



January 17, 2006

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

RE: Docket No. 2000P-0586

Dear Sir:

On behalf of the nearly 300,000 family farm and ranch members of the National Farmers Union (NFU), I am pleased to respond to the Food and Drug Administration's (FDA) proposed rule to amend regulations to provide for the use of fluid ultra-filtered milk (UF) in the manufacture of standardized cheeses dated October 19, 2005.

In September 2003, members of NFU delivered over 4,000 individually signed petitions to the FDA's Center for Food Safety and Nutrition, opposing changing the definition of milk. Our members, who are both producers and consumers, remain adamantly opposed to potentially jeopardizing decades of work and investment by America's dairy producers and quality cheese makers.

Milk is a wholesome and nutritious product containing biodynamic properties that enhance health; it is the milk itself which provides the health benefits. The World Health Organization has concluded it is the food themselves, not the specific nutrients in the foods, which create the beneficial effects on health.

To allow cheese processors to redefine the ingredients used in standardized cheese is disingenuous and only serves to increase processor profit margins. Currently, over 70 different cheeses covered by the FDA's standard of identity regulations do not allow fluid ultra-filtered milk as an approved ingredient and there is no consumer demand for it to be an approved ingredient. The October 19, 2005 Federal Register notice states, FDA tentatively concludes that this action will promote honesty and fair dealing in the interest of consumers, however our members would believe just the opposite.

A consumer study commissioned by Dairy Farmers of Canada and conducted by the Consumer Interest Alliance Inc. in July 2005 found that nutritional value was listed as the first reason for buying cheese¹. Additionally, consumers responded that they felt very strongly that changes in the composition of cheese should not be made unless documented evidence demonstrates that the changes will not negatively affect the bioactive components of milk and products made from milk. The October 2005 Federal Register notice does not include evidence that suggests changing the definition of milk will not negatively affect the bioactive components of milk and milk products.

National Farmers Union members are concerned with the lack of comprehensive, producer economic analysis or consumer nutritional analysis in FDA's notice.

FDA states the use of ultra-filtered milk must not adversely affect the physical or chemical characteristics of the dairy product. A 2001 investigation by the federal government's General Accounting Office (GAO) reported ultra-filtered milk is not nutritionally equivalent to fluid milk². The GAO report states the filtration process removes most of the milk's vitamins, minerals, enzymes and lactose.

A 2003 study by the University of Illinois at Urbana-Champaign reports the main minerals found in milk, calcium and phosphorous are soluble, and therefore some would be removed during the ultra-filtration process³. To claim ultra-filtered milk is identical to milk is scientifically untrue, according to this study. Furthermore, ultra-filtered milk has not undergone mandatory safety tests under FDA's own "Generally Recognized as Safe" rules.

With current FDA rules, standardized cheese products are identified as being of high nutritional quality and play an integral role in the USDA Food Pyramid recommended to American consumers to maintain a healthy and balanced diet. Cheese makes a very important contribution to the nutritional well-being of Americans. It is negligent to change the nutritional composition of a major class of food, like standardized cheeses, without a thorough consumer education program. Consumers will be misled about the nutritional value of the cheese they consume, and the health of Americans, particularly adolescents and seniors, will be jeopardized. Due to the diminished nutritional value of cheese made from UF milk, it will be necessary for consumers to increase consumption of these products to achieve the same nutritional benefit as cheese produced from milk.

A 2002 Purdue University study reports that women who consume three servings of dairy products each day over the course of a year, burned more fat and calories, compared to women who fall short of government daily dairy-intake recommendations, consuming less than three servings of dairy products per day⁴. Clinical studies cited in the Purdue study also show that dairy foods exert a significantly greater effect on body weight and fat loss than calcium supplements, suggesting that the mix of nutrients in dairy beyond calcium contribute to dairy's superior effect. Obesity is the second largest preventable cause of death in the United States; more than 40 million adult Americans are affected by obesity. Increasing calcium can aid in weight loss and in the prevention of obesity. The reduction in calcium and other nutrients through the ultra-filtration process results in a product that is not nutritionally equivalent to milk and deceives consumers into believing they are consuming appropriate amounts of calcium.

According to a 2003 national study, medical costs attributed to the treatment of both overweight and obese Americans accounted for 9.1 percent of total U.S. medical expenditures in 1998 and may have reached as high as \$78.5 billion⁵. Two other academic studies, one from the University of Hawaii and one from the Laval University in Canada, both report that people with higher calcium intake have less fat than those

with lower calcium intake and are better able to manage their body weight, as increased calcium intake causes the body to break down fat easier and also decreases fat synthesis.

Milk should not be an interchangeable ingredient during the manufacturing of dairy products. The definition of milk means, “the lacteal secretion, free from colostrum, obtained by the complete milking of one or more healthy cows.” America’s dairy producers have spent billions of hard-earned checkoff dollars marketing the “Real Seal” to promote wholesome dairy products to America’s consumers.

Changing the definition of milk will drastically change America’s dairy production as we know it. Processors will seek low-cost, low-quality imported product, not the high-quality, locally produced milk American consumers have come to depend upon. National Farmers Union strongly urges FDA to reverse its support to change the definition of milk

Thank you for the opportunity to respond to the request for comments on cheese standards and the definition of milk.

Sincerely,

A handwritten signature in black ink that reads "David J. Frederickson". The signature is written in a cursive, flowing style.

David J. Frederickson, President

¹ Consumer Interest Alliance Inc. July 2005. Cheese Standards and the Consumer Interest.

² *United State General Accounting Office.* March 2001. Imports, Domestic Production, and Regulations of Ultra-Filtered Milk. www.gao.gov

³ Hurley, W.L. November 11, 2003. Minerals and Vitamins. Lactation Biology Lesson, University of Illinois Urbana-Champaign. Department of Animal Sciences.

⁴ Choi, Lynn. September 17, 2002. “The Effect of Dietary Calcium on Obesity and Weight Loss. Graduate Seminar, Purdue University, Food Science Department.

⁵ Finkelstein, EA, Fiebelkorn, IC, Wang, G. *Health Affairs* 2003. National medical spending attributable to overweight and obesity: How much, and who’s paying? W3;219–226.