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FENTORA™
fentanyl buccal tablet
Sales Training on the
Risk Minimization Action Plan
(Risk MAP)
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What Is a
Risk Minimization Action Plan
(RiskMAP)
A document describing tools and interventions intended to reduce potential risks associated with a product (e.g., diversion)
Sponsor may volunteer or FDA proposes
Implementation is based upon the risk/benefit ratio of the commercialization of the product
Currently there are a number of products with RiskMAPs (e.g., Thalidomide, Accutane, Oxycontin, Actiq)
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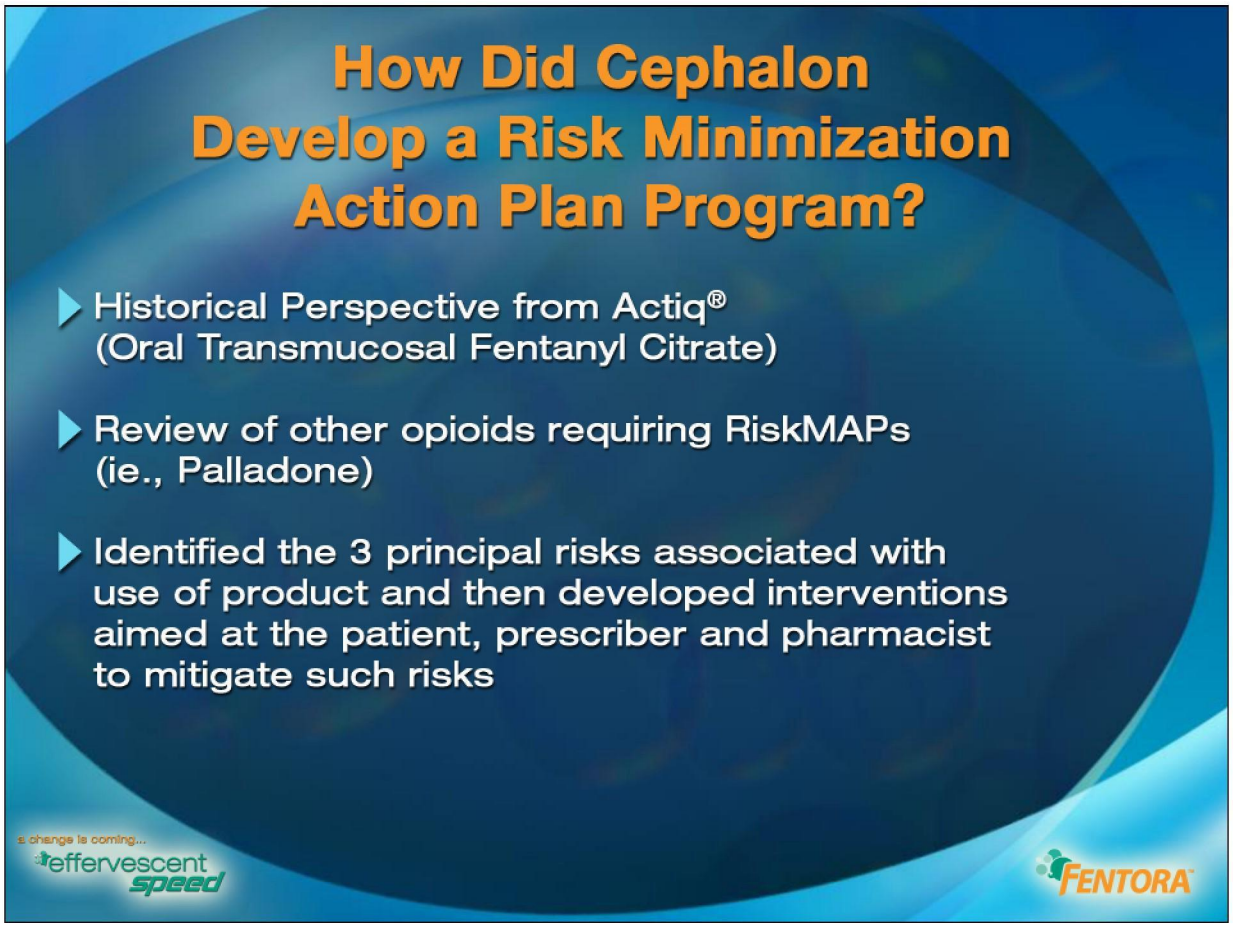
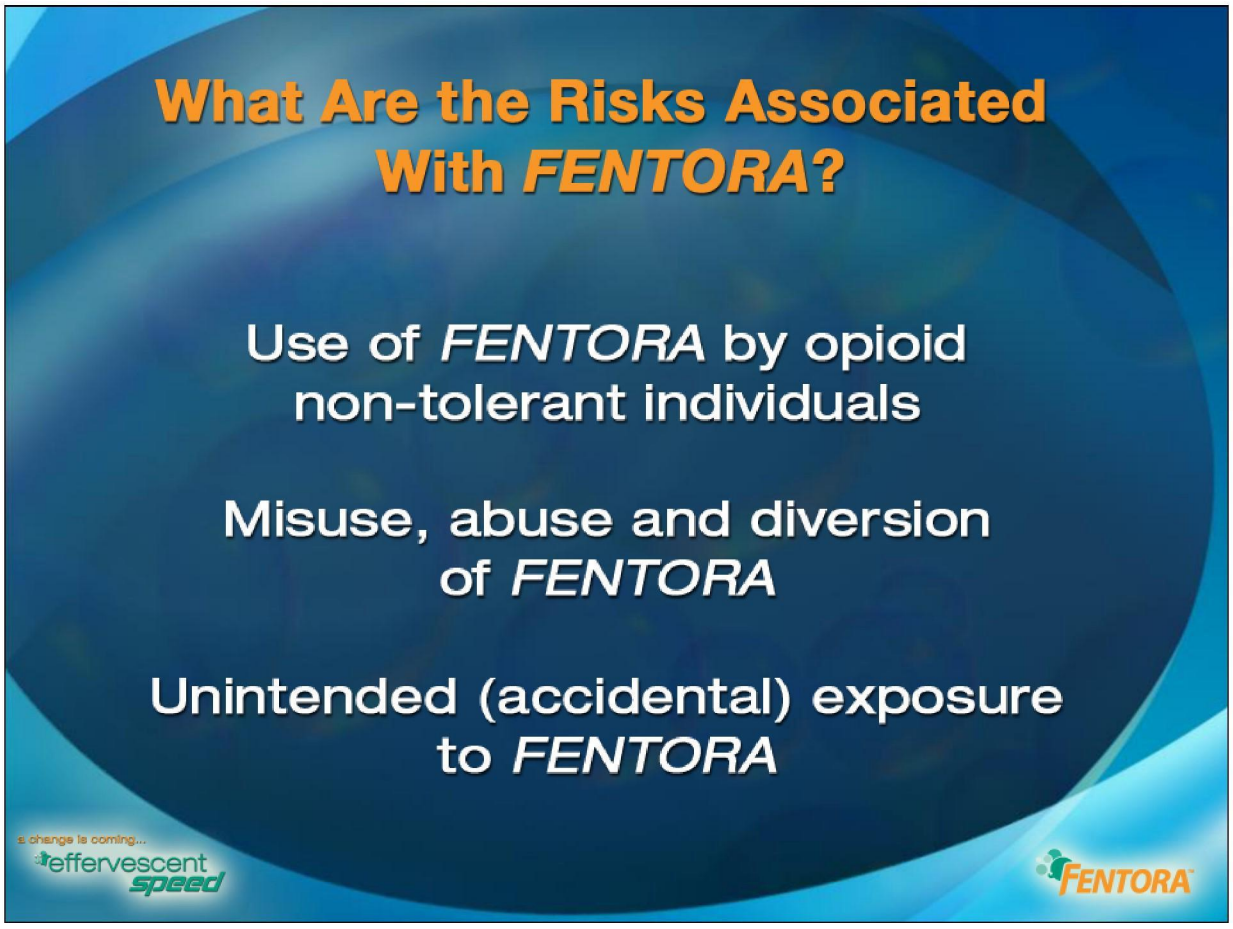
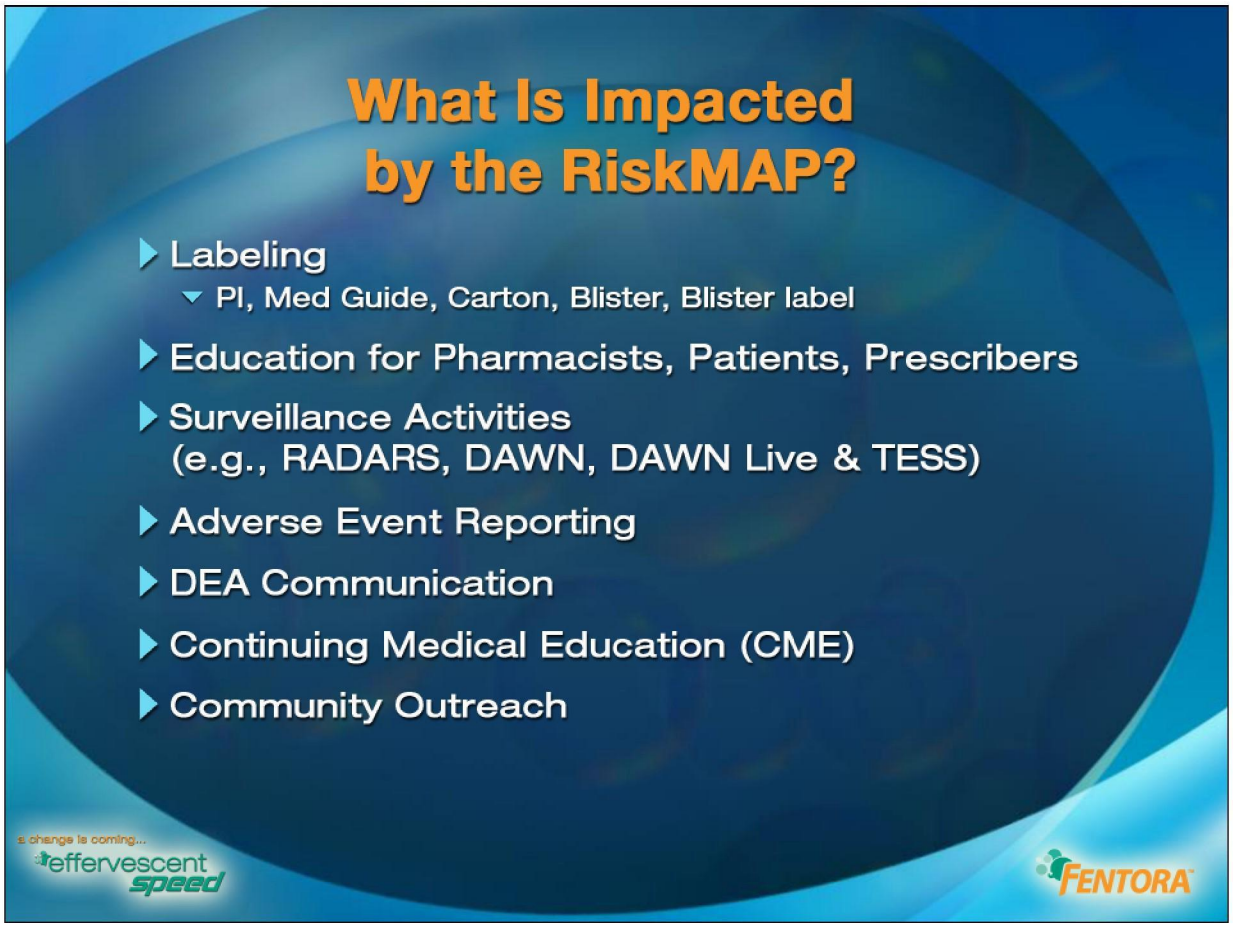


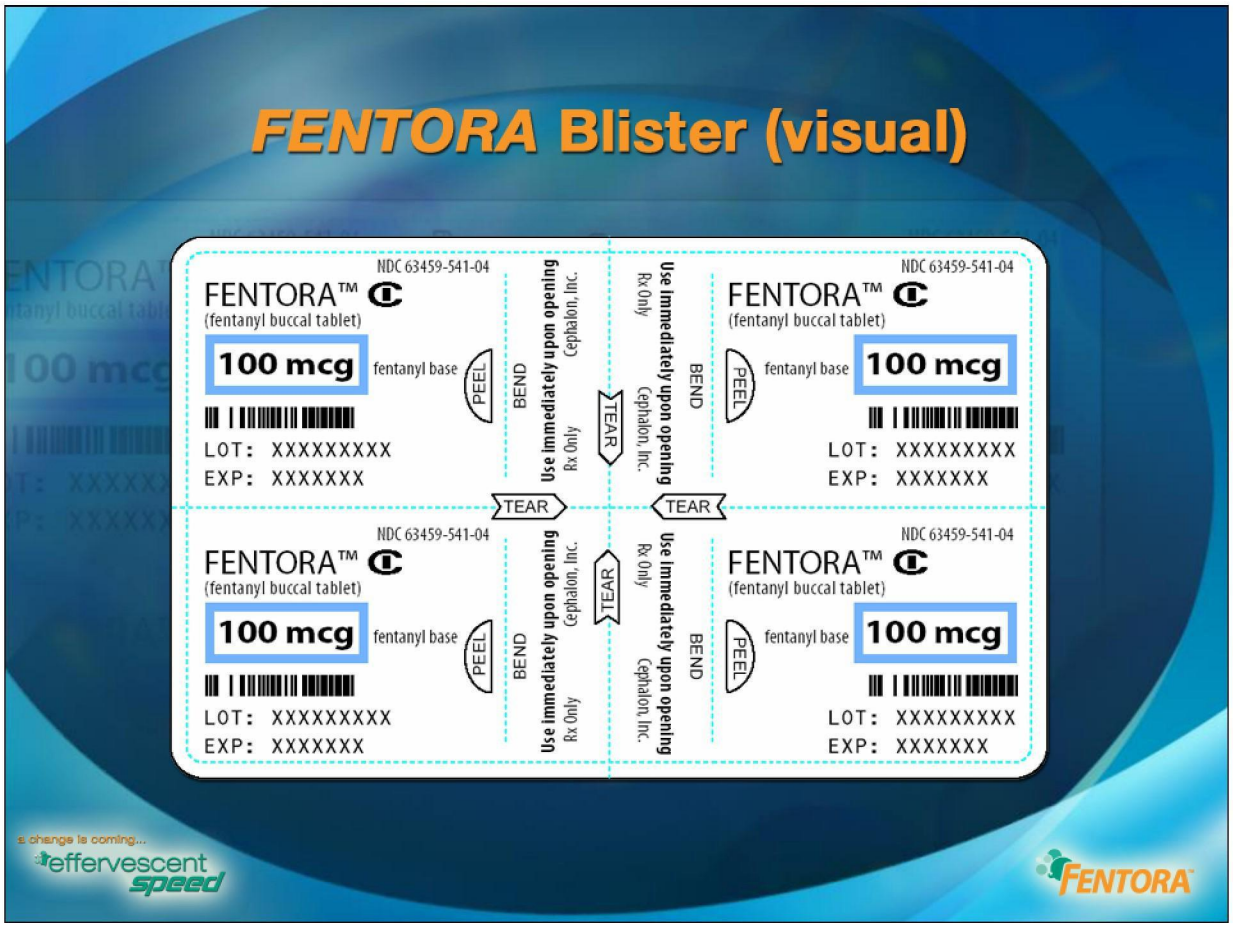

The NDA was submitted August 2005; initial agreement on RiskMAP reached between FDA and Review Division June 2006; however, change in policy at FDA warranted RiskMAP to then be circulated to chief counsel (lawyers) for their review.




Proper Patient Selection Messages
Definition of opioid tolerant patient
Contraindicated in opioid non-tolerant patients
Contraindicated for use in acute/postop pain
Indicated solely for treatment of BTCP in chronic opioid tolerant cancer patients
Prevention of Diversion/Abuse Messages
Classified as CII medication [Schedule II drugs require distribution tracking, import and export controls, registration of prescribers and dispensers and no refills]
To be used only by patient for whom it is dispensed
May be habit forming
Requires appropriate disposal of unused medication
Child Safety Messages
Keep out of the reach of children
Could be harmful or fatal to a child if accidentally ingested
Must be properly stored and disposed of
Healthcare professionals must counsel patients on child safety messages
Accessible and easily understood directions on what to do in case of accidental ingestion



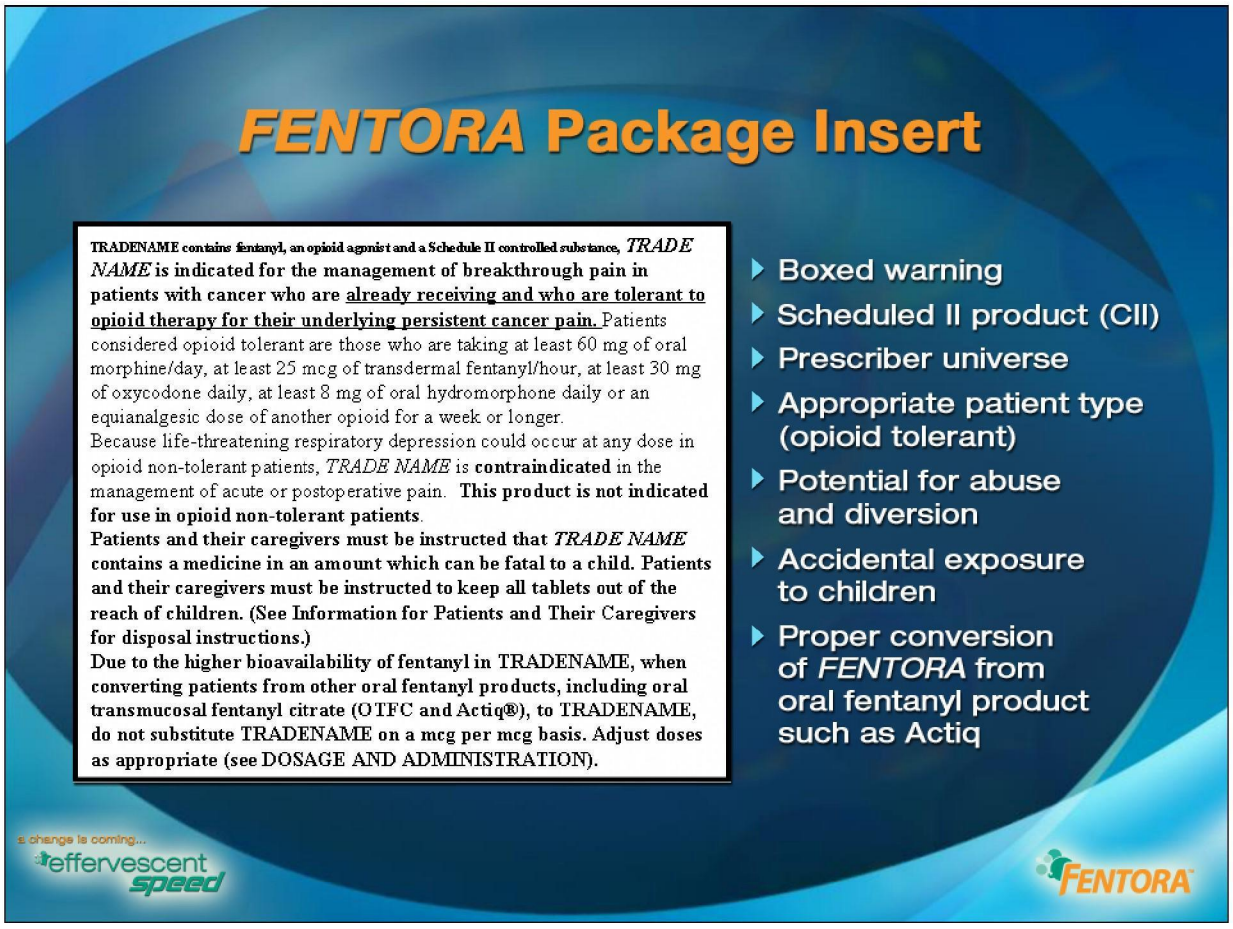

Labeling includes the blister, carton, package insert and Medication Guide and all have been designed to enhance child safety – covered with warnings and yellow warning triangles (carton only); appearance of tablet impacted – made to look very plain and medicinal – all labeling is described in detail in the RiskMAP




The blister label and carton both have the product name and dose. The carton also has a yellow warning triangle. .


The FENTORA carton now contains 28 tablets. It also has the yellow warning triangle and all of the safety messages (directions for suspected overdose, plain-language child safety warnings and opioid tolerance warnings).

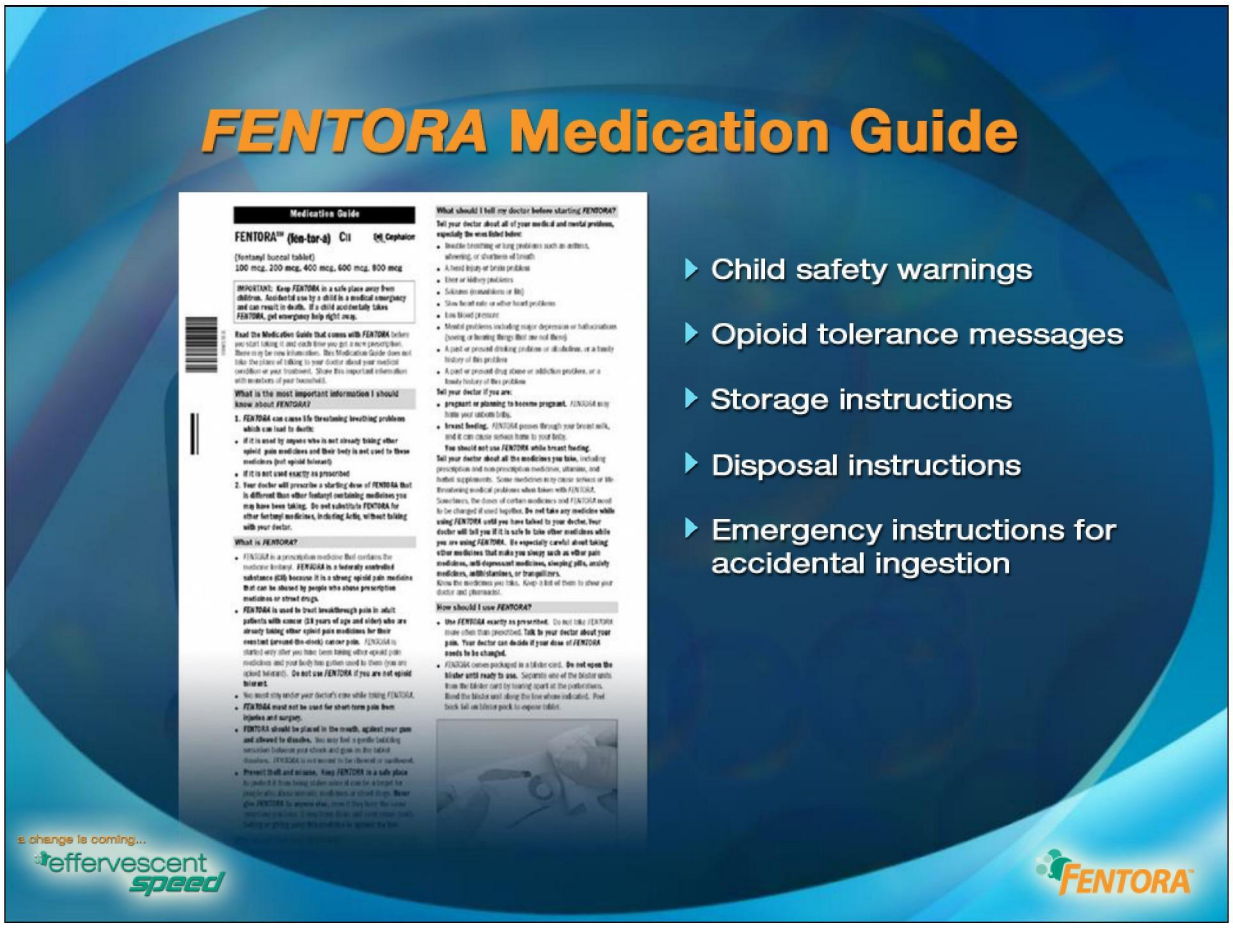
In addition it has a pharmacy dispensing checklist for the pharmacist to assure that all essential information is relayed to the patient.




The PI is attached to the carton via a hitchhiker

- >60 mg morphine/day
- >50 □g transdermal fentanyl/hour
- >1 week

life threatening hypoventilation at any dose in patients not taking chronic opioids
contraindicated in acute/postoperative pain
must not be used in opioid non-tolerant patients
only oncologists/pain specialists... skilled in use of Schedule II opioids
can be fatal to a child




Each carton contains 4 Medication Guides. Guides have patient-friendly language with a boxed warning for child safety warnings along with the other pertinent warnings.


Feedback on
Risk Management Effectiveness
Targets
1. Patients
2. Prescribers
3. Pharmacists
Evaluation
Intervention
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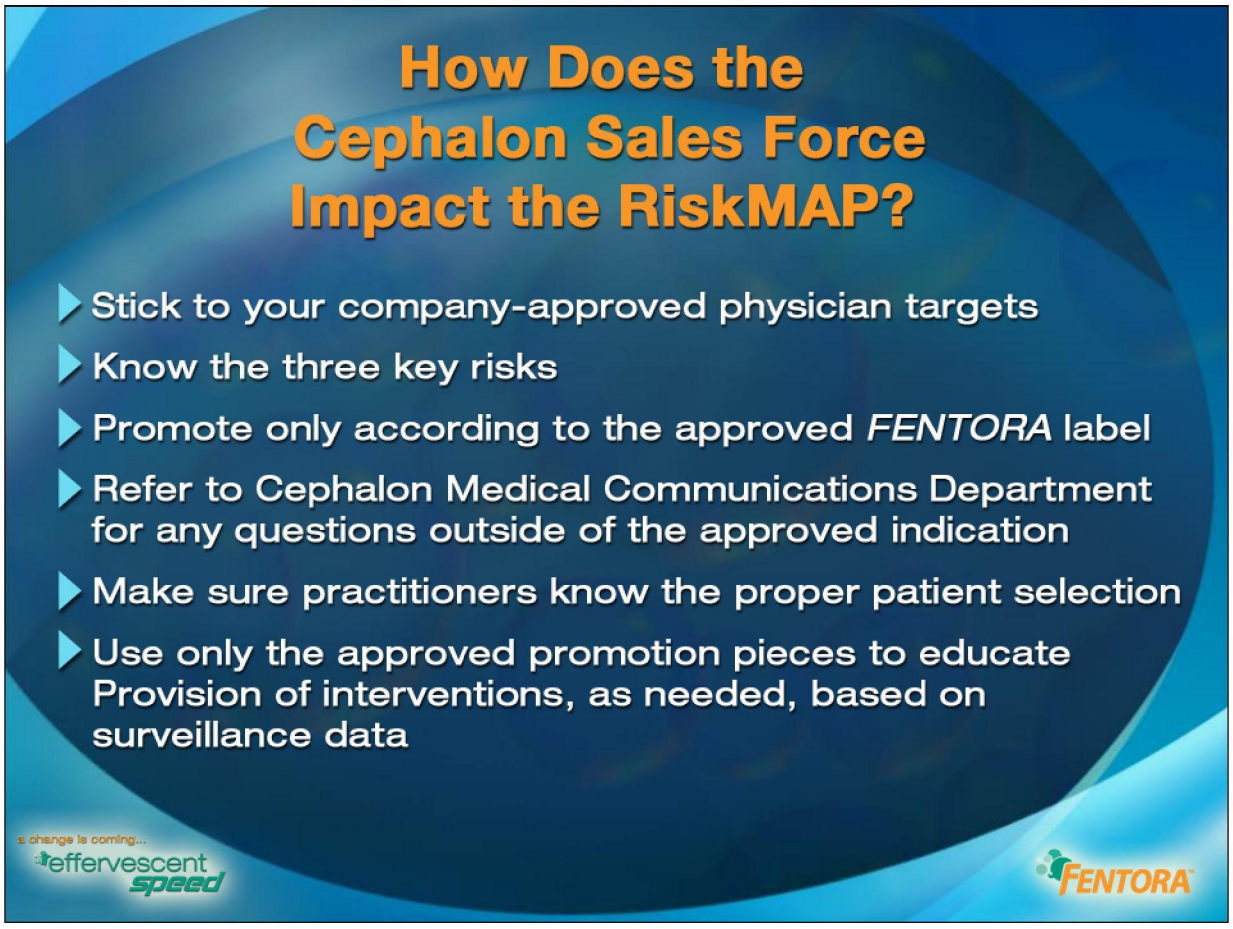
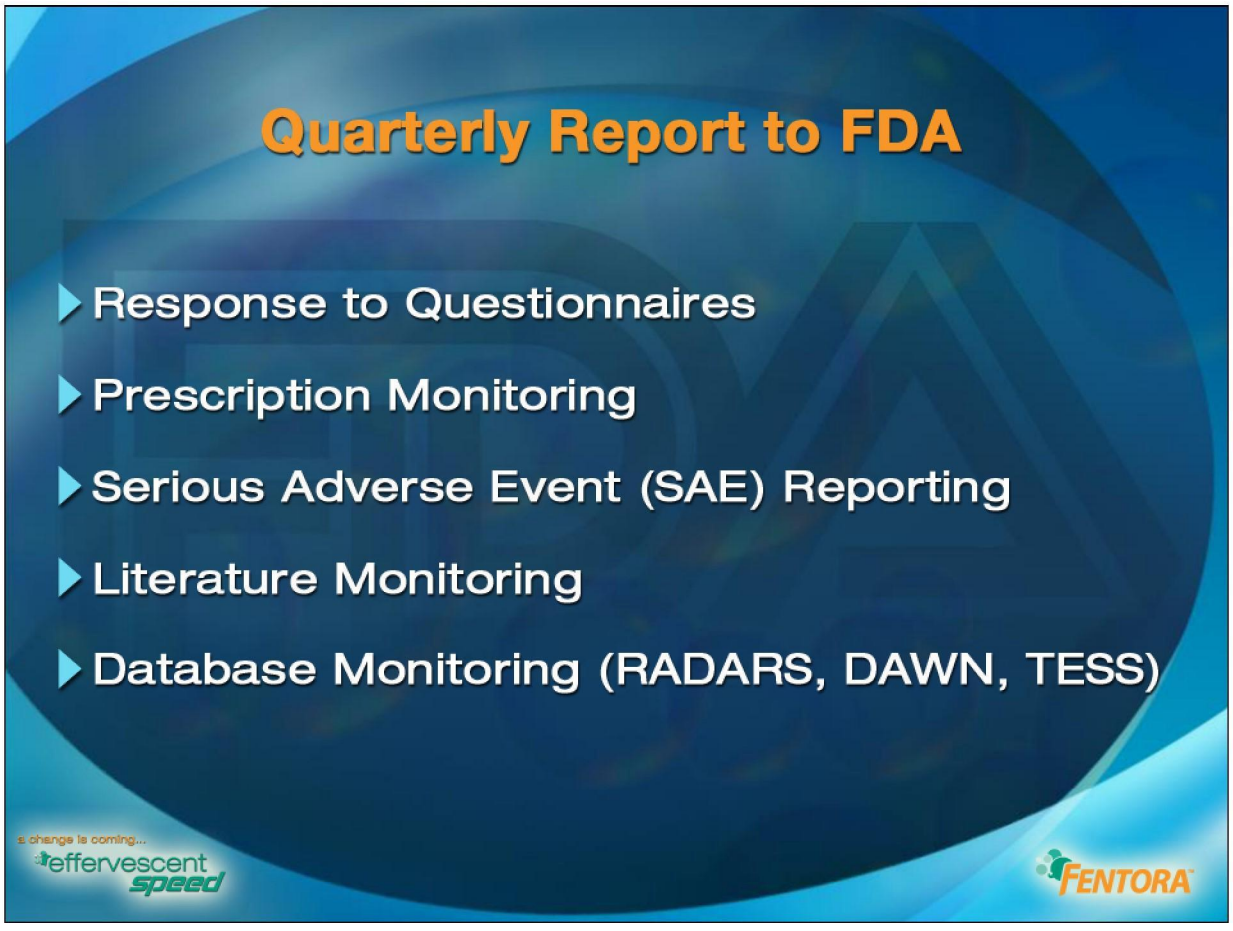
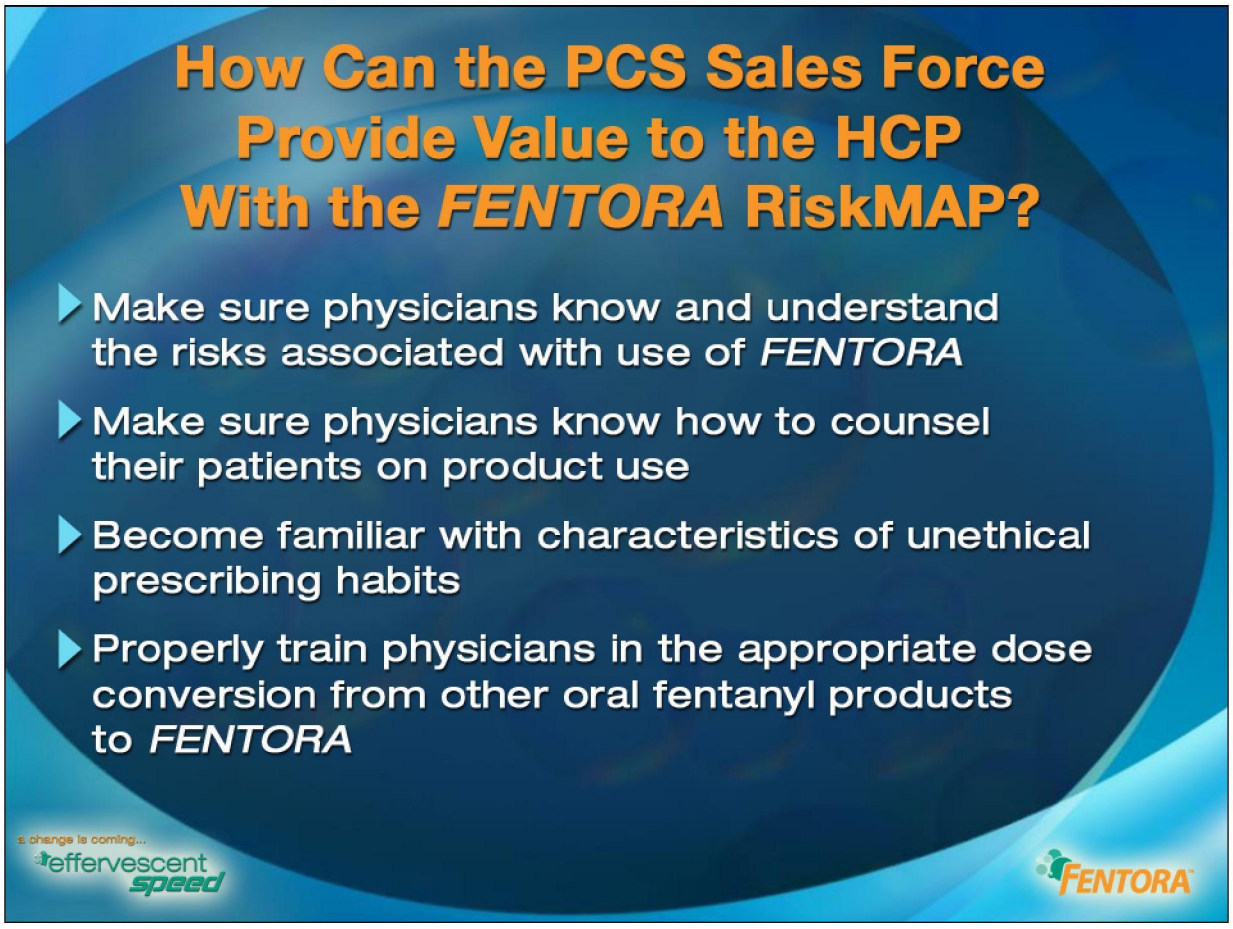



As part of the RiskMAP requirements, there is a Promotional Message Audit conducted 2x annually
Preclearance of core promotional pieces was submitted to DDMAC in efforts to get their feedback prior to launch




The following information listed on the next two slides are provided to FDA on a quarterly basis in a report that is usually between 20 and 25 pgs in length.

Patients who receive an FENTORA prescription at a participating pharmacy will receive a follow-up phone call by a company pharmacist and are asked these questions. They are also reminded about FENTORA's indication; child safety reminders and are given the toll-free number to ask any questions pertaining to the product.
Prescription information are captured in databases and prescribing specialties are monitored segmented by physician specialty to determine prescribing trends.
SAEs are reported for non opioid tolerant population, all unintended pediatric exposures and any SAEs related to diversion.
Literature is monitored for SAEs or pediatric exposure; this is something that is not required for other products
TESS – reviews poison center database for exposure (unusual ingestion, etc. )
Review of Drug Abuse Warning Network (DAWN) – this is voluntary national data collection system that gathers information on substance abuse resulting in an ER visit




The PI recommends that the 1st Rx is for the lowest dose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