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FDA Approves Class-based REMS (fentanyl citrate products)

NOTICE

On December 28, 2011, the FDA approved the first class-based REMS program for all fentanyl citrate products, known as the TIRF REMS Access program. The TIRF REMS is scheduled to become active in March 2012 replacing all current fentanyl citrate REMS programs.

BACKGROUND

The FDA Amendments Act (FDAAA) of 2007 granted the FDA with the authority to require that a manufacturer implement a REMS, or Risk Evaluation and Mitigation Strategy, when a medication's risk-to-benefit ratio can only be achieved when special training is provided to individuals involved in the direct prescribing, dispensing, or utilization of certain prescription medications. The ultimate goal of REMS is to prevent inappropriate prescribing, reduce the risk of abuse by patients, and to ensure that patient education occurs in a timely fashion. Unfortunately, the FDA has been reluctant to provide specific guidelines for what components a REMS must possess; thereby, making inferences about future drug product requirements difficult to predict. Due to significant clinical issues surrounding the use of fentanyl citrate products, such as a rapid onset of action and previous drug-related fatalities, recently approved newcomers to the fentanyl citrate market (i.e. Abstral and Onsolis) have been required to incorporate REMS into their drug approval process. In order to ensure consistency across all medications containing this opioid analgesic, previously approved fentanyl citrate products, such as Actiq and Fentora were instructed to implement REMS as part of their continued FDA-approval status. In December 2011, the FDA announced that it had approved a fentanyl citrate-based REMS program that would be required for all products containing fentanyl citrate in an effort to streamline the REMS process and encourage provider and patient program compliance. Scheduled for a "go-live" date of March 2012, the TIRF REMS represents the first FDA REMS program designed to incorporate all current and future drug products containing fentanyl citrate.

RECOMMENDED ACTIONS

The TIRF REMS program will require that prescribers, pharmacies, and patients review educational materials and become active registrants of the program in order to prescribe, dispense, and receive fentanyl citrate products, regardless of the product name or manufacturer. Registrants will be required to re-enroll in the REMS program every two years, ensuring that ongoing education is received. Due to the program's March 2012 activation date, no action is required at this time. Once active, all registrants of current fentanyl citrate REMS programs will automatically be enrolled in the TIRF REMS program. PMSI's Mail Order Pharmacy will take all the necessary steps to comply with all REMS requirements as soon as they have been disclosed according to the FDA's specified timeline. It is expected that the FDA will continue to work with drug manufacturers to approve similar REMS programs for other opioid analgesics in the near future.

Reference: Questions and Answers: FDA Approves a Class Risk Evaluation and Mitigation Strategy (REMS) for Transmucosal Immediate-Release Fentanyl (TIRF) Medicines. FDA. <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm284717.htm> <Accessed January 5, 2012>

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