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FDA Experts Urge Ban on Cold Medicines for Young Children

Safety review finds 123 deaths linked to the products since 1969

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SATURDAY, Sept. 29 (HealthDay News) -- U.S. health experts on Friday urged the federal Food and Drug Administration to consider banning the sale of over-the-counter cough and cold medicines for young children.

The recommendation, from FDA safety officials, would apply to decongestant use in children under 2, and antihistamines in those younger than 6, according to agency documents released Friday, the *Associated Press* reported.

The products include approximately 800 popular medicines that are sold in the United States under names like Toddler's Dimetapp, Triaminic Infant and Little Colds, *The New York Times* reported.

A group of outside experts advising the FDA will consider the recommendation during a meeting on Oct. 18 and 19, and will then offer an opinion to the full agency.

In the safety review released Friday, the FDA experts recommended that all infant cough and cold products be removed from the market. They also recommended that the sizes of the droppers, cups and syringes packaged with products be standardized to reduce the possibility of confusion and overdose, the *Times* said.

An FDA review of records filed with the agency between 1969 and September 2006 found 54 reports of deaths in children associated with decongestant medicines made with pseudoephedrine, phenylephrine or ephedrine. It also found 69 reports of deaths associated with antihistamine medicines containing diphenhydramine, brompheniramine or chlorpheniramine, the *AP* said.

Most of the deaths were children younger than 2.

The Consumer Healthcare Products Association, which represents makers of over-the-counter medicines, backs the recommendation that the cold and cough treatments not be used in children younger than 2. As for antihistamines, the group recommends adding a warning that the drugs not be used to sedate young children, the *AP* said.

Also Friday, FDA officials announced a crackdown on drug companies that make unapproved prescription drugs containing the narcotic hydrocodone, which is used as a cough suppressant and pain killer.

Hydrocodone is one of the strongest drugs used to treat pain or to suppress cough. It's also widely abused and, if improperly used, can lead to illness and death. Overdoses of hydrocodone can cause breathing problems or cardiac arrest and can impair motor skills and judgment, U.S. Food and Drug Administration officials said.

"The FDA is announcing an action to stop the illegal marketing of any unapproved drug product containing hydrocodone," Deborah M. Autor, director of the agency's Office of Compliance, Center for Drug Evaluation and Research, said during a Friday teleconference.

Some pain-relief products containing hydrocodone, such as Vicodin, are FDA-approved. But most of the drugs with hydrocodone now marketed to suppress coughs have not been approved, officials said.

Autor said the unapproved products are made by some 100 manufacturers.

The FDA said it was particularly concerned about improper pediatric labeling of unapproved hydrocodone cough suppressants -- also known as antitussives. None of the drugs that contain hydrocodone has been approved for children younger than 2 years old.

"There are hydrocodone-containing products on the market that claim they are suitable for children as young as 2," Autor said.

Also, many of the products don't carry the proper warning label and often have similar names to other medications, creating a high risk of medication error, Autor added.

"Product names are so similar that the wrong doses or wrong medication may be dispensed," she said.

Hydrocodone is a narcotic regulated by the U.S. Drug Enforcement Administration, Autor said.

Friday's announcement came one day after President George W. Bush signed a five-year renewal of a law that helps fund the FDA's ability to oversee prescription drug safety.

The new law allows the FDA to collect higher fees from drug and medical device makers, which helps defray the agency's costs of reviewing products submitted for approval. The law also gives the agency more powers to take action when there are problems with drugs already on the market. For example, the FDA can order drug companies to do further studies on the safety of medicine and to put new label warnings on products. The agency now has the authority to fine companies that fail to comply with such orders.

Under the new law, the Food and Drug Administration Amendments Act of 2007, drug and medical device companies must also publicly release results of all clinical trials that show how well approved drugs performed, according to published reports.

But the FDA's ability to oversee clinical trials was called into question Friday with the release of a highly critical report by the inspector general of the U.S. Department of Health and Human Services.

In the report, Daniel R. Levinson said he found that FDA officials didn't know how many clinical trials were being conducted and audited fewer than 1 percent of clinical testing sites. In the few instances where FDA inspectors did check a site, they generally showed up long after the tests had been completed, Levinson noted, the *Times* reported.

The FDA has 200 inspectors to monitor about 350,000 testing sites. Even when inspectors identified serious problems in human clinical trials, top FDA officials downgraded the inspectors' findings 68 percent of the time, Levinson found. In the rest of the cases, it was rare for the FDA to follow up with inspections to assess whether corrective actions ordered by the agency had been done, the *Times* reported.

The Levinson report echoes other recent criticisms of the FDA's oversight of imported food, foreign drug manufacturers, animal food and medication safety.

In announcing Friday's decision on hydrocodone, the FDA said it was prompted to take the action because it had received reports of "medication errors associated with unapproved hydrocodone products and reports of confusion over the similarity of the names of unapproved products to approved drug products."

Autor said that about 2 percent of all prescriptions written in the United States are for unapproved drugs. With some 200 unapproved drugs containing hydrocodone on the market, it's highly likely that most of the prescriptions for cough medicines that contain hydrocodone are for unapproved brands, she said.

Currently, she added, the approved cough medications containing hydrocodone are: TussiCaps, Tussionex Pennkinetic, Hydrocodone Compound, Mycodone Homatropine Methylbromide, Hycodan, Tussion, and Vicodin.

According to the FDA, companies marketing unapproved hydrocodone products that are labeled for use in children younger than 6 years of age must stop manufacturing and distributing the products by Oct. 31.

Companies making other unapproved hydrocodone drug products must stop manufacturing such products on or before Dec. 31, 2007, and must "cease further shipment in interstate commerce on or before March 31, 2008."

The FDA said there are alternatives to unapproved hydrocodone-containing products. These include one of the seven approved cough medicines that contain hydrocodone as well as other cough suppressants that don't use hydrocodone.

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