DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket N0. 91N-0344]

RIN 0905-AD08

Labeling: Use of Nutrient Content Claims Food for Butter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting a regulation that will permit nutrient content claims that are defined by regulation in 21 CFR part 101 to be made for butter. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: May 8, 1994.

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SUPPLEMENTARY INFORMATION:

I. Background

In response to the 1990 amendments (Pub. L. 101-535) and to a citizen petition submitted by Johanna Farms, Inc., Flemington, NJ 08822, (Docket No. 90P-0141), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60523), a proposal to adopt § 101.67, which would permit nutrient content claims that are defined by regulation in part 101 (21 CFR part 101) to be made for butter. Interested persons were given until February 25, 1992, to comment on this proposed regulation.

FDA received approximately 70 responses on the proposal, each of winch contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, retailers, consumer groups, State groups, private organizations, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., serving size and nutrient content claims definitions) and will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

II. Use of Nutrient Content Claims for Butter Under the 1990 Amendments

A. The Proposed Approach

FDA requested comments on its proposed approach to permit nutrient content claims to be made for butter (56 FR 60523 at 60525).

1. Two comments stated that FDA had the authority to promulgate § 101.67 independent of the 1990 amendments. One of the comments said that a better approach would have been under the general provisions of proposed § 130.10 or through a standard of identity. It stated that a food that does not meet the statutory standard for butter is not butter, and that accordingly, a product with less milkfat simulating butter would need to be labeled "imitation" in the absence of some other governing agency mechanism, such as a standard of identity for "light butter." The comment maintained that since "light" would be part of the name, the product would not be butter because the definition would be different. The product would not be nutritionally inferior, the comment continued, because it would be required to provide the same nutrients as butter (except for less fat), and it would not be deceptive because properly informative labeling would be required and monitored by the agency.

The agency disagrees with the comments. As explained in the proposal (56 FR 60523 at 60524), the agency does not have the authority to establish a definition and standard of identity for "light butter." Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) states that no definition and standard of identity can be established for butter. Moreover, FDA has historically taken the position that a product using the term "butter" must comply with the statutory definition of butter, or its labeling would be false, and it would be misbranded under section 403(a)(1) of the act (21 U.S.C, 343(a)(1)) (see 56 FR 60523 at-60524). In addition, a food sold under the name "butter" that does not comply with the statutory standard' for butter also is in violation of section 403 (b) of the act in that it is sold under the name of another food.

As discussed in the proposed rule, FDA sought an interpretation that gave effect both to section 3(b)(1)(A)(viii) of the 1990 amendments (21 U.S.C. 343 note), which stated that FDA could establish a regulation that would permit a nutrient content claim, such as "light," to be made for butter, and to section 401 of the act. FDA believes that it achieved this goal, in proposed § 101.67. These comments, since they rely on section 401 of the act, have not provided any basis to conclude to the contrary.

2. A number of comments opposed providing for the use of nutrient content claims for butter. Several comments recommended that the term "butter" be used only if the product complies with the statutory standard for butter, and that other names such as "dairy spread" be used for other butter products. Some comments stated that if a product is good it will develop its own distinctive name.

The agency understands the concerns expressed by these comments. However, the 1999 amendments and their legislative history make clear that Congress fully intended that a claim described in section 403(r)(1)(A) of the act (such as "light") be permitted to be made for butter (H. Rept 101-538,101st Cong., 2d sess, 22-23 (June 13, 1990)). Given this fact, there is no basis to require the use of terms such as "dairy spread" in the common or usual names of these products. Accordingly, FDA is allowing, as proposed, nutrient content claims to be made for butter.

B. The Nutrient Content Claim

3. Several comments expressed concern about consumers being able to identify butter products on the store shelf. The comments were concerned that nutrient content claims could mislead and confuse consumers even if they are defined.

The agency appreciates that concerns expressed by the comments. In response to the requirements of the 1990 amendments, published elsewhere in this issue of the **Federal Register**, in a document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule), FDA is establishing in part 101 definitions for nutrient content claims together with general principles governing their use. FDA has carefully considered each nutrient content claim to ensure that these definitions will be meaningful to consumers. Each of the definitions for the nutrient content claims also prescribes specific labeling that must accompany the claim. The agency believes that as consumers learn what a claim means, they will be able to understand that a product such as "light butter" is reduced a certain amount in fat. Thus, the use of nutrient content claims for butter products in accordance with new § 101.67 will not mislead or confuse consumers but will assist them in maintaining healthy dietary practices.

New § 101.67 only provides for the use for butter of nutrient content claims

that have been defined by FDA. Any product labeled as "butter" that does not come within the provisions of new § 101.67 will need to comply with the statutory standard for butter, or its labeling will be false, and it will be misbranded under the act.

FDA notes, however, that there are two potential problems that proposed § 101.67 failed to address that could cause confusion among consumers. In the proposal, FDA did not require that the nutrient content claim be included as part of the statement of identity of the butter product. Consequently, a claim could be made for the butter product in an inconspicuous location on the label, and consumers could be misled about the identity of the product that does not comply with the statutory standard for butter (section 201a of the act (21 U.S.C. 321a)).

In addition, FDA did not distinguish between express and implied claims in the proposal. Yet section 403(r)(1)(A) of the act applies to both types of nutrient content claims.

Therefore, to rectify this potential confusion. FDA is adding § 101.67(a)(4) to make clear that while nutrient content claims may be made anywhere on the label, if the product would violate section 201a of the act but for the nutrient content claim that characterizes the level of nutrients, that claim must be included as part of the common or usual name of the product. This provision will ensure that consumers are not misled about the identity of the product.

New § 101.67(a)(4) also provides that if the name of the butter product is necessary to distinguish it from butter, the claim must be an express claim as defined in new § 101.13(b)(1). If the claim is not express, consumers will not understand how the new modified food differs from the traditional food. Thus, only expressed nutrient content claims may be used in the name of the food under new § 101.67. While implied claims may be used as provided in new § 101.13(b)(2), they may not be used in conjunction with the name of the butter product because they would not be adequately informative to consumers.

4. One comment stated that FDA should decide on a more appropriate name than "light butter," such as "light butter product."

The agency does not believe the suggested additional term (i.e., '"product") is necessary. If a butter product does not comply with the statutory standard for butter or the requirements of new § 101.67 set forth below, FDA requires that it be labeled either as an imitation food if it is nutritionally inferior to butter (§ 101.3(e)(1)), or as a substitute or alternative food if it is not nutritionally inferior to the food for which it substitutes, with an appropriately descriptive common or usual name that is not false and misleading, as provided for in § 102.5 (21 CRR 102.5), or, in the absence of an existing common or usual name, an appropriately descriptive term that is not false and misleading (§101.3(e)(2) (21 CFR 101.3(e)(2))). As explained above in comment 2 of this document, the legislative history of the 1990 amendments makes clear that Congress fully intended that a claim described in section 403(r)(1)(A) of the act (such as "light") be permitted to be made for butter (H. Rept. 101-538, supra, 22-23). Given this fact, there is no basis to require the use of additional terms such as "product" in the common or usual names of these foods. The use of a nutrient content claim that is permitted by regulation with the term "butter" in the statement of identity will provide a clear indication to consumers that the food is different from traditional butter and will describe the nature of the modification. In addition, the label must comply with all the requirements for the use of the nutrient content claim. Accordingly, the agency is not making the suggested modification to new §101.67.

5. A number of comments suggested that FDA should develop unique nutrient content claims for butter because the proposed nutrient content claim requirements for fat in proposed § 101.62 are not appropriate or realistic for butter products. Two comments added that the use of unique nutrient claims for butter is consistent with the directive in the President's Executive Order 12630 that regulations harness the mechanisms of the market (e.g., competition in percentage reductions) to accomplish, the agency's goal. One comment stated that it had test marketed a 50-percent reduced fat butter for over a year, but that the product failed to meet consumers' expectations, principally in physical performance characteristics. Another comment suggested that a reduced fat butter containing one-third less fat than butter is a product that will significantly reduce fat consumption while having all the characteristics of full-fat butter. The comments urged FDA to adopt simple definitions for nutrient content claims that will allow the industry to make dairy products with less fat and cholesterol available to consumers. One comment noted that a number of states have established regulations for light butter that differ from FDA's proposal. The comment urged FDA to use the knowledge and information obtained by these states in their respective hearing processes to modify FDA's proposed regulations to redefine the term "light" as used with butter products.

FDA notes that because no uniform set of definitions has existed for many nutrient content claims, these claims have been used in an inconsistent manner, which has resulted in consumers being confused and misled. The legislative history of the 1990 amendments makes clear that Congress was aware that many food labels bear terms such as "light" when a product may not be as "light" as the label indicated, or the product was "light" in different ways (e.g., calories or sodium). The purpose of the 1990 amendments was to correct this deceptive and misleading state of affairs by requiring that terms such as "light" have a single meaning (136 Congressional Record H5844, July 30, 1990).

The agency recognizes that because butter is at least 80 percent milkfat, a significant reduction in milkfat produces a significant change in the product. In the nutrient content claims final rule, FDA is redefining "reduced" and "less" to be a reduction of 25 percent or more. Thus, many butter products will be able to meet these requirements and make a nutrient content claim. Also, there is evidence that some manufacturers will be able to meet the 50-percent reduction to qualify for use of the term "light." Thus, FDA sees no reason to create a special set of definitions for butter products under new §101.67.

FDA recognizes that some states and foreign governments have developed their own definitions for nutrient content claims for butter. However, FDA concludes that use of nutrient content claims in an inconsistent manner would be confusing to consumers, and, thus, the agency is not considering the use of any unique nutrient content claims for butter.

C. Minimum Milkfat Level

In the House report on the 1990 Amendments, FDA is directed to consider arguments concerning the appropriate characteristics of butter. In a footnote, the report states:

> The Committee is aware that the dairy industry takes the position that products containing less than approximately 50 percent milkfat lose some of the characteristics of butter. In connection with the promulgation of the regulations, representatives of dairy interests and health experts will have the opportunity to present their views on the issue to the Secretary. (H. Rept. 101-538, supra, 23, n.3.)

In the proposal, FDA requested comments on whether its tentative

decision not to include a minimum milkfat level in proposed § 101.67 was appropriate (56 FR 60523 at 60526).

6. A number of comments concurred with the agency's tentative decision. Comments stated that there is no need to stipulate minimum levels. The comments also stated that not requiring a minimum milkfat level for butter products would leave room for advances in food processing technology that could lead to products with lower levels of milkfat and greater health benefits while still maintaining the characteristics of standardized butter. Another comment concurred as long as the product bearing the term "butter" is describable as a form of butter, because of the fact that its similarities to butter nutritionally, organoleptically, functionally, and in other ways would clearly outweigh its dissimilarities to butter.

One comment stated that FDA should set a minimum butterfat level, below which the product is no longer a butter product. However, the comment did not recommend a minimum level.

FDA agrees with the comments suggesting that a minimum milkfat level is not necessary. A product remains a butter product as long as the major ingredients used in manufacturing it are cream, milk, or constituents of milk and cream and as long as it can be used like butter. In addition, the butter product must comply with all the requirements of new § 101.67 for the use of nutrient content claims for butter products. For example, the milkfat content of butter contributes some of the basic characteristics of the food. New § 101.67(b) provides that the performance characteristics must be similar to those of butter, or the differences must be stated on the principal display panel.

The agency notes that Canadian regulations do not stipulate a minimum milkfat level for "calorie reduced butter."

Therefore, for the above reasons, the agency concludes that there is no need to specify a minimum milkfat level for butter products. The absence of a minimum level will permit technological advances that will provide consumers with butter products that have even greater reductions in fat and calories.

D. Ingredients

FDA requested comments on the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend shelf life, FDA also requested comments concerning the addition of water as well as skim milk, whey, or milk to replace milkfat as an ingredient in substitute butter products. FDA stated in the proposal that if the comments supported file use of safe and suitable nondairy ingredients and provided a substantial basis for their use, FDA might provide for the use of these ingredients in the final rule (56 FR 60523 at 60526).

(1) Safe and Suitable Nondairy Ingredients

7. A number of comments stated that the use of nondairy ingredients should not be permitted. Several comments argued that if manufacturers are adding anything that makes the food something other than butter, it should be labeled as "margarine," "spread," or "margarine." One comment stated that use of nondairy ingredients in a butter product would mislead consumers because consumers expect "butter" to be a dairy product. It added that use of such ingredients would erode the goodwill associated with the term "butter." The comment stated that the fact that current reduced fat butter produces made without nondairy ingredients are not satisfactory for some cooking applications is not a reason to permit the use of such ingredients in products whose statement of identity includes the term "butter." It stated that consumers who want reduced fat, reduced calorie products for use in cooking can turn to products properly labeled as margarines and spreads.

Another comment stated that consumers purchasing and using a butter product expect it to be a 100 percent dairy product and thus made from the ingredients and constituents of the ingredients listed in section 201a of the act for standardized butter. It added that use of additional safe and suitable ingredients is not necessary for butter products. It stated that the only exception should be the permitted addition of nutrients to prevent nutritional inferiority and the permitted use of safe and suitable bacterial cultures as proposed in the regulation.

A number of other comments urged FDA to allow the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend the shelf life of the product. One comment stated that FDA should permit the addition of safe and suitable nondairy ingredients that are not fat ingredients for such purposes. Another comment urged FDA to allow the use of safe and suitable ingredients without the restriction that they must be used to maintain the traditional food's performance characteristics as long as the use is in keeping with current good manufacturing practices. The comment stated that the potential need to use safe and suitable ingredients for processing as well as performance, purposes is most apparent for reformulated butter products because butter is a high fat food, and fat affects processing characteristics as well as final performance characteristics. Several comments argued that providing for the use of safe and suitable ingredients would allow the development of additional products with lower saturated fat, total fat, and cholesterol.

One comment stated that using current technology, "reduced fat" butter made strictly from dairy ingredients is not suitable for frying or baking. It stated that in the event that a "reduced fat" butter made primarily from dairy ingredients cannot be developed with good baking characteristics, then the field needs to remain open to "reduced fat" butter that is made with some nondairy ingredients and that has good baking properties. It added that without these additional ingredients, consumers will have trouble finding "reduced fat" butter that meets their needs and will be discouraged from shifting from full fat to reduced fat butter.

One comment argued that FDA's authority to allow the use of nutrient content claims for butter also gives the agency the authority to allow safe and suitable ingredients, including nondairy ingredients, in a product that is named by using a nutrient content claim with the term "butter." The comment added that FDA has already recognized this authority by providing for two types of ingredients (nutrients and bacterial cultures) in the proposed rule that are not permitted in standardized butter. It urged FDA to modify the regulation consistent with the regulation for substitute foods.

One comment stated that a reduction in milkfat of 50 percent in a butter product made without the use of safe and suitable nondairy ingredients results in a product that fails to meet consumers' expectations for many of the principal uses of a butter product (e.g., baking, frying, melting, sauteing). The comment stated that a light butter product that meets the proposed requirements in proposed § 101.67 (i.e. 50 percent less milkfat than butter and no ingredients other than those allowed in proposed § 101.67) is currently being marketed in Canada. The comment stated that Professor David Bandler of Cornell University testified before the New York Department of Agriculture and Markets regarding a hearing to establish a standard of identity in New York for light butter. The comment stated that Professor Handler testified that the Canadian light butter product that he evaluated was really a

combination of butter and cream mixed together, and one could easily determine that the product may not be butter for many of the principal uses a consumer would have for butter. (Hearing Transcript, December 4, 1990. State of New York Department of Agriculture and, Markets, p. 66.) The comment stated that New York and five other states have established standards for light butter end have provided for the use of safe and suitable nondairy ingredients. The comment urged FDA to allow safe and suitable nondairy ingredients in butter products for which nutrient content claims are made.

Other comments added that use of other safe and suitable ingredients was acceptable as long as the addition of these ingredients is clearly stated on the label and explained in the labeling.

The legislative history of the 1990 amendments makes clear that Congress intended that consumers should be able to use nutrient content claims made for butter to assist them in following dietary guidelines (see H. Rept 101-538,101st Cong., 2d sess. 10, 23 (1990)). This intent has two necessary implications. First, Congress obviously intended that FDA adopt provisions that authorize that butter products that bear nutrient content claims be marketed. This intent is reflected in section 3(b)(1)(A)(viii) of the 1990 amendments.

Secondly, it is not enough to merely allow such products on the market. If these products are to be used to accomplish the purpose envisioned by Congress, they must have consumer acceptance, and they must be available for the full range of uses for which people use butter. If not, the products will quickly disappear from the market, or the uses of these products will be so limited as to have little dietary significance.

In light of these factors and of the comments that the agency received, FDA has reconsidered the proposal and concludes that it took too narrow an approach to defining the products that can appropriately include the term "butter" in their names. The comments have demonstrated that there are instances in which the minor addition of safe and suitable nondairy ingredients is necessary to reduce the fat and calories in butter products while maintaining the characteristics of butter, thereby increasing the products' consumer acceptability.

The agency notes that the use of nondairy ingredients in a daily product like butter is not unprecedented, does not change its character, and, thus, would not mislead consumers. FDA has reviewed the dairy standards of identity in parts 131, 133, and 135 (21 CFR parts 131, 133, and 135) to determine what nondairy ingredients may be optionally added to dairy products. A number of the dairy standards provide for the use of ingredients such as flavors, emulsifiers and stabilizers (e.g., lowfat dry milk (§ 131.123), evaporated milk (§ 131.13G), skim milk (§ 131.143), and heavy cream (§ 131.150)). The standard of identity for sour cream (§ 131.160) provides for the optional use of safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product. The standard for spour cream also provides for the optional use of fruit and fruit juice and safe and suitable natural and artificial food flavoring as flavoring ingredients. Therefore, safe and suitable nondairy ingredients are already added to many types of dairy products to improve texture, add flavor, prevent syneresis, and extend shelf life, and these products remain dairy products. If these nondairy ingredients are useful in dairy products standardized in parts 131, 133, and 135, FDA believes that they may be useful in butter products.

FDA disagrees with the comment that urged FDA to allow the use of safe and suitable ingredients without restriction. The agency concludes that butter products should contain minor amounts of safe and suitable nondairy ingredients only when necessary to achieve the functions of ingredients or components of ingredients that are no longer present in the mandated quantities. As required in new § 101.67(b), the performance characteristics (e.g., physical properties, organoleptic charaacteristics, functional properties, and shelf life) of the butter product must be similar to those of butter. Safe and suitable ingredients added only as necessary to butter products to improve texture, add flavor, prevent syneresis, and extend shelf life will compensate for many deficiencies in performance characteristics.

The agency disagrees that it should permit safe and suitable ingredients in butter products to be consistent with the general standard in all cases. As explained in the proposal (56 FR 60523 at 60524 and 60525) and in a document entitled "Foods Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard final rule) published elsewhere in this issue of the **Federal Register,** the legal and policy, analysis of butter is different from foods standardized by regulation. Therefore, butter products are not included in § 130.10 foods but, are regulated separately.

However, in § 130.10(d)(1), FDA provides for the use of safe and suitable ingredients in modified standardized foods to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the traditional standardized food. FDA believes that the additional purposes (i.e., to improve appearance and add sweetness) for adding safe and suitable ingredients to modified foods also has application to butter products. Butter products with significantly less fat may appear more translucent than butter. Thus, ingredients to improve appearance are necessary to ensure that the product is not inferior in performance characteristics. Additionally, butter products may lack the sweetness of unsalted, sweet cream butter. Thus, ingredients to add sweetness may also be necessary to ensure that the product is not inferior in organoleptic characteristics.

Thus, FDA concludes that it is reasonable to provide for the use of safe and suitable ingredients because such use would enhance manufacturers' ability to produce butter products that perform as consumers expect. However, butter products must be made from cream or milk, or their constituents, with only those safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, improve shelf life, improve appearance, and add sweetness. FDA emphasizes that butter products in compliance with new § 101.67 are dairy products, and that any addition of safe and suitable nondairy ingredients must be only in minor amounts. The addition of safe and suitable nondairy ingredients to butter products labeled under § 101.67 in excess of that which is reasonably required to achieve the performance characteristics of butter produced under 21 U.S.C. 321a constitutes deception and will be deemed to adulterate the food under section 402(b) of the act in that these ingredients ere substituting for a valuable constituent. Therefore, FDA is including in new § 101.67(b) a requirement that deviations from ingredient provisions of 21U.S.C. 321a must be the minimum necessary to achieve this effect, or the food will be deemed to be adulterated under section 402(b) of the act. The agency advises that products with nondairy ingredients in excess of these amounts fall outside of new § 101.67 and must be labeled as imitation butter if nutritionally inferior to regular butter, as butter alternatives or substitutes if not nutritionally

inferior to butter, or, if appropriate, as margarine, a margarine product, or a spread.

The agency also concludes that butter products labeled according to applicable regulations will not decrease the significance associated with the term "butter." The addition of safe and suitable ingredients must be declared in the ingredient statement as required in § 101.67(c).

FDA advises that if flavors are added to a butter product, the label must comply with § 101.22. According to §101.22(1), if the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor, by word, vignette, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor is considered to be the characterizing flavor. If the food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, under § 101.22(i), the name of the food on the principal display panel or panels of the label must be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food. In addition, the name of the characterizing flavor must be accompanied by the word or words "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(2) Water

8. A few comments opposed the addition of water to butter products. One comment maintained that water is not an ingredient traditionally added to butter. It stated that with current technology, the addition of water is not needed to produce a reduced fat butter, and, therefore, the addition of water to butter products should not be permitted. Another comment stated that added water would constitute a deviation from the butter standard and is not required to make an acceptable reduced fat butter product.

A number of comments stated that FDA should allow food manufacturers to add water to replace milkfat and reduce the caloric content of the product. Comments stated that water should be allowed if needed to yield an acceptable "butter" product. They stated that this might allow the development of additional products with lower saturated fat, total fat, and cholesterol. Two comments stated that the addition of water would be appropriate as long as it is clearly stated on the food label.

FDA acknowledges that the addition of water is not provided for in the statutory standard for butter, but the agency has decided to permit butter products to include ingredients that are not included in the statutory standard so that consumers may purchase such products with the characteristics of butter. There is consumer demand for products that have a significant reduction in fat and calories. Water is an ingredient that can be used to produce such a reduction as a replacement for milkfat in butter products. Although FDA agrees that with current technology, the addition of water may not always be needed to produce a reduced fat butter, the consumer may benefit from the increased reduction in saturated fat, total fat, cholesterol, and calories that can be accomplished through the addition of water. Thus, the addition of water will provide more flexibility in the formulation of butter products that may have an improved nutrition profile and may perform better than butter products formulated without any water. Therefore, FDA concludes that water may be added to butter products to replace milkfat.

Water can be added to replace milkfat in butter products in potentially very large amounts. In fact, none of the comments supporting the use of water to replace milkfat suggested any maximum level. However, to preserve the food's identity as a dairy product, the amount of water added may not exceed the amount of milk or cream ingredients. Therefore, FDA is providing in new§ 101.67(a)(2) that the product may contain water to replace milkfat, although the amount of water added must be less than the amount of cream, milk, or milk constituents in the product.

The addition of water must be declared in the ingredient statement as required in § 101.67(c).

E. Minimum Dairy Ingredient Requirement

9. One comment recommended that a minimum percentage by weight of dairy ingredients (milk and its natural constituent components) be required in order to use the name "butter." The comment stated that without a minimum dairy ingredient requirement, the distinction between butter and margarine essentially vanishes. However, the comment did not recommend a specific level.

The agency disagrees with the comment. As discussed above, new § 101.67(a)(2) requires that the major ingredients in butter products be milk, cream, and derivatives of milk and cream. Because these ingredients are not generally used, or are used only in small amounts, in margarine, the distinction between the two products will be maintained. Therefore, FDA concludes that the requirement in new § 101.67(a)(2) is adequate, and that there is no need to specifically establish a minimum dairy ingredient level for butter products.

F. Nutritional Inferiority

10. One comment stated that the proposed regulation lacked specificity as to what is necessary to satisfy the requirement that the product not be nutritionally inferior. It stated that the standard for margarine (§166.110 (21 CFR 166.110)) specifies the required amount of vitamin A (15,000 International Units (IU) per pound) and an optional level of vitamin D (1,500 IU per pound).

The agency acknowledges that the standard for margarine designates the amount of vitamin A that must be added to margarine (§ 166.110(a)(3)) and the amount of vitamin D that may optionally be added to margarine (§ 166.100(b)). However, FDA disagrees that proposed § 101.67 lacks specificity concerning nutritional inferiority. Under proposed § 101.67(a)(3), the butter product must not be nutritionally inferior, as defined in § 101.3(e)(4), to standardized butter. This general requirement is adequate because § 101.3(e)(4) sets very specific requirements defining nutritional inferiority. The agency concludes that new § 101.67 need not specify required amounts of essential nutrients that must be added to butter products, and that no change is necessary in new § 101.67. The agency notes that general points for comparison of the nutrient values of the traditional standardized product can be found in a current valid composite data base.

G. Labeling Concerning Performance Characteristics

11. One comment recommended that the label statement be mandatory only for differences in performance characteristics that materially limit the uses of the butter product compared to the traditional standardized food that it resembles. It stated that market forces will encourage manufacturers to inform consumers about positive differences, and that consumers who select a product for its reformulated nutrient content will not be misled if they are not told about a positive change that the manufacturer believes is not sufficiently important to highlight on the product label. The comment noted that FDA

would not object if the label did not alert consumers to a minor improvement in a performance characteristic that consumers consider to be relatively unimportant for that food. In addition, the comment stated, a product may have several differences in performance characteristics, and several label statements could be confusing to consumers. The comment recommended that FDA modify proposed § 101.67(b) by limiting the labeling requirement to adverse changes that materially affect the use of the product.

The agency has been persuaded by these comments. FDA agrees that there are differences in performance characteristics that consumers may not consider important. In addition, unnecessary label statements may be confusing to consumers and may detract from other important information on the label.

Therefore, the agency is modifying new § 101.67(b) to state that;

* * * if there is a significant difference in performance characteristics that materially limits the uses of the product compared to butter, the label shall include a statement informing the consumer of such difference (e.g.,-If appropriate, "not recommended for baking purposes").

12. One comment noted that there is an apparent conflict in the agency's proposed requirements for the location of the disclosure of differences in performance characteristics. It stated that proposed § 101.67(b) provides that such statement must appear on the principal display panel within the bottom 30 percent of the area of the label panel; proposed § 101.67(a)(1) requires that a nutrient content claim for a butter product comply with proposed § 101.13; and proposed § 101.13(d)(1) states that if there is a difference in performance characteristics, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim. The comment requested that the final versions of proposed §§ 101.67(b) and 101.13(d)(1) be consistent. It stated that a disclosure in the bottom 30 percent of the principal display panel could easily be as prominent as, or more prominent than. a disclosure that immediately follows disclosures about the nature of the product and the reference statement. The comment stated that it is in the interest of consumers that the required disclosure of differences in performance characteristics be located in the bottom 30 percent of the principal display panel, as provided in proposed § 101.67(b). Another comment requested that FDA allow any statements concerning differences in performance characteristics to appear on any panel of the label of the product.

Under section 403(f) of the act, FDA believes that the statement informing consumers of differences in performance characteristics must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. The agency concludes that the statement must appear in the sama area of the label as the statement of identity for the butter product so that consumers will know where to find such information. Moreover, because the statement is a material fact that helps to describe the differences between the modified food and the traditional food, it must appear in close proximity to the statement of identity. See, e.g., *United States v. An Article of Food * * * "Manischewstz * * * Diet Thins,"* 377 F. supp. 746, 749 (E.D. N.Y. 1974).

FDA recognizes that it inadvertently proposed in § 101.67 to require statements informing consumers of differences in performance characteristics to appear in possibly two separate locations on the label. The agency acknowledges that one statement is sufficient to inform consumers. To be consistent with the labeling of other foods, the agency concludes that the statement concerning differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d)(1). Thus, the agency has modified new § 101.67(b) to state that the statement explaining differences in performance characteristics must appear on the label in compliance with the requirements of §101.13(d).

13. Some comments suggested that, in order to use nutrient content claims for butter, the product must perform at least one of the principal functions of regular butter substantially as well as butter produced under section 201a of the act. Consumers can then choose to purchase the product instead of regular butter for use in that function.

FDA agrees that at a minimum, a butter product must perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a. Consumers should be able to count on using a butter product in the same manner in which they use regular butter for. at the very least, one of its principal functions. To achieve this objective, FDA is requiring in § 101.67(b) that butter products must resemble butter as produced under section 201a of the act, and that differences in the performance characteristics must be clearly stated on the principal display panel of the label. In addition, the agency is adding a statement to new § 101.67(b) to require that "the modified product must perform as least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a." FDA believes that this action is necessary to ensure the minimum necessary similarity between the modified and traditional products.

H. Other Labeling

14. One comment stated that products made with n on dairy ingredients should be labeled, with appropriate prominence on the principal display panel of the label, "contains nondairy ingredients."

FDA does not agree that it should require this statement on the principal display panel of the label. The agency is requiring that the major ingredients in butter products be cream, milk, or derivatives of cream or milk and is only providing for minor additions of safe and suitable ingredients (e.g., nondairy ingredients) as necessary, so that the butter product has the same characteristics as butter. Although the agency is providing for the addition of water to replace milkfat, it must not be the predominant ingredient in the product. In addition, FDA points out that new §101.67(c)(1) requires that each of the ingredients added to the product be listed in the ingredient statement, as required by the applicable sections of part 101.

However, to further assist the consumer in differentiating between regular butter and butter products with nontraditional ingredients added, FDA is establishing a requirement in new § 101.67(c)(2) that all safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness and water added to replace milkfat must be appropriately identified with an asterisk in the ingredient statement. The statement "* Ingredients not in regular butter" must immediately follow the ingredient statement in the same type size. FDA is requiring similar labeling for modified standardized foods in new § 130.10, as explained in the general standard final rule.

FDA believes, however, that consumers may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. In addition, because butter has historically been a cultured product, the addition of safe and suitable bacterial cultures does not

require identification with an asterisk. Therefore, the agency is not requiring that nutrients added to restore nutrients or added safe and suitable bacterial cultures be identified by an asterisk in the ingredient statement.

15. One comment stated that the percentage of water in light butler products should be declared on the label.

FDA disagrees with the comment. As discussed above in comment 8, cream, milk, and milk constituents will be the predominant ingredients in butter products. Any water added to butter products may not be present in an amount greater than the amount of the dairy ingredients. According to § 101.4(a), all ingredients, including water, must be listed by common or usual name in descending order of predominance by weight on the label. In addition, new § 101.67(c)(2) requires that water that is added to replace rniikfat must be identified with an asterisk in the ingredient statement, followed by a statement explaining that the ingredient is not in regular butter. Therefore, FDA concludes that listing water as an ingredient in this manner is adequate, and percentage labeling is not necessary.

16. One comment stated that in addition to the comparative statements allowed to appear on the label of a butter product, the label for such a product should also include a clear statement of the identity and percentage of characterizing fat or oil, for example: "Reduced Fat Butter—40% Milkfat." It stated that such a prominent statement will allow consumers to easily and readily discern the nature of the food and, thus, facilitate comparisons with other table spreads, both dairy based and vegetable based.

The agency disagrees that the additional labeling is necessary. The provisions, in §101.56(b)(3) and § 10.1.62(b)(4)(ii) for use of the terms "light" and "reduced fat" require that the percent reduction in fat and the identity of the reference food be declared in immediate proximity to the most prominent claim and that quantitative information comparing the fat content in the product per serving size with that of the reference food be declared adjacent to the most prominent claim or on the information panel. Under § 101.9(a), nutrition information must be provided for all butter, margarine, and substitute products. The serving size for butter, margarine, and their substitutes is one table spoon (§ 101.12(b)). The nutrition labeling must provide information on a food product's nutrition profile, including total fat, saturated fat, and cholesterol (§ 101.9(c)(12)). In addition, information on unsaturated fat may be included in the nutrition information. The only fat ingredient permitted in butter products is milkfat, and the ingredient statement will reflect this requirement. Consumers may use this information to compare the amount of fat in butter products and margarine products. Therefore, FDA concludes that there is adequate information to inform consumers concerning the fat content of a product already required to be present on the label without requiring the additional labeling requested by the comment. However, the agency will not object if manufacturers include additional labeling to state the percentage and type of fat in the product, provided that the information is not false or misleading.

17. One comment opposed the proposed rule on the grounds that people with food sensitivities will be placed at greater risk because of difficulties of knowing what is in a product.

Section 403(i) of the act requires that all ingredients used in a food be included in the ingredient statement. Consistent with the provisions of section 403(i) of the act, FDA is including a provision in § 101.67(c)(1) that each of the ingredients used in the food must be declared on the label, as required by part 101. This requirement will ensure that consumers that have food sensitivities are informed of the presence of ingredients to which they may have allergies.

III. Conclusion

In response to comments submitted regarding the proposal for use of nutrient content claims for butter (56 FR 60523), FDA has modified proposed § 101.67. The following summarizes the changes being made to proposed § 101.67 by this final rule:

FDA has modified § 101.67(a)(2) to provide for the use of safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. FDA also has modified this paragraph to provide for the addition of water to replace milkfat, although the amount of water in the product must be less than the amount of cream, milk, or milk constituents.

FDA has added new § 101.67(a)(4) to require that if the product would violate section 201a of the act but for the nutrient content claim that characterizes the level of nutrients, that claim must be included as part of the common or usual name of the product.

FDA has added a statement to new § 101.67(b) to require that deviations from ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act.

The agency has modified § 101.67(b) by limiting the labeling requirement to changes that materially affect the use of the product.

FDA has revised § 101.67(b) to require that the mandated label statement concerning any differences in performance characteristics be in accordance with the requirements of §101.13(d).

The agency has added a statement to new § 101.67(b) to require that the product must perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

In new § 101.67, paragraph (c) has been redesignated as paragraph (c)(1) and new paragraph (c)(2) has been added to require that water and safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement In the same type size.

IV. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of

obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to not make this rule effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency 's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 at seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management. Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

List of Subjects in 21 CFR Part 101

Food-labeling, Reporting, and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101— FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Sees. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.67 is added to subpart D to read as follows:

§ 101.67 Use of nutrient content claims for butter

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of § 101.13 and with the requirements of the regulations in this subpart that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C.321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients added to comply with paragraph (a)(3) of this section, and, with or without safe and suitable bacterial cultures. The product may contain safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. The product may contain water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents.

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 2.1 U.S.C. 321a; and

(4) If the product would violate 21 U.S.C. 321a but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of the common or usual name of the product.

(b) Deviations from the ingredient provisions of 21 U.S.C. 1321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter,) the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall comply with the requirements of § 101.13(d). The modified product shall perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

(c)(1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

(2) Safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness and water added to replace milkfat shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

Dated: October 20,1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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