers-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 healthcare settings within 180 calendar days after they become certified and have received at least one shipment, and every 3 years thereafter, to ensure that all REMS processes and procedures are in place, functioning and support the REMS Program requirements. To be audited, a healthcare setting must have received at least one shipment of ADASUVE in the past 12 months.

14. Audit wholesalers-distributors no later than one year after the wholesaler-distributor is authorized and at least one every calendar year to ensure that all REMS processes and procedures are in place, functioning and support the REMS Program requirements.

15. Take reasonable steps to improve operations of and compliance with the requirements in the ADASUVE REMS Program based on monitoring and evaluation of the ADASUVE REMS Program.

IV. REMS Assessment Timetable

Alexza Pharmaceuticals, Inc. must submit REMS assessments annually from the date of approval of the REMS modification (01/27/2022). 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. Alexza 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 ADASUVE REMS:

Enrollment Forms
Healthcare Setting:

1. Healthcare Setting Enrollment Form

Training and Educational Materials
Healthcare Setting:

2. Education Program for Healthcare Setting

Other Materials

3. REMS website (www.adasuverems.com)
To become certified in the ADASUVE REMS Program, review the Education Program for Healthcare Settings, complete this enrollment form and do one of the following:

Fax 855-755-0493 (Fax both pages) or Scan and e-mail to Enrollment@AdasuveREMSProgram.com Submit online at www.adasuverems.com/enrollment

### HEALTHCARE SETTING INFORMATION

*indicates required field

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<th>Healthcare Setting Name*:</th>
<th>Setting DEA or* NPI Number:</th>
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Setting Type*: □ Medical Hospital □ Psychiatric Hospital □ Other (describe):

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Authorized Healthcare Setting Representative Information

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Preferred communication method*: □ Email □ Fax

### HEALTHCARE SETTING ATTESTATIONS

As an authorized representative for the healthcare setting:

- I have reviewed the Education Program for Healthcare Settings.
- I must establish processes and procedures to:
  - assess the patient for respiratory abnormalities before administration (by medical and medication history, and chest auscultation),
  - monitor the patient for a minimum of 1 hour after administration for bronchospasm,
- My healthcare setting has immediate access to supplies and personnel onsite competent in the management of acute bronchospasm including: a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer and access to emergency assistance for symptoms that require immediate medical attention.
On behalf of the healthcare setting, we must comply with the following REMS requirements:

Before administering:

- Assess the patient's health status for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD) and other lung diseases associated with bronchospasm, acute respiratory signs and symptoms (e.g. wheezing), and current use of medications to treat airway disease such as asthma or COPD.
- Assess the patient's health status for respiratory abnormalities by chest auscultation.

After administering, for a minimum of 1 hour:

- Assess the patient's health status for signs and symptoms of bronchospasm.

During treatment, within a 24-hour period:

- Dispense no more than a single dose per patient.

At all times:

- Not dispense ADASUVE for use outside the certified healthcare setting.
- Report any adverse events of bronchospasm that occur following ADASUVE treatment to the ADASUVE REMS.
- Not distribute, transfer loan or sell ADASUVE. Maintain appropriate documentation that all processes and procedures are in place and being followed.
- Comply with audits by Alexza Pharmaceuticals, Inc., or a third party acting on behalf of Alexza Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense:

- Have any new Authorized Representative enroll in the ADASUVE REMS by completing the Healthcare Setting Enrollment Form and submitting to the ADASUVE REMS.

I confirm that the information above is correct. I understand that this information will be used to document healthcare facilities that are eligible to receive ADASUVE. I also understand that this information may be shared with government agencies.

Authorized Healthcare Setting Representative Signature

Date

Authorized Healthcare Setting Representative (Print)

Title
Use this page to add each additional healthcare setting location for which the same **Authorized Representative** will be responsible:

### ADDITIONAL HEALTHCARE SETTING INFORMATION

*indicates required field

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ADASUVE® (LOXAPINE) INHALATION POWDER

EDUCATION PROGRAM for HEALTHCARE SETTINGS

August 2021

Alexza Pharmaceuticals
2091 Stierlin Court
Mountain View, CA 94043
WHAT IS ADASUVE®?

- ADASUVE is a drug-device combination product that delivers an aerosol of the antipsychotic agent loxapine in a single oral inhalation.

- ADASUVE is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults.

- ADASUVE is contraindicated in patients with the following:
  - Current diagnosis or history of asthma, COPD, or other lung disease associated with bronchospasm
  - Acute respiratory symptoms or signs (e.g., wheezing)
  - Current use of medications to treat airways disease, such as asthma or COPD
  - History of bronchospasm following ADASUVE treatment
  - Known hypersensitivity to loxapine or amoxapine. Serious skin reactions have occurred with oral loxapine and amoxapine.

- Limitation of Use: As part of the ADASUVE REMS Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare setting.

BOXED WARNING (BRONCHOSPASM)

- ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest, particularly in patients with lung diseases.

- **Administer ADASUVE only in a certified healthcare setting that has immediate access on site to supplies and healthcare professionals competent in the management of acute bronchospasm and access to emergency assistance for symptoms that require immediate medical attention.** Certified healthcare settings must have a short-acting bronchodilator (e.g., albuterol) available for the immediate treatment of bronchospasm; this short-acting bronchodilator can be delivered by inhaler (with spacer) or nebulizer.

- Prior to administering ADASUVE, screen patients regarding a current diagnosis, history, or symptoms of asthma, COPD and other lung diseases, and assess (including chest auscultation) patients for respiratory signs.

- Monitor for signs and symptoms of bronchospasm following treatment with ADASUVE.
WHAT IS THE ADASUVE REMS (RISK EVALUATION AND MITIGATION STRATEGY)?

- The ADASUVE REMS is a safety program that helps ensure that the benefits of ADASUVE outweigh its risks.

- The ADASUVE REMS is required by the Food and Drug Administration (FDA) because ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest, particularly in contraindicated patients with lung diseases.

ADASUVE REMS – OVERVIEW

- ADASUVE is dispensed only in certified healthcare settings that have:
  
  o Immediate access on site to supplies and healthcare professionals competent in the management of acute bronchospasm, and access to emergency assistance for symptoms that require immediate medical attention. Healthcare settings must have a short-acting bronchodilator (e.g., albuterol) available, delivered by inhaler (with spacer) or nebulizer, for the immediate treatment of bronchospasm.

  o Processes and procedures in place to ensure that patients are screened for conditions for which ADASUVE is contraindicated and monitored for signs of bronchospasm.

- Wholesalers/distributors will ship ADASUVE only to certified healthcare settings.

HEALTHCARE SETTING REQUIREMENTS: AUTHORIZED REPRESENTATIVE

- The Authorized Representative is a healthcare professional with the appropriate level of responsibility within the healthcare setting and is authorized to act on behalf of the healthcare setting.

- For each certified healthcare setting, an Authorized Representative is required to:
  
  o Review the ADASUVE Education Program for Healthcare Settings

  o Complete and sign the Healthcare Setting Enrollment Form, and submit the completed form on-line, via fax, or via email

  The Healthcare Setting Enrollment Form is available at [www.adasuverems.com](http://www.adasuverems.com) or by calling 855-755-0492.
Any new Authorized Representative must recertify the healthcare setting

**ADASUVE REMS STAKEHOLDER REQUIREMENTS**

<table>
<thead>
<tr>
<th>Healthcare Setting</th>
<th>Patients</th>
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<tbody>
<tr>
<td>Must have immediate access to supplies and healthcare professionals competent in the management of acute bronchospasm, and access to emergency assistance for symptoms that require immediate medical attention.</td>
<td>Before treatment administration, complete a medical history and/or medication history if requested, and be assessed for signs and symptoms of breathing problems if requested by the prescriber.</td>
</tr>
<tr>
<td>Must have a short-acting bronchodilator (e.g., albuterol), for the immediate treatment of bronchospasm; this short-acting bronchodilator can be delivered by inhaler (with spacer) or nebulizer.</td>
<td>During treatment, for a minimum of 1 hour, be monitored for signs and symptoms of bronchospasm.</td>
</tr>
<tr>
<td>Establish processes and procedures to (1) assess the patient for respiratory abnormalities before administration (medical history, medication history, and chest auscultation), (2) monitor the patient for a minimum of 1 hour after administration for bronchospasm, (3) provide that no more than a single dose of ADASUVE is administered within a 24-hour period, and (4) provide that ADASUVE is not dispensed outside of the certified healthcare setting.</td>
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<tr>
<td>Do not administer more than one dose of ADASUVE in a 24-hour period.</td>
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<tr>
<td>Do not dispense ADASUVE for use outside of the certified healthcare setting.</td>
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<tr>
<td>Do not distribute, transfer, or loan or sell ADASUVE.</td>
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<tr>
<td>Maintain appropriate documentation that all processes and procedures are in place and are being followed.</td>
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<td>Comply with audits.</td>
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### Healthcare Setting Processes and Procedures
**Requirements: Patient Screening, Monitoring, and Management**

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<thead>
<tr>
<th>Steps for Safe Use of ADASUVE®</th>
<th>Details</th>
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<tr>
<td><strong>SCREEN</strong></td>
<td>Ask if patient is taking medication to treat asthma or COPD and/or check medical records</td>
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<tr>
<td></td>
<td>Ask if patient has a current diagnosis or history of asthma, COPD or other lung disease and/or check medical records</td>
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<tr>
<td></td>
<td>If current diagnosis cannot be determined or if there is no access to patient’s medical records, treat with ADASUVE only after assessing patients (including chest auscultation) for respiratory abnormalities (e.g. wheezing)</td>
</tr>
<tr>
<td></td>
<td><strong>Do not use in patients with acute respiratory signs or symptoms; with a current diagnosis or history of asthma, COPD or other lung disease associated with bronchospasm; or with current use of medications to treat airways disease, such as asthma or COPD</strong></td>
</tr>
<tr>
<td><strong>COUNSEL</strong></td>
<td>Counsel patient/caregiver on potential for bronchospasm that may occur after dosing and the need for them to report symptoms immediately</td>
</tr>
<tr>
<td><strong>MONITOR</strong></td>
<td>Monitor patient for at least 1 hour after treatment for signs and symptoms of bronchospasm</td>
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<tr>
<td><strong>MANAGE</strong></td>
<td>Treat bronchospasm with an inhaled short-acting beta-agonist bronchodilator (e.g., albuterol)</td>
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RESOURCES AVAILABLE

- The ADASUVE REMS Education Program for Healthcare Settings (this document) is available to review or print at www.adasuverems.com

- Other Resources available at www.adasuverems.com
  - Healthcare Setting Enrollment Form
  - Prescribing Information
  - ADASUVE Medication Guide

REPORTING ADVERSE EVENTS ASSOCIATED WITH ADASUVE

Healthcare professionals should report all events of bronchospasm, in addition to any fatalities that occur following ADASUVE treatment.

Suspected adverse events may be reported by the following methods:

- ADASUVE Medical Information at 800-284-0062 or email medinfo@alexza.com
- FDA at 1-800-FDA-1088
- FDA at www.fda.gov/medwatch/report.htm
This template is to be used as a guideline for developing procedures and protocols around the use of ADASUVE to ensure that REMS requirements are being met.

INDICATION

☐ Agitation associated with bipolar I disorder
☐ Agitation associated with schizophrenia

PATIENT SCREENING

Prior to dosing:

Inquire and/or check medical records for:

☐ current diagnosis or history of asthma, COPD or other lung diseases associated with bronchospasm
☐ current use of medications to treat airways disease, such as asthma or COPD
☐ history of bronchospasm following ADASUVE treatment
☐ known hypersensitivity (e.g. serious skin reaction) to loxapine or amoxapine

Assess for acute respiratory signs and symptoms (including chest auscultation):

☐ wheezing
☐ cough
☐ dyspnea
☐ other: __________

If any of the above screening is positive, DO NOT USE ADASUVE. ADASUVE is contraindicated in these patients.

DOSE ADMINISTRATION

Limit ADASUVE use to a single dose per patient within a 24-hour period.

POST-TREATMENT OBSERVATION / MONITORING

Patient must be monitored for at least 1 hour after treatment for signs / symptoms of bronchospasm.

MANAGEMENT OF BRONCHOSPASM

☐ Immediately treat patient with short acting bronchodilator (e.g. albuterol) delivered by inhaler (with spacer) or nebulizer
☐ Report any case of bronchospasm

Phone 855-755-0492       Fax 855-755-0493       www.adasuverems.com
ADASUVE REMS Website

ADASUVE REMS Home Page ........................................................................................................................................ 2
Contact Us Page ....................................................................................................................................................... 3
Healthcare Setting Landing Page ................................................................................................................................. 4
Healthcare Setting Online Enrollment Page .................................................................................................................. 5
Healthcare Setting Online Enrollment Page with a Second Healthcare Setting Added ............................................. 6
What is the ADASUVE REMS?

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ADASUVE to ensure that the benefits of treatment outweigh the risks of bronchospasm.

The purpose of the ADASUVE REMS is to mitigate the risk of bronchospasm that has the potential to lead to respiratory distress and respiratory arrest.

Only healthcare settings certified in the ADASUVE REMS may dispense ADASUVE.
Healthcare Setting

Only healthcare settings certified in the ADASUVE REMS may dispense ADASUVE.

To become certified to dispense:

1. **Site Requirements**
   Have immediate access to supplies and personnel competent in the management of acute bronchospasm including: a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer, and access to emergency assistance for symptoms that require immediate medical attention.

2. **Designate an Authorized Representative**
   Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the ADASUVE REMS on behalf of the healthcare setting.

3. **Review the Healthcare Setting Guide**
   Have the authorized representative review the Education Program for Healthcare Settings.

4. **Complete the Healthcare Setting Enrollment Form**
   Have the authorized representative enroll in the Adasuve REMS by completing the Healthcare Setting Enrollment Form and submitting it to the Adasuve REMS.

5. **Establish Processes and Procedures**
   Establish processes and procedures to:
   - assess the patient for respiratory abnormalities before administration by medical history, medication history, and chest auscultation,
   - monitor the patient for a minimum of 1 hour after administration for bronchospasm,
   - provide that no more than a single dose of ADASUVE is administered within a 24-hour period, and
   - provide that ADASUVE is not dispensed outside of the certified healthcare setting.
As an authorized representative for the healthcare setting:

- I have reviewed the Education Program for Healthcare Settings.
- I will establish and follow processes and procedures to:
  1. assess the patient for respiratory abnormalities before administration (by medical and medication history and chest auscultation),
  2. monitor the patient for a minimum of 1 hour after administration for bronchospasm,
  3. ensure no more than a single dose of ADASUVE is administered within a 24-hour period,
  4. ensure ADASUVE is not dispensed outside of the certified healthcare setting.
- My healthcare setting has immediate access to supplies and personnel onsite competent in the management of acute bronchospasm including: a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer and access to emergency assistance for symptoms that require immediate medical attention.

On behalf of the healthcare setting, we must comply with the following REMS requirements:

Before administering:
- Assess the patient’s health status for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD) and other lung diseases associated with bronchospasm, acute respiratory signs and symptoms (e.g., wheezing), and current use of medications to treat airway disease such as asthma or COPD.
- Assess the patient’s health status for respiratory abnormalities by chest auscultation.

After administering, for a minimum of 1 hour:
- Assess the patient’s health status for signs and symptoms of bronchospasm.

During treatment, within a 24-hour period:
- Dispense no more than a single dose per patient.

At all times:
- I will dispense ADASUVE for use outside of the certified healthcare setting.
- Report any adverse events of bronchospasm that occur following ADASUVE treatment to the ADASUVE REMS.
- I will distribute, transfer, lose, or sell ADASUVE. Maintain appropriate documentation that all processes and procedures are in place and are being followed.
- Comply with audits by Alexza Pharmaceuticals, Inc., or a third party acting on behalf of Alexza Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.
- To maintain certification to dispense:
  - Have any new Authorized Representatives enroll in the ADASUVE REMS by completing the Healthcare Setting Enrollment Form and submitting to the ADASUVE REMS.

I authorize the above signature to be the legally binding equivalent of my handwritten signature.
Healthcare Setting Enrollment

Healthcare Setting Information (* indicates required field)

Healthcare Setting Name*
MEMORIAL HOSPITAL

Healthcare Setting NPI #* Healthcare Setting DEA #
1871547570 or* B96125341

Setting Type*

[ ] Medical Hospital [ ] Psychiatric Hospital [ ] Other

Setting Address*

Setting Address

City* State* ZIP Code*

City State ZIP Code

Phone* Fax*

( ) ( ) ( ) ( )

Add Another Healthcare Setting Location

Healthcare Setting Authorized Representative (* indicates required field)

First Name* Last Name*
First Name Last Name

Position/Title*

Position/Title

Phone* Fax* Email*

( ) ( ) ( ) ( )

Preferred communication method*

[ ] Email [ ] Fax
As an authorized representative for the healthcare setting:

- I have reviewed the Education Program for Healthcare Settings.
- I must establish processes and procedures to:
  1. Assess the patient for respiratory abnormalities before administration (by medical and medication history, and chest auscultation).
  2. Monitor the patient for a minimum of 1 hour after administration for bronchospasm.
  3. Ensure no more than a single dose of ADASUVE is administered within a 24-hour period.
  4. Ensure ADASUVE is not dispensed outside of the certified healthcare setting.

- My healthcare setting has immediate access to supplies and personnel onsite competent in the management of acute bronchospasm, including:
  - A short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer.
  - Access to emergency assistance for symptoms that require immediate medical attention.

On behalf of the healthcare setting, we must comply with the following REMS requirements:

Before administering:

- Assess the patient's health status for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD), and other lung diseases associated with bronchospasm, acute respiratory signs and symptoms (e.g., wheezing), and current use of medications to treat airway disease such as asthma or COPD.
- Assess the patient’s health status for respiratory abnormalities by chest auscultation.

After administering, for a minimum of 1 hour:

- Assess the patient’s health status for signs and symptoms of bronchospasm.

During treatment, within a 24-hour period:

- Dispense no more than a single dose per patient.

At all times:

- Not dispense ADASUVE for use outside of the certified healthcare setting.
- Not distribute, transfer, loan, or sell ADASUVE.
- Maintain appropriate documentation that all processes and procedures are in place and are being followed.
- Comply with audits by Alexza Pharmaceuticals, Inc., or a third party acting on behalf of Alexza Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense:

- Have any new Authorized Representative enroll in the ADASUVE REMS by completing the Healthcare Setting Enrollment Form and submitting it to the ADASUVE REMS.

Please use your mouse or stylus to sign below.

I authorize the above signature to be the legally binding equivalent of my handwritten signature.