

**To Print: Click your browser's PRINT button.**

**NOTE:** To view the article with Web enhancements, go to:  
<http://www.medscape.com/viewarticle/563604>



## FDA to Crack Down on Unapproved Drugs Containing Hydrocodone

**Miranda Hitti**

Medscape Medical News 2007. © 2007 Medscape

October 1, 2007 — The US Food and Drug Administration (FDA) plans to crack down on unapproved prescription drug products — including some 200 cough suppressants — containing hydrocodone.

Hydrocodone is a narcotic widely used to treat pain and suppress coughs. The FDA is particularly concerned about unapproved hydrocodone cough suppressants (antitussives) marketed for kids, as well as the risk of medication errors involving unapproved products.

On September 28, the FDA announced deadlines for companies to stop marketing unapproved hydrocodone products. FDA-approved hydrocodone drugs including the painkiller Vicodin aren't affected.

Consumers have some alternatives to unapproved hydrocodone cough suppressants. The FDA says the approved products are *Tussicaps* (Tyco Healthcare), *Tussionex Pennkinetic* (UCB Inc), *Hydrocodone Compound* (Actavis Mid Atlantic), *Mycodone* (Morton Grove), *Homatropine Methylbromide* and *Hydrocodone Bitartrate* (Actavis Totowa), *Hycodan* (Endo Pharms), and *Tussigon* (King Pharmaceuticals).

There also are various FDA-approved antitussive products that do not contain hydrocodone. The FDA advises consumers to consult a healthcare professional for detailed guidance on treatment options.

### About Hydrocodone

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 those of approved drug products.

As part of the drug approval process, the FDA considers the possibility of medication errors and name confusion so that potential safety issues associated with these factors can be minimized.

### Approved Drugs Not Affected

Some hydrocodone pain-relief products are FDA approved, but most hydrocodone formulations marketed to suppress coughs have not been approved by the FDA.

"Companies marketing these unapproved products have not demonstrated the safety and efficacy of these drugs," the FDA's Steven Galson, MD, MPH, says in a news release.

"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," says Galson, who directs the FDA's Center for Drug Evaluation and Research.

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.

Failure to heed those deadlines may draw FDA enforcement.

---