



FDA: Cough and Cold Medicines for Children

As we approach the cold weather, you may see your kids sniffing more, having sore throats and stuffy noses.

Choosing the appropriate remedy from a wide variety of over-the-counter medications is an important choice for parents. Over the past year there has been a lot of communication about whether or not these products should be used to treat children. The rules for marketing many of these products were developed many years ago. These rules do not always require that the products be studied in children to show whether they work for children but instead allow conclusions from experience of their effectiveness in adults.

MyTake is that we must now understand scientifically that children are

not just little adults. Current scientific standards must be used to assure these medications are effective and safe for your children in the correct prescribed dose to treat your child's cough and cold.

FDA has been gathering information on these products, and we have held two public meetings with stakeholders. Thus far, we have recommended that these products not be used in children under the age of two because of concerns about serious and potentially life-threatening side effects.

In the meantime, manufacturers are taking voluntary actions. Some have announced that they will change the labeling of these products to include the statement "do not use" in children under four years of age. Manufacturers are also introducing other ways to help better inform consumers and to prevent misuse – such as

new child-resistant packaging and new measuring devices for use with these products.

One thing is for certain: we must not give children medication labeled only for adults. And, when deciding on the right doses for children we need to rely on modern scientific standards.

While the FDA works to gather data and revise the labeling of certain ingredients and dosing for cough and cold products for children, please consult with your doctor or pharmacist with your particular questions about the use of these medications for your child or grandchild. www.fda.gov/bbs/topics/NEWS/2008/NEW01899.html.

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About Andy's Take

Through this communications column on the FDA Web site, Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., will discuss weekly FDA issues of interest to the American consumer and occasionally preview upcoming FDA issues and events.



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