



## FDA News

### FOR IMMEDIATE RELEASE

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### **FDA Takes Action to Stop Marketing of Unapproved Hydrocodone Products** *Action to impact approximately 200 cough-suppressant products*

The U.S. Food and Drug Administration today announced its intention to take enforcement action against companies marketing unapproved prescription drug products containing hydrocodone, a narcotic widely used to treat pain and suppress coughs. The action does not affect other hydrocodone formulations, which have FDA approval.

Hydrocodone is one of the strongest medications available to treat pain or to suppress cough. The drug has also been an extremely popular drug of abuse and can lead to serious illness, injury, or death, if improperly used. Hydrocodone overdose can result in breathing problems or cardiac arrest, and its use may impair motor skills and judgment.

The FDA has received reports of medication errors associated with formulation changes in unapproved hydrocodone products and reports of confusion over the similarity of the names of unapproved products to approved drug products. As part of the drug approval process, the agency considers the possibility of medication errors and name confusion, so that potential safety issues associated with these factors can be minimized.

Some hydrocodone pain-relief products, such as Vicodin, are FDA-approved. However, most of the hydrocodone formulations now marketed to suppress coughs have not been approved. The agency is particularly concerned about improper pediatric labeling of unapproved hydrocodone cough suppressants (also known as antitussives), and the risk of medication error involving the unapproved products.

"Companies marketing these unapproved products have not demonstrated the safety and efficacy of these drugs," said Steven K. Galson, M.D., M.P.H., director of the FDA's Center for Drug Evaluation and Research (CDER). "A case in point – no hydrocodone cough suppressant has been established as safe and effective for children under 6 years of age and some of these unapproved products carry labels with dosing instructions for children as young as 2 years of age."

Today's action is part of FDA's broader initiative on marketed unapproved drugs that was announced in June 2006. At that time, the agency published a Compliance Policy Guide describing the FDA's risk-based enforcement approach to these products.

"This is another example of the kinds of safety risks that warrant priority enforcement under our Compliance Policy Guide," said Deborah M. Autor, J.D., director of CDER's Office of Compliance. "There are products on the market with inadequate safety information on their labeling improperly suggesting that the products may be used safely by very young children. In addition, these products may pose a higher risk of medication error than approved products. These products need to come off the market until they meet FDA approval standards."

There are a number of alternatives for patients who might be using unapproved hydrocodone cough suppressants. There are seven FDA-approved cough suppressant products containing hydrocodone. There also are a variety of approved antitussive products that do not contain hydrocodone. Consumers should consult a health care professional for detailed guidance on treatment options.

Anyone marketing unapproved hydrocodone products that are currently labeled for use in children younger than 6 years of age must end further manufacturing and distribution of the products on or before October 31, 2007. Those marketing any other unapproved hydrocodone drug products must stop manufacturing such products on or before December 31, 2007 and must cease further shipment in interstate commerce on or before March 31, 2008. Further legal action could be taken against those failing to meet these deadlines.

For more information:

[Hydrocodone Drug Products Information](#)