

## Opioid Drugs and Risk Evaluation and Mitigation Strategies (REMS)

Opioids are at the center of a major public health crisis of addiction, misuse, abuse, overdose and death. FDA is taking action to protect patients from serious harm due to these drugs. This action represents a careful balance between continued access to these necessary medications and stronger measures to reduce their risks.



### List of Transmucosal Immediate-Release Fentanyl (TIRF) Products

#### Brand Name Products

	Trade Name	Generic Name	Sponsor
1	Abstral	Fentanyl sublingual tablets	ProStraken, Inc
2	Actiq	Fentanyl citrate oral transmucosal lozenge	Cephalon, Inc
3	FENTORA	Fentanyl citrate buccal tablet	Cephalon, Inc
4	Lazanda	Fentanyl nasal spray	Archimedes Development Ltd
5	Onsolis	Fentanyl buccal soluble film	Meda Pharmaceuticals Inc

### Update on Implementation of Opioids REMS

On May 16, 2011, the FDA met with members of the Industry Working Group (IWG) and other sponsors of Long Acting and Extended Release opioid drugs. The purpose of the meeting was to discuss the next steps in implementing A Risk Evaluation and Mitigation Strategy (REMS) for these products through a single shared system. Topics discussed included:

- 1) prescriber training
- 2) Medication Guides
- 3) REMS assessment plan
- 4) administrative requirements

The meeting was productive and resulted in greater clarity for how drug sponsors will proceed with the opioids REMS implementation. The minutes of this meeting, along with a set of questions submitted by the IWG and responses from FDA, will be posted to this site in the near future.

For further information, please contact: [OpioidREMS@fda.hhs.gov](mailto:OpioidREMS@fda.hhs.gov).

(<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>)