

**The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program
Wholesaler / Distributor Enrollment Form**

For real-time processing of this enrollment form electronically, please go to www.TIRFREMSaccess.com and 'Log In' (if you have previously enrolled in a REMS program for one of the TIRF medicines) or 'Create an Account' to get started.

To submit this form via fax, please complete all required fields below and fax pages 1 and 2 to 1-866-822-1487. You will receive enrollment confirmation via email or fax.

TIRF medicines are available only through a FDA mandated REMS (Risk Evaluation and Mitigation Strategy), a restricted distribution program, called the TIRF REMS Access program. Under the TIRF REMS Access program, only prescribers, pharmacies, wholesalers / distributors and patients enrolled in the program are able to prescribe, dispense, distribute, purchase or receive TIRF medicines. Refer to the 'List of TIRF Medicines Available Only through the TIRF REMS Access Program' in Attachment 1.

Under the TIRF REMS Access program, wholesalers / distributors must verify the current enrollment of a pharmacy in the TIRF REMS Access program prior to distributing a TIRF medicine to that pharmacy. If the pharmacy location is not enrolled, the distributor must not fill any orders for TIRF medicines until enrollment can be confirmed.

The current list of enrolled pharmacies may be accessed via:

- receipt of a complete pharmacy registry daily in a mutually agreed format,
- a daily download from a secure FTP site,
- a password protected section of the website (www.TIRFREMSaccess.com), or
- by calling 1-866-822-1483.

Your company will receive login information (unique secure user ID and password) to access the TIRF REMS Access program website and you will be contacted regarding the secure FTP site once your enrollment is complete.

The Wholesaler / Distributor understands that TIRF medicines are only available through the TIRF REMS Access program and acknowledges that they will comply with the following program requirements:

1. The Wholesaler / Distributor will ensure that relevant staff are trained on the TIRF REMS Access program procedures and will follow the requirements of the TIRF REMS Access program.
2. The Wholesaler / Distributor will ensure that TIRF medicines are only distributed to pharmacies whose enrollment has been verified in the TIRF REMS Access program.
3. The Wholesaler / Distributor will provide complete unblinded and unblocked data (i.e. EDI 867 transmission) to the TIRF REMS Access program, including information on shipments to enrolled pharmacies.
4. The Wholesaler / Distributor will cooperate with periodic audits or non-compliance investigations to ensure that TIRF Medicines are distributed in accordance with the program requirements.

Authorized Representative Name* (please print): _____

For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS

Authorized Wholesaler / Distributor Representative:	
Signature* _____	Date _____
First Name* _____	Last Name* _____
Phone Number* _____	Email* _____
*Required Fields	
Wholesaler / Distributor Information:	
Corporate Wholesaler / Distributor Name* _____	DEA* _____
Address* _____	
City* _____	
State* _____	ZIP* _____
Email* _____	
Phone Number* _____	Fax Number* _____
*Required Fields	

Preferred Method of Communication (please select one): Fax E-mail

^ If a DEA number is not available at corporate enter N/A for DEA number in the field above and please provide a list of Distribution Centers with their DEA numbers below.

Distribution Centers (DC) Information

Please populate the information below for each of your Distribution Centers.

DC information:

DC Name	DEA	Address	City	State	Zip Code	Title	Contact First Name	Contact Last Name	Fax Number	Email

If you have any questions or require additional information or further copies of any TIRF REMS Access documents, please visit either www.TIRFREMSaccess.com, or call the TIRF REMS Access program at 1-866-822-1483.

Authorized Representative Name* (please print): _____

For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS

Attachment 1:

List of TIRF Medicines Available Only through the TIRF REMS Access Program

- ABSTRAL® (fentanyl) sublingual tablets
- ACTIQ® (fentanyl citrate) oral transmucosal lozenge
- FENTORA® (fentanyl citrate) buccal tablet
- LAZANDA® (fentanyl) nasal spray
- ONSOLIS® (fentanyl buccal soluble film)
- SUBSYS™ (fentanyl sublingual spray)
- Approved generic equivalents of these products are also covered under this program.