



National Milk Producers Federation

National Milk Producers Federation · 2101 Wilson Blvd., Arlington, VA 22201 · 703-249-6111 FAX 703-841-9328

February 14, 2000

Joseph A. Levitt, Director (HFS-001)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street SW, Room 6815
Washington, DC 20204

Dear Mr. Levitt:

The National Milk Producers Federation (NMPF) wishes to register a trade complaint concerning what we believe to be the rapidly expanding misuse of the name of a standardized food in the labeling of certain food products. In submitting this complaint, NMPF is requesting that FDA take appropriate enforcement action to prevent misbranded products from entering the marketplace and to promote honesty and fair dealing in the interest of consumers.

The National Milk Producers Federation, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 26 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 50,000 dairy producers on Capitol Hill and with government agencies.

Recently, NMPF has observed a growing number of beverages on the store shelves in the Washington, DC area and elsewhere which we feel are misbranded. We have also received a number of trade complaints from our member cooperatives throughout the U.S. regarding these same types of products. The products referenced are various soy-based beverages which are inappropriately using the name of a standardized food (i.e., "milk") on the label for their products. The term "milk" is appearing not only in the name of the food, but also in the ingredient statement and supporting information on the label. On occasion, other cereal or grain-based (e.g., rice or oat) non-dairy beverages also use the term "milk" in their labeling, but our marketplace information has shown this practice is not as common within these segments as it is within the soy beverage industry.

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Jerome J. Kozak, Chief Executive Officer James P. (Tom) Camerlo, Jr., President Elwood Kirkpatrick, First Vice President
Charles Beckendorf, Second Vice President Robert Dever, Third Vice President
Donald Storhoff, Secretary/Treasurer Clyde Rutherford, Assistant Secretary/Treasurer

Milk as a standardized food is very clearly described in the standard of identity under 21 CFR 131.110 (a) as follows:

Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in the final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8¼ percent milk solids not fat and not less than 3¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

In the view of NMPF, any product which uses the term "milk" as part of the name of the food on the label, therefore, must comply with the above standard of identity. Of course, the use of the term "milk" from non-bovine species is also well established and referenced in other standards of identity (e.g., goats milk ice cream). NMPF contends that this allowance for milk from non-bovine animals was never intended to include soy mixtures, it is merely recognition that other species of animals provide milk through lactation.

NMPF also recognizes that some products, such as coconut milk, have a well-established historical use of the term "milk" in their nomenclature. These products, however, do not attempt to directly compete with traditional fluid beverage milk (from milking animals) in the market place. Soy-based beverages, on the other hand, are attempting to directly compete with dairy products and are inappropriately taking advantage of the familiarity (and positive image) of dairy terminology in their labeling.

In regard to ingredient labeling, FDA has provided for some grouping of dairy products for the purpose of labeling. These regulations are described in 21 CFR 101.4 (b) (4) as follows:

Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".

Consequently, NMPF would maintain that any product which is not milk as defined in 21 CFR 131.110 and which uses the term "milk" as an ingredient, therefore, must comply with the above ingredient declaration requirements. Since soy protein is not listed in the above regulation, it may not be declared as "milk" in the ingredient listing.

Historically, non-dairy beverage products have been primarily sold in limited quantities in specialty supermarkets and health food stores. However, many of these products have recently been appearing in main stream, major grocery chains. With the

recent promulgation of 21 CFR 101.82 *Health claims: Soy protein and risk of coronary heart disease* by FDA, this trend can only be expected to increase.

In many instances, these soy-based beverage products are positioned on the grocery shelf alongside milk and other dairy products in a clear attempt to compete with dairy products as a beverage. In addition, the labeling of soy beverages and accompanying marketing language attempt to portray to consumers that these products are, in fact, dairy-like products by using the term "milk" on the label. In fact, the labeling and accompanying graphics for such products often directly depict the appearance and customary labeling of milk (e.g., "1% LOWFAT").

NMPF believes that these soy-based beverage products are, at best, imitations or substitutes, as defined in 21 CFR 101.3 (e) and must be prominently labeled as such if they are to continue to use the term "milk" as part of the fanciful name for the products. NMPF believes that the true common or usual name for these products is "Soy beverage" or "Soya drink", since they have traditionally been marketed as such, and, in fact, many firms continue to do so. In fact, as noted earlier, many similar product manufacturers, such as rice and oat beverage firms, comply with the regulations in the labeling of their products.

Although some non-dairy beverages may resemble cow's milk in appearance, they are very different in nutritional value and composition from the standardized product described as milk in 21 CFR 131.110. NMPF believes that the food described in the standard of identity is the food that most consumers in the U.S. customarily consider as "milk". These soy beverage products are certainly not the lacteal secretion from cows as described and required by the standard of identity, but rather a formulated liquid extracted from soybeans and water. Soy beverages are a creamy-white emulsion resembling milk in appearance, but are made from dried soybeans. In addition, these products are nutritionally inferior to milk, as they lack the appropriate level of protein when compared to milk products. One serving of milk provides 8g of protein whereas one serving of soy beverage in the examples enclosed only contains 4-7g of protein. Nutritional inferiority is defined by the Agency as any reduction in the content of an essential nutrient. Protein is an essential nutrient that is clearly lacking in these soy beverages.

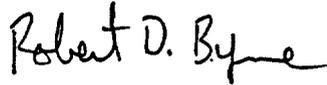
In summary, NMPF requests that FDA take appropriate regulatory action necessary to bring these violative products into compliance with the appropriate labeling regulations. Our complaint is regarding the rise of fraudulent labeling and marketing of an expanding number of products labeled as "soymilk". This practice is in direct violation of the Food Drug and Cosmetic Act, Sections 403 (a), (b), (c), and (g) and Sections 301 (a) and (g).

In order to assist you with this request and to provide evidence of these misbranded products, enclosed are examples of violative cartons of soy beverages which include the use of the term "soymilk" as the name of the food, on the principal display panel, and in the ingredient statement. NMPF respectfully requests that the

Agency take immediate regulatory action to correct this improper labeling situation before this practice becomes more pervasive in the soy-based beverage industry.

Thank you for your prompt attention to this matter. Please feel free to contact me if you have any questions or if further information is needed.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Byrne". The signature is written in a cursive style with a prominent initial "R".

Robert D. Byrne, Ph.D.
Vice President of Regulatory Affairs

Enclosures

Cc: Janice F. Oliver, Deputy Director for Operations
Christine J. Lewis, Acting Director, Office of Nutritional Products, Labeling, and
Dietary Supplements
Joseph M. Smucker, Chief, Milk Safety Team