

Using Over-the-Counter Cough and Cold Products in Children

On Oct. 8, 2008, the Food and Drug Administration (FDA) released a statement that supports recent voluntary actions by many drug manufacturers regarding the use of nonprescription, over-the-counter (OTC) cough and cold products in children.

The voluntary actions announced by the Consumer Healthcare Products Association (CHPA) are intended to help prevent and reduce the misuse of these products in children and to better inform consumers about their safe and effective use. CHPA represents most of the manufacturers of these products.

Members of CHPA have volunteered to modify the product labels of OTC cough and cold medicines to state "do not use" in children under 4 years of age. (Many of the products currently state "do not use" in children under 2 years of age.) Additionally, the manufacturers are introducing new child-resistant packaging and new measuring devices for use with the products.

CHPA's voluntary actions will not affect the availability of the medicines, but will result in a transition period where the instructions for using some OTC cough and cold medicines in children will be different from others. Some product instructions will state "do not use" in children under 4 years of age, while others will instruct not to use in children under 2 years of age.

FDA does not typically request that OTC products with previous labeling be removed from the shelves during a voluntary label change such as this one. The agency recommends following the



Tips for Parents & Caregivers

1. Don't give children adult medicines.
2. Talk to your health care professional first.
3. Choose child-resistant safety caps.
4. Check the active ingredients.
5. Never give two or more medicines if they contain the same active ingredients.
6. Follow the directions.
7. Only use measuring devices made for measuring medicine.
8. Understand that cough and cold medicines only treat the symptoms.

See details on next page ...

Understand that using OTC cough and cold medicines does not cure the cold or cough.

dosage instructions and warnings on the label that accompanies the medication if you have or buy a product that does not have the voluntarily modified labeling.

Recent FDA Actions

- FDA has held two public meetings over the past year on the safe use of nonprescription OTC cough and cold medicines in children. The most recent meeting on Oct. 2, 2008, focused on labeling of these products.
- FDA issued a nationwide Public Health Advisory in January 2008 recommending that these products not be used in children under the age of 2 because of the risk of serious and potentially life-threatening side effects.
- FDA continues to reach out to other public health agencies, consumer and patient groups, drug manufacturers, CHPA, and the scientific community. As it obtains more up-to-date information and scientific data about the safety and effectiveness of these products in children, FDA can take the appropriate regulatory steps moving forward.

Tips for Parents and Caregivers

1. Do not give children medications labeled only for adults.
2. Talk to your health care professional, such as your doctor or pharmacist, if you have any questions about using cough or cold medicines in children.
3. Choose OTC cough and cold medicines with child-resistant safety caps, when available. After each use, make sure to close

the cap tightly and store the medicines out of the sight and reach of children.

4. Check the "active ingredients" section of the "Drug Facts" label of the medicines that you choose. This section will help you understand what symptoms the active ingredients in the medicine are intended to treat. Cough and cold medicines often have more than one active ingredient, such as an antihistamine, a decongestant, a cough suppressant, an expectorant, or a pain reliever and fever reducer.
5. Be very careful if you are giving more than one medicine to a child. Make sure the medicines do not have the same type of active ingredients. For example, do not give a child more than one medicine that has a decongestant. If you use two medicines that have the same or similar active ingredients, your child could be harmed by getting too much of an ingredient.
6. Carefully follow the directions for how to use the medicine in the "Drug Facts" part of the label. These directions tell you how much medicine to give and how often you can give it. If you have a question about how to use the medicine, ask your pharmacist or other health care professional. Overuse or misuse of these products can lead to serious and potentially life-threatening side effects, such as rapid heartbeat, drowsiness, breathing problems, and seizures.
7. Only use measuring devices that come with the medicine or those

specially made for measuring drugs. Do not use household spoons to measure medicines for children because household spoons come in different sizes and are not meant for measuring medicines.

8. Understand that using OTC cough and cold medicines does not cure the cold or cough. These medicines only treat your child's symptoms, such as runny nose, congestion, fever, and aches. They do not shorten the length of time your child is sick. [FDA](#)

This article appears on FDA's Consumer Health Information Web page (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

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Safe Use of Over-the-Counter Drug Products
www.fda.gov/cder/offices/otc/consumer.htm

FDA 101: How to Use the Consumer Complaint System and MedWatch
www.fda.gov/consumer/updates/reporting061008.html

Your Guide to Reporting Problems to FDA
www.fda.gov/consumer/updates/reporting_guide061008.html

Improving Medical Products for Children: Q & A with Dianne Murphy, M.D.
www.fda.gov/consumer/updates/murphy091407.html