



NATIONAL DAIRY COUNCIL®

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

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[Docket No. 02F-0160] Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D₃ 68 Federal Register 9000, February 27, 2003]

Dear Sir or Madam:

The NATIONAL DAIRY COUNCIL® (NDC) wishes to provide comments and specific objections to FDA's final rule that amends the food additive regulations [21 CFR part 172] to allow the addition of vitamin D₃ to calcium fortified *fruit juices* and to *fruit juice drinks*.

NDC is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The NATIONAL DAIRY COUNCIL® has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NATIONAL DAIRY COUNCIL® is recognized throughout the nation as a leader in nutrition research and education.

NDC objects to FDA's decision to allow vitamin D₃ addition to calcium fortified *fruit juices* and *fruit juice drinks* for the following reasons:

1. There is high risk that calcium and vitamin D fortified fruit juices and sweetened fruit drinks with added sugars will displace milk in the diets of children and adolescents that negatively impact other essential nutrients leading to poorer diet quality.
2. Fortification of sweetened fruit drinks with as little 10% of the RDI for calcium is inconsistent with the Dietary Guidelines for Americans and the USDA Food Guide Pyramid.

The rationales for our concerns are provided below.

1. **There is high risk that fruit juices and fruit drinks fortified with calcium and vitamin D will displace milk in the diets of children and adolescents leading to poor diet quality and increased risk of chronic diseases.**

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In this final rule, FDA evaluated the safety of vitamin D fortification based solely on a toxicological risk assessment model using the upper tolerable limits (UL) for vitamin D set by the Committee on Dietary Reference Intakes of the Food and Nutrition Board at the National Academy of Sciences Institute of Medicine (IOM). NDC objects that in assessing the safety of fruit juice and fruit drink fortification with Vitamin D, the FDA did not address an equally important safety issue, that of the likelihood that this decision will result in an increase in the average daily consumption of these beverages leading to poorer diet quality, higher energy intakes and potential exacerbation of the obesity epidemic in the U.S. Furthermore, there is the risk that this action will result in a false security on the part of consumers that nutrient needs can be met equally well by fortified “alternatives” to milk – a beverage traditionally recognized as a source of calcium and vitamin D but also providing good to excellent sources of other essential nutrients.

The American Academy of Pediatrics (AAP) has already recognized the potential detrimental health effects of high fruit juice and fruit drink consumption in children by setting limits on intake¹. 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 fruit juice and fruit drink consumption above the AAP recommended upper limits and further displace milk in the diets of young children and adolescents. A preliminary assessment of the most recent National Health and Nutrition Examination Survey (NHANES IV - 1999-2000)² indicates that replacing one serving of milk with a serving of a fruit drink in the diets of adolescent milk consumers (14 – 18 yrs.) results in a higher intake of carbohydrates (mainly added sugars) and lower intakes of potassium, phosphorus, magnesium, zinc, riboflavin and vitamin A. NDC urges the FDA not to finalize this rule until it is clearly established that vitamin D fortification of fruit juice and juice drinks will not further encourage excessive juice intake and compromise fluid milk consumption in the diets of young children and adolescents.

NDC also strongly objects to the part of this rule allowing the addition of vitamin D to fruit drinks fortified with as little as 10 percent of the RDI for calcium per serving [68 Federal Register 9003, February 27, 2003]. This decision underscores NDC's concern that vitamin D and calcium fortified fruit drinks with added sugars will negatively impact the overall quality of children and adolescents diets in part by displacing consumption of fluid milk. Milk and other dairy foods are the major sources of calcium and vitamin D in the U.S. diet, providing 72% of the calcium available in the food supply as well as protein, phosphorus, zinc, magnesium and vitamins A, and B₁₂. Government and health professional organizations including NIH, NICHD, FNB/NAS and the American Academy of Pediatrics (AAP) identify milk and other dairy products as the preferred source of calcium in the diet because they contain large amounts of calcium along with other essential nutrients that interact for optimal bone health and human development³⁻⁶. Beverage consumption patterns in the U.S. have changed markedly over the past half-century. From 1965 - 1996, soft drink intake increased by 187% for boys and 123% for girls, sugar sweetened fruit drinks (< 10% fruit juice) intake increased by 112% for boys and 65% for girls, and milk intake declined by 37% for boys and 43% for girls⁷. It is now widely believed that milk has been largely displaced by soft drinks and other sugar-sweetened juices and drinks in the U.S. diet^{6,8-11}. Studies have demonstrated that high intakes of sugar-sweetened beverages result in a significant deterioration in nutrient adequacy and overall diet quality^{8,12,13}. FDA

In the absence of data demonstrating that vitamin D addition to calcium fortified fruit juice and juice drinks will improve the overall nutritional quality of children and adolescents diets and not exacerbate higher energy intakes, NDC strongly urges the FDA not to permit the addition of vitamin D to fruit juice and juice drinks.

NDC also questions whether the fortification of fruit juice and sweetened fruit drinks is consistent with FDA's own fortification policy [21 CFR 104.20 p. 180] which states that nutrients may be appropriately added to food to correct a dietary insufficiency recognized by the scientific community.... if: "Sufficient information is available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients".

2. Finally, fortification of fruit drinks with vitamin D is inconsistent with the Dietary Guidelines for Americans (DG) and the USDA Food Guide Pyramid.

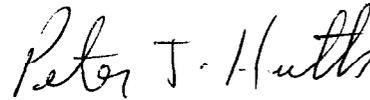
The DG and FGP recommend limiting the intake of sugar from foods and beverages. Carbonated and non-carbonated beverages such as fruit juice drinks are included because they are the primary source of added sugars in the U.S. diet. Although dental caries continue to provide a major rationale for this guideline, the Dietary Guidelines Committee expressed very serious concerns about current trends in the consumption of sugars by the U.S. population. These trends raised concerns because of their coincidence with other undesirable changes in the country's nutritional well being, e.g., increasing rates of obesity and type 2 diabetes in children and adults. NDC strongly urges the FDA not to set a precedent of allowing nutrient fortification of beverages high in added sugars and minimal in nutritional value such as fruit drinks that are at odds and inconsistent with major U.S. public health policy guidelines.

The NDC does not request a hearing on this matter but strongly urges the FDA to table the final rule regarding the proposed fortification of fruit juice and juice drinks with vitamin D until the issues raised above are resolved. We are confident that the agency will act on this matter in the interest of assuring the health and well being of America's children.

Sincerely,



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Cc: Christine L. Taylor, Office of Nutritional Products, Labeling and Dietary Supplements.

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