FDA issues Tussionex safety alert

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The U.S. Food and Drug Administration issued a safety alert, saying incorrect usage of a specific cough medicine can result in serious health risks.

The FDA said its alert concerns the safe and correct use of Tussionex Pennkinetic Extended-Release Suspension -- a prescription cough medicine containing hydrocodone, a narcotic ingredient and the antihistamine chlorpheniramine. The product is approved for use in adults and children over the age of 6 and should be given no more frequently than every 12 hours.

"There is a real and serious risk for overdosing if this medication is not used according to the labeling," said Dr. Curtis Rosebraugh, acting director of the FDA's Office of Drug Evaluation II.

The FDA said adverse event reports associated with Tussionex have included life-threatening side effects and deaths in patients, including children, resulting from taking more than the recommended dose or taking the medication more frequently than every 12 hours.

The federal agency said reports also show Tussionex is sometimes prescribed or given to children younger than 6 years, for whom the medication isn't approved.

Tussionex Pennkinetic Extended-Release Suspension is manufactured by UCB Inc. of Smyrna, Ga.