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Christopher A. Brown
202.408.9213
cbrown@sonnenschein.com

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VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket No. 00P-06851
Comments on Advance Notice of Proposed Rulemaking, Milk and Cream
Products and Yogurt Products; Petition to Revoke Standards for Lowfat
Yogurt and Nonfat Yogurt and to Amend Standards for Yogurt and
Cultured Milk**

Dear Sir/Madam:

On behalf of our client Snow Brand Milk Products Co., Ltd., we hereby submit these comments in response to the Advance Notice of Proposed Rulemaking, Milk and Cream Products and Yogurt Products; Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend Standards for Yogurt and Cultured Milk, Docket Number 00P-06851, published in the Federal Register on July 3, 2003 (68 Fed. Reg. 39873) ("ANPR").

Snow Brand Milk Products Co., Ltd., ("Snow Brand") located at 13, Honshio-cho, Shinjuku-ku, Tokyo 160-8575, Japan, is an international producer, manufacturer and distributor of dairy products.

I. BACKGROUND OF PROPOSED RULE

On January 30, 1981, the U.S. Food and Drug Administration ("FDA" or "the Agency") published a final rule wherein the Agency established three standards of identity for yogurt.¹ Those standards of identity established definitions for yogurt, lowfat yogurt and nonfat yogurt.

¹ 46 Fed. Reg. 9924 (Jan. 30, 1981).

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Within those standards the Agency included, among other things, provisions regarding the inclusion of optional dairy ingredients and other optional ingredients.²

On September 21, 1982, FDA issued a notice wherein it confirmed the effective date of the three yogurt standards and amended and stayed provisions of the standards.³ Notably, FDA stayed provisions on the timing of measuring milkfat and the minimum acceptable acidity of yogurt.⁴ Additionally, FDA stayed provisions concerning the use of reconstituted dairy ingredients, milk-derived ingredients and preservatives.⁵

On April 9, 1995, FDA proposed to revoke the standards of identity for, among other things, lowfat yogurt and nonfat yogurt.⁶ In that notice, FDA stated that manufacturers would be permitted to name yogurt products as lowfat and nonfat yogurt in accordance with the Nutrition Labeling Education Act ("NLEA").⁷

On February 18, 2000 the National Yogurt Association ("NYA") submitted a Citizen's Petition requesting the revocation of the yogurt standards of identity at 21 C.F.R. §§ 131.200, 131.203, and 131.206, and replacement of those standards with NYA's proposed standards of identity.⁸ Specifically, NYA requested, among other things, that any milk-derived ingredients used for technical or functional purposes and any safe and suitable ingredients added for nutritional or functional purposes be permitted to be included in the products subject to the standards.⁹

The NYA stated that the current standards of identity are incomplete and unclear which jeopardizes the integrity of the term "yogurt."¹⁰ NYA stated that its proposal "recognizes the defining characteristics of yogurt; establishes that yogurt is the product of fermentation of certain characterizing cultures and that yogurt contains a significant quantity of live and active cultures."¹¹ NYA claimed that its proposed standard would take into account current industry

² Id.

³ 47 Fed. Reg. 41519 (Sept. 21, 1982).

⁴ Id.

⁵ Id.

⁶ 60 Fed. Reg. 67492 (Dec. 29, 1995).

⁷ Id.

⁸ National Yogurt Association Citizen Petition, February 18, 2000.

⁹ Id. at 8 and 11.

¹⁰ Id. at 2.

¹¹ Id.

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practices, and would recognize the need to allow for use of future technologies and that the proposed standard would constitute a modernized and flexible yogurt standard.¹²

On July 3, 2003, FDA published an Advance Notice of Proposed Rulemaking wherein it published NYA's proposed yogurt and cultured milk standards and solicited public comment on those standards.¹³ In the ANPR, in response to NYA's proposal to permit the use of any safe and suitable ingredient added from a nutritional or functional purpose, FDA stated that it "recognizes the need for food standards to permit flexibility in food technology, so long as that technology does not alter the basic nature or essential characteristics of the food."¹⁴ The Agency also stated that the existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose.¹⁵ In the ANPR, the Agency also made clear that it views functional substances to be substances such as emulsifiers or preservatives.¹⁶

II. COMMENTS

Snow Brand supports the NYA's proposed standards. Specifically, Snow Brand believes that any changes to these standards must allow for technological advancements in both food processing and food ingredient technology. Specifically, Snow Brand believes that the yogurt and cultured milk standards should permit the inclusion of any generally recognized as safe ("GRAS") substance so long as that substance does not alter the basic nature or essential characteristics of the food.

A. Need for a Flexible Standard that Allows for Technological Advancements in Both Food Processing and Food Ingredient Technology

FDA has not modified the yogurt or cultured milk standards since they were finalized in 1996. Since 1996, food processing and food ingredient technology has changed dramatically. Manufacturers, among other things, have developed food processing technology that can extend the shelf life of products. Additionally, manufacturers have developed new food substances that can be safely added to food that grant health benefits beyond those associated with the nutritive value of the food product. Unfortunately, FDA's food standards have not changed or evolved at a rate that allows for consumers to realize the economic and public health benefits of such technological change. Therefore, Snow Brand believes that the standards need to become

¹² Id.

¹³ 68 Fed. Reg. 39873, 39874 (July 3, 2000).

¹⁴ Id. at 39875.

¹⁵ Id.

¹⁶ Id.

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flexible as to allow for technological changes in both food processing and food ingredient technology.

1. All GRAS Substances Should be Permitted to be Included as a "Functional" Ingredient

One manner in which the standards could be flexible is to allow the inclusion of any GRAS substance as a permitted functional ingredient. Snow Brand notes that it appears that FDA's views the term "functional" to mean a substance's effect on the food product such as, emulsifiers or preservatives and not the substance's functional effect on the consumer.¹⁷ Snow Brand believes that the term "functional" should incorporate both the effect on the food product and the effect on the consumer and that such substances should be permitted to be included in the food standard so long as the substance is GRAS and does not alter the basic nature or essential characteristics of the food.

a. GRAS Process Ensures Safety of Substance

Today, manufacturers are developing numerous substances that provide many health benefits to consumers. However, before a substance can be added to a conventional food, the substance must either be GRAS, or approved for inclusion in food through a food additive petition.¹⁸ Typically, the GRAS process requires a manufacture to either notify the FDA, or self affirm that a substance is GRAS for its intended conditions of use, including the foods in which substance is to be used, the levels of use in such foods, and the purposes for which the substance is used, including when appropriate, a description of the population expected to consume the substance.¹⁹ The notification must also state the basis for which the manufacturer believes the substance is GRAS.²⁰ That basis must be predicated on published data, through scientific procedures or through experience based on common use in food. If the FDA does not have any questions concerning the manufacturer's GRAS determination, the Agency sends a letter to the manufacturer stating so. After receiving the "no questions" letter, manufacturers are free to include the substance in the food so long as there is no standard governing the food or if there is a standard, that the standard permits inclusion of the GRAS substance. The GRAS notification process can be costly and time consuming. Furthermore, petitioning the FDA to modify a food standard can be even more costly and can take numerous years for the Agency to issue a determination. Therefore, many substances with health benefits cannot be used in conventional foods, particularly standardized foods.

¹⁷ 68 Fed. Reg. at 39865.

¹⁸ 21 C.F.R. §§ 170 et. seq.

¹⁹ Id.

²⁰ Id.

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In this case, under FDA's current standards for yogurt and/or cultured milk products, a manufacturer would first have to determine that a "functional" substance is GRAS. After making a GRAS determination, in most circumstances, a manufacturer would be required to petition the Agency to modify the standards to permit inclusion of the GRAS substance. As evidenced by the NYA's petition, it can take several years before the Agency issues a decision on such petitions. Therefore, in order to maintain a modern and flexible standard, Snow Brand believes that all GRAS substances should be permitted as a "functional" ingredients in the proposed yogurt and cultured milk standards so long as inclusion of such ingredients does not alter the basic nature or essential characteristics of the food.

In the ANPR, FDA stated that it "recognizes the need for food standards to permit flexibility in food technology, so long as that technology does not alter the basic nature or essential characteristics of the food."²¹ FDA stated that the "existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose."²² However, the regulatory framework FDA describes only permits inclusion of ingredients not included in the standard if those ingredients are safe and suitable ingredients that are used "to improve texture, add flavor, prevent syngeresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food . . ."²³ Thus, under the current FDA regulatory framework, a manufacturer could not add an ingredient to a standardized food that was deemed GRAS but was included for reasons other than "to improve texture, add flavor, prevent syngeresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food." This gap in the regulations denies consumers the ability to purchase and consume standardized foods which contain ingredients that have a functional effect on their health. Therefore, Snow Brand believes that any GRAS substance should be permitted to be included in a standardized food so long as the basic nature or essential characteristics of the food product is not changed.

b. Basic Nature or Essential Characteristics of Food Product Not Changed

The NYA petition describes the basic nature and/or essential characteristics of yogurt to be a food "containing a minimum level of certain live and active cultures."²⁴ Additionally, according to the NYA petition, "consumers identify yogurt with live and active cultures and expect that when they purchase yogurt, it will contain a significant amount of these cultures."²⁵

²¹ 68 Fed. Reg. at 39875.

²² Id.

²³ 21 C.F.R. § 130.10(d).

²⁴ National Yogurt Association Citizen Petition at 2.

²⁵ Id. at 4.

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Presently, the yogurt standard does not specify a minimum level requirement for live and active cultures. NYA suggests amending the yogurt standard such that yogurt must contain at least 10⁷ CFU/g active cultures *Lactobacillus delbrueckii* subspecies *bulgaricus* and *Streptococcus thermophilus* at the time of manufacture.²⁶ Thus, under NYA's proposed standard, the basic nature and essential characteristics of yogurt are its levels of certain live and active cultures.

The NYA petition describes the basic nature and/or essential characteristics of cultured milk to be a food that produced by culturing one or more of the standard dairy ingredients (cream, milk, partially skimmed milk, or the reconstituted versions of any of these standard dairy ingredients) with characterizing microbial organisms.²⁷ Cultured milk should also contain not less than 8.25 percent milk-solids-not-fat from standard dairy ingredients and have a titratable acidity of not less than 0.5 percent, expressed as lactic acid, before addition of bulky flavors.²⁸

In the ANPR, FDA stated that it "recognizes the need for food standards to permit flexibility in food technology, so long as that technology does not alter the basic nature or essential characteristics of the food." Snow Brand agrees with FDA but wish to add that they believe that any GRAS substance should be included in the yogurt and cultured milk standards so long as inclusion of such substance does not alter the basic nature or essential characteristics of yogurt and/or cultured milk. Such a requirement would permit the inclusion into yogurt or cultured milk any GRAS substances which would grant yogurt or cultured milk added health benefits so long as it did not alter the basic nature or essential characteristics; in the case of yogurt - the levels of certain live and active cultures; in the case of cultured milk - the percent milk-solids-not-fat and the titratable acidity.

c. Benefit to Public Health

Maintaining a flexible standard that allows for technological advancements in both food processing and food ingredient technology will greatly benefit public health. The amendments to the standards described above would ensure that consumers consume a product with a significant amount of live and active cultures while at the same time consumers will obtain greater health benefits by being able to purchase yogurt or cultured milk products that contain GRAS "functional" ingredients. Being able to purchase healthier foods and foods that provide added health benefits becomes more important as health care costs continue to rise at alarming rates. Consumers will be able to make healthier choices obviating the need for higher cost medical care.

²⁶ Id.

²⁷ Id. at 5-6.

²⁸ Id.

B. Any GRAS Substance Should be Permitted to be Included in the Standard so long as the Basic Nature or Essential Characteristics of the Product are not Altered.

For the reasons stated above we believe that any GRAS substance should be permitted to be included in the standard so long as the basic nature or essential characteristics of the product are not altered. Therefore, we request that the yogurt and cultured milk standards be modified such that:

§ 131.200 Yogurt

(c) Optional Ingredients. (1) Any GRAS substance so long as inclusion of such substance does not cause the yogurt to contain less than 10^7 CFU/g active cultures *Lactobacillus delbrueckii* subspecies *bulgaricus* and *Streptococcus thermophilus* at the time of manufacture.

(2) Optional safe and suitable cultures, in addition to the characterizing cultures.

(3) Safe and suitable sweeteners.

(4) Flavoring ingredients.

(5) Color additives.

(6) Stabilizers and emulsifiers.

(7) Preservatives.

(8) Vitamins and minerals. (i) If added, vitamin A shall be present in a minimum quantity of 500 International Unites per reference amount customarily consumed.

(ii) If added, vitamin D shall be present in a minimum quantity of 100 International Units per reference amount customarily consumed.

§ 131.112 Cultured Milk/Fermented Milk

(c) Optional Ingredients. (1) Any GRAS substance so long as inclusion of such substance does not cause the cultured milk to contain less than 8.25 percent milk-solids-not-fat from standard dairy ingredients and have a titratable acidity of not less than 0.5 percent, expressed as lactic acid, before addition of bulky flavors.

(2) Optional safe and suitable cultures, in addition to the characterizing cultures.

(3) Safe and suitable sweeteners.

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- (4) Flavoring ingredients.
- (5) Color additives.
- (6) Stabilizers and emulsifiers.
- (7) Preservatives.
- (8) Vitamins and minerals. (i) If added, vitamin A shall be present in a minimum quantity of 500 International Unites per reference amount customarily consumed.
(ii) If added, vitamin D shall be present in a minimum quantity of 100 International Units per reference amount customarily consumed.
- (9) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.
- (10) Salt.
- (11) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

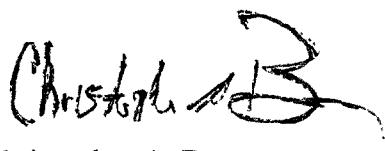
III. CONCLUSION

For the reasons stated above, Snow Brand supports NYA's petition to amend the standards for Yogurt and Cultured Milk. Additionally, Snow Brand believes that when determining what is considered a "functional" substance that can be added as an optional ingredient to yogurt or cultured milk, FDA permit any GRAS substance to be included so long as inclusion of that substance does not alter the basic nature or essential characteristics of yogurt (the levels of certain live and active cultures) or cultured milk (the percent milk-solids-not-fat and the titratable acidity). FDA should permit inclusion into the yogurt and cultured milk standards any GRAS substance that provides added health benefit.

Sincerely,

SONNENSCHN NATH & ROSENTHAL LLP

By:


Christopher A. Brown