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National Milk Producers Federation

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February 21, 2017

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

(Submitted electronically: www.regulations.gov)

Re: Docket No. FDA-2016-D-2343: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food*. NMPF appreciates the effort that FDA has put into creating the document to assist the regulated community with compliance with the rule, and we wish to provide comment specifically on the food product categories.

Appendix 1 "Potential Hazards for Foods and Processes" contains information on the potential hazards represented by 17 food categories comprised of numerous subcategories. NMPF offers comment on two subcategories: one within "Beverages" and one within "Other". Beverage Subcategory 11 "Milk substitutes" includes, as example products, "Rice milk, Soy milk, Almond milk…". Other Subcategory 17 "Non-Dairy frozen desserts" includes, as example products, "Soy milk frozen desserts".

NMPF requests changes in the names for the example products in Beverage Subcategory 11 and Other Subcategory 17 to "rice beverage, soy beverage, almond beverage" and "soy-based frozen dessert", respectively. Alternatively, as these substitutes meet the definition of imitation products – in that they resemble a traditional food, are a substitute for the traditional food, and contain less protein or a lesser amount of any essential vitamin or mineral – these nutritionally inferior products could also be referred to by a name that includes the word "imitation" [21 CFR 101.3 (e)(1)].

For consistency, clarity, and to avoid consumer confusion, it is important that the names of any non-dairy alternatives referenced reflect current federal regulations and standards of identity. As you may know, NMPF filed a complaint with the FDA

objecting to the misuse of the word "milk" on beverages that contain no dairy ingredients, the most obvious example of this misbranding being the term "soy milk".

Milk is a standardized product very clearly described under 21 CFR 131.110. In essence, milk is a product that comes from cows. Products made from soybeans or rice or almonds or any other plant are not milk and it is a misuse of the term and illegal to call them milk. In fact, FDA has issued a number of warning letters to soy product manufacturers for just such misuses.

Consumers have a variety of reasons for selecting certain foods and they should have a variety of options from which to choose. NMPF is simply saying that soy and similar non-dairy beverages are not milk, nor are they nutritionally equivalent to milk, and they should not be marketed as milk. The guidance documents published by the FDA should not encourage or perpetuate this misbranding, no matter how often it is seen in advertising or packaging.

Imitation plant-based beverages are all too often misbranded through the misuse of standardized dairy products (e.g., "soy milk", "rice yogurt", etc.) in the marketplace. It is FDA's own lack of enforcement on this issue that has led to the explosive proliferation of misbranding among the products in the dairy imitator category. Further, NMPF believes that the agency's negligence has directly contributed to a public perception that any beverage bearing the word "milk" as part of its identity statement is nutritionally equivalent to milk from dairy cows.

As FDA finalizes these guidance documents and other related materials, NMPF would again strongly urge FDA to be consistent with established food labeling policies, including the statement of identity, specifically for imitation dairy products. We hope you'll keep this in mind as the FDA continues to work on implementation of the rules of the Food Safety Modernization Act.

Respectfully Submitted by,

Path Panko Britzinski

Beth Briczinski, Ph.D. Vice President, Dairy Foods & Nutrition

cc: J. Sheehan F. Billingslea The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.