

## FDA weighs new dose info for kids' pain relievers (Update)

May 13 2011, By MATTHEW PERRONE , AP Health Writer

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(AP) -- Federal health officials are considering adding dosing instructions for children younger than 2 years old to Children's Tylenol and similar products, a change favored by drugmakers and many doctors.

The Food and Drug Administration meets next week to consider changes to children's over-the-counter formulas containing acetaminophen, the most common pain reliever and fever-reducing ingredient. While safe when used as directed, acetaminophen has long been subject to warning labels because of its potential to cause liver damage when overused.

Next week's meeting will focus on a small group of liquid medicines, including Children and Infants' Tylenol, Triaminic, Little Fevers and various drugstore brands. These products have never contained dosing information for children younger than 2 because of the liver risk and to encourage parents to seek medical attention for sick infants.

In documents posted Friday, the FDA said it will ask an outside panel whether that policy should be changed. An analysis by the agency showed that the majority of acetaminophen overdoses in children are in those younger than 2. FDA staffers said the most common causes for the problems include: parents misreading dosing information, giving an adult formula to a child or using a spoon or other administration device instead of the cup included with the formula.

The FDA will also consider requiring weight-based dosing instructions alongside age-based instructions on packaging, along with a universal

measuring cup for all children's formulas. Nearly all manufacturers have already taken those steps voluntarily, but an FDA regulation would make them mandatory.

The lack of instructions for the youngest children - an FDA requirement since the 1950s - is intended to point parents toward professional advice, but some experts say it causes more confusion and stress than anything else.

"I don't know if it worked 30 years ago - I doubt it - but it certainly doesn't work today because you can't get your doctor on the phone," said Dr. Richard Dart, president of the American Association of Poison Control Centers. "It places this enormous burden on parents and caregivers because they don't know what to do."

Dosing errors with children's acetaminophen products accounted for 2.8 percent, or 7,500, of the 270,165 emergencies reported to poison centers last year, according to Dart's group.

Johnson & Johnson and other manufacturers will point out next week that all other drug ingredients approved for children, including ibuprofen, already carry dosing information for children younger than 2.

Currently parents can get acetaminophen dosing information for babies through a doctor, pharmacist or various educational websites.

"It's available almost everywhere besides the product label, and this is simply another location for parents to find it when they need it," said Barbara Kochanowski, vice president for regulatory affairs at the Consumer Healthcare Products Association. The trade association will represent the over-the-counter medicine industry at next week's meeting. Member companies include J&J, Novartis, Procter & Gamble Co. and makers of generic cold medicines.

Last week the group took the voluntary step of eliminating infant drops of acetaminophen drugs. For decades the industry marketed high-dose infant formula, usually delivered with a dropper, so that parents could give babies a smaller amount of liquid. But starting later this year manufacturers will switch all infant formulas to the same dosage used in children's acetaminophen products. They will also replace the dropper with a syringe, which is thought to be a more accurate measuring device.

Those actions and others are expected to gain support from medical groups presenting next week, including the American Academy of Pediatrics.

"If there are data out there to support ways we can make these products safer and easier to use, the academy will support that," said Dr. Daniel Frattarelli of Dearborn, Mich., who chairs the academy's drug committee.

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