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March 19, 2003

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

Re: Docket No. 02F-0160

Dear Colleagues:

As Director of the Food Intake Laboratory in the Department of Nutrition of the University of California at Davis, I am writing in response to FDA's proposed ruling on the petition by the Minute Maid Company for approval of fortification of calcium-fortified juices and juice drinks with vitamin D.

I submit these objections not only at the director of the UC Davis Food Intake Laboratory, but also as a prominent member of the American nutrition science community. I have served as president of the American Society of Clinical Nutrition and the North American Association for the Study of Obesity, the current Vice President of the American Obesity Association, and an elected member of the Institute of Medicine of the National Academy of Science. It is from the perspective of my life-long professional commitment to understanding the scientific origins of obesity and the pursuit of scientifically valid interventions to prevent and manage obesity that I submit these objections to the proposed FDA ruling noted above.

Reviewing the FDA proposed ruling (www.fda.gov/OHRMS/DOCKETS/98fr/03-4604.html) I was struck by its inclusion of the American Academy of Pediatrics (AAP) policy publication on juice consumption in infants, children, and adolescents (*Pediatrics* 2001; 107:1210-12). That document contains scientific documentation of the health risks associated with juice and juice drink consumption in the younger age segments of the American population. I have strong concerns regarding the scientific understanding of the origins of obesity in our children and the unequivocal evidence as summarized in the AAP publication that excessive juice drink consumption is a contributing factor to this. My objections to the to the approval of vitamin D fortification relate primarily to that of juice drinks.

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First, in this ruling the FDA assessed the safety of this maneuver only in terms of whether vitamin D would remain below the safe upper limit established by the Food and Nutrition Board's report on daily reference intakes (DRI). In light of the documented link between juice drink consumption in children and adolescents and the development of obesity, it is imperative that risk benefit analysis be provided that balances the risk of this proposed ruling, which could promote increased intake of empty calories in our children and thus contribute to the development of childhood weight problems, against the putative benefits of vitamin D fortification. It is my opinion that the increase in vitamin D exposure that would ensue from juice drink fortification is far outweighed by the adverse impact that increased intake would have on excess caloric intake and body weight. It is critical that the FDA provide an analysis of data that this proposed ruling will not result in an overall increase in juice drink consumption and the almost certain increase in "nutritionally poor" calories in children and adolescents.

Second, there is now clear evidence that adequate intake of dairy products with their high content of calcium and other essential nutrients is associated with reduced risk of weight problems among Americans. In a recent review of the available data in this area, the National Institute of Child Health and Human Development (NICHD) reported that the rapidly increasing evidence supporting this potentially critical benefit of milk and other dairy products warrants population-based studies to verify their anti-adiposity effects (*American Journal of Clinical Nutrition* 2003:7:281-7). The proposed FDA ruling runs the risk of promoting precisely the opposite, the inadvertent execution of an "uncontrolled" trial testing the reverse hypothesis.

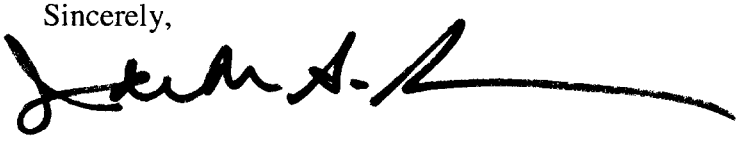
Specifically, the FDA should provide evidence that fortifying juice drinks with vitamin D will not result in further replacement of fluid milk with these beverages in the diets of young Americans. The limits on spontaneous daily fluid intake that all individuals face would dictate that fluid milk consumption would decrease in parallel, particularly in young peoples, as juice drink intake increases. The FDA must provide data that the fortification of juice drinks will not result in a parallel decrease in fluid milk consumption. As noted in the 1999 policy statement of the AAP regarding calcium requirements, dairy products, particularly fluid milk, are the preferred source of dietary calcium for children and adolescents (*Pediatrics* 1999; 104:1152-7).

Finally, the proposed ruling fails to consider the impact of vitamin D-fortified juice drinks on the overall quality of the diets of children and adolescents. Consistent with my previous objection, it is necessary to demonstrate that vitamin D fortification of juice drinks will not have an adverse impact on overall diet quality. In the absence of data to the contrary, the request for approval of vitamin D fortification of these beverages must be predicated in part on the assumption that fortification will increase juice drink consumption in younger age individuals. There are now ample data validating the major importance of the total diet on both short-term and long-term health (e.g., *JAMA* 2002; 287:2081-9; *Current Atherosclerosis Reports* 2000; 2:482-6; *JAMA* 2000; 283:2109-15), and this must be considered in federal policies that can directly affect the diet, and thus the health of America's children today and throughout their lives.

It is the FDA's regulatory responsibility to utilize nutrition and consumption data to provide evidence that diet quality will not be adversely affected by this ruling. The likely substitution of fluid milk with juice drinks will not only reduce the intake of optimal calcium sources, but also of other critical minerals (potassium and magnesium), essential fatty acids, and vitamins (vitamin A and folate). As just one example, decreasing folate exposure among teenage girls would be potentially harmful if they become pregnant.. Such an unintended outcome is in direct conflict with the FDA's successful initiative on folate fortification, which has produced a dramatic decline in neural tube defects (*Semin Perinatol* 2002; 26:277-85)

As a an advocate of improved nutrition in our population, I respectfully request that the FDA consider a more expansive evaluation of this proposed ruling to include the objections noted above. The American public, and particularly our children, deserve nothing less.

Sincerely,



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