

# FDA Pulls 500 Cold Medicines From the Market

March 2, 2011

The FDA today announced steps to remove more than 500 prescription cold, cough, and allergy products from the market because of potential safety concerns.

The FDA asked companies to stop manufacturing the 500 products within 90 days and stop shipping them within 180 days. Some manufacturers must stop making and shipping their products immediately, the FDA warns.

There are no data on how often these now-banned medications are prescribed today, but many doctors may be unaware that they contain unapproved ingredients because these drugs are listed in the *Physicians' Desk Reference* and may be advertised in medical journals.

## Questions on Drug Safety

The FDA does not know if these prescription drugs are safe or not largely because they were grandfathered in before changes to the FDA's drug approval process were enacted.

"We don't know what they are, whether they work properly, or how they are made," said Deborah M. Autor, director of the FDA's Office of Compliance at the Center for Drug Evaluation and Research (CDER) in Silver Spring, Md., during a teleconference. "The problem is that we don't know what the problem is."

For example, some of these cough, cold, and allergy drugs are labeled as "time-release." These are complicated to manufacture, and the FDA has not reviewed whether the active ingredient is released in a consistent matter over a period of time, she says. "They may be released too slowly, too quickly, or not at all."

## Kids Under Age 2

Others contain an "irrational" combination of the same types of products, such as two or more antihistamines, and some are inappropriately labeled for use by infants and young children, she says. Many contain the same ingredients as the over-the-counter cough and cold products that are no longer supposed to be used in kids under 2.

Yolandra Hancock, MD, a pediatrician at Children's National Medical Center in Washington, D.C., praises the FDA's move.

"The new FDA decision supports modern-day pediatric practice to avoid cough syrups in children under 2 because they do more harm than good," she says. Some may slow down breathing, and others decrease cough and allow mucus to sit in the chest, where it can cause other problems such as lung infection, she says.

"I fully support the FDA's move in controlling access to these medications in children; it is highly appropriate and long overdue," she says.

As to the risks these drugs pose, "for the most part, [these adverse reactions] are not serious," says Charles E. Lee, MD, medical officer of the division of new drugs and labeling compliance at the CDER.

After the FDA crackdown on the use of over-the-counter cough and cold medicine in children younger than 2, the number of emergency room visits for adverse events decreased by 50%, he says.

"We also know that 15% of these events came from prescription cough, cold, and allergy products and included sedation/drowsiness and irritability," Lee says.

Dr. Bob's Comments:

**"DRUGS DO NOT HAVE BRAINS TO CONTROL THEIR ACTIONS"**

