A320–200, A321–100, A330–300, A340–200, and A340–300 series airplanes;

Beech Models 1900 and BE–65 through –90 (inclusive) series airplanes;

Boeing Models 727–100, 727–200, 737–200, 737–300, 737–400, 737–500, 747–100, 747–200, 747–300, 747–400, 747SP, 757–200, 767–200, 767–300, and 777–200 series airplanes;

Convair Model CV–580 airplanes;

de Havilland DHC–7 series airplanes and Model DHC–8–100 airplanes;

Embraer Model EMB–120 series airplanes;

Fairchild Model F227 airplanes;

Fokker Models F28 Mark 100, Mark 1000, and Mark 4000 series airplanes;

General Dynamics Models Convair 340 and 440 airplanes;

Gulfstream Models G–159 and G–IV airplanes;

Lockheed Model L1011 series airplanes;

McDonnell Douglas Models DC–8–60, DC–9–31, DC–9–51, DC–10–10; DC–10–30, DC–10–30F, MD–11, and MD–80 series airplanes;

Rockwell International NA–265–65 airplanes;

Saab Model 340 series airplanes; and

Shorts Model 360 series airplanes.

Note 1: This AD applies to each airplane on which the TCAS unit identified in the preceding applicability provision has been installed, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For affected TCAS units or airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Note 2: CAS–81 Traffic Alert and Collision Avoidance Systems (TCAS) processors having serial numbers 6066 and subsequent, are not subject to the requirements of this AD.

Compliance: Required as indicated, unless accomplished previously.

To ensure that the flightcrew is advised of the potential hazard associated with failure of the audio output of the CAS–81 TCAS, and of the procedures necessary to address it, accomplish the following:

(a) Except as provided by paragraph (b) of this AD: Within 3 calendar days after February 5, 1996 (the effective date of AD 95–26–15, amendment 39–9495), revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following. This may be accomplished by inserting a copy of this AD in the AFM.

''In order to ensure that the audio output of the CAS–81 TCAS operates properly, accomplish the following:

- Prior to the first flight of the day; prior to the accumulation of 10 hours of uninterrupted power; and at the mid-point of any one flight scheduled to exceed 10 hours of power: Cycle the power to the TCAS processor via the circuit breaker or power bus.
- Prior to taxi before takeoff: Initiate the TCAS functional test in accordance with AFM procedures to verify operational condition of the CAS–81 TCAS.''

(b) For airplanes on which the manufacturer has substantiated 30 degrees Celsius as a maximum ambient temperature for the TCAS processor location, the following is considered to be an alternative method of compliance for the AFM revision requirements specified in paragraph (a) of this AD: Revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following. This may be accomplished by inserting a copy of this AD in the AFM. After revising the AFM, the AFM revision required by paragraph (a) of this AD may be removed from the AFM.

''In order to ensure that the audio output of the CAS–81 TCAS operates properly, accomplish the following:

Prior to each flight of up to 18 hours duration, reset the TCAS circuit breaker and conduct a TCAS self-test.''

(c) Modification of the TPA–81A TCAS processor receiver in accordance with Allied Signal Service Bulletin TPA–81A–34–82, dated January 1996, or Allied Signal Service Bulletin TPA–81A–34–84, dated January 1996, constitutes terminating action for the requirements of this AD. After this modification is accomplished, the AFM revisions specified in paragraphs (a) and (b) of this AD may be removed from the AFM.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective on December 26, 1996.

Issued in Renton, Washington, on November 13, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–29605 Filed 11–19–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 131, and 133

[Docket Nos. 95P–0125, 95P–0250, 95P–0261, and 95P–0293]

Lowfat and Skim Milk Products, Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Revocation of Standards of Identity; Food Labeling, Nutrient Content Claims for Fat, Fatty Acids, and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing the standards of identity for various lowfat milk, sour half-and-half, and cottage cheese products, based in part on a petition filed jointly by the Milk Industry Foundation (MIF) and the Center for Science in the Public Interest (CSPI), and a petition filed by the American Dairy Products Institute (ADPI). FDA is also amending the standard of identity for dry cream; deferring action on its proposal to revoke the standards of identity for lowfat and nonfat yogurt; and amending the nutrient content claims regulations for fat, fatty acids, and cholesterol content to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products. This rule will provide for consistency in the nomenclature and labeling of most nutritionally modified milk products and other foods bearing ''lowfat'' and ''nonfat'' claims; promote honesty and fair dealing in the interest of consumers; increase flexibility for manufacturers of lower-fat dairy products; and increase product choices available to consumers. This action is a part of the agency's ongoing review of existing regulations under President Clinton's Regulatory Reinvention Initiative.

DATES: Effective January 1, 1998, except as to any provisions in revised parts 131 and 133 (21 CFR parts 131 and 133) that may be stayed by, or as a result of, the filing of proper objections. Compliance may begin on November 20, 1996. If any provisions are stayed, FDA will publish timely notification in the Federal Register. Written objections and requests for a hearing for parts 131 and 133 by December 20, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

One of the main purposes of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535), which amended the Federal Food, Drug, and Cosmetic Act (the act), was to establish the circumstances in which claims that describe the nutrient content of food could be made. In response to the mandates of the 1990 amendments, in part 101 (21 CFR part 101), FDA established definitions for specific nutrient content claims together with principles for their use (hereinafter referred to as the nutrient content claims final rule) (58 FR 2302, January 6, 1993). In addition, in the Federal Register of January 6, 1993 (58 FR 2431), FDA published a final rule, entitled ''Food 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), which established the general standard in § 130.10 (21 CFR 130.10) for foods named by use of a nutrient content claim defined in part 101, such as ''nonfat,'' ''lowfat,'' ''reduced fat,'' ''light,'' or ''reduced calorie,'' in conjunction with a standardized term, for example, ''sour cream.''

As FDA noted in that final rule, certain standards of identity for dairy products incorporate terms such as ''nonfat,'' ''light,'' and ''lowfat'' in the names of the foods, such as the standards for lowfat dry milk (§ 131.123), nonfat dry milk (§ 131.125), nonfat dry milk fortified with vitamins A and D (§ 131.127), lowfat milk (§ 131.135), acidified lowfat milk (§ 131.136), cultured lowfat milk (§ 131.138), light cream (§ 131.155), lowfat yogurt (§ 131.203), nonfat yogurt (§ 131.206), and lowfat cottage cheese (§ 133.131). The agency has also established standards for skim milk products that provide for use of the synonym ''nonfat'' in place of the term ''skim'' in the names of these foods. The use of the terms ''nonfat,'' ''light,'' and ''lowfat'' in some of the names in these standards are inconsistent with the definitions established for the same terms as nutrient content claims under the 1990 amendments.

Under section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), a food is misbranded if it bears a claim that characterizes the level of any nutrient unless the claim is made using terms defined by the regulations of the Secretary of the Department of Health and Human Services (the Secretary). Section 403(r)(5)(C) of the act provides an exemption from this requirement, however, for nutrient content claims that are part of the name of a food that is defined by a standard of identity that was issued before enactment of the 1990 amendments. However, the legislative history of the 1990 amendments affirmed that the Secretary (and, by delegation FDA) has the authority to amend the standards of identity to conform with the regulations issued under section 403(r) of the act (H. Rept. 101–538, 101st Cong., 2d sess. 22 (1990)).

The agency stated in the general standard final rule that, at a later date, it would consider amending the existing standards of identity for foods that use nutrient content claims in their names to make the content requirements for these foods consistent with the claims definitions that it adopted (58 FR 2431 at 2444). The agency stated that, alternatively, it could delete some of the standards and allow the foods defined by these standards to be named using a nutrient content claim with a standardized term in accordance with the general standard (§ 130.10).

B. Petitions

Two petitions dated May 10, 1995 (Docket No. 95P–0125) and August 2, 1995 (Docket No. 95P–0250), respectively, were filed by MIF and CSPI. These petitions requested that the agency revoke the standards of identity for lowfat milk (§ 131.135) and skim milk (§ 131.143), as well as those for certain related lower-fat dairy products in parts 131 and 133 (i.e., sweetened condensed skimmed milk (§ 131.122), acidified lowfat milk (§ 131.136), cultured lowfat milk (§ 131.138), acidified skim (nonfat) milk (§ 131.144), cultured skim (nonfat) milk (§ 131.146), sour half-and-half (§ 131.185), acidified sour half-and-half (§ 131.187), lowfat yogurt (§ 131.203), nonfat yogurt (§ 131.206), and lowfat cottage cheese (§ 133.131)). The petitions requested that FDA regulate these products under the general standard in § 130.10. Subsequently, ADPI filed a petition (Docket No. 95P–0261) requesting that the agency revoke the standards of identity for two additional products in part 131, evaporated skimmed milk (§ 131.132) and lowfat dry milk (§ 131.123), and that it amend the standard of identity for dry cream in § 131.149 by removing the reference to § 131.135 (the lowfat milk standard). The petitioners stated that the purpose of their request is to promote consistency in the use of nutrient content claims concerning fat on food labels and to remove product specifications that potentially conflict with authorized nutrient content claims applicable to foods in general.

MIF submitted a third petition, dated August 2, 1995 (Docket No. 95P–0293), requesting that, if FDA revokes the standards for skim milk products, it concurrently amend the nutrient content claims regulations in § 101.62 to permit the continued use of the term ''skim'' as a synonym for the term ''nonfat.'' A similar petition, dated August 10, 1995 (Docket No. 95P–0293), was submitted by ADPI.

C. Regulatory Reinvention Initiative—Review of Regulations

This final rule is a part of a larger agency project being undertaken in response to President Clinton's memorandum of March 4, 1995, to heads of departments and agencies, entitled ''Regulatory Reinvention Initiative.'' This memorandum, among other things, directs departments and agencies to do a page-by-page review of their regulations and to eliminate or revise those that are outdated or otherwise in need of reform. The review of the standards of identity for dairy products revealed that a number of the products that are defined by individual standards in parts 131 and 133 could be more appropriately covered by the general standard in § 130.10.

D. The Proposal

In the Federal Register of November 9, 1995 (60 FR 56541), FDA proposed (hereinafter referred to as the November 9, 1995, proposal) to remove those standards cited by the MIF, CSPI, and ADPI petitions that are inconsistent with food labeling regulations established under the 1990 amendments and that are unnecessary in light of the general standard in § 130.10. Interested parties were given until January 23, 1996, to comment on the proposal.

II. Summary of and Response to Comments to Proposal

FDA received 15 letters, each containing one or more comments, on the November 9, 1995, proposal. The majority of comments supported the proposal. A few comments expressed concerns about, or included suggestions for, implementing the proposed revocations. Several comments addressed issues outside the scope of the proposal (e.g., amending the milk solids content requirements in whole

milk) that will not be discussed here. A summary of the comments and the agency's responses follow.

A. ''Skim'' as a Synonym for ''Nonfat''

As noted in the November 9, 1995, proposal (60 FR 56541 at 56543), MIF and CSPI stated that most products currently labeled as ''nonfat milk'' would be eligible to retain that name under the general standard because these products generally contain less than 0.5 gram (g) of fat per serving, which would comply with the definition of ''nonfat'' in § 101.62(b)(1)(i). However, the fat content claims regulations in § 101.62 do not authorize the use of the term ''skim.'' Consequently, at the request of the petitioners, and because of its historic use in dairy product nomenclature, FDA proposed to amend the fat content claims regulations in § 101.62(b)(1)(i) to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products.

1. All comments that addressed this issue supported FDA's proposal to provide for the use of the term ''skim.'' Several comments maintained that most consumers understand that ''skim'' and ''nonfat'' have the same meaning. Other comments noted consumers' reliance on the term ''skim'' to readily identify nonfat milk products.

Thus, given the support expressed in comments to the November 9, 1995, proposal, and given consumer reliance on the term ''skim'' to identify nonfat milk products, FDA is amending its claims regulations under sections 403(r) and 701(a) of the act (21 U.S.C. 371(a)) to provide for the use of the term ''skim'' as a synonym for ''nonfat'' in describing milk products (§ 101.62(b)(1)). Because of the history of use of the term ''skim'' to identify nonfat milk products, FDA concludes that providing for continued use of this term to identify nonfat milk products will minimize consumer confusion and facilitate trade.

B. Dry Cream

As noted in the November 9, 1995, proposal (60 FR 56541 at 56542), ADPI requested that the agency amend the standard of identity for dry cream in § 131.149 by removing the reference to § 131.135 (the lowfat milk standard, which FDA proposed to revoke). The petitioner maintained that the requested change would bring the standard for dry cream into conformity with the other suggested changes in the milk product standards. FDA agreed with ADPI that, because it was proposing to delete the standard of identity for lowfat milk (§ 131.135), reference to that standard should be deleted from the standard of identity for dry cream (60 FR 56541 at 56545). Therefore, the agency proposed to amend the standard of identity for dried cream to remove the reference to the standard of identity for lowfat milk. FDA did not receive any comments on this proposed action. Consequently, FDA is amending the standard of identity for dry cream in § 131.149, in the manner that it proposed.

C. Percent Fat Declaration

As noted in the November 9, 1995, proposal (60 FR 56541 at 56544), MIF stated in its petition that it views the indication of the milkfat percentage before the name of the product as an indispensable aspect of lower-fat milk labeling because consumers have come to rely so heavily on these numbers to differentiate among milk products. The petitioner further stated that it would not be requesting the revocation of the lower-fat milk standards if it believed that such an action would affect milk processors' ability to state the milkfat percentage in the name of the foods.

FDA responded to this concern in the November 9, 1995, proposal, noting that while standards of identity require that the percentage of milkfat be declared as part of the name of the food (e.g., lowfat cottage cheese (§ 133.131(b)(2)), there is no provision requiring percentage declaration of milkfat content in the name of the food under § 130.10. However, under § 101.13(i), manufacturers may continue to declare fat content as part of the name of the food for lower-fat milk products, and on the labels of other products, when such statements are not misleading.

2. Two comments expressed concern about percent fat labeling in general but stated that, in the case of reduced fat and lowfat milk products, special circumstances mitigate these concerns. These comments noted that, under § 130.10, lower-fat milks, originally exempt from the 1990 amendments, will need to comply with the claims requirements. Thus, percentage fat declaration would appear only on labels of milk products that qualify to make a fat content claim (i.e., that contain at least 25 percent less fat compared to whole milk). The comments also noted that fat content per serving is provided in nutrition labeling, and that products labeled as ''reduced fat'' must also bear a comparative statement comparing the amount of fat per serving of the food with the amount of fat in the reference food (§ 101.62(b)(4)). The comments concluded that, therefore, percent fat declaration on labels of milk products that are lower in fat than whole milk would not be misleading.

FDA agrees with the comments that the nutrient content claims requirements (§ 101.13(i)(1)) will be sufficient to ensure that, when percent fat labeling in the names of reduced fat and lowfat milk products characterizes the level of fat in the food, such statements are consistent with the terms defined under the act. Furthermore, under § 101.13(i)(3), foods that do not meet the requirements for a nutrient content claim (e.g., whole milk containing 3.25 percent milkfat) may still bear statements about the percent milkfat in the food provided that the statement does not in any way implicitly characterize the level of fat in the food, and that it is not false or misleading in any respect.

D. Light Cream

In the November 9, 1995, proposal (60 FR 56541 at 56545), the agency noted that standards of identity for two cream products contain the term ''light'' in the name of the foods, i.e., light cream in § 131.155 and light whipping cream in § 131.157. FDA noted that these products have a different texture than the higher fat cream product, heavy cream, defined in § 131.150. Because of the long history of use of these names (since 1940), FDA did not propose to change these standards. However, FDA requested comment on the appropriateness of these names and on whether consumers find the use of the term ''light'' in the names of these foods to be misleading. The agency stated that if comments demonstrated that amendment of these regulations is necessary, such action would be the subject of a later rulemaking.

3. One comment objected to the continued use of the term ''light'' in the names ''light cream'' and ''light whipping cream.'' The comment maintained that retaining the term ''light'' in the names of these foods would undermine the agency's attempt to make all dairy products subject to the same nutrient content claim definitions as other food products. The comment did not, however, include any data or other evidence that consumers find the use of the term ''light'' in the names of these foods to be misleading.

As the agency noted in the nutrient content claims final rule (58 FR 2302 at 2359), the term ''light'' can be used to describe physical or sensory characteristics of a food (e.g., to describe color or texture). The agency also stated that, to the extent that the term ''light'' had become part of the statement of identity (i.e., it describes characteristics of a food), use of the term would not be considered a nutrient content claim (58 FR 2302 at 2359). FDA notes that the

standards of identity for light cream (§ 131.155) and light whipping cream (§ 131.157) describe foods that differ from heavy cream (§ 131.150) in that they are less dense. The agency acknowledges that light cream and light whipping cream also contain less milkfat compared to heavy cream, and that it is this difference in fat content that is largely responsible for differences in the density of these products. However, FDA does not have any evidence, nor did the comment provide any, that the use of the term ''light'' in the names of these standardized foods is misleading. Therefore, FDA is not persuaded that there is a need to amend or revoke the standards of identity for light cream or light whipping cream. However, FDA reiterates that if it is demonstrated that amendment of these regulations is necessary to prevent consumers from being misled, such action will be the subject of a future rulemaking.

E. Deviations From Traditional Products

4. A few comments expressed concern about how the composition of traditional dairy products may change under the general standard. One comment questioned the impact of this action on consumer acceptance of new products, while another comment stated that FDA may need to educate consumers about the possible changes in ingredients and characteristics of foods to which they have become accustomed.

FDA acknowledges that this action will permit products to be formulated in ways that were not previously allowed. For example, § 130.10 will allow a product named ''nonfat milk'' to contain flavors, colors, and texturizers that provide defatted milk with the sensory properties of whole milk. The standard of identity for nonfat milk does not permit the addition of such flavors, colors, and texturizers. Some manufacturers may continue to produce foods under § 130.10 that are identical to the traditional lower-fat dairy products to which consumers have become accustomed, except that nutrient content claims in the name of the food (e.g., nonfat milk or lowfat cottage cheese) will be subject to the claims requirements. Alternatively, some manufacturers may choose to formulate new products, e.g., a nonfat milk product with the sensory characteristics of whole milk.

Further, some individuals may prefer a new food to a traditional food, whereas others may prefer the traditional food. It is not the function of the agency to determine the likes or dislikes of consumers. Rather, the function of the agency is to ensure that foods are safe, and that labeling is informative and not misleading. Section 130.10 provides for proper labeling of these foods and their ingredients. Adequate product labeling, including defined nutrient content claims, label statements required to accompany certain claims, nutrition labeling, and ingredient declaration, will enable consumers to distinguish traditional foods from modified versions of these products.

5. One comment maintained that the driving force behind the petitioners' request to revoke the standards of identity for lower-fat dairy products is to allow manufacturers to use ''non-dairy fillers'' in lower-fat dairy products made under the general standard, thus cheapening the standardized products.

FDA disagrees with the comment's contention that this action would promote the cheapening of products covered by standards of identity. As noted in response to the preceding comment, this action will permit products to be formulated in ways that were not previously allowed. However, § 130.10 contains a number of provisions to ensure that modified foods named by use of a nutrient content claim and a standardized term bear a close enough resemblance to the standardized food to warrant use of the term. For example, ingredients required by the standard must be present in the substitute food and may not be replaced by a similar ingredient from another source. Ingredients prohibited by the standard are also prohibited in modified foods made under the general standard. Ingredients not provided for, and ingredients used in excess of the levels provided for, by the standard must be identified, at least in the ingredient declaration. Furthermore, in the preamble for the general standard final rule (58 FR 2431 at 2439), FDA specifically provided examples of circumstances in which certain ingredients, such as caseinate, would, or would not, be appropriate for use in dairy products made under § 130.10. FDA concludes, therefore, that the provisions set out in § 130.10 are adequate in this regard.

F. Vitamin Addition—Milk Products

As noted in the November 9, 1995, proposal (60 FR 56541 at 56545), under the existing standards of identity for lowfat and skim milk products in part 131, vitamin A addition is mandatory, while vitamin D addition is optional. Vitamin A is required to be added to a level of 2,000 International Units (IU) per quart (500 IU or 10 percent of the daily value (DV) per reference amount customarily consumed (RACC)). When vitamin D is added to lower-fat milk products, the level must be 400 IU per quart (100 IU or 25 percent of the DV per RACC). However, under the general standard, the only requirement for lower-fat milk products is that they not be nutritionally inferior to milk as defined in § 131.110. The standard of identity for whole milk provides for the optional addition of vitamin A to a level of not less than 2,000 IU per quart and vitamin D to a level of 400 IU per quart. Because the addition of these nutrients to whole milk is optional, their addition at these levels to lower-fat milks under § 130.10 would also be optional.

On average, whole milk, before fortification, contains approximately 6 percent of the DV of vitamin A per RACC. Thus, lower-fat milks made according to § 130.10 may contain less vitamin A than currently required under the standards of identity for lowfat and skim milks.

6. Two comments urged FDA to retain current levels of vitamin A and D in lower-fat milk products to ensure that reduced fat, lowfat, and nonfat milk contain sufficient amounts of these vitamins. These comments noted the importance of standardized, lower-fat milks as a dietary source of vitamins A and D. One comment expressed concern that, in the absence of the standards of identity, the levels of vitamins A and D in lower-fat milk products would decline. Another comment appeared to believe that revoking the standards of identity for lower-fat milks would allow these products to have less vitamin A and D than whole milk. Based on this assumption, the comment stated that some consumers may be discouraged from drinking the lower-fat milks. One comment acknowledged that, while the addition of vitamin D is currently optional for all milk products, most fluid milk (up to 95 percent) is fortified to contain 400 IU per quart. However, the comment urged FDA to take the opportunity of this rulemaking to make the addition of vitamin D mandatory for all fluid milk.

In contrast, another comment stated that revoking the standards of identity for lower-fat milk products would not diminish the nutritional benefits of these foods. This comment maintained that the current milk fortification practices would almost certainly continue in the absence of the specific standards of identity for lower-fat milks. In support of its contention, the comment noted that the general standard (§ 130.10(b)) requires that a food named by use of a nutrient content claim and a standardized term be nutritionally equivalent to its

standardized counterpart. The comment stated that since the process of removing fat from milk unavoidably removes some vitamin A, processors will have to add some amount of vitamin A to lower-fat milk products to bring their vitamin A levels at least up to the level naturally found in whole milk (i.e., approximately 6 percent of the DV per RACC). However, under the applicable terms of the whole milk standard (§ 131.110), processors will still have the option of fortifying lower-fat milk products with vitamin A up to 10 percent of the DV per RACC.

The comment maintained that, in the absence of standards of identity, several incentives remain for fortifying lower-fat milk products to the current level (10 percent of the DV). First, ''good source'' nutrient content claims (§ 101.54(c)) require that a food contain at least 10 percent of the DV for the subject nutrient. In contrast, if processors choose to add vitamin A only to the level normally found in milk before fortification, they cannot make claims about vitamin A content (e.g., ''vitamin A added''). The comment noted that consumers have become accustomed to seeing the presence of vitamin A highlighted in the labeling of lowfat and skim milk. The comment further noted that industry-wide promotional efforts focus on the high levels of essential nutrients in lower-fat milk products. Consequently, any change in fortification practices would disrupt marketing and partially undermine nutrition based promotional campaigns. Finally, according to the comment, the primary cost of vitamin A fortification is not the vitamin itself but the equipment needed to add the vitamin, as well as the analytical processes required to ensure quality control. The comment argued that it is, therefore, highly unlikely that a processor of lower-fat milks would choose to add only enough vitamin A to achieve the percent of the DV for the required nutritional equivalency and forego the obvious benefits of fortifying its products to 10 percent of the DV per RACC.

This comment also noted that almost all of the fluid milk sold in this country is vitamin D fortified, even though the addition of vitamin D is optional under the standards of identity for whole milk, lowfat milk, and skim milk. The comment concluded that any concerns that processors will cease to fortify lower-fat milk products, simply because such fortification is no longer technically required, are unjustified.

FDA disagrees with the comment that stated that lower-fat milk products made under the general standard may contain lower levels of vitamins A and D when compared to unfortified whole milk. As noted in the November 9, 1995, proposal (60 FR 56541 at 56545), and reiterated in this preamble, lower-fat dairy products made according to the general standard may not be nutritionally inferior to the full fat product that they resemble and for which they substitute. Therefore, FDA concludes that concerns that lower-fat milk products will contain lower levels of vitamins A and D when compared to whole milk are unfounded. The question, rather, is whether deleting the standards for lowfat and skim milk products would likely result in a change in the levels or frequency of addition of vitamins A and D to these foods.

FDA knows of no evidence that supports the contention that revoking the standards of identity, as proposed, will cause manufacturers of lower-fat milks to discontinue fortifying these products at the current levels. On the contrary, current industry practice of fortifying nearly all milk products with vitamin D, even though vitamin D addition is optional, evidences that fortification at the current level is likely to continue, even in the absence of an affirmative requirement. Furthermore, as noted by the latter comment, there is considerable incentive (e.g., the use of label statements and promotional programs) to continue the practice of adding vitamin A at the current levels. The agency concludes, therefore, that the provisions of §§ 130.10(b) and 101.3(e) are adequate, and that special provisions (beyond the nutritional equivalency requirements of § 130.10) are not necessary, to ensure that lower-fat milk products continue to serve as an important dietary source of vitamins A and D. However, if this action were to result in significant changes in the current industry practice of adding vitamins A and D to lower-fat milk products, and changes were to adversely affect the levels of these vitamins in the diet, FDA would consider amending its regulations to require fortification of lowfat, reduced fat, and nonfat milk products manufactured under § 130.10.

7. One comment expressed concern about difficulties that might be encountered in determining whether a food complies with the requirements of § 130.10. The comment noted, for example, that, under this provision, lower-fat milk products named by use of a nutrient content claim and a standardized term have to be compared to whole milk. The comment maintained that regulatory agencies would generally need to run comparison tests using a particular manufacturer's whole milk to determine whether the manufacturer's lower-fat product is nutritionally equivalent to the standardized food. The comment pointed out, however, that some manufacturers do not produce whole milk. Therefore, the comment urged FDA to provide for the use of an industry average as a reference food or to provide specific nutrient content requirements for lower-fat milk products made under § 130.10. The comment suggested that the nutrient requirements (i.e., for vitamin content) be similar to what is currently required in the standards for lower-fat milks.

FDA agrees that it will be necessary to compare the levels of essential nutrients in lower-fat milk products named by use of a nutrient content claim and a standardized term to the nutrient profile of the standardized food. However, the agency advises that it is not necessary for a manufacturer to process whole milk for FDA to ensure that a lower-fat milk is nutritionally equivalent to the food for which it substitutes. FDA set out principles for determining an appropriate reference food in § 101.13(j)(1)(ii). For example, the comparison product may be the manufacturer's regular product or that of another manufacturer, an average value determined from the top three national (or regional) brands, or a market basket norm. Though § 101.13(j)(1)(ii) specifically applies to reference foods used to make a relative nutrient content claim (e.g., ''reduced fat''), the options therein would be applicable to nutrient comparisons to determine nutritional equivalency. Furthermore, FDA noted in the general standard final rule (58 FR 2431 at 2435), that nutrient values in a current valid composite data base can be used for standardized products. In that final rule, the agency acknowledged that target levels for nutrients necessary to determine nutritional equivalency of a food will depend on the specific foods being compared (58 FR 2431 at 2436). However, FDA determined that it would not be appropriate, beyond the provisions of § 130.10(b), to mandate specific levels of nutrients that must be added to substitute foods.

Much of the concern raised in the comment apparently comes from the fact that there may be wide variations in vitamin A content of milk because of seasonal and other factors. As noted in the November 9, 1995, proposal (60 FR 56541 at 56545), vitamin A levels in milk in winter have been reported to range from 500 to 1,000 IU per quart, while in summer (pasture), these levels range from 2,000 to 3,000 IU per quart. However, FDA does not expect that processors will choose to recalibrate equipment for vitamin fortification of

lower-fat milk products to accommodate daily or seasonal fluctuations in the vitamin A content of the processor's whole milk. Rather, the agency expects that manufacturers will choose the simplest option available to them, such as fortifying products to be nutritionally equivalent to the level of vitamin A listed in a composite data base. This approach would also be the simplest option from a regulatory standpoint.

FDA concludes that the requirement in § 130.10(b) that the modified product must not be nutritionally inferior, as defined in § 101.3(e)(4), to the standardized product is adequate, and that, therefore, it is not necessary to specify further the required amounts of essential nutrients that must be added to lower-fat milk products.

G. Vitamin Addition—Dairy Products Other Than Milk

8. One comment supported the proposal to make nutrient content claims for the referenced dairy products consistent with nutrient content claims for fat in other foods. However, the comment suggested that, in its current form, FDA's proposal would unduly penalize manufacturers of lower-fat yogurt products without any corresponding benefit to either public health or consumer awareness. The comment stated that full fat yogurt, before fortification, contains between 0.2 and 0.8 percent of the reference daily intake (RDI) for vitamin D. This is less than a ''measurable amount,'' as defined in § 101.3(e)(4)(ii). Therefore, vitamin D fortification (currently optional for all standardized yogurt products) would not be required for lower-fat yogurt products made under § 130.10. However, the comment stated that full fat yogurt contains between 2 and 14 percent of the RDI for vitamin A. In contrast, lowfat and nonfat yogurt contain between 0.9 and 6 percent and between 0.2 and 1 percent, respectively, of the RDI for vitamin A. Therefore, some amount of vitamin A would need to be added to most lower-fat yogurt products for the food to be nutritionally equivalent to full fat yogurt. The comment hypothesized that, therefore, a processor of a lower-fat yogurt that contains 1 percent of the RDI of vitamin A may be forced to fortify its product with 3 percent of the RDI for vitamin A to reach the 4 percent level found in some full fat yogurt. The comment maintained that such fortification (i.e., adding 3 percent of the RDI for vitamin A) is not dietetically significant. The comment further argued that, although the vitamin A fortification requirement would add little in terms of dietary value, it would impose a significant financial burden on yogurt manufacturers.

Another comment noted that sour half-and-half contains 2 percent of the DV for vitamin A compared to 4 percent of the DV in full fat sour cream. The comment maintained that requiring fortification at such low levels would impose a significant cost on manufacturers with relatively little benefit for consumers.

Conversely, several comments expressed concern about maintaining requirements that will ensure that modified foods are not nutritionally inferior to the food for which they substitute. In fact, one comment urged FDA to make the addition of vitamin D mandatory in yogurt. The comment stated that many consumers use yogurt as a substitute for milk and assume that the two foods are nutritionally equivalent, when, in fact, yogurt products generally do not contain vitamin D.

In response to the latter comment, FDA notes that vitamin D is currently optional in all standardized yogurt products. Therefore, it would also be optional in yogurt products made under § 130.10. To amend the standard for yogurt to make addition of vitamin D mandatory is outside the scope of this rulemaking. However, as mentioned below in comment 12 of this document, FDA is in the process of evaluating all of its regulations pertaining to standards of identity. The comment's suggestion may have relevance in a future rulemaking as a part of that initiative.

The agency is not persuaded by the comments that maintained that the nutritional equivalency requirements for lower-fat dairy products made under § 130.10 (e.g., lowfat yogurt or sour cream) will be of little benefit to consumers. As noted in comments, full fat yogurt may contain as much as 14 percent of the RDI for vitamin A, making the food a good source of vitamin A. Furthermore, the diet is made up of a variety of foods, not all of which are a ''good source'' (i.e., contain 10 percent or more of the DV) of a particular nutrient. Even when nutrients are present in lesser amounts, the nutritive value of a food may make a significant contribution to meeting dietary goals. However, as noted in the December 28, 1995, final rule entitled ''Food Labeling; Reference Daily Intakes'' (60 FR 67164 at 67170), adequacy of intake of a particular nutrient or public health concerns are not criteria for determining whether a substitute food is nutritionally inferior to the food for which it substitutes. Rather, § 101.3(e)(4)(i) defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in a measurable amount (excluding fat or calories). Section 101.3(e)(4)(ii) defines a measurable amount of an essential nutrient in a food as 2 percent or more of the daily reference value (DRV) of protein listed under § 101.9(c)(7)(iii), of potassium listed under § 101.9(c)(9), and of the RDI of any vitamin or mineral listed under § 101.9(c)(8)(iv). The agency considers, per § 101.9(a)(4), a measurable amount to be a significant amount for this purpose. Therefore, consistent with the agency's longstanding definition of nutritional inferiority in § 101.3(e)(4), FDA concludes that a 2 percent or greater reduction in the RDI for vitamin A in lower-fat sour cream or lower-fat yogurt products is significant, and that such a reduction will make these foods nutritionally inferior to the foods for which they substitute.

9. One comment maintained that application of §§ 130.10 and 101.3(e) to lower-fat dairy products will impose, for the first time, a requirement that well established, standardized products (e.g., lowfat and nonfat yogurt and sour half-and-half) be nutritionally equivalent to their full fat counterparts. The comment argued that even the final rule revoking the standard of identity for ice milk (hereinafter referred to as the 1994 final regulation) (59 FR 47072, September 14, 1994) did not have this overall effect. According to the comment, the lower-fat ice cream products created by that action were not established, standardized products bearing a new name but were essentially ''new'' products created by the revisions.

The agency disagrees with the comment's contention that this rulemaking will, for the first time, require fortification of traditional lower-fat dairy products to achieve nutritional equivalency to their full fat counterparts. A number of the standards of identity for lower-fat dairy products contain provisions to ensure that the foods are at least nutritionally equivalent to the full fat version of the food (e.g., lowfat and skim milk must contain not less than 2,000 IU vitamin A (§§ 131.135 and 131.143)). Furthermore, before establishing the general standard, FDA issued more than 150 temporary marketing permits (TMP's) for the market testing of lower-fat dairy products such as ''light eggnog,'' ''light sour cream,'' ''nonfat sour cream,'' and ''nonfat cottage cheese.'' One of the criteria used in evaluating the acceptability of these test products was that they be nutritionally equivalent to the full fat standardized food.

Since the agency adopted § 130.10, there has been a proliferation of lower-fat dairy products labeled by use of a standardized term in conjunction with a nutrient content claim (e.g., ''light sour cream'') that are nutritionally equivalent to the full fat foods. Therefore, FDA disagrees with the comment and notes that there are several examples of lower-fat dairy products that resemble and substitute for full fat standardized foods and that are fortified to be nutritionally equivalent to the foods for which they substitute.

The nutritional equivalence requirement in § 130.10 follows, in large measure, the approach embodied in § 101.3(e) with respect to substitute foods. The authority for § 101.3 is section 403(c) of the act. When this section of the act was adopted in 1938, Congress was seeking to protect the consumer from the uninformed purchase of an inferior substitute product that could be mistaken for the traditional food product (38 FR 2138, January 19, 1973). In 1973, in a proposal pertaining to ''imitation foods,'' the agency noted that vast strides in food technology had taken place since section 403(c) had been enacted, and that since 1938 many new wholesome and nutritious food products had entered the marketplace, some of which resembled and substituted for traditional foods (38 FR 2138). The agency stated that it was no longer the case that such products were necessarily inferior to the traditional foods for which they substituted. However, FDA still believed that the consumer must be protected from unwittingly purchasing a product that is different from what he or she may reasonably expect (38 FR 2138).

FDA continues to believe that, as substitute products proliferate, it is important to ensure that these products contain essential nutrients in amounts consistent with the reference food, so that consumers can continue to have confidence that a varied diet will supply adequate nutrition. This principle, that substitute foods must not be nutritionally inferior to the foods for which they substitute, was incorporated into the general standard final rule, in which FDA stated that foods having significantly less essential nutrients than the standardized food for which they are named are not modified versions of the standardized food, do not comply with the requirements of the general standard, and must be labeled as ''imitation'' (58 FR 2431 at 2435).

Finally, FDA is not convinced by the comment that revoking the standards of identity for lower-fat dairy products in parts 131 and 133 differs from the rulemaking to revoke the standard of identity for ice milk so that such products could be labeled as nutritionally modified versions of ice cream under § 130.10 in the 1994 final regulation. Specifically, FDA disagrees with the comment's contention that the final rule revoking the standard for ice milk did not affect a standardized product because ice milk was not being sold under that name. FDA notes that a number of companies were marketing the standardized product ''ice milk'' before the 1994 final regulation made it possible to market this product either as ''reduced fat'' or ''low fat'' ice cream (Ref. 1) depending on the level of fat in the product. The effect of the 1994 final regulation was to provide for the labeling of lower-fat ice cream products, such that the product names are consistent with the requirements for nutrient content claims, the food for which the product substitutes is clearly identified, and the substitute food is nutritionally equivalent to the standardized food (ice cream).

10. One comment argued that, because standardized lower-fat yogurt and sour cream products have never been nutritionally equivalent to the full fat standardized foods, continued consumption of unfortified versions of these products will not result in any unanticipated diminution of vitamin A intake by consumers, nor would it deprive consumers of nutrients that they were previously obtaining.

FDA disagrees with the comment's contention that, because nutritional equivalency with the full fat food has not been required heretofore in some standardized lower-fat dairy products, failure to add this requirement now will not diminish the nutrient value of the food or its contribution to the diet. This view would only be true if dietary patterns were static. However, consumers' tastes, dietary needs, and knowledge about nutritional content of foods change. There are numerous ongoing educational programs designed to encourage consumers to eat a healthier diet (e.g., a diet lower in fat) and to encourage increased calcium consumption (from such sources as dairy products) by that part of the population at risk for osteoporosis. The nutrient intake of consumers who are now switching from full fat to lower-fat dairy products, and of those who are increasing their consumption of dairy products by eating lowfat or nonfat foods, may indeed be decreased. FDA notes, for example, that the consumption of yogurt products increased more than fivefold between 1970 and 1993 (Ref. 1). As the population ages, dietary recommendations will take on even greater significance. Therefore, FDA cannot agree that exempting lower-fat dairy products from the requirement that they be nutritionally equivalent to the full fat foods for which they substitute would not have an adverse effect on the diet of consumers.

Furthermore, FDA has promised consumers since 1973 that substitute foods will be nutritionally equivalent to the foods for which they substitute, or that if they are not, this fact is to be revealed on the label. In the general standard final rule (58 FR 2431 at 2435), FDA stated that all nutrients that are considered in determining the status of a food under § 101.9(c)(7)(iv) are important. FDA also stated that any measurable reduction in an essential nutrient is significant, and that if a food is nutritionally inferior to the standardized food, it cannot be labeled as a modified version of the food but, rather, as an ''imitation.'' The comments have not provided any reason to establish an exemption from the agency's general approach for lower-fat yogurt or sour cream products.

11. One comment stated that vitamin A fortification frequently has a negative impact on the taste of dairy products. The comment maintained that vitamin A fortification could, therefore, drive some consumers away from the lower-fat products to which they were accustomed in favor of higher fat products in which the naturally occurring vitamin A does not cause a taste problem. The comment did not, however, provide any data in support of its contention.

FDA is not persuaded by the comment that there exist sufficient technical difficulties (e.g., taste considerations) that would warrant exempting lower-fat dairy products made under § 130.10 from the requirement that they be nutritionally equivalent to the standardized food. The agency notes that that requirement did not prevent manufacturers from submitting scores of applications for TMP's. Furthermore, the agency does not have any information that vitamin A fortification has been a significant impediment to the manufacture or marketing of lower-fat dairy products as part of the market tests conducted before or after the enactment of the 1990 amendments or under § 130.10.

12. One comment that objected to requiring lower-fat dairy products to be nutritionally equivalent to the full fat version of the foods supported the basic proposition that foods bearing names that include a defined nutrient content claim should conform to the requirements for that claim as defined by FDA. However, it disagreed with the

agency's proposed approach of revoking standards of identity for lower-fat dairy products and subjecting them to the general standard and with the requirement that they not be nutritionally inferior, as defined in § 101.3(e)(4), to the standardized food in parts 131 and 133. As an alternative, the comment suggested that FDA consider amending either § 101.3(e) or § 130.10 such that fortification would not be required at low levels. A second alternative suggested by the comment would be to combine into one standard the existing standards of identity for each group of dairy products, specifying the particular fat levels applicable to reduced fat, lowfat, and nonfat versions of the food. Finally, the comment suggested that FDA could leave the standards of identity for lower-fat dairy products in place but amend them by reducing the maximum milkfat percentages to levels that correspond with the nutrient content claims requirements. For example, the maximum milkfat content requirement for lowfat yogurt in § 131.203 could be reduced from 2 percent to 1.3 percent so that the food would contain no more than 3 g fat per reference amount as required for a ''low fat'' claim.

FDA notes that it published an advance notice of proposed rulemaking (ANPRM) in the Federal Register of December 29, 1995 (60 FR 67492), announcing that it intends to review its regulations pertaining to standards of identity, quality, and fill of container and asking for comment on the utility of these regulations. Among the regulations on which the agency requested comment were those pertaining to the labeling of imitation and substitute foods in § 101.3(e) (60 FR 67492 at 67502). Further, in another ANPRM that FDA published in the Federal Register of June 12, 1996 (61 FR 29701 at 29702), the agency requested comments on certain regulations pertaining to food labeling, including the provisions for labeling imitation and substitute foods set out in § 101.3(e).

In the June 12, 1996, ANPRM, FDA noted that, in 1973, the agency proposed that ''imitation'' only be applied to substitute foods that are nutritionally inferior to the foods for which they substitute (38 FR 2143 at 2148), and that, in its final regulation (38 FR 20702, August 2, 1973), FDA confirmed this view and defined ''nutritional inferiority'' as the reduction in the content of an essential nutrient that is present in a measurable amount (§ 101.3(e)(4)). In the June 12, 1996, ANPRM, FDA requested comment on the appropriateness of the current definition of nutritional inferiority for the purpose of determining whether a food is an imitation. FDA noted that it had not reevaluated its definition of nutritional inferiority for purposes of imitation labeling when it recently revised these regulations to accommodate new RDI's for several nutrients (60 FR 67164), but that it had raised the question in the December 29, 1995, ANPRM on standards of identity. The agency further noted that it would evaluate any proposed changes in its policy on labeling of imitation foods in light of any changes that it ultimately decides to make in its approach to standards of identity and common or usual name regulations.

Therefore, FDA is not proposing to amend its requirements in the general standard (§ 130.10(b)) or in § 101.3(e) that require fortification of a modified food to restore nutrient levels so that the product is not nutritionally inferior as defined in § 101.3(e)(4), as requested by the comment. However, if FDA receives comments to the December 29, 1995, or June 12, 1996, ANPRM's suggesting changes in its treatment of imitation and substitute foods, it will consider such changes as part of those rulemakings.

Additionally, while modifying the existing standards as suggested by the comment could achieve consistency between milkfat content requirements in the standards of identity and the definitions for nutrient content claims for fat, this change would not address fat from sources other than milkfat (e.g., bulky flavors containing fat can increase total fat content such that the food would not comply with the requirements for the claim). Furthermore, the claims requirements contain provisions in addition to nutrient content requirements (e.g., explanatory label statements). However, foods covered by a standard of identity are exempt from the claims requirements (section 403(r)(5)(C) of the act), while most other nutritionally modified foods are covered. Thus, the comment's suggestion would neither promote uniformity in food labeling nor minimize consumer confusion. It makes more sense to choose an approach that will, as much as possible, provide for uniform treatment of all nutritionally modified foods.

As noted above in comments 9 and 10 of this document, some nutritionally modified versions of standardized dairy products are already being made under § 130.10. Many of the products that resemble or purport to be (i.e., have similar functional, physical, and sensory properties as) the standardized, lower-fat food, but that do not comply with the standard of identity for the food because their fat content falls outside of the ranges provided for in the current standards (e.g., nonfat sour cream), would not be covered by any of the approaches suggested by the comment. Therefore, formulation and labeling requirements for similar foods within a product class would continue to be different. Such a situation could lead to consumer confusion and to inefficient enforcement of the act.

In contrast, taking the approach suggested in the petitions and proposed by the agency, i.e., deleting the standards for lower-fat dairy products and providing for their composition and labeling in accordance with the general standard, will provide maximum flexibility for manufacturers in using new ingredients and technologies and increased product choices for consumers. Therefore, the agency concludes that this approach most closely fulfills the goals of the President's reinventing government initiative of simplifying regulations and easing the burden on the regulated industry.

13. Two comments objected that the proposed rule that would require lower-fat yogurt to be fortified with vitamin A to the level in full fat yogurt. The comments argued that such a requirement would make little sense because full fat yogurt is not widely marketed in this country. (One comment maintained that full fat yogurt constitutes less than 1 percent of the yogurt market in the United States.) These comments argued that, because full fat yogurt is not widely marketed, the purpose for the nutritional equivalence requirement in § 130.10, i.e., to ensure that foods that substitute for traditional products contain essential nutrients in amounts consistent with the reference food, does not apply. These comments argued that, because consumers are not replacing full fat yogurt with lower-fat yogurt products but rather are consuming lower-fat yogurt as their primary product, it is not only inappropriate but also unnecessary to require that lower-fat yogurt products be nutritionally equivalent to full fat yogurt. Conversely, several comments noted that full fat yogurt is a significant source of vitamin A, containing up to 14 percent of the RDI.

FDA disagrees with comments that argued that requiring a substitute food to be nutritionally equivalent to a product that is rarely marketed (i.e., full fat yogurt) is inappropriate. Market share is not a criterion for deciding the traditional food for which the new food named in accordance with § 130.10 substitutes. Foods named in accordance with § 130.10 use the name of the

traditional standardized food and a nutrient content claim that describes how the new food deviates from the traditional food. Thus, in the case of ''lowfat'' or ''nonfat yogurt'' that is named in accordance with § 130.10, the traditional standardized food is ''yogurt'' as defined in § 131.200.

Further, as FDA noted in the general standard final rule (58 FR 2431 at 2436), a food may resemble or substitute for more than one food (e.g., nonfat cottage cheese may substitute for cottage cheese (§ 133.128) or for dry curd cottage cheese (§ 133.129)). However, the food may not be nutritionally inferior to the standardized food whose name is used in the identity statement for the substitute food. If the agency were to revoke the standards for both lowfat and nonfat yogurt, lower-fat yogurt products made under § 130.10 would have to be nutritionally equivalent to the standardized food (i.e., yogurt) whose name is used in the identity statement of the foods.

FDA advises that such a result is fully consistent with the regulatory approach that FDA has taken since 1973. As FDA stated above in comments 9 and 10 of this document, since that time, consumers have had the assurance that substitute foods are nutritionally equivalent to the foods for which they substitute, or that, if they are not, this fact is disclosed on the label, i.e., by the use of the term ''imitation.'' Furthermore, it would be inconsistent to use the fat level of full fat yogurt for claims purposes (the name ''lowfat yogurt'' implies that there is a yogurt that is not lowfat, or else the food would have to be called ''yogurt, a lowfat food''), but not for purposes of establishing a nutrient baseline (i.e., the vitamin A level). Therefore, the agency rejects this argument.

At the same time, the agency recognizes that, for some dairy product manufacturers, this final rule will result in relabeling, reformulation, and equipment costs. Whether, and to what extent, a manufacturer incurs costs as a result of this final rule will depend, in part, on the types of products that the manufacturer produces and whether those products are in compliance with the nutrient content claim requirements.

FDA notes, however, that yogurt is unique among the products listed in the proposal in that both of the following conditions apply. First, the existing standards of identity for yogurt products do not require vitamin addition. Secondly, these standards cover nearly the full range of possible fat contents (i.e., full fat yogurt, lowfat yogurt, and nonfat yogurt). In contrast, the standards of identity for cottage cheese, for example, are limited to full fat and lowfat foods. Thus, historically, the yogurt industry has not had the same need to produce modified versions of the standardized food under TMP's or under the general standard as manufacturers of other standardized dairy products have had to do to make lowfat and nonfat products. To cite another example, although the standards for fluid milk products in part 131 cover a wide range of fat levels, vitamin A addition is mandatory in the lower fat foods, and the industry voluntarily adds vitamin D to almost all milk products. Thus, although fluid milk products have generally not been produced under TMP's or the general standard, the milk industry has the experience and equipment necessary for adding vitamins to lower-fat milk products to meet the nutritional equivalency requirements of § 130.10(b). In contrast, yogurt manufacturers have significantly less experience in producing products that are fortified with vitamin A.

Therefore, although FDA concludes that vitamin A addition will not result in insurmountable technical difficulties, the agency acknowledges that it may take some time for the yogurt industry to overcome any problems it may encounter in fortifying lower-fat yogurt products. Furthermore, because the yogurt industry has generally not heretofore produced vitamin fortified lower-fat yogurt products, manufacturers who produce only yogurt may well not possess the equipment necessary for vitamin fortification. One comment maintained that 69 percent of the yogurt industry produces only yogurt. In the analysis of impacts section of this preamble, using data from the same comment, FDA estimates that the cost of vitamin metering equipment for the yogurt industry could be as high as $52 million. In contrast, FDA estimates that the total cost of this regulation to the rest of the dairy industry will be approximately $2.7 million. Therefore, FDA believes that revoking the lower-fat dairy standards as proposed would likely impose a disproportionately larger financial burden on yogurt manufacturers compared to the rest of the dairy industry.

Taking into consideration the technical difficulties and economic considerations associated with the agency's proposal to revoke the standards for lowfat and nonfat yogurt, the agency finds that fairness suggests that it should delay final action on its proposal to revoke these standards. Therefore, FDA is deferring action on its proposal to revoke the standards of identity for lowfat yogurt and nonfat yogurt for 120 days. During that period, the yogurt industry will have an opportunity to meet with the agency and to discuss its progress in addressing the vitamin A problems. FDA believes that a 120-day deferral will provide an appropriate balance between the problems the industry faces and consumers' interest in consistently and fairly labeled foods.

FDA advises that, at the end of the 120-day period, the agency intends to move to resolve the inconsistencies between use of the terms ''lowfat'' and ''nonfat'' in the names of standardized yogurt and the definitions for these terms established under the nutrient content claims regulations. FDA further advises that deferring action on the proposal to revoke the standards of identity for lowfat and nonfat yogurt does not change the agency's conclusions with regard to deleting the other standards of identity for lower-fat dairy products.

The agency does not believe that its decision to defer, for a limited time, action on the standards of identity for yogurt products will pose a serious problem for consumers because essentially all nonfat yogurt, and the majority of lowfat yogurt, already complies with the nutrient content claims requirements with respect to fat in that they contain less than 0.5 and 3.0 g fat per RACC, respectively. In contrast, approximately two-thirds of the lowfat milk products are 2 percent milk and, therefore, contain up to 60 percent more fat than is permitted under the definition for ''lowfat'' (Ref. 1).

H. Effective Date

14. One comment objected to the proposed effective date of January 1, 1998. The comment stated that an effective date of January 1, 1998, is overly generous. It maintained that this final rule could have a significant impact on American's health and should be implemented as quickly as possible. The comment urged the agency to move up the effective date of the final rule to January 1, 1997.

FDA agrees that this final rule should be implemented as quickly as possible. However, FDA disagrees that the proposed effective date, January 1, 1998, would represent an unduly long compliance period. To minimize the economic impact of required label changes, FDA periodically announces uniform effective dates for new food labeling requirements. On April 15, 1996, FDA published a proposed rule (61 FR 16422) to establish January 1, 1998, as its new uniform effective date for all food labeling regulations that

issue before January 1, 1997. Thus, FDA has placed this change on the same schedule as virtually all other regulatory changes made before December 31, 1996. Given the exemption in the act for claims on standardized foods (section 403(r)(5)(C)), FDA sees no basis for an earlier date.

I. Other Actions—Unresolved Hearing Issue on the Lowfat Milk and Skim Milk Standards

As noted in the November 9, 1995, proposal (60 FR 56541 at 56546), FDA published a notice of hearing on objections in the Federal Register of October 6, 1983 (48 FR 45545), to a final rule (45 FR 81734, December 12, 1980) concerning the standards of identity for lowfat milk and skim milk (Docket Nos. 81N–204F and 76N–0175). The hearing was granted on four issues, three of which were resolved. The remaining issue, dealing with labeling requirements of the standardized foods, i.e, the reasonableness of the decision to prohibit use of the terms ''protein fortified'' and ''fortified with protein'' on labels of lowfat milk and skim milk products containing not less than 10 percent milk-derived nonfat milk solids), has been rendered moot by this final rule which removes the standards of identity for lowfat milk and skim milk in §§131.135 and 131.143. No further rulemaking procedures regarding the stayed provisions are necessary.

III. Conclusions Regarding Comments

After review and consideration of the comments it received in response to the November 9, 1995, proposal, FDA concludes that no evidence or information has been presented that would provide a basis for altering the agency's tentative conclusion that it should remove the standards of identity for sweetened condensed skimmed milk (§ 131.122), lowfat dry milk (§ 131.123), evaporated skimmed milk (§ 131.132), lowfat milk (§ 131.135), acidified lowfat milk (§ 131.136), cultured lowfat milk (§ 131.138), skim (nonfat) milk (§ 131.143), acidified skim (nonfat) milk (§ 131.144), cultured skim (nonfat) milk (§ 131.146), sour half-and-half (§ 131.185), acidified sour half-and-half (§ 131.187), and lowfat cottage cheese (§ 133.131); that it should amend the standard of identity for dry cream (§ 131.149) by removing the reference to the lowfat milk standard; and that it should amend the nutrient content claims regulations for fat, fatty acids, and cholesterol content (§ 101.62) to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products.

Therefore, in this final rule, FDA is removing these standards of identity and amending the standard of identity for dry cream, as proposed. In addition, FDA is amending the nutrient content claims regulations for fat, fatty acids, and cholesterol content to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products. FDA is not revoking the standards of identity for lowfat and nonfat yogurt at this time.

Because this rulemaking involves the removal and amendment of standards of identity for dairy products, it is subject to the formal rulemaking procedures of section 701(e) of the act. Section 701(e) of the act requires that the agency provide an opportunity for objections to the final rule. If any objections raise issues of material fact, the agency is to hold a formal evidentiary hearing on those issues.

IV. Analysis of Impacts

Although this rule is issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556 and 557, and is, therefore, exempted from the economic analysis requirements of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), FDA has examined the economic implications of this rulemaking.

A. Label Changes

There are approximately 1,600 lowfat milk and 770 skim (nonfat) milk stock keeping units (SKU's) currently on the market. As a result of this rule, all milks currently using the terms ''lowfat'' and ''nonfat'' (or ''skim'') in their names must comply with the nutrient content claim requirements for those terms. Some of these products are already in compliance with the claim requirements. Any milk not in compliance with the nutrient content claim requirements for ''lowfat'' or ''nonfat'' must be relabeled. According to the petitioners, most products currently labeled as ''nonfat milk'' would be eligible to retain that name. However, many products currently labeled as ''lowfat milk'' (i.e., products containing more than 1 percent milkfat) would not be eligible to retain that name and must be relabeled. Approximately 1,000 lowfat milk SKU's will need to be relabeled.

This regulation will also require changes in the labels of sour half-and-half, acidified sour half-and-half, and, potentially, in labels of lowfat cottage cheese products. There are approximately 16 sour half-and-half SKU's and approximately 420 lowfat cottage cheese SKU's. There are no acidified sour half-and-half products in FDA's data base. FDA estimates that approximately 192 lowfat cottage cheese product SKU's do not comply with FDA's nutrient content claims definitions and will, therefore, require relabeling. However, all sour half-and-half products (16 SKU's) will need to be relabeled under the general standard to be named using a nutrient content claim and the name of the standardized food (e.g., ''reduced fat sour cream'').

There are approximately 570 firms manufacturing products affected by this regulation. Of these firms, approximately 440 are small firms with fewer than 500 employees.

The costs of the relabeling associated with this final rule include administrative, redesign, and inventory disposal costs. The administrative costs are estimated to be $850 per small firm and $6,300 per large firm. The total administrative costs associated with this proposed regulation are approximately $1 million.

The agency estimates that the changes required by this final regulation will result in a simple two-color label redesign. Also, because firms will have a minimum of 1 year to comply, redesign costs will be reduced by the fact that they can incorporate mandated changes with previously planned label changes. Redesign costs of this regulation are estimated at $1,200 per label or a total of $1.5 million.

An additional cost category is the label inventory loss associated with the transition from old to new labels. The cost of label inventory loss depends on average label inventory and the length of the compliance period. FDA is establishing an effective date for this final regulation that will provide approximately 1 year for firms to make any necessary changes. A 1-year compliance period is sufficient to allow producers of milk, sour half-and-half, and cottage cheese to use up existing stocks of labels. Therefore, label inventory disposal costs will be zero.

B. Vitamin Addition

Two comments to the November 9, 1995, proposal objected to the absence of a discussion in the economic analysis section of the costs of fortification for lower-fat yogurt and sour half-and-half. One comment suggested that the cost to obtain and install vitamin metering equipment would be $250,000 per plant. Additionally, using information provided in the same comment, FDA estimates the cost of obtaining and adding vitamin A to be $100 per item per year.

FDA acknowledges that it neglected to consider these costs when analyzing the impact of the proposed rule. FDA notes

that the recurring cost of obtaining and adding vitamin A will apply to nearly all lower-fat dairy products because the removal of fat also unavoidably removes some vitamin A. However, the cost of obtaining equipment necessary to add vitamins to lower-fat dairy products will only be incurred by those plants that do not already possess such equipment (i.e., those firms that do not currently manufacture other standardized or nonstandardized products to which they routinely add vitamins).

As previously stated in this preamble, FDA has issued over 150 TMP's for the market testing of lower-fat dairy products such as ''light eggnog,'' ''light sour cream,'' ''nonfat sour cream,'' and ''nonfat cottage cheese.'' FDA required that these test products be nutritionally equivalent to the full fat, standardized food. The proliferation of requests for TMP's indicates that, in spite of the costs of fortification, many dairy product manufacturers considered the ability to market modified foods named by use of a nutrient content claim and a standardized term to be of benefit to them and to consumers.

As noted earlier, most fluid milk products (approximately 95 percent) are currently fortified. FDA does not expect this rule to have a significant impact on the fortification practices for milk products. Therefore, this final rule will not impose significant costs of vitamin fortification of lower-fat milk products. Furthermore, lower-fat yogurt and sour cream products were the only products noted by comments to the November 9, 1995, proposal for which comments claimed the fortification requirements would be burdensome.

According to FDA data, the 16 sour half-and-half products currently on the market represent 12 brands. Products made under the general standard, e.g., ''light sour cream'' or ''nonfat sour cream'' are sold under 11 of those 12 brands. Because these products are currently being made under § 130.10, the firms producing these products should already possess the necessary equipment for vitamin fortification and will only bear the cost of obtaining and adding vitamin A. The one firm producing only sour half-and-half may need to purchase equipment for vitamin addition. Therefore, the cost of requiring fortification of sour half-and-half products may be approximately $0.25 million in the first year and $1,600 in each subsequent year.

One comment stated that 69 percent of the yogurt industry produces only standardized yogurt and, therefore, will have to purchase vitamin metering equipment. Thus, it is possible that the cost to the yogurt industry to meet the fortification requirement could be as high as $52 million (300 plants X 0.69 (percent of plants that need to purchase equipment) X $250,000 (for equipment) plus a total of $240,000 per year to obtain and add vitamin A). The agency notes it has not fully evaluated these figures.

C. Conclusion of Analysis

The agency estimates that the total costs of this regulation will be approximately $2.7 million. Because FDA is deferring action on the standards of identity for lower-fat yogurt products, this assessment does not include costs to the yogurt industry in the costs of this final rule. The agency believes that consumers will benefit from this regulation because it will provide consistency in the nomenclature of both standardized and nonstandardized foods that bear nutrient content claims. The agency also believes that firms will benefit from this regulation in that it provides for greater flexibility than current standards of identity allow.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 20, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Summary of market and consumption data for lower-fat dairy products, Laina Bush, Center for Food Safety and Applied Nutrition, FDA, 1996.

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, parts 101, 131, and 133 are amended as follows:

PART 101—FOOD LABELING

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

Authority: Secs. 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 101.62 is amended by revising the introductory text of paragraph (b)(1) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(b) * * * (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' or, in the case of milk products, ''skim'' may be used on the label or in labeling of foods, provided that:

* * * * *

PART 131—MILK AND CREAM

3. The authority citation for 21 CFR part 131 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 131.122 [Removed]

4. Section 131.122 *Sweetened condensed skimmed milk* is removed from subpart B.

§ 131.123 [Removed]

5. Section 131.123 *Lowfat dry milk* is removed from subpart B.

§ 131.132 [Removed]

6. Section 131.132 *Evaporated skimmed milk* is removed from subpart B.

§ 131.135 [Removed]

7. Section 131.135 *Lowfat milk* is removed from subpart B.

§ 131.136 [Removed]

8. Section 131.136 *Acidified lowfat milk* is removed from subpart B.

§ 131.138 [Removed]

9. Section 131.138 *Cultured lowfat milk* is removed from subpart B.

§ 131.143 [Removed]

10. Section 131.143 *Skim milk* is removed from subpart B.

§ 131.144 [Removed]

11. Section 131.144 *Acidified skim milk* is removed from subpart B.

§ 131.146 [Removed]

12. Section 131.146 *Cultured skim milk* is removed from subpart B.

13. Section 131.149 is amended by revising the second sentence of paragraph (a) to read as follows:

§ 131.149 Dry cream.

(a) * * * Alternatively, dry cream may be obtained by blending dry milks as defined in §§ 131.125(a) and 131.147(a) with dry cream as appropriate: *Provided*, That the resulting product is equivalent in composition to that obtained by the method described in the first sentence of this paragraph. * * *

* * * * *

§ 131.185 [Removed]

14. Section 131.185 *Sour half-and-half* is removed from subpart B.

§ 131.187 [Removed]

15. Section 131.187 *Acidified sour half-and-half* is removed from subpart B.

PART 133—CHEESE AND RELATED CHEESE PRODUCTS

16. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 133.131 [Removed]

17. Section 133.131 *Lowfat cottage cheese* is removed from subpart B.

Dated: November 12, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–29485 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 510, 520, and 522

Animal Drugs, Feeds, and Related Products; Clindamycin Hydrochloride Liquid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for expanding the use of clindamycin hydrochloride liquid by adding indications for the treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with certain, susceptible stains of bacteria in cats.

EFFECTIVE DATE: November 20, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, is sponsor of NADA 135–940, which provides for use of Antirobe® Aquadrops Liquid (clindamycin hydrochloride) in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by or associated with certain, susceptible strains of aerobic or anaerobic bacteria in accordance with § 520.447 (21 CFR 520.447). The firm has filed a supplemental NADA that expands use of the drug product to cats by providing for treatment of: (1) Soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of the aerobic bacteria *Staphylococcus aureus, S. intermedius,* and *Streptococcus spp.*, and (2) soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of the anaerobic bacteria *Clostridium perfringens* and *Bacteroides fragilis*. The supplemental NADA is approved as of October 7, 1996, and the regulations are amended in § 520.447 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the existing ''Limitations'' paragraph for use of the drug in dogs (§ 520.447(c)(3)) is being revised to add chinchillas and ruminating animals to the list of animals for which the drug product is contraindicated.

Also, the regulations are amended in 21 CFR 510.600(c)(1) and (c)(2) and § 522.1145(a) (21 CFR 522.1145(a)) to reflect a change of sponsor resulting from the merger of The Upjohn Co. and Pharmacia, Inc. The new sponsor, Pharmacia & Upjohn Co., informed FDA of the change and subsequently requested that the agency amend the regulation in § 522.1145(a) that provides for use of Pharmacia's Hylartin V Injection (hyaluronate sodium, NADA 112–048) to indicate the new sponsor.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval for use in cats qualifies for 3 years of marketing exclusivity beginning October 7, 1996, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.