

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals:

Fentanyl Transdermal System:

Recall - Potential for Active Ingredient to Release Faster Than Specified

AUDIENCE: Pharmacist, Anesthesia

ISSUE: FDA notified healthcare professionals and patients that laboratory testing identified a patch that released its active ingredient faster than the approved specification. An accelerated release of Fentanyl can lead to adverse events for at-risk patients, including excessive sedation, respiratory depression, hypoventilation (slow breathing), and apnea (temporary suspension of breathing).

BACKGROUND: Fentanyl Transdermal System is indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate release opioids. The product is manufactured for Actavis by Corium International in the United States.

RECOMMENDATION: Wholesalers and retailers are being asked to return the product they have on hand or in stock. See the Press Release for recalled product lots. The Control/Lot number appears on the bottom of the product box and on the black and white side of each individual patch packaging, in the lower left corner.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the company Press Release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm230639.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful

to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.