

**To become certified in the FILSPARI REMS, enroll by completing and submitting this form online at [www.FILSPARIREMS.com](http://www.FILSPARIREMS.com) or complete and fax this form to 1-833-483-4736.**

Due to the risks of hepatotoxicity and embryo-fetal toxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS (Risk Evaluation and Mitigation Strategy). All inpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

An authorized representative must be designated to carry out the certification process and oversee implementation and compliance with the FILSPARI REMS on behalf of the pharmacy. As the authorized representative, complete and submit this form on behalf of your inpatient pharmacy.

If you have any questions, require additional information, or need further copies of FILSPARI REMS materials, please visit the REMS Website at [www.FILSPARIREMS.com](http://www.FILSPARIREMS.com), or call the FILSPARI REMS at 1-833-513-1325.

**1. Inpatient Pharmacy Information (\*indicates required field)**

*Inpatient Pharmacy Name:			
*Inpatient Pharmacy Location: <input type="checkbox"/> Hospital <input type="checkbox"/> Nursing Home <input type="checkbox"/> Hospice <input type="checkbox"/> Mental Health Facility <input type="checkbox"/> Assisted Living <input type="checkbox"/> Prison <input type="checkbox"/> Rehabilitation Facility <input type="checkbox"/> Other (please specify):_____			
*Facility National Provider Identifier (NPI) #:		Drug Enforcement Administration Number (DEA #):	
<b>Inpatient Pharmacy Address</b>			
*Address Line #1:			
Address Line #2:			
*City:		*State:	*Zip:
*Phone:		*Fax:	
<b>Pharmacy Ship To Contact</b>			
*First Name:		*Last Name:	
<b>Pharmacy Shipping Address, if different from above</b>			
*Address Line #1:			
Address Line #2:			
*City:		*State:	*Zip:
*Phone:		*Fax:	

## 2. Inpatient Pharmacy Authorized Representative Information (\*indicates required field)

* First Name:	Position/Title: <input type="checkbox"/> Hospital pharmacist <input type="checkbox"/> Head of Pharmacy and Therapeutics (P&T) committee <input type="checkbox"/> Other (please specify):
* Last Name:	
*Authorized Representative Office Phone:	*Fax:
*Authorized Representative Email:	*Contact Preference (select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax

## 3. Inpatient Pharmacy Authorized Representative Agreement

### To become certified to dispense FILSPARI, my pharmacy must:

- Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
- Have the authorized representative review the **Prescriber and Pharmacy Guide**.
- Have the authorized representative certify by enrolling in the REMS by completing the **Inpatient Pharmacy Enrollment Form** and submitting it to the REMS.
- Train all relevant staff involved in dispensing on the REMS requirements using the **Prescriber and Pharmacy Guide**.
- Establish processes and procedures to verify and document the patient is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.
- For patients who can become pregnant: Establish processes and procedures to verify and document pregnancy testing is complete.

### Before dispensing FILSPARI, my pharmacy must:

- Counsel the patient on the risk of hepatotoxicity. Document and submit confirmation of counseling through the processes and procedures established as a requirement of the REMS.
- For patients who can become pregnant: Counsel the patient on the risk of embryo-fetal toxicity. Document and submit confirmation of counseling through the processes and procedures established as a requirement of the REMS.
- Verify and document the patient is enrolled or will be enrolled prior to discharge, the patient is under the care of a certified prescriber, and liver testing is complete.
- For patients who can become pregnant: Verify and document pregnancy testing is complete.

### At discharge, my pharmacy must:

- Dispense no more than a 30-days' supply.

### At all times, my pharmacy must:

- Report pregnancies to the REMS.
- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Trave Therapeutics, Inc. or a third party acting on behalf of Trave Therapeutics, Inc. to ensure that all processes and procedures are in place and are being followed.
- Have a new authorized representative enroll by completing and submitting an **Inpatient Pharmacy Enrollment Form**, if the authorized representative changes.

## 4. Inpatient Pharmacy Authorized Representative Consent (\*indicates required field)

By signing below, you agree that you have read the above responsibilities and understand your obligations as an inpatient pharmacy authorized representative, the risks of FILSPARI treatment, and you agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy.

 *Authorized Representative Signature:	*Signature Date (MM-DD-YYYY):
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Healthcare providers should report adverse events suggestive of hepatotoxicity and pregnancies to the FILSPARI REMS at 1-833-513-1325. Report all other suspected adverse events or product quality complaints associated with FILSPARI to Trave Therapeutics, Inc. at 1-877-659-5518 or the FDA at 1-800-FDA-1088 or online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).