

FDA cracks down on hydrocone products

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The U.S. Food and Drug Administration says it will start taking enforcement action against companies marketing unapproved hydrocodone products.

About 200 cough-suppressant products on the market will be impacted, the FDA said Friday in a release.

Hydrocodone, a narcotic widely used to treat pain and suppress coughs, can lead to serious illness, injury or death if improperly used.

While some hydrocodone-relief products such as Vicodin are FDA-approved, most hydrocodone formulations now marketed to suppress coughs are not.

The agency said it is especially concerned about improper pediatric labeling of unapproved hydrocodone cough suppressants, and the risk of medication error involving the unapproved products. Dr. Steven K. Galson, director of the FDA's Center for Drug Evaluation and Research, said no hydrocodone cough suppressant has been established as safe and effective for children under 6.

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