

OTC Cough Medicines Nixed for Children Under 2

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The Food and Drug Administration has released a public health advisory strongly recommending against the use of over-the-counter cough and cold products in children and infants aged under 2 years, but will not issue recommendations until the spring about the use of these products in children aged 2-11 years.

During a telebriefing, Dr. Charles Gan-

ley, director of the FDA's Office of Nonprescription Products, said that the agency had completed its safety review of these products in children aged under 2 years and concluded that the products should not be used in this age group because of the risk of "serious and potentially life-threatening side effects." The advisory is based on a review of information the agency received about serious side effects—including deaths and seizures—associated with the use of these products in

children this young. Also contributing to the decision were discussions and recommendations made at the FDA's Nonprescription Drugs Advisory Committee and Pediatric Advisory Committee joint meeting in October 2007, where the advisory panel members agreed that there was no available scientific evidence that these products were safe and effective in children aged under 12 years, and they voted 21-1 that these products should not be used in children under age 2.

Still pending, however, is the final decision about the use of over-the-counter (OTC) cough and cold products in children aged 2-11 years. An internal working group is continuing to deliberate over what to recommend for this age group.

At the October meeting, the panels voted 13-9 that these products should not be used in children aged 2-5 years, but they voted 15-7 in favor of keeping them available for children aged 6-11 years. Dr. Ganley said that there was debate over differences of opinion among the working group, which has been reviewing this issue since the panel meeting in October. The agency plans to make final recommendations in the spring, he said.

But the group unanimously agreed that the data in children under 2 years raised significant concerns and that OTC cough and cold products should not be used in this age group. Part of the reason the FDA decided to release the advisory now is that it is the middle of cough and cold season and there is evidence that parents and caregivers of children may be continuing to administer these products to children under age 2 without consulting their health care providers, according to Dr. Ganley.

He referred to a survey of parents of children younger than 2 years of age—conducted by National Public Radio, the Kaiser Family Foundation, and the Harvard School of Public Health in November 2007. When asked what best described their reaction to the recent news about the safety and effectiveness of the OTC cough and cold products for children, 20% said they planned to continue using these products, 26% were undecided, and 15% had not heard about the discussions. (Sixteen percent said they planned to stop using these products, 22% said they had never used or planned to use them, and 1% were in the "other" category.)

And at a workshop on OTC product use among adolescents, held by the FDA and Consumer Healthcare Products Association (CHPA) last fall, a survey of parents aged 16-25 years with infants younger than 12 months of age found that 86% considered the use of OTC cough and cold medications appropriate for children under age 2 years, without consulting a physician. "That's the problem we're trying to address today," Dr. Ganley said.

The agency has never endorsed the use of these products in children this young, and in the past, has left it up to the discretion of the health care provider to decide whether their use was appropriate. Shortly before the October panel meeting, manufacturers of products with wording and images of infants on the packaging of these products voluntarily pulled them off the market, and the CHPA and its member companies recommended to the FDA that the "ask a doctor" statement on the labels of these products be changed to "do not use" in children under age 2—a suggestion which is supported by the agency, he said. ■

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