



December 20, 2005

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

RE: Docket No. 2003P-0132

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) advance notice of proposed rulemaking on petitions to amend the standards of identity for ice cream and frozen custard, sherbet and water ices, dated September 27, 2005.

National Farmers Union opposes any effort to allow ingredients other than real milk from dairy cattle to be used in the manufacture of ice cream and frozen dairy products. One of the first questions posed by FDA in the September 27 notice is whether the actions proposed in the petition from the International Ice Cream Association would promote honesty and fair dealing in the interest of consumers. NFU contends that this petition does not promote honesty and fair dealing in the interest of consumers; it simply aims to promote greater profit margins for processors. America's dairy producers have dedicated years of effort and billions of dollars to establish high standards for their products to meet consumer expectations and establish an honest and fair relationship with their customers. Permitting the use of non-milk ingredients in the production of ice cream and other dairy products is misleading and threatens the long-standing relationship America's dairy producers have with consumers.

National Farmers Union members are concerned with the lack of comprehensive, producer economic analysis and consumer nutritional analysis included in the petition or in FDA's advanced notice. Allowing ultra-filtered milk, milk protein concentrates and milk from animals such as water buffalo and goats, as approved ice cream ingredients will have a devastating economic impact on America's dairy producers. There is very little domestic production of the ingredients mentioned above, meaning if the proposed changes were adopted by FDA, these products would be imported from other countries, further displacing domestic production.

Milk from dairy cattle is a wholesome, nutritious product containing biodynamic properties that enhance health; it is the milk itself which provides the health benefits. The World Health Organization (WHO) concludes that it is the foods themselves, not the specific nutrients in the foods, which creates the beneficial effects on health. 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 milk¹.

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 process². To claim ultra-filtered milk is identical to milk is scientifically untrue, according to this study.

The use of any "safe and suitable" milk-derived ingredients in the manufacture of frozen desserts other than real milk should not be permitted. The undefined list of "safe and suitable" ingredients is cause for concern, considering ultra-filtered milk and milk protein concentrates have not been put through FDA's own safety tests under its "Generally Recognized as Safe" rules. Safe and suitable are two relative terms that should not be left open for definition by processors seeking to increase profit margins.

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 from a meal, compared to women who fall short of government daily dairy-intake recommendations, consuming less than three servings of dairy products per day³. 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 contributes 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 billion⁴. 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.

The use of milk from "source" animals other than cows in the production of ice cream and other frozen dairy desserts should not be allowed, as milk from other sources do not contain the same levels of nutrients and vitamins or have the same palatability as cows' milk. The Wageningen University in the Netherlands states that lactose is the most important carbohydrate present in milk⁵. The University reports that the lactose content of goat milk is about 10 percent lower than that of cow's milk. The University also reports that goat's milk has a 'goat flavor' caused by either unhygienic milking practices,

certain feed sources, poor processing and storage of the milk, or by spoilage⁶. Consumers expect their ice cream to be made with cow's milk, not milk from animals rarely found within the United States. Comprehensive studies have found buffalo milk and cow's milk produced in India exceed the World Health Organization guidelines for acceptable DDT residues. DDT use has been banned in the United States for more than 30, years due to the serious risks it poses to human health. Using goat's milk, buffalo milk or any other "source" animal milk as a substitute for cow's milk in ice cream would jeopardize consumer confidence in these products, which would undoubtedly have an impact on America's dairy producers.

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 oppose the petition filed by the International Ice Cream Association to make standard changes for approved ingredients in the production of ice cream and other frozen dairy products.

Thank you for the opportunity to respond to the request for comments on ice cream standards.

Sincerely,

A handwritten signature in black ink, reading "David J. Frederickson". The signature is written in a cursive style with a large initial "D" and "F".

David J. Frederickson, President

¹ *United State General Accounting Office*. March 2001. Imports, Domestic Production, and Regulations of Ultra-Filtered Milk. www.gao.gov

² Hurley, W.L. November 11, 2003. Minerals and Vitamins. Lactation Biology Lesson, University of Illinois Urbana-Champaign. Department of Animal Sciences.

³ Choi, Lynn. September 17, 2002. “The Effect of Dietary Calcium on Obesity and Weight Loss.” Graduate Seminar, Purdue University, Food Science Department.

⁴ 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.

⁵ Wageningen University. What is the difference in composition between cow’s milk and goat milk? www.food-info.net/uk/qa/qa-fp89.htm (Found on December 20, 2005).

⁶ Wageningen University. Why does goat milk taste differently from cow’s milk? www.food-info.net/uk/qa/qa-fp90.htm (Found on December 20, 2005).