

**Transmucosal Immediate-Release Fentanyl (TIRF) shared system
RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

Current application holders of the shared system REMS

Product name	Application number	Application holder
Subsys	NDA 202788	Insys Therapy
Lazanda	NDA 022569	DepoMed, Inc.
Abstral	NDA 022510	Galena BioPharma
Onsolis	NDA 022266	Meda Pharmaceuticals
Fentora	NDA 021947	Cephalon, Inc.
Actiq	NDA 020747	Cephalon, Inc.
fentanyl citrate	ANDA 78907	Mallinckrodt
fentanyl citrate	ANDA 077312	Par Pharm

Number of total products= 8