

[CDER Home](#)[About CDER](#)[Drug Information](#)[Regulatory Guidance](#)[CDER Calendar](#)[Specific Audiences](#)[CDER Archives](#)

Search



powered by Google™

## Questions and Answers About FDA's Enforcement Action Regarding Unapproved Hydrocodone Drug Products

### 1. What action is FDA taking regarding hydrocodone drug products?

The Food and Drug Administration (FDA) is publishing a notice in the Federal Register on October 1, 2007 that directs companies to stop making and distributing any **unapproved** drug product containing hydrocodone bitartrate, or any other salt or ester of hydrocodone. The action applies to any drug product containing hydrocodone that lacks the required FDA approval, including both products marketed as cough suppressants and any unapproved products marketed as pain relievers.

### 2. What is hydrocodone?

Hydrocodone is a semi-synthetic opioid, which acts as an analgesic (pain reliever) and as an antitussive (cough suppressant). It is one of the strongest and most widely-prescribed medications available for these uses. It can also produce feelings of euphoria, and is an extremely popular drug of abuse. The Drug Enforcement Administration has classified hydrocodone alone as a Schedule II narcotic. The drug products currently sold in the U.S. combine the hydrocodone with other drugs, and are classified as Schedule III controlled substances.

Hydrocodone is an addictive drug that can lead to serious illness, injury, or death if not used properly. For example, overdose can result in respiratory depression and cardiac arrest. In addition, normal use may impair motor skills or judgment, making it unsafe to operate machinery, drive, or engage in other potentially hazardous activities while taking the drug.

### 3. Why is FDA taking this action?

FDA is taking the action as part of its continuing effort to ensure that drugs marketed in the U.S. have the required FDA approval and that they are safe, effective, of good quality, and appropriately labeled. Some unapproved hydrocodone products may bear inadequate safety-related labeling or improperly suggest the drug is safe for young children. Unapproved versions also pose a greater risk of medication error than approved products. There are a variety of unapproved drugs on the market, and consistent with the policies FDA announced in June 2006, unapproved drugs that may pose safety risks are among the agency's higher priorities.

### 4. What effect will FDA's action have on people who use products that contain hydrocodone? Are there alternatives?

Today's action will have the most impact on consumers who use unapproved cough suppressant products that contain hydrocodone. It appears that the many currently-marketed hydrocodone pain relief products (e.g., Vicodin) that are listed with the agency have FDA-approved applications. Most of the hydrocodone cough suppressants on the market, however, lack FDA approval.

There are seven FDA approvals for cough suppressant products containing hydrocodone (see attachment), including both tablet and syrup dosage forms. There are also a number of antitussive products, both prescription and OTC, that do not contain hydrocodone. Consumers should consult a healthcare professional for detailed guidance on the treatment options that are right for them.

### 5. Is it safe to use the unapproved products?

The safety of unapproved drugs is unknown. There are reports of adverse drug experiences specifically involving unapproved hydrocodone products. In particular, there are a number of reports, indicating medication errors, associated with changes in the formulation of the unapproved products, and also with confusion when the names of unapproved hydrocodone cough suppressants look or sound similar to the names of other drug products. In addition, some unapproved product labeling includes dosage instructions purportedly suitable for children as young as 2 years old, even though hydrocodone cough suppressants have not been proven safe or effective for children under 6 years old. The drug approval process enables FDA to evaluate the drug's formulation, manufacturing process, and labeling, as well any changes to the formulation, process, and labeling that occur after approval.

Unapproved drug products also have not been proven effective for their intended use. Many of the unapproved hydrocodone cough suppressants on the market contain hydrocodone with other purportedly active ingredients. Because no applications have been filed for them, FDA has not evaluated whether those combinations are safe or effective, or whether each ingredient makes a contribution to the drug's overall effect.

**6. How can people tell the difference between FDA-approved and unapproved products?**

The FDA-approved, immediate-release hydrocodone antitussive formulations contain only hydrocodone bitartrate and homatropine methylbromide. Proprietary names for these products include Hycodan, Mycodone, and Tussigon.

Some drug products do not use unique proprietary names. But cough suppressants that combine hydrocodone and homatropine with other drugs, like an expectorant such as guaifenesin, or a decongestant such as phenylephrine or pseudoephedrine, are currently unapproved.

Of the approved products noted above, two are extended-release antitussive formulations that contain hydrocodone polistirex and chlorpheniramine polistirex, an antihistamine. They are Tussionex Pennkinetic, a suspension, and Tussicaps, a capsule.

In addition, there is an approved product, Hydrocodone Bitartrate and Homatropine Methylbromide Syrup (application number 40-285, approved July 19, 1999), that was voluntarily discontinued by the manufacturer, IVAX, in December 2006.

**7. When is this action going to take effect?**


The Notice is effective immediately, but FDA will exercise its enforcement discretion for a brief period before evaluating whether to take any further action against a specific firm or individual. Firms must stop making and distributing products on or before October 31, 2007, that are labeled for use in children under the age of 6. Firms marketing any unapproved hydrocodone drug products that are not labeled for use in children under 6 must stop manufacturing new product on or before December 31, 2007, and must cease any new or further shipment on or before March 31, 2008. Companies or others engaged in manufacturing or shipping these products may use these periods to wind down their activities. Unapproved formulations may still appear on pharmacy shelves for a period after these deadlines pass.

**Approved Antitussive Products Containing Hydrocodone**

Application Number	Ingredients	Dosage Form	Ingredient Strengths	Products Name	Applicant
<a href="#">077273</a>	CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX	CAPSULE, EXTENDED RELEASE; ORAL	EQ 8MG MALEATE;EQ 10MG BITRATRATE  EQ 4MG MALEATE;EQ 5MG BITARTRATE	TUSSICAPS	TYCO HLTHCARE
<a href="#">019111</a>	CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX	SUSPENSION, EXTENDED RELEASE; ORAL	EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML	TUSSIONEX PENNKINETIC	UCB INC

<a href="#">088017</a>	HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE	SYRUP; ORAL	1.5MG/5ML;5MG/5ML	HYDROCODONE COMPOUND	ACTAVIS MID ATLANTIC
<a href="#">088008</a>	HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE	SYRUP; ORAL	1.5MG/5ML;5MG/5ML	MYCODONE	MORTON GROVE
<a href="#">040295</a>	HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE	TABLET; ORAL	1.5MG;5MG	HOMATROPRINE METHYLBROMIDE AND HYDROCODONE BITARTRATE	ACTAVIS TOTOWA
<a href="#">005213</a>	HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE	TABLET; ORAL SYRUP; ORAL	1.5MG;5MG 1.5MG/5ML;5MG/5ML	HYCODAN	ENDO PHARMS
<a href="#">088508</a>	HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE	TABLET; ORAL	1.5MG;5MG	TUSSIGON	KING PHARMS

[↑ Back to Top](#)   [↩ Back to Unapproved Drugs](#)

 PDF requires the free [Adobe Acrobat Reader](#)

Date created: September 28, 2007, updated October 1, 2007

---

[CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)  
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#) | [HHS Home Page](#)

FDA/Center for Drug Evaluation and Research