

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 00P-0685]

**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**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Advance notice of proposed rulemaking.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a petition has been filed requesting that the agency revoke the standards of identity for lowfat yogurt and nonfat yogurt; amend the standard of identity for yogurt in numerous respects, including incorporation of provisions for lowfat and nonfat yogurt; and amend the standard of identity for cultured milk in numerous respects, including allowing for the use of the alternate term "fermented milk." We request comment on whether the actions requested by the petition would promote honesty and fair dealing in the interest of consumers.

**DATES:** Submit written or electronic comments by [*insert date 90 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. The petition is available for review at the Division of

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Dockets Management or electronically on FDA's Web site at <http://www.fda.gov/ohrms/dockets/98fr/00p-0685-cp00001.pdf>. You may also request a copy of the petition from the Division of Dockets Management.

**FOR FURTHER INFORMATION CONTACT:** Ritu Nalubola, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

**SUPPLEMENTARY INFORMATION:**

**I. The Petition**

The National Yogurt Association (NYA) submitted a citizen petition on February 18, 2000, requesting that FDA revoke the standards of identity in part 131 (21 CFR part 131) for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206), amend the current standard of identity for yogurt (§ 131.200), and amend the standard of identity for cultured milk (§ 131.112).

In its petition, NYA stated that its proposed standard establishes that: (1) Yogurt is a food product containing a minimum level of certain live and active cultures; (2) takes into account current industry practices; (3) recognizes the need to allow for use of future technologies; and (4) establishes a clear, consistent, modernized, and flexible yogurt standard that would benefit both industry and consumers. Specifically, NYA's proposed yogurt standard: (1) Requires a minimum level of active cultures of  $10^7$  colony-forming units (CFU) per gram (/g); (2) requires an acidity of pH 4.6 or lower; (3) requires a minimum level of total dairy ingredients of 51 percent; (4) provides for preculture homogenization and pasteurization; (5) permits the use of reconstituted milk and whey protein concentrate (WPC) as "standard dairy ingredients"; (6) provides for the use of any milk-derived ingredients under optional dairy

ingredients; (7) permits the use of safe and suitable sweeteners, emulsifiers, and preservatives; (8) permits the optional use of any safe and suitable ingredients added for nutritional or functional purpose; and (9) makes provisions for lowfat and nonfat yogurts based on total fat content of the food per reference amount customarily consumed (RACC). In addition, NYA requested that the current standard of identity for cultured milk be amended to “conform” to the proposed standard for yogurt. Specifically, NYA’s proposed amendments to the cultured milk standard: (1) Provide for the alternate term “fermented milk”; (2) require a minimum level of total dairy ingredients of 51 percent; (3) permit the use of reconstituted milk and WPC as “standard dairy ingredients”; (4) provide for the use of any milk-derived ingredient under optional dairy ingredients; (5) permit the use of safe and suitable sweeteners, emulsifiers, and preservatives; and (6) permit the use of any safe and suitable ingredients added for a nutritional or functional purpose.

FDA is publishing this document in accordance with section 701(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(1)), which directs the Secretary of Health and Human Services to publish proposals made by petition to amend or repeal a dairy food standard, so long as the petition includes reasonable grounds for the action requested, and to provide interested persons with an opportunity to present their views. FDA tentatively finds that NYA’s petition presents reasonable grounds. Therefore, FDA requests comment on whether the actions proposed in the petition would promote honesty and fair dealing in the interest of consumers.

## **II. Grounds for the Suggested Changes to Yogurt, Lowfat Yogurt, Nonfat Yogurt, and Cultured Milk Standards**

NYA pointed out that several provisions of the standards of identity for cultured milk, yogurt, lowfat yogurt, and nonfat yogurt are currently stayed

(47 FR 41519, September 21, 1982). The stayed provisions are: (1) Those provisions of §§ 131.112(d)(1), 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) that restrict the type of milk-derived ingredients that may be used, to those so named, to increase the nonfat solids content of cultured milk and yogurts; (2) those provisions of §§ 131.200(a), 131.203(a), and 131.206(a) that exclude the use of reconstituted dairy ingredients as the basic ingredient in the manufacture of yogurts; (3) those provisions of §§ 131.200(c), 131.203(c), and 131.206(c) insofar as they exclude the addition of preservatives to yogurts; (4) those provisions of §§ 131.200(a), 131.203(a), and 131.206(a) that set a minimum titratable acidity of 0.9 percent, expressed as lactic acid; and (5) the provision in § 131.200(a) that the 3.25 percent minimum milkfat level applies to yogurt after the addition of one or more of the optional sources of milk solids not fat listed in § 131.200(c)(1). NYA contended that these stayed provisions create multiple gaps in the standards for which no guidelines exist and, as a result, the integrity of the food “yogurt” is not maintained.

According to NYA, yogurt has been characterized for centuries by its live and active cultures, and thus a minimum content of live and active cultures is crucial to the yogurt standard of identity to promote honesty and fair dealing in the interest of consumers. NYA noted that consumers identify yogurt with live and active cultures and expect yogurt to contain a significant amount of these cultures when they purchase the product, but have no assurance under the current standard that the yogurt will contain such cultures. NYA maintained that its proposed standard recognizes the defining characteristics of yogurt and establishes that yogurt is a product of fermentation of certain characterizing cultures, and that the finished food contains a significant

quantity of these live and active cultures consistent with consumer expectations.

NYA also stated that the proposed amendments to the standard for cultured milk would further serve consumer interest. Under its proposed actions, NYA maintained that foods otherwise satisfying the standard of identity for yogurt that do not contain the required level of the characterizing live and active cultures would not be named “yogurt”; rather they would be named “cultured milk” or “fermented milk.” Consequently, NYA stated, consumers would not be misled into believing that these foods contain a significant amount of live and active cultures.

NYA also maintained that its proposal would ensure that aspects of yogurt labeling, such as the use of nutrient content claims, are consistent with the requirements of the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535). NYA stated that its proposed standard maintains the three yogurt types (full fat, lowfat, and nonfat yogurts) so manufacturers can continue to make lowfat and nonfat yogurts without meeting the nutritional equivalence requirement as described in § 130.10 (21 CFR 130.10). In addition, NYA maintained that its proposed standard would change the milkfat content requirements of lowfat and nonfat yogurts to “directly parallel” the nutrient content claim requirements for the terms “lowfat” and “nonfat” established under the NLEA (21 CFR 101.62(b)).

Additionally, NYA noted that food technology has advanced and industry practices related to yogurt manufacturing have changed since the yogurt standards have been in place. Consequently, NYA asserted that the current yogurt standards impede the yogurt industry and do not allow manufacturers to implement advances in food technology. NYA stated that its proposed

standard establishes a modernized, flexible standard of identity for yogurt, taking into account current industry practices and recognizing the need to allow for use of future technologies.

### **III. Matters of Particular Interest to FDA**

FDA requests that interested persons submit data and information concerning the need for, and the appropriateness of, revoking the standards for lowfat and nonfat yogurt and amending the standards for yogurt and cultured milk. FDA specifically requests comment on the following provisions set forth in the petition:

1. A single standard of identity for yogurt, which includes provisions for lowfat and nonfat yogurts;
2. A minimum of  $10^7$  CFU/g of live and active characterizing cultures at the time of manufacture of yogurt;
3. An acidity of pH 4.6 or lower, rather than the current requirement of titratable acidity expressed as lactic acid in yogurt;
4. The use of optional milk-derived ingredients after pasteurization and culturing of yogurt;
5. The use of reconstituted dairy ingredients and WPC as basic dairy ingredients in yogurt, and the specifications related to WPC, when used;
6. The optional use of any milk-derived ingredient that provides a technical or functional purpose in yogurt;
7. The minimum dairy ingredients content requirement of 51 percent of the total weight of yogurt;
8. The use of any safe and suitable nutritive or nonnutritive sweeteners in yogurt;
9. The use of safe and suitable emulsifiers in yogurt;
10. The use of safe and suitable preservatives in yogurt;

11. The use of any safe and suitable ingredient added for a nutritional or functional purpose in yogurt;

12. The use of the descriptor “nonfat” on a yogurt that may contain less than 0.5 g of total fat per RACC (i.e., 225 g for yogurt (21 CFR 101.12));

13. The use of the descriptor “lowfat” on a yogurt that may contain at least 0.5 g but not more than 3.0 g total fat per RACC; and

14. The need to amend the standard for cultured milk to provide for the alternate term “fermented milk” and to make it consistent with any changes made in the standard for yogurt, and the appropriateness of the proposed amendments to the standard for cultured milk.

After reviewing the comments received, FDA will determine the need for, and appropriateness of, each of the amendments requested by NYA and will decide what actions are appropriate. To facilitate comment, in the following paragraphs FDA discusses some of the amendments requested by NYA.

1. The standards for yogurt and cultured milk proposed by NYA permit the use of any safe and suitable ingredient added for a nutritional or functional purpose. NYA states that this provision is necessary to maintain enough flexibility in the standards to permit the use of novel ingredients as they are developed. FDA 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. The existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose. Under the provisions of § 130.10, standardized foods may be modified to contain nutrients not specifically permitted by the relevant standard of identity and to make an expressed nutrient content claim defined by FDA regulation. FDA also notes that flexibility in the use of ingredients

for a functional purpose may be achieved by specifying the ingredients by functional use category, e.g., “emulsifiers” or “preservatives,” rather than by listing the specific ingredients. FDA seeks comment on the need for any functional ingredient categories, in addition to the ones proposed by the petition, in the manufacture of yogurt.

2. NYA proposed amendments to the current standard of identity for cultured milk (§ 131.112) to provide for the alternate term “fermented milk” and to allow the use of currently prohibited ingredients that would be permitted by NYA’s proposed standard for yogurt. NYA stated that under its proposed amendments, if the food otherwise meets the yogurt standard of identity but does not contain the characterizing cultures at the required levels, then the food qualifies as cultured milk or fermented milk. The standard of identity for cultured milk has been in place for several decades. In light of consumer experience with the standard for cultured milk, FDA solicits comment on the need to amend it and the appropriateness of the amendments requested by NYA.

3. The current standards for yogurt, lowfat yogurt, and nonfat yogurt permit heat treatment after culturing, with the requirement that such treatment be declared in the name of the food. FDA notes that NYA’s proposed standard does not allow for heat treatment after culturing, and seeks comment on the appropriateness of omitting this provision.

4. NYA proposed a maximum pH of 4.6 for yogurt and stated that this level reflects the lower end of titratable acidity levels found in common industry practice. NYA also stated that measuring pH, rather than titratable acidity expressed as lactic acid, reflects the current industry practice and is a more accurate and convenient method of measuring acidity. FDA seeks

comment both on the acidity level proposed by NYA and the use of pH rather than titratable acidity.

5. FDA notes NYA's assertion that consumers expect yogurt to contain significant amounts of live and active cultures, as well as NYA's proposed requirement to measure live and active cultures at the time of manufacture. NYA proposed that manufacturers "may" test their yogurt products to demonstrate that the products, under proper distribution and storage conditions, would be expected to contain at least  $10^6$  CFU/g of live and active cultures through the manufacturer's designated code life (i.e., shelf life) for the product and at the anticipated time of consumption. However, as a legal requirement, NYA proposed a minimum of  $10^7$  CFU/g at the time of manufacture because, NYA maintained, once the products enter the stream of commerce, products are subject to different distribution and storage conditions that are not within the manufacturer's control. FDA seeks comment on: (1) Whether the presence of live and active cultures is an essential characteristic of yogurt and, if so, in what amounts; (2) the appropriateness of NYA's proposed provision that manufacturers "may" conduct tests to ensure the presence of live and active cultures through the assigned code life for the product; and (3) whether NYA's proposed standard of identity for yogurt would adequately ensure the presence of appropriate amounts of live and active cultures in yogurt throughout the shelf life of the product and at the point of purchase or consumption. FDA also seeks comment on any alternative provisions that may be needed to fulfill this requirement.

Finally, FDA seeks comment on vitamin A fortification. FDA previously proposed to revoke a number of lowfat and nonfat standards in parts 131 and 133 (21 CFR part 133) (i.e., §§ 131.122 (Sweetened condensed skimmed milk),

131.123 (Lowfat dry milk), 131.132 (Evaporated skimmed milk), 131.135 (Lowfat milk), 131.136 (Acidified lowfat milk), 131.138 (Cultured lowfat milk), 131.143 (Skim milk), 131.144 (Acidified skim milk), 131.146 (Cultured skim milk), 131.185 (Sour half-and-half), 131.187 (Acidified sour half-and-half), 131.203 (Lowfat yogurt), 131.206 (Nonfat yogurt), and 133.131 (Lowfat cottage cheese) (60 FR 56541, November 9, 1995)) to ensure that the use of nutrient content claims in the labeling of these products would be consistent with the provisions of the NLEA. In the final rule (61 FR 58991, November 20, 1996), FDA revoked all of the previously mentioned standards except for lowfat yogurt and nonfat yogurt. FDA delayed final action on its proposal to revoke these standards for 120 days because of the technical difficulties and economic considerations associated with their revocation (61 FR 58991 at 58999). FDA acknowledged that if the standards for lowfat and nonfat yogurts were revoked, modifying the standardized food yogurt to make the nutrient content claims “lowfat” or “nonfat” under the provisions of § 130.10 would require vitamin A fortification to make the product nutritionally equivalent to full fat yogurt. FDA also acknowledged that such a fortification requirement could potentially result in significant relabeling, reformulation, and equipment costs to manufacturers. The agency had hoped that the 120-day deferral would provide an appropriate balance between the problem the industry was facing and consumers’ interest in consistently and fairly labeled foods. Unfortunately, this issue has not been resolved. According to the yogurt standard proposed by NYA, manufacturers would continue to be able to make lowfat and nonfat yogurts without having to meet the nutritional equivalence requirement. FDA seeks comment on whether the yogurt industry is better able and equipped to meet the nutritional equivalence requirements of § 130.10 than it was in

1996 when FDA deferred action on this issue. FDA also seeks comment on the need and appropriateness of continuing to exempt yogurt from the nutritional equivalence requirement, unlike other standardized foods making lowfat and nonfat nutrient content claims.

#### IV. NYA Requested Amendments

The requested amendments of the yogurt standard and the cultured milk standard submitted by NYA are set forth in the following paragraphs. The following language is as suggested by NYA; FDA has made only minor nonsubstantive changes. FDA will evaluate the need and appropriateness of these regulations proposed by NYA following the receipt of public comments.

NYA's suggested standard of identity for yogurt is as follows:

##### *Section 131.200 Yogurt.*

(a) *Description.* Yogurt is the food produced by culturing one or more of the standard dairy ingredients specified in paragraph (b) of this section. Yogurt contains at least  $10^7$  CFU/g active yogurt cultures, at the time of manufacture, of the characterizing lactic acid-producing bacteria, *Lactobacillus delbrueckii subsp. Bulgaricus* and *Streptococcus thermophilus*, and the manufacturer may have records demonstrating that, under proper conditions of distribution and storage, the yogurt will contain at least  $10^6$  CFU/g live and active cultures through the manufacturer's assigned code life (i.e., shelf life) for the product. One or more of the optional ingredients specified in paragraph (c) of this section may also be added. All ingredients used are safe and suitable. Yogurt, before the addition of optional ingredients specified in paragraph (c) of this section, contains not less than 8.25 percent milk solids not fat from the standard dairy ingredients specified in paragraph (b) of this section, and has a pH of 4.6 or lower. Dairy ingredients comprise at least 51 percent of the food's overall ingredients by weight. The food may be homogenized and the ingredients specified in paragraph (b) of this section shall be pasteurized

or ultra-pasteurized prior to the addition of the characterizing yogurt bacterial cultures.

(b) *Standard dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of these standard dairy ingredients may be used alone or in combination. Whey protein concentrate (WPC), minimum protein concentrate 34 percent, may be used if the total quantity of WPC used in this paragraph and paragraph (c) of this section does not result in a quantity of WPC that exceeds 25 percent of the total milk solids not fat. When one or more of the ingredients specified in this paragraph is used, it shall be included in the culturing process.

(c) *Optional dairy ingredients.* (1) Dairy ingredients. Any milk-derived ingredients used for technical or functional purposes.

(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 Units (IU) per reference amount customarily consumed (RACC).

(ii) If added, vitamin D shall be present in a minimum quantity of 100 IU per RACC.

(9) Any safe and suitable ingredients added for nutritional or functional purposes.

(d) *Methods of analysis.* (1) Enumeration of live and active cultures—As determined by the method prescribed by the International Dairy Federation.

(2) Milk solids not fat content—Calculated using the following methods from the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 15th Ed. (Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2417, or available for inspection at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC). Subtract the milkfat content (as determined by the method prescribed in section 16.059 “Roese-Gottlieb Method (Reference method) (11)—Official Final Action, under the heading “Fat”) from the total milk solids content (as determined by the method prescribed in section 16.032, “Method I—Official Final Action,” under the heading “Total Solids”).

(3) pH—As determined under § 114.90(a) of this chapter, “Potentiometric method for the determination of pH.”

(e) *Nomenclature.* (1) If the food contains the amount of live and active *Lactobacillus delbrueckii subsp. Bulgaricus* and *Streptococcus thermophilus* cultures as indicated in paragraph (a) of this section, the food is “yogurt,” except:

(i) If the finished food complies with the requirements of § 101.62(b)(4)(i) of this chapter, and is not “lowfat yogurt” or “nonfat yogurt,” then the food must comply with § 101.62(b)(4)(ii) of this chapter, and the name of the food is “reduced fat yogurt.”

(ii) If the finished food contains at least 0.5 g, but not more than 3.0 g, total fat per RACC, then the name of the food is “lowfat yogurt.”

(iii) If the finished food contains less than 0.5 g total fat per RACC, the name of the food is “nonfat yogurt.”

(2) The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(3) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word “sweetened” if a sweetener is added without the addition of characterizing flavor.

(ii) The phrase “vitamin A” or “vitamin A added,” or “vitamin D” or “vitamin D added,” as appropriate. The word “vitamin” may be abbreviated “vit.”

(f) *Declaration of ingredients.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

NYA’s suggested standard of identity for cultured milk is as follows:

*Section 131.112 Cultured Milk/Fermented Milk.*

(a) *Description.* Cultured milk or fermented milk is the food produced by culturing one or more of the standard dairy ingredients specified in paragraph (b) of this section with characterizing microbial organisms. One or more of the optional ingredients specified in paragraph (c) of this section may also be added. All ingredients used are safe and suitable. Cultured milk or fermented milk, before the addition of optional ingredients specified in paragraph (c) of this section, contains not less than 8.25 percent milk solids not fat from the standard dairy ingredients specified in paragraph (b) of this section, and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid, before the addition of bulky flavors. Dairy ingredients comprise at least 51 percent of the food’s overall ingredients by weight. The food may be homogenized and the ingredients specified in paragraph (b) of this section shall be pasteurized or ultra-pasteurized prior to the addition of the microbial cultures.

(b) *Standard dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of any of these standard dairy ingredients may be used. Whey protein concentrate (WPC), minimum protein concentrate 34 percent, may be used if the total quantity of WPC used in this paragraph and paragraph (c) of this section does not result in a quantity of WPC that exceeds 25 percent of the total

milk solids not fat. When one or more of the ingredients specified in this paragraph is used, it shall be included in the culturing process.

(c) *Optional ingredients.* (1) Dairy ingredients. Any milk-derived ingredients used for technical or functional purposes.

(2) Aroma- and flavor-producing microbial culture.

(3) Safe and suitable sweeteners.

(4) Flavoring ingredients.

(5) Color additives that do not impart a color simulating that of milkfat or butterfat.

(6) Stabilizers and emulsifiers.

(7) Preservatives.

(8) Vitamins and minerals.

(i) If added, vitamin A shall be present in a minimum quantity of 500 IU per RACC.

(ii) If added, vitamin D shall be present in a minimum quantity of 100 IU per RACC.

(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.

(12) Any safe and suitable ingredients added for nutritional or functional purposes.

(d) *Methods of analysis.* (1) Milk solids not fat content—Calculated using the following methods from the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 15th Ed. (Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg,

MD 20877–2417, or available for inspection at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC). Subtract the milkfat content (as determined by the method prescribed in section 16.059 “Roese-Gottlieb Method (Reference method) (11)—Official Final Action, under the heading “Fat”) from the total milk solids content (as determined by the method prescribed in section 16.032, “Method I—Official Final Action,” under the heading “Total Solids”).

(2) Titratable acidity—As determined by the method prescribed in section 16.023, “Acidity (2)—Official Final Action,” or by an equivalent potentiometric method.

(e) *Nomenclature.* (1) The name of the food is “cultured milk” or “fermented milk,” except:

(i) If the finished food complies with the requirements of § 101.62(b)(4)(i) of this chapter, and is not “lowfat fermented milk” or “lowfat cultured milk” or “nonfat fermented milk” or “nonfat cultured milk,” then the food must comply with § 101.62(b)(4)(ii) of this chapter, and the name of the food is “reduced fat fermented milk” or “reduced fat cultured milk.”

(ii) If the finished food contains at least 0.5 g, but not more than 3.0 g, total fat per RACC, then name of the food is “lowfat fermented milk” or “lowfat cultured milk.”

(iii) If the finished food contains less than 0.5 g total fat per RACC, the name of the food is “nonfat fermented milk” or “nonfat cultured milk.”

(2) The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(3) The name of the food shall be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., “kefir cultured milk,” “acidophilus fermented milk,” or when characterizing ingredients such as those in paragraphs (c)(2), (c)(9), (c)(10), and (c)(11) of this section

and lactic acid-producing organisms are used, the food may be named “cultured buttermilk.”

(4) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word “sweetened” if a sweetener is added without the addition of characterizing flavoring.

(ii) The phrase “vitamin A” or “vitamin A added,” or “vitamin D” or “vitamin D added,” or “vitamin A and D added,” as appropriate. The word “vitamin” may be abbreviated “vit.”

(5) The parenthetical phrase “(heat-treated after culturing)” shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

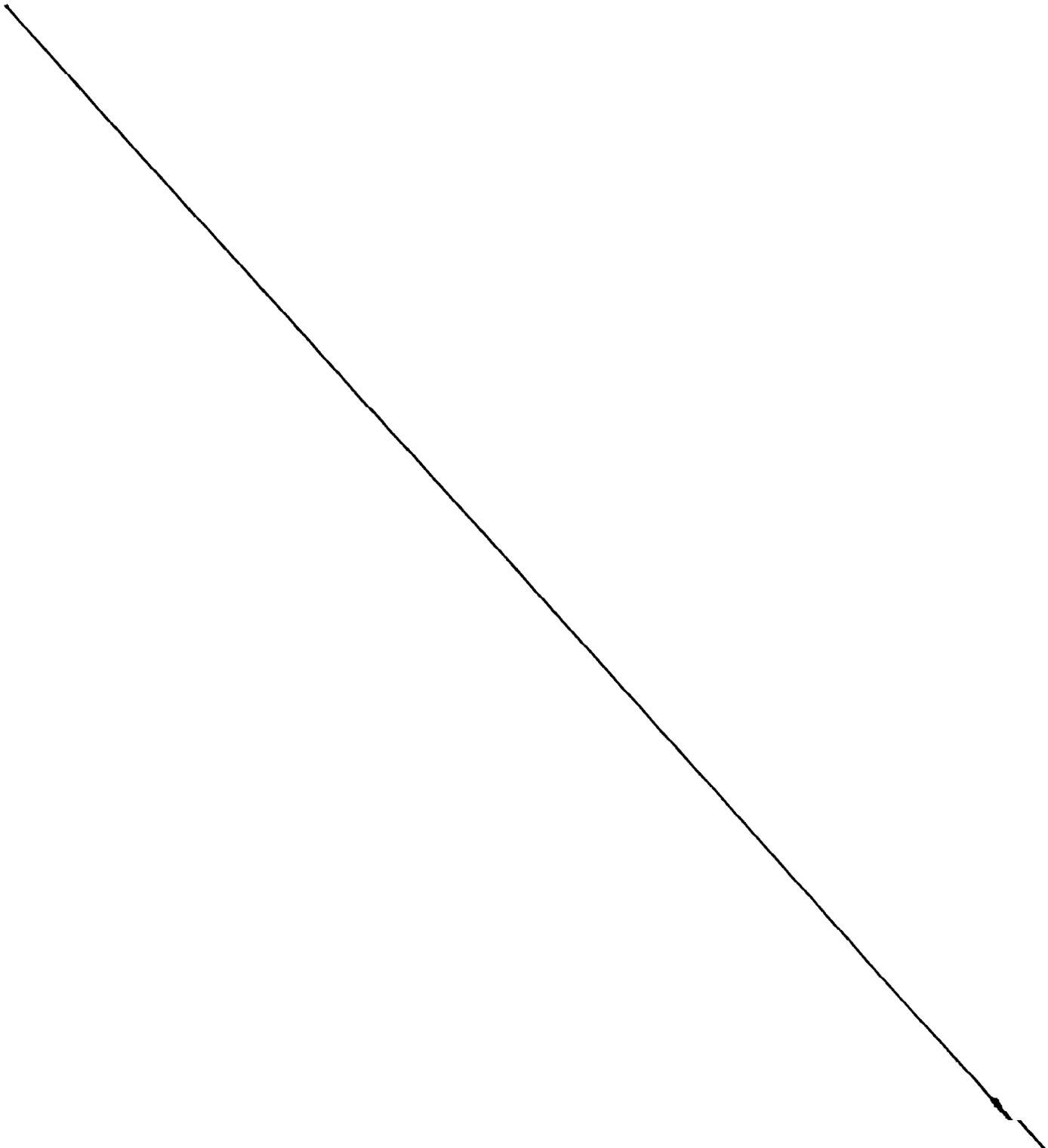
(f) *Declaration of ingredients.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

## **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. The petition and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**VI. Authority**

This advance notice of proposed rulemaking is issued under sections 201, 401, 403, 409, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, and 379e), and under the authority of the



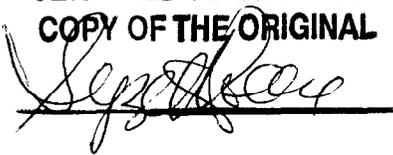
Commissioner of Food and Drugs, as redelegated to the Director, Center for Food Safety and Applied Nutrition.

Dated: 6/3/03  
June 3, 2003.

  
L. Robert Lake,  
Director,  
Office of Regulations and Policy,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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