

### Important Drug Warning

**Subject: Announcement of a single shared REMS (Risk Evaluation and Mitigation Strategy) program for all Transmucosal Immediate Release Fentanyl (TIRF) products due to the potential risk of misuse, abuse, addiction, overdose and serious complications due to medication errors**

**The TIRF REMS Access program is a Food and Drug Administration (FDA) required risk management program**

Dear Wholesaler/Distributor:

The purpose of this letter is to make you aware of a change from individual REMS programs to a shared REMS program (the TIRF REMS Access program) and to provide guidance on enrollment into the new shared REMS program **beginning mm/dd/yyyy**. The individual REMS programs are being converted to the TIRF REMS Access program to reduce the burden on the healthcare providers and the healthcare system of having multiple individual programs. The products covered under this new program include:

- Abstral<sup>®</sup> (fentanyl) sublingual tablets
- Actiq<sup>®</sup> (fentanyl citrate) oral transmucosal lozenge
- Fentora<sup>®</sup> (fentanyl citrate) buccal tablet
- Lazanda<sup>®</sup> (fentanyl) nasal spray
- Onsolis<sup>®</sup> (fentanyl buccal soluble film)
- Subsys<sup>™</sup> (fentanyl sublingual spray)
- Approved generic equivalents of these products are also covered under this program.

This new shared program replaces the individual product REMS that were previously available, and any prescribers, pharmacies, patients and distributors enrolled in these programs will be automatically transitioned to the new shared TIRF REMS Access program. If you have not enrolled in one or more of these individual REMS programs and you wish to purchase these products in order to fulfill orders from enrolled pharmacies, you must enroll in the TIRF REMS Access program.

#### **Distributor Action:**

##### ***Option 1: If you are already enrolled in at least one individual REMS program***

- **Beginning mm/dd/yyyy**, your enrollment information will be automatically entered into the new shared TIRF REMS Access program. The website for the shared TIRF REMS Access program can be accessed at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com).
- You can use your existing secure user ID and password from any one of your individual REMS programs to access the TIRF REMS Access website at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)
  - The user ID and password you use to initially log on will become your permanent user ID and password for the shared TIRF REMS Access program.
- You will be required to re-enroll in the shared TIRF REMS within two years after your last enrollment in an individual REMS if you wish to continue distributing these products. You will be notified by the REMS program in advance of the need to re-enroll.
- By enrolling in the shared TIRF REMS Access program a distributor/wholesaler may distribute all of the TIRF medicines. However, the decision to maintain a direct selling relationship with the wholesaler/distributor is at the sole discretion of each individual TIRF manufacturer.

***Option 2: If you do not have an existing enrollment in any individual REMS program***

- Review and understand the requirements of the TIRF REMS Access program.
- Verify that relevant staff are trained on the TIRF REMS Access program requirements and procedures
- Complete the Distributor Enrollment Form. Forms are available at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) or by calling **1-866-822-1483**.
- By enrolling in the shared TIRF REMS Access program a distributor/wholesaler may distribute all of the TIRF medicines. However, the decision to maintain a direct selling relationship with the wholesaler/distributor is at the sole discretion of each individual TIRF manufacturer.

**Distributor Responsibilities in the TIRF REMS Access Program:**

**Verification of TIRF REMS Access program Pharmacy Enrollment Prior to Distributing TIRF medicines**

- Obtain the current list of enrolled pharmacies by:
  - Downloading (daily) a complete electronic registry of enrolled pharmacies from a secure FTP site (you will be contacted regarding the TIRF REMS Access secure FTP site once your enrollment is complete), or
  - Receiving (daily) a complete electronic registry, or
  - Accessing the website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)) using a user ID and password, or
  - Calling the TIRF REMS Access program call center at **1-866-822-1483**.
- Ensure that pharmacies are enrolled in the TIRF REMS Access program before distributing TIRF medicines.
- If a pharmacy places an order for a TIRF medicine, but is not listed on the enrolled list for the TIRF REMS Access program, do not distribute TIRF medicines.

**Provide periodic distribution data**

- Provide weekly product activity data (i.e. EDI 867 transmission) to the TIRF REMS Access program including complete (unblinded/unblocked) information to validate compliance with the TIRF REMS Access program.

Please note that a manufacturer of products included in [Attachment 1](#) cannot ship TIRF medicines to distributors who have not completed and signed the Distributor Enrollment Form. Refer to the 'List of TIRF Medicines Available only through the TIRF REMS Access program' in Attachment 1.

**Adverse Event Reporting**

Promptly report suspected adverse events including misuse, abuse, addiction and overdoses directly to the TIRF REMS Access program at **1-866-822-1483**. You also may report adverse event information to the FDA MedWatch Reporting System by telephone at 1-800-FDA-1088 or by mail using Form 3500, available at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**To access the above information and to enroll in the TIRF REMS Access program, visit [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) or call 1-866-822-1483 to have enrollment materials sent to you.**

Sincerely,

TIRF REMS Access Industry Group

**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.