

SOYFOODS

ASSOCIATION OF NORTH AMERICA

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March 9, 2000

Joseph A. Levitt, Director (HFS-1)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (FDA)
200 C Street, S.W., Room 6815
Washington, D.C. 20204

Re: *"Soymilk": Response to Letter to FDA from the National Milk Producers Federation; a Copy of This Letter Will Also Be Sent to FDA Docket No. 97P-0078*

Dear Mr. Levitt:

The Soyfoods Association of North America (hereafter "Soyfoods Association") is a trade association that represents 60 manufacturers and distributors of soy-based products, including soymilk, tofu, miso, tempeh, and other items, in the United States and elsewhere in North America.

We write to you in response to a letter dated February 14, 2000 that we have recently learned has been sent to you by the National Milk Producers Federation ("NMPF"). In that letter, the NMPF complains to FDA about use in labeling of the nomenclature "soymilk" to describe beverages that are made from soy and asks FDA to take enforcement action to prevent use of such labeling.

As set forth below in this letter, we respectfully submit that the NMPF letter misstates the law applicable to use of "milk" terminology in food labeling. Contrary to the NMPF's allegations, the term "soymilk" is a truthful and appropriate name for a soy-derived beverage; the term does not violate FDA's definition and standard of identity regulation that governs use of the term "milk" (i.e., that governs use of the unqualified term "milk"). Furthermore, the NMPF letter fails to advise you of the highly relevant fact (which must have been known to the NMPF) that there is a substantial citizen petition already pending before FDA on this subject, originally logged in by the FDA Hearing Clerk more than three years ago, which asks FDA to recognize that "soymilk" has become the appropriate "common or usual name" for certain soy-based beverages and to issue a "common or usual name regulation" to recognize that fact, and which provides substantial evidence on behalf of such action. It would be inappropriate for FDA to take regulatory action against "soymilk" products based upon the NMPF letter without first responding to the prior, pending citizen petition. We believe FDA should file the letter from the NMPF as a comment in the citizen petition docket, and then take action upon the pending citizen petition as soon as the agency is able to do so.

97P-0078

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I. THE NMPF LETTER MISSTATES THE LAW CONCERNING USE OF THE TERM "MILK"; "SOYMILK" NOMENCLATURE IS PROPER FOR A BEVERAGE DERIVED FROM SOY

The NMPF letter states, correctly, that FDA has issued a definition and standard of identity for "milk" that requires, among other things, that products labeled as "milk" be derived from cows. 21 C.F.R. § 131.110. However, the NMPF incorrectly extends this initial point by asserting, wrongly, that the definition and standard of identity for "milk" prevents the word "milk" from also being used together with additional qualifying language as part of the name for other products that may not be derived from cow's milk.

The Federal Food, Drug, and Cosmetic Act (FDC Act) states that a food shall be deemed to be "misbranded" (illegal) if it "purports to be" or is "represented as" a food for which a definition and standard of identity has been prescribed by FDA and fails to conform to the definition and standard. 21 U.S.C. § 343(g). "Soy milk," however, does not "purport to be" and is not "represented as" ordinary "milk" (unqualified); indeed, use of the term "soy" proclaims that the product is not bovine in nature. Use of the term "soymilk" does not violate the definition and standard of identity for "milk" or the relevant section of the FDC Act.

To appreciate fully the unacceptable consequences of adopting the NMPF's approach to interpreting the legal effect of a definition and standard of identity for a single unqualified word, it may be helpful to consider the directly-analogous situation presented by the FDA definition and standard of identity for "bread." 21 C.F.R. § 136.110. That regulation requires that "bread" be made from wheat. 21 C.F.R. §§ 136.110(c)(1), 137.105(a), 137.155, 137.175.¹ Nevertheless, so far as we can tell, neither FDA nor the wheat-based "bread" producers have ever had any objection to a product that is labeled as "rye bread," "oatmeal bread," "5-grain bread" or any other kind of "bread" that is not made from wheat – so long as the use of the term "bread" is qualified to show that the product is not a wheat product.

In exactly the same manner, just because FDA has defined "milk" (unqualified) as a product of the dairy cow does not mean that the term "milk" may not also be used as part of the name for a nonbovine liquid product, provided, that the use of the term "milk" is appropriately qualified to show that the product is not a bovine product. Just as it is proper to label a product as "rye bread," notwithstanding a definition and standard of identity for "bread" that requires that "bread" (unqualified) be made from wheat, so also, it is equally proper to label a product as "soymilk," notwithstanding a definition and standard of identity for "milk" that requires that "milk" (unqualified) be derived from cows.

¹ 21 C.F.R. § 136.110, the standard of identity for "bread," provides that "bread" must be "prepared from one or more of the farinaceous ingredients listed in paragraph (c)(1)" of the regulation. 21 C.F.R. § 136.110(a). Those farinaceous ingredients are listed in 21 C.F.R. § 136.110(c)(1) as "flour," "bromated flour," and "phosphated flour." Companion FDA definitions and standards of identity describe "flour," "bromated flour," and "phosphated flour," as foods that are "prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat." 21 C.F.R. §§ 137.105(a), 137.155, and 137.175. (Emphasis added.) Although the definition and standard for "bread" also allows "nonwheat flours" to be present "if the total quantity is not more than 3 parts for each 100 parts by weight of flour [i.e., flour from wheat] used," *see* 21 C.F.R. § 136.110(c)(11), products labeled as "bread" must be prepared primarily from "cleaned wheat, other than durum wheat and red durum wheat." (Emphasis added.)

The NMPF interpretation of the legal effect of a standardized term would not only put an end to "rye bread" et al., it would overturn longstanding, commonsense practice with respect to use of "milk" terminology as part of other qualified nomenclature for nonbovine products, and with respect to use of other standard dairy terms as part of qualified nomenclature for other nondairy products. For example:

- ** "Goat's milk" contains no standardized (bovine) "milk."²
- ** Even before FDA issued a definition and standard of identity for "peanut butter," 21 C.F.R. § 164.150, it was never seriously suggested that that name, which describes a product that contains no "butter," was somehow improper.
- ** "Coconut milk" contains no "milk."
- ** "Nondairy creamer" products contain no "cream."

The bottom line of all of this is that whether "soymilk" is an appropriate name for a beverage derived from soy, and if so, what criteria should be applicable to use of the name, is not a matter controlled by the definition and standard of identity for "milk," as the NMPF would have it be, but instead is a matter to be resolved by taking an honest look at current real-world usage and acceptance of the term "soymilk," to decide whether it is an appropriate "common or usual name" or an "appropriately descriptive term." 21 C.F.R. § 101.3(b)(2) and (3). In this regard, a pending citizen petition, filed with FDA by the Soyfoods Association of America (the predecessor of the Soyfoods Association of North America) on February 28, 1997, which is described below in section II. of this letter, provides extensive evidence of record about the current usage and acceptance of "soymilk" as an appropriate "common or usual name."

However, before we turn to the matter of the pending citizen petition in section II. below, we cannot help but take note of the fact that in recent years even FDA has been using the term "soymilk" as an appropriate name for a soy-derived beverage. For example:

- ** In *FDA Enforcement Report* Number 99-42 (October 20, 1999), the agency announced a recall of approximately 3,480 cases of a product identified as "LUNA, Drinks That Work" because the product contained "undeclared soy milk." FDA reported that this product was the subject of a

² We recognize that there is a definition and standard of identity for "goat's milk ice cream," 21 C.F.R. § 135.115, which establishes requirements for that product that are distinct from the requirements for "ice cream," which is subject to a definition and standard of identity that requires that that product be derived from cow's milk. 21 C.F.R. § 135.110. However, there is no FDA definition and standard of identity for "goat's milk," and so far as we are aware neither the FDA, nor the NMPF, nor anyone else has ever suggested that the FDA definition and standard of identity for "milk," which requires derivation from the cow, somehow prohibits a distinct product from being sold as "goat's milk."

"nationwide" recall because it failed to declare on its label the presence of "soy milk."

** FDA Talk Paper No. T98-80 (November 10, 1998), which described FDA's then-newly-proposed rule to authorize a "health claim" about "soy protein and coronary heart disease," stated that the new rule would authorize use of the "health claim" on products including "soy milk." (Emphasis added.)

** FDA's Federal Register preamble statement about the same proposed rule includes the following pronouncement:

Soy protein is also consumed in the diet as a component of traditional fermented and nonfermented soy foods such as tofu, tempeh, and miso, in addition to whole soybeans, soynuts, soy milk, soy yogurt, and soy cheese.

63 Fed. Reg. 62977, 62978 (November 10, 1998). (Emphasis added.)

We believe the facts speak for themselves: Today, "soymilk" is appropriate terminology that is used by persons and institutions, including FDA, to describe a beverage that is derived from soy.

II. IF FDA IS TO RULE UPON THE PROPRIETY OF "SOYMILK" NOMENCLATURE, IT SHOULD DO SO BY ACTING UPON THE SOYFOODS ASSOCIATION'S PENDING CITIZEN PETITION

On February 28, 1997, more than three years ago, following established FDA procedure, 21 C.F.R. § 10.30, the Soyfoods Association of America (the predecessor of the Soyfoods Association of North America) filed with the FDA Dockets Management Branch a citizen petition that asks FDA to issue a regulation to recognize that the term "soymilk" is an appropriate "common or usual name" that has now become established through common usage. As shown in that citizen petition, "soymilk" is a term that "has come to be widely used, recognized, and accepted to describe this particular type of food, and . . . this term now should be officially recognized by FDA as the correct name for the product." Citizen Petition, p. 5. FDA has accepted the petition, has assigned it to Docket No. 97P-0078, and has received and filed a number of comments.

On August 4, 1997, FDA issued an interim response to the Soyfoods Association, stating that the agency had not yet been able to address this matter because of other priorities and limited resources. However, the petition remains pending and the FDA docket remains open, until the time that FDA is able to attend to the matter.

Given all of the above, we believe it is clear that the appropriate way for FDA to proceed at this time is for the agency to forward a copy of the NMPF letter of February 14, 2000 to the docket for the pending citizen petition, and for FDA to rule upon the pending petition as soon as the agency is able to do so. That way, FDA will respect its established procedures and the efforts

of responsible persons who prepare and submit to the agency a citizen petition in accordance with the agency's rules and who rely upon the agency to respond in due course in a manner consistent with its procedural regulations. (Of course, if it should choose to do so, the agency could take any reasonable action in light of the citizen petition, including publishing a notice in the Federal Register requesting public input about appropriate nomenclature for "soymilk" products.)

III. ADDITIONAL OBSERVATIONS

Since the NMPF has raised this matter with you directly, we believe we should also take note of the following points in this response:

The NMPF letter is a barely-disguised effort to try to get the FDA to expend its resources to protect dairy milk producers from honest free-market competition by a nutritious and truthfully-described product. As more people in the United States have come to hear about soymilk, and to try it, and to read about its nutritional and health-related benefits, the product is becoming more popular. If this development causes the immense dairy milk producer industry to be concerned that rational citizens might decide to drink some beverages other than cow's milk, it nevertheless is not a proper basis for the NMPF to ask FDA to draw upon the public purse and the agency's limited resources to help cow's milk producers to suppress competition by taking away the competition's name.

For FDA to assist the NMPF in this regard would not only be contrary to law, and inconsistent with prior agency practice, as described above in section I. of this letter, it would also be contrary to the public health. FDA itself has recently approved a health claim about the usefulness of soy protein to help reduce the risk of coronary heart disease. 21 C.F.R. § 101.82, published in the Federal Register of October 26, 1999 (64 Fed. Reg. 57700-57733). As also cited in section I. above, FDA explicitly noted in this proceeding that "soy milk" products can be eligible to bear the health claim. The last thing that FDA should be doing in this context is to adopt regulatory interpretations that would suppress the promotion of healthful soy-based products under nomenclature that is readily recognized by consumers, i.e., nomenclature such as "soymilk."

Furthermore, there are a great many Americans, especially people of color, who are lactose intolerant, and who find the NMPF's bovine dairy products difficult or impossible to digest. For these persons, soymilk provides an excellent beverage option. It would be contrary to the public interest for FDA to act in concert with the cow's milk producers by trying to compel soymilk producers to use other, less-attractive nomenclature than the now-widely-recognized and widely-accepted "soymilk" name.

IV. CONCLUSION

For the reasons discussed above, we respectfully request that FDA reply to the NMPF that its letter dated February 14, 2000 will be forwarded for inclusion in FDA Docket No.

Joseph A. Levitt
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97P-0078 and that the agency will address the propriety of "soymilk" labeling in the context of the agency's ruling on the pending citizen petition.

Sincerely,

A handwritten signature in cursive script that reads "Nancy Chapman".





Nancy Chapman
Executive Director

cc: Janice F. Oliver, FDA
Christine J. Lewis, FDA
Joseph M. Smucker, FDA

Peter Golbitz, Chair, Soyfoods Association Standards Committee
Stephen H. McNamara, Hyman, Phelps & McNamara, P.C.

USDA-Iowa State University Database on the Isoflavone Content of Foods, Release 1.1 - 1999

This database was created through a collaborative effort between the USDA and Iowa State University and was partially funded with grants from the U.S. Army. You will need the **Adobe Acrobat** viewer to view these reports. Release 1.1 contains a few minor corrections to descriptions for infant formulas.

- Documentation 
- Data table (Daidzein, Genistein, Glycitein and total Isoflavones) 
- Coumesterol, Formononetin and Biochanin A 
- References (sources of data) 
- Complete database (Zip file, for use in database programs)



Last modified: February 16, 2000

Post-it [®] Fax Note		7671	Date	3/10	# of pages	5
To			Steve McNamara			
From			Jennifer			
Co./Dept.			Co.			
Phone #			SANA			
Fax #			986-9600			
Phone #			737-9329			
Fax #			387-5553			

USDA-Iowa State University Database on the Isoflavone Content of Foods - 1999

11

(Units = mg/100 g edible portion for Mean, Standard error of the mean (SEM), Min, and Max; #S = the total number of means/individual values; CC=Confidence code)

NDB No	Description	NutrDesc	Mean	SEM	#S	Min	Max	CC	Reference No.
16120	Soymilk, fluid	Daidzein	4.45	0.75	14	1.14	9.84	a	1, 5, 10, 14, 15, 16, 21, 34, 35
		Genistein	6.06	0.84	16	1.12	11.28	a	1, 5, 10, 12, 14, 15, 16, 21, 34, 35
		Glycitein	0.56	0.09	5	0.36	0.86	a	1, 21, 35
		Total Isofl.	9.65	1.76	14	1.26	21.13	a	1, 5, 10, 14, 15, 16, 21, 34, 35
99014	Soymilk, iced	Daidzein	1.90		2	0.34	3.45	c	5
		Genistein	2.81		2	1.78	3.85	c	5
		Total Isofl.	4.71		2	2.12	7.31	c	5
99096	Soymilk skin or film (Fook or yuba), cooked	Daidzein	18.20		1	18.20	18.20	c	10
		Genistein	32.50		1	32.50	32.50	c	10
		Total Isofl.	50.70		1	50.70	50.70	c	10
99053	Soymilk skin or film (Fook or yuba), raw	Daidzein	79.88		2	43.76	116.00	c	10, 34
		Genistein	104.80		2	77.91	131.70	c	10, 34
		Glycitein	18.40		1	18.40	18.40	c	10
		Total Isofl.	193.88		2	121.66	266.10	c	10, 34
99049	Soy noodles, flat	Daidzein	0.90		1	0.90	0.90	c	36
		Genistein	3.70		1	3.70	3.70	c	36
		Glycitein	3.90		1	3.90	3.90	c	36
		Total Isofl.	8.50		1	8.50	8.50	c	36
99038	Soy paste	Daidzein	15.03	3.79	6	3.00	27.20	a	5, 34, 36
		Genistein	15.21	4.87	6	0.31	29.98	a	5, 34, 36
		Glycitein	7.70		1	7.70	7.70	c	36
		Total Isofl.	31.52	9.26	6	3.31	59.40	a	5, 34, 36



DEAN FOODS COMPANY

March 8, 2000

Dr. Christine Lewis
Acting Director of the Office of Nutritional
Products, Labeling & Dietary Supplements

Virginia Wilkening
Director of the Division of Standards &
Labeling Regulations

RE: 'National Milk Producers Federation' Objection to Use of the Term Soymilk

I would like to voice an industry opinion regarding the NMPF's petition to the FDA regarding objection to the use of the term 'Soymilk'.

As a dairy foods processor, Dean Foods Company would like to state that the term 'soymilk' has been widely recognized in our industry as the commonly used name for natural beverages made out of soybeans, water and other vegetable based ingredients for a number of years. We recognize this term to be accurately descriptive, meaningful and widely understood as the term used for natural, non-dairy products made from soybeans. We have not found this term to be misleading to ourselves or our customers in the distribution and retail supermarket trades. We have not received any complaints from customers or consumers regarding this issue. In fact when discussed, the term 'soymilk' is most often if not always the generic term used in conversation or written reference to this product category.

We are not in agreement with the NMPF's objection to the use of this term.

I appreciate your consideration of this statement in evaluating the merit of the petition in front of the FDA.

Respectfully,

George Muck, Ph.D.
Vice President, Research & Development
DEAN FOODS COMPANY

GM/jlh

cc: D. Purcell

Western Quality Food Products, LC.

Extended Freshness Through Technology

TO:

Dr. Christine Lewis

Acting Director of the Office of Nutritional Products, Labeling, and Dietary Supplements

Virginia Wilkerson

Director of the Division of Standards and Labeling Regulations

From:

John H. Warner Jr

Western Quality Foods, LC.

St. George, UT

Re: 'National Milk Producers Federation' Objection to Use of the Term Soymilk

Date: March 8, 2000

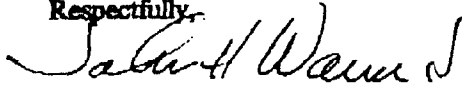
I would like to voice an industry opinion regarding the NMPF's petition to the FDA regarding objection to the use of the term 'Soymilk'.

As a dairy foods processor I would like to state that the term 'soymilk' has been widely recognized in our industry as the commonly used name for natural beverages made out of soybeans, water and other vegetable based ingredients for a number of years. We recognize this term to be accurately descriptive, meaningful and widely understood as the term used for natural, non-dairy products made from soybeans. We have not found this term to be misleading to ourselves or to our customers in the distribution and retail supermarket trades. We have not received any complaints from customers or consumers regarding this issue. In fact, when discussed the term 'soymilk' is most often if not always the generic term used in conversation or written reference to this product category.

We are not in agreement with the NMPF's objection to the use of this term.

I appreciate your consideration of this statement in evaluating the merit of the petition in front of the FDA.

Respectfully,



John H. Warner Jr.
President

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Dr. Christine Lewis
Ms. Virginia Wilkening
March 9, 2000
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have not received any complaints or comments from our customers and consumers regarding this issue.

It industry discussion with suppliers, packaging companies, marketing firms, etc, Soymilk is the generic term used for this product.

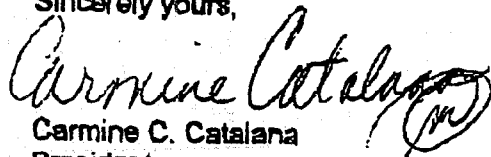
We currently produce both dairy and non-dairy products including soymilk. In our opinion, the use of the terms soymilk is not misleading at all to the consumer. In fact, we believe that accurately represents that the product that is being sold.

We disagree with the NMPF and their opinion on the use of soymilk and do not feel that this opinion represents the entire dairy industry. Only a portion of the supply chain is represented by NMPF. AS a processor and marketing of these products, we see things differently than the milk producers on this topic.

On behalf of our family and our company, I appreciate your time in considering our opinion as you decide the merits of this petition and other regarding soymilk.

If you have any question or would like additional information, please do not hesitate to contact me. I can be reached at 856-451-1300 ext. 3316 or on e-mail at ccatalana@cumberlanddairy.com.

Sincerely yours,



Carmine C. Catalana
President
Cumberland Dairy, Inc.

CCC:mpm

1468 '00 APR 12 A9:55



P.O. BOX 308
 LANDIS & KENYON AVENUES
 ROSENHAYN, NEW JERSEY 08352
 856/451-1300

March 9, 2000

Dr. Christine Lewis
 Acting Director
 Office of Nutritional Products
 Labeling, and Dietary Supplements

Ms. Virginia Wilkening
 Director
 Division of Standards and Labeling Regulations
 Food and Drug Administration
 Washington, DC

Dear Dr Lewis and Ms. Wilkening:

I am writing to you today to voice an dairy industry opinion regarding the National Milk Producers Federation's (NMPF) petition to the FDA regarding their objection to the use of the term 'Soy milk'.

Our company is celebrating our 67th year in the dairy business. In light of the recent consolidation in our industry, we are some unique in that we are a third generation family owned and operated business. We are the last independently held dairy company producing fluid milk in New Jersey. Our business currently consists of producing fluid milk, milk products, and creams, ice cream mixes and other dairy and non-dairy based products. These are sold to supermarkets, quick service restaurants, other dairy companies, convenience stores, food service distributors and the like. Our products are currently distributed in over 20 states.

We believe that the term "Soy milk" is one that accurately describes the product that is being produced. It is widely recognized in our industry as the commonly used name for natural beverages made out of soybeans, water and other vegetable based ingredients for a number of years.

We have not found this term to be misleading to anyone in our industry or our customers in the distribution and retail supermarket trades. To date we



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Good Taste, Good Health

SOY ASSOCIATION OF NORTH AMERICA

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FDA Dockets Management Branch

HFA-305 D

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