# American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

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*Via Facsimile: 301-827-6870*

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

**Re: Docket No. 02F-0160**



To whom it may concern:

On behalf of the 57,000 members of the American Academy of Pediatrics (AAP), I offer the following objections to the Final Rule, *Food Additives Permitted for Direct Addition to Food for* 2003 (68 FR 9000).

The AAP is the national professional organization representing physicians who provide healthcare to our infants, children, and adolescents. In that role, the AAP has developed policy guidelines regarding fruit juice and juice drink consumption in these age groups. It is our position, first, that the increased intake of fruit juices and juice drinks would have adverse health effects on America's youth; and, second, that this FDA ruling would likely foster increased juice and juice drink intake in this vulnerable population.

In the Final Rule, the FDA has defined safety for the proposed vitamin D fortification only in terms of exposure to vitamin D, and the safe upper limit as set forth by the NAS Food and Nutrition Board's Dietary Reference Intakes (DRI)[1]. We are concerned that the FDA failed to address another critical safety issue, that of the impact of juice drink fortification with vitamin D on the average daily consumption of juice drink. As documented in the AAP guidelines[2], higher intake of juice drinks may be associated with obesity in children and adolescents. In the face of the national epidemic of childhood obesity, the AAP believes data must be provided that demonstrate that vitamin D fortification of juice drinks will not result in the increased consumption of unnecessary calories in these age groups.

The critical importance of this issue is highlighted by the recent summary observations reported from the National Institute of Child Health and Human Development[3]. That publication argued persuasively that adequate exposure to dietary calcium or some other component(s) of dairy products was associated with reduced incidence of adiposity. The authors called for large scale, population-based studies of this potentially modifiable nutrition pattern to characterize its effects on body weight. While the proposed FDA ruling might improve calcium intake, it would also likely decrease the intake of fluid milk and the associated nutrients that



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track with calcium in that food source. We are also concerned that in assessing the safety of juice drink fortification with vitamin D, the FDA failed to address the likelihood that this maneuver will produce an increase in average daily consumption of juice drinks, above the AAP recommended upper limit of 6 fl oz/day for children 1-6 years of age, and 12 ounces for children 7-18 years old. Data from the most recent National Health and Nutrition Examination Survey (NHANES - IV)[4] indicate that current average consumption of juice drinks in children 2-10 years of age already exceeds the AAP recommended intake level. Without data that clearly establish that vitamin D fortification of juice drinks will not exacerbate an existing dietary pattern which the AAP believes is detrimental to the health and well being of infants, children, and adolescents, the FDA should not move forward with implementation of this Final Rule.

Finally, we are concerned that the FDA's assessment of safety in terms of vitamin D exposure and the FNB/DRI safe upper limit of dietary vitamin D failed to consider potential effects of combined exposure to vitamin D *and* calcium. With the increase in recent years of calcium-fortified foods in the marketplace, limiting this safety assessment solely to vitamin D is incomplete; how vitamin D fortification of juice drinks will affect consumption of the safe upper limit of vitamin D, particularly in younger children, must be considered concurrently with that of calcium intake. While the potential for adverse effects from either excess vitamin D or calcium is minimal, there are not sufficient consumption data available for assessing the risk in children of higher combined intakes of these two nutrients. Individuals with renal disease might be at special risk. The AAP believes that before final approval is given for vitamin D fortification of juice drinks, such a risk assessment must be conducted.

In light of these concerns, the AAP objects to the Final Rule, *Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin $D_3$*, and respectfully requests that a hearing be held to fully explore all of the issues concerning the proposed fortification of juice drinks with vitamin D. We appreciate the FDA's thoughtful consideration of these comments offered in the interests of the well being of America's children, and look forward to your response.

Sincerely,

E. Stephen Edwards, MD, FAAP
President
American Academy of Pediatrics

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***References***


1. National Institute of Medicine. Dietary Reference Intakes of Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. Washington DC: National Academy Press, 1997.
2. American Academy of Pediatrics. Policy statement. The use and misuse of fruit juice in pediatrics (RE0047). Pediatrics 2001; 107:1210-1213.
3. Parikh SH, Yanovski JA. Calcium intake and adiposity. Am J Clin Nutr 2003; 7:281-287.
4. US Department of Health and Human Services. National Health and Nutrition Examination Survey (NHANES - IV, 1999-2000). http://www.cdc.gov/nchs/nhanes.htm National Center for Health Statistics, Hyattsville MD.