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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–384H and 95P–0241]

RIN 0910–AA19

Food Labeling: Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its food labeling regulations by amending the definition of the term ''healthy'' to permit certain processed fruits and vegetables and enriched cereal-grain products that conform to a standard of identity to bear this term. This action is being taken to provide consumers with information that will assist them in achieving their dietary goals. This action also responds to petitions submitted to the agency by the American Frozen Food Institute (AFFI), the National Food Processors Association (NFPA), and the American Bakers Association (ABA).

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, 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

In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule entitled ''Food Labeling: Nutrient Content Claims, Definition of Term: Healthy'' (hereinafter referred to as ''the healthy final rule''), which established a definition for the use of the implied nutrient content claim ''healthy'' under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990 (the NLEA). The regulation permits the use of the term ''healthy'' and its derivatives on the labels of individual foods, main dishes, and meal products that are particularly useful, because of their nutrient profile, in assisting consumers to construct a diet that conforms to current dietary guidelines.

The definition for ''healthy'' in § 101.65(d) (21 CFR 101.65(d)) provides that an individual food, main dish, or meal product may bear this term if: (1) It is ''low'' in fat and saturated fat; (2) its content of sodium and cholesterol does not exceed the levels for these nutrients established in the definition; and (3) it contributes at least 10 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) of 1 or more of the following nutrients: Vitamin A, vitamin C, calcium, iron, protein, or fiber (that is, the food must be a ''good source'' of one or more of these six nutrients). In addition, the definition provides that a food can be fortified to meet the 10 percent nutrient contribution requirement if the fortification is done in accordance with the agency's fortification policy in § 104.20 (21 CFR 104.20). The definition further provides that raw fruits and vegetables are exempt from the 10 percent nutrient contribution requirement and may bear the term provided they meet the other requirements.

Following publication of the healthy final rule, three trade associations, AFFI, NFPA, and ABA, submitted petitions to FDA (Docket Nos. 91N–384H/PRC1, 91N–384H/PRC2, and 95P–024, respectively) requesting that the agency amend the definition of ''healthy.''

Two of the petitioners, AFFI and NFPA, requested that FDA reconsider its decision to exempt only raw fruits and vegetables from the 10 percent nutrient contribution requirement. Both petitioners argued that precluding certain processed fruits and vegetables from bearing the term ''healthy,'' especially when they are nutritionally equivalent to raw fruits and vegetables, would undermine the intent of the definition for ''healthy,'' which is to assist consumers to construct a diet that conforms to current dietary guidelines. AFFI further argued in their petition that the blanching and freezing processes do not significantly change the nutrient profile of frozen fruits and vegetables. In support of this argument, AFFI presented data to FDA comparing nutrient profiles of various raw and frozen fruits and vegetables, single ingredient versions of the same fruits and vegetables.

The third petition, submitted by ABA, requested that the agency amend the definition of ''healthy'' to permit the claim on enriched cereal-grain products that conform to the standards of identity in part 136, 137, or 139 (21 CFR part 136, 137, or 139) and bread that conforms to the standard of identity for enriched bread in 21 CFR 136.115, except that it contains whole wheat or other grain products not permitted under that standard. ABA argued that most nutritional authorities agree that grain products play a central role in a healthy diet. In fact, the petitioner argued, precluding enriched cereal-grain products from bearing a ''healthy'' claim was inconsistent with the basis of the ''healthy'' claim because these foods are particularly helpful in assisting consumers to construct a diet that conforms to current dietary guidelines.

Having considered the arguments raised in the petitions, the agency tentatively concluded in the **Federal Register** of February 12, 1996 (61 FR 5349), (hereinafter referred to as ''the 1996 healthy proposal''), that certain frozen fruit and vegetable products and enriched cereal-grain products that conform to a standard of identity should not be barred from using the term ''healthy'' because these foods can be particularly useful in assisting consumers in achieving dietary goals. Accordingly, in that document, FDA proposed to amend the definition of ''healthy'' to allow frozen fruit and vegetable products comprised solely of fruits and vegetables, and enriched grain products that conform to a standard of identity in part 136, 137, or 139, that do not contain 10 percent of vitamin A, vitamin C, calcium, iron, protein, or fiber, but otherwise meet the requirement of the ''healthy'' definition, to bear the term.

Interested parties were given until April 29, 1996, to comment. FDA received approximately 100 letters in response to the proposal, each containing one or more comments, from industry, trade organizations, consumers, consumer interest groups, and academia. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., changing the 10 percent nutrient contribution requirement to a 5 percent requirement, revising the nutrient contribution requirement so that it is based on the caloric contribution of the food, and changing the word ''enriched'' to ''partially restored'') and they will not be discussed here. A number of comments suggested modifications and revisions in various provisions of the proposal. A summary of these comments and the agency's responses follow:

II. Comments and Agency Response

A. General Comments

1. One comment that supported the concept of extending use of the ''healthy'' claim to processed fruits and vegetables and enriched grain products contended that the exemption approach is both discriminatory and piecemeal and that a new regulation providing a rational and consistent approach should be issued.

Similarly, another comment stated that the 1996 healthy proposal would lead to inequity in the marketplace and confuse consumers. The comment asserted that the agency is creating ''regulatory chaos'' by a desire to fix a problem that in reality does not exist under the current regulations. The comment suggested that the importance of fruits and vegetables as part of a healthy diet, whether they are raw, frozen, or canned, can be highlighted on product labels under the existing regulation even if no exemption to the good source requirement is included in the rule. For example, fruit and vegetable products ineligible to bear the term ''healthy'' may bear information on general dietary guidance that promotes consumption of fruit and vegetable products as part of an overall healthy diet. Such language, in the absence of an expressed or implied claim, would not require the food bearing the label to meet the requirements of the ''healthy'' claim. The comment further asserted that the only thing the current regulation would prevent is the use of the word ''healthy'' in a nutritional context on the label to indicate that the food is, in and of itself, ''healthy.'' Neither of these comments, however, presented any alternative approaches that the agency had not considered when it first established the definition for ''healthy.''

The agency appreciates the concerns raised in the comments regarding the regulatory approach the agency is taking in this rulemaking in amending the definition of ''healthy.'' Still, it is not persuaded that this approach is discriminatory and will create regulatory chaos. To the contrary, by extending this exemption to other fruit and vegetable products and to enriched cereal-grain products that conform to a standard of identity, the agency will permit the ''healthy'' claim on products that are particularly helpful in assisting consumers to achieve dietary goals yet are currently precluded from bearing the claim because they do not contain at least 10 percent of the subject nutrients, and in many cases cannot be reformulated to do so. The agency believes that a failure to provide for these foods to bear ''healthy'' would decrease the utility of the claim in assisting consumers in achieving dietary goals. Therefore, the agency concludes that the approach it is taking in amending the definition of ''healthy'' in this rulemaking is equitable, consistent with dietary guidelines, and unlikely to confuse consumers regarding use of the term ''healthy.''

In addition, the approach that FDA is taking in this final rule is similar to the approach that it took in establishing the definition of ''healthy'' for seafood and game meats. As discussed in the 1996 healthy proposal, FDA adopted different provisions for the use of the term ''healthy'' on raw, single ingredient seafood and game meat products with regard to the amount of fat, saturated fat, and cholesterol. FDA established different provisions for these foods because, in part, they would not qualify for the claim if held to the criteria of being ''low fat'' and ''low saturated fat'' because they are inherently higher in fat and in saturated fat than many other foods, yet some are recommended by the Surgeon General and the Food and Nutrition Board as foods to include in a healthy diet. In this document, FDA is relying on the same general concept on which it based its decision to provide alternative criteria for raw, single ingredient seafood and game meats. Namely, the agency would consider it inappropriate if the requirements in the definition of ''healthy'' precluded use of the claim for fruits and vegetables and cereal-grain products, which play such an important role in the diet and that dietary guidelines recommend be included in a healthy diet, especially in cases where manufacturers do not have the flexibility to reformulate the food to qualify it to bear the claim. This regulatory approach ensures that the term ''healthy'' is used in a way that enables consumers to have confidence that the foods that bear this term will in fact be particularly useful in constructing diets that conform to dietary guidelines.

The agency acknowledges that products described in the latter comment do have other claims available to them. However, the fact that these products have other claims available to them is not an adequate basis for the agency to find that they should be precluded from bearing the term ''healthy.'' The agency believes that the more compelling argument is that in cases where the frozen or canned version of the fruit or vegetable is nutritionally comparable to the raw version of the same fruit or vegetable, and it is as beneficial as the raw version, they should be eligible to bear the ''healthy'' claim under the same conditions as the raw version. Furthermore, consumers should be informed that these foods serve as appropriate and useful alternatives to raw fruits and vegetables in assisting them in achieving their dietary goals.

B. Single Ingredient Fruit and Vegetable Products

The data that AFFI presented in supplemental comments to its petition comparing nutrient profiles of various raw fruits and vegetables and frozen, single ingredient versions of the same fruits and vegetables indicated that frozen fruits and vegetables generally are nutritionally comparable to raw fruits and vegetables. This indication is consistent with the agency's review of literature comparing raw fruits and vegetables to frozen and canned fruits and vegetables (Ref. 1). Based on a preliminary review of the AFFI data, the agency tentatively concluded in the 1996 healthy proposal that frozen, single ingredient fruits and vegetables should not be barred from bearing the term ''healthy'' because they are nutritionally comparable to raw fruits and vegetables. Moreover, like raw fruits and vegetables, they can contribute significantly to a healthy diet and to achieving compliance with dietary guidelines. Thus, the agency proposed to amend § 101.65(d)(2)(iv) to exempt frozen, single ingredient fruit and vegetable products and mixtures of frozen, single ingredient fruit and vegetable products from the 10 percent nutrient contribution requirement.

2. Some comments were opposed to exempting frozen, single ingredient fruit and vegetable products and mixtures of frozen, single ingredient fruit and vegetable products from the 10 percent nutrient contribution requirement because, the comments contended, frozen, single ingredient fruits and vegetables were nutritionally inferior to the raw fruits and vegetables. These comments argued that allowing manufacturers to label their products as ''healthy'' when the food did not contain 10 percent of one of the six listed nutrients was not a good idea because of the way that frozen fruits and vegetables were processed (e.g., blanching, trimming, washing, chopping, and freezing). One of these comments asserted that frozen food products are not comparable to raw food products because frozen products tend to diminish in quality during transportation and storage due to temperature changes. The comment contended, therefore, that frozen fruit and vegetable products should bear the term ''healthy'' only when they meet all

the requirements of the claim, including the 10 percent nutrient contribution requirement.

Many of the comments supported the proposal to exempt frozen, single ingredient fruit and vegetable products and mixtures of frozen, single ingredient fruit and vegetable products from the 10 percent nutrient contribution requirement. They agreed that these foods are nutritionally comparable to raw fruits and vegetables, can be used interchangeably in the diet with raw fruits and vegetables, can make a significant contribution to achieving dietary compliance, and the absence of a claim on frozen versions of a raw product that bears a claim could be misleading. In addition, the comments noted that the appearance of the ''healthy'' claim on frozen, single ingredient fruits and vegetables communicates something broad, powerful, and positive about the described food consistent with its role in achieving compliant diets and, therefore, would contribute to a balanced and healthful diet by encouraging increased consumption of these products in accordance with dietary guidelines.

The agency disagrees with the first comments. While those comments stated that frozen food products are nutritionally inferior to raw fruits and vegetables, they did not provide the agency with any data or other information to support their position or to cause the agency to reconsider its tentative conclusion that frozen, single ingredient fruits and vegetables are nutritionally comparable to raw fruits and vegetables and can be used interchangeably in the diet.

In efforts to evaluate the nutrient content of frozen fruits and vegetables compared to that of raw fruits and vegetables, the agency reviewed both the AFFI's supplemental data and similar data from the U.S. Department of Agriculture (USDA) (Ref. 2). The nutrient profiles of selected raw fruits and vegetables and frozen, single ingredient versions of the same fruits and vegetables revealed relatively equivalent nutrient profiles. The data reviewed by the agency did not support the argument raised in the comments that blanching and/or freezing fruits and vegetables generally reduces their nutrient content. In fact, some data showed that the nutrient content level for certain nutrients was higher in the frozen version of the food than in the raw version of the food. This is probably attributable to the fact that unprocessed (i.e., raw) fruits and vegetables may lose some of their nutrients over time under certain storage conditions (Ref. 1). Further, both sets of data supported the argument raised by the petitioners that frozen fruits and vegetables have comparable nutritional profiles when compared to the raw version. Therefore, the agency continues to believe that single ingredient frozen fruits and vegetables are nutritionally the same as raw fruits and vegetables. Moreover, these foods can contribute significantly to a healthy diet and to achieving compliance with dietary guidelines, even if particular products do not meet the 10 percent nutrient contribution requirement.

Further, based on these data, the agency concludes that because single ingredient, frozen fruit or vegetable products are nutritionally comparable to the raw versions, they would likely have the same inherent beneficial effects as the raw version. Precluding such foods from bearing the term ''healthy'' could undermine an important element of current dietary guidance, as well as the basis for the ''healthy'' claim that is to assist consumers in constructing a diet that conforms to dietary guidelines. Consumers should be informed, moreover, that these foods serve as appropriate and useful alternatives to raw fruits and vegetables in constructing diets consistent with current dietary recommendations even if the products do not meet the 10 percent nutrient contribution requirement. Therefore, the agency concludes that such foods should not be barred from bearing the term ''healthy.'' Accordingly, the agency is amending § 101.65(d) to exempt frozen, single ingredient fruit and vegetable products and mixtures of frozen, single ingredient fruits and vegetables from the 10 percent nutrient contribution requirement.

C. Multi-Ingredient Fruit and Vegetable Products

As discussed in the 1996 healthy proposal (61 FR 5349 at 5352), FDA tentatively concluded that providing an exemption for multi-ingredient fruit and vegetable products would be inconsistent with current dietary recommendations and, consequently, inconsistent with the basis of the ''healthy'' claim because such foods may increase the consumption of certain undesirable nutrients and decrease consumption of micronutrients. Thus, FDA did not propose to extend the exemption to multi-ingredient fruit and vegetable products composed of ingredients other than fruits or vegetables that do not contain at least 10 percent of one of the six listed nutrients.

3. Two comments requested that the agency reconsider its tentative position regarding the eligibility of multi-ingredient fruit and vegetable products (i.e., products that contain added oils, sodium, sauces, syrups, or similar ingredients) to bear the term ''healthy'' when the food did not meet the 10 percent nutrient contribution requirement. One comment contended that if a product contains minimal amounts of these added ingredients and the levels of fat, saturated fat, cholesterol, or sodium are not significantly increased, then the product should be granted an exemption. The comment opined that the addition of insignificant amounts of these nutrients should not cause the product to be inconsistent with the purpose of the ''healthy'' claim or incompatible with current dietary guidelines. The other comment argued that multi-ingredient fruit and vegetable products will likely be better tasting when compared to fruit and vegetable products without these ingredients and, therefore, are more likely to be selected by consumers in their efforts to meet the public health goal of increasing fruit and vegetable consumption.

The agency is not persuaded by these comments that multi-ingredient fruit and vegetable products with added oils, sodium, sauces, syrups, or similar ingredients should be exempt from the 10 percent requirement. These foods do not have the same nutrient profile as fruits or vegetables not containing these added ingredients and therefore, have the potential, when used interchangeably in the diet with such fruits or vegetables, of increasing the dietary intake of substances that dietary guidelines recommend be decreased. Consumers who rely on the appearance of the term ''healthy'' to construct a diet consistent with current dietary recommendations could be misled to believe that multi-ingredient fruit and vegetable products with added oils, sodium, sauces, syrups, or similar ingredients are just as useful and helpful as raw and single ingredient fruits and vegetables in achieving dietary goals, when in fact, they could increase dietary intake of less desirable nutrients. Furthermore, the usefulness of a food labeled ''healthy'' is not based on how it compares to a similar food (for example, in taste), but on how, because of its nutrient profile, it contributes to achieving a total diet consistent with dietary recommendations.

The agency notes that the comment suggested minimal or insignificant amounts of these ingredients be permitted. The comments, however, did not provide a basis on which the agency could establish a minimal or insignificant amount. The agency notes,

however, that manufacturers should be advised that fruit and vegetable products composed of ingredients other than fruits or vegetables can be formulated and fortified in accordance with § 104.20 to meet the 10 percent contribution requirement, and, when so formulated, a food that meets the nutrient contribution requirement as well as the other requirements of the claim can bear the term ''healthy.'' Accordingly, FDA is not exempting multi-ingredient fruit and vegetable products that contain added oils, sodium, sauces, syrups, or similar ingredients from the 10 percent nutrient contribution requirement. As discussed below, however, certain nonnutritive ingredients (i.e., ingredients that do not change the levels of macro or micronutrients in the food) may be added under certain conditions.

4. One comment stated that products that meet the standard of identity for fruit, fruit juices, and fruit products (e.g., applesauce) should also be exempt from the 10 percent nutrient contribution requirement. The comment stated that these products contribute to healthful diets. The comment contended that discriminating against apple products, in particular, would confuse consumers and discourage them from consuming fruit products such as apple slices and apple juice. The comment cited no basis for exempting these foods other than the fact that some of the foods cited in the comment met a standard of identity. The comment did not provide any data or other information to suggest which of these products were currently prohibited from bearing the ''healthy'' claim.

Nevertheless, the agency considered it prudent to review the standards of identity to ensure that fruit products conforming to a standard of identity that are particularly helpful in assisting consumers in constructing diets consistent with dietary guidelines are not unfairly precluded from bearing the term because of the provisions in the standard. Several standards of identity governing fruit products permit the optional fortification of one or more of the six listed nutrients at levels sufficient to meet the 10 percent nutrient contribution requirement. There are fruit products under standards of identity that do not provide for fortification, that are consistent with the basis of the ''healthy'' claim, and that are not covered by the exemptions issued in this final rule. The agency reviewed USDA's database (Ref. 2) to determine whether these fruit products' nutrient profiles preclude them from bearing the term. Based on this review, the agency determined that these foods have nutrient profiles that would allow them to bear the term ''healthy'' even under the current regulations without an exemption. The agency therefore concludes that a general exemption for fruit products governed by the standards of identity is not warranted.

D. Canned and Processed Fruit and Vegetable Products

The agency stated in the 1996 healthy proposal (61 FR 5349 at 5352) that if appropriate data were submitted, the agency was prepared to extend the exemption from the 10 percent nutrient contribution requirement to other single ingredient processed fruit and vegetable products. The agency solicited comments and data on the effects of other types of processing (e.g., drying and canning) and on how these processes affect the nutritional profile of fruits and vegetables.

5. Three comments requested that the agency exempt canned fruits and vegetables from the minimum nutrient contribution requirement. In support of this request, one of the comments contained data comparing the nutrient profiles of canned fruits and vegetables to raw and frozen versions of the fruits and vegetables.[1] This comment stated that an exemption should be granted for a broad category of fruit and vegetable products, including canned varieties packed in a medium that may contain other ingredients such as water, spices, flavors, or other additives that do not weaken the requirement that the food be composed solely of fruits and vegetables, for the purpose of bearing the ''healthy'' claim.

The agency has considered the requests made in the comments as well as reviewed the data submitted in each of the appendices. The data in Appendix A were obtained from laboratory analysis and directly compared nutrient levels of raw and processed versions of the subject fruit or vegetable on a per 100-gram basis. The agency considers the data in Appendix A to be the most relevant in terms of demonstrating the effects of canning on the nutritional profile of fruits and vegetables. The data in Appendix A show that fruits and vegetables that are subjected to freezing and canning processes generally maintain nutrient levels comparable to the raw version. These data were collected nearly 2 decades ago and may not be reflective of current canning technology and its effect on nutrient levels, however. Consequently, the agency reviewed the literature to assess: (1) Whether current canning technologies differ significantly from those used 20 years ago; and (2) if so, whether use of these current technologies results in processed fruits or vegetables with significantly altered nutrient levels as compared to the raw version.

This review indicates that any improvements in canning technologies that have occurred over the last 20 years have not significantly altered nutrient levels in canned foods when compared to raw food (Ref. 3). Consequently, the agency concludes that canned, single ingredient fruit and vegetable products generally have comparable nutrient profiles to the raw and frozen versions of the fruit and vegetable. Accordingly, the agency is revising proposed § 101.65(d)(2)(iv) to include canned, single ingredient fruit and vegetable products in the list of foods that are exempt from the 10 percent nutrient contribution requirement. In deciding to extend this exemption to canned, single ingredient fruit and vegetable products, the agency is acknowledging that these products are nutritionally comparable to, and as beneficial as, raw fruits and vegetables and, therefore, can be used interchangeably in the diet with raw fruits and vegetables. Consequently, these products, like frozen, single ingredient fruits and vegetables, should be permitted to bear the ''healthy'' claim under the same conditions as raw fruits and vegetables. Moreover, canned, single ingredient fruits and vegetables, like raw and frozen, single ingredient fruits and vegetables, can be particularly helpful in assisting consumers in achieving dietary goals and should not be precluded from bearing a ''healthy'' claim.

Furthermore, the agency is concerned that an inappropriate message could be sent to consumers if a ''healthy'' claim were permitted to appear on the raw or frozen version of the fruit or vegetable product but were precluded from appearing on the canned version. Such a situation might not only confuse consumers, it would also be inconsistent with the 1995 Dietary Guidelines. These guidelines state that ''the availability of fresh fruits and vegetables varies by season and region of the country, but frozen and canned vegetables ensure a plentiful supply of these healthful foods throughout the

[1] The data submitted to the agency were presented in three appendices, A, B, and C. The Appendix A data directly compared nutrient levels of several versions of the subject fruit or vegetable, including raw, frozen, and canned. The Appendix B data compared nutrient levels before and after heating of each version of the fruit or vegetable (i.e., nutrient levels of frozen products were compared to nutrient levels of frozen products that had been heated). Appendix C contained data comparing nutrient profiles of raw products that had been cooked with other versions of the fruit or vegetable that were either cooked or uncooked.

year.'' The guidelines therefore recognize that canned as well as frozen fruits and vegetables can be used interchangeably in the diet with, and are just as helpful as, raw fruits and vegetables. Moreover, consumers should be informed that these foods serve as appropriate and useful alternatives to raw fruits and vegetables in assisting them in achieving their dietary goals.

In response to the request that the agency permit the addition of ingredients such as water, spices, flavors, or other additives, the agency would not object to the addition of ingredients that do not change the level of macro or micronutrients in the food because fruits or vegetables with such added ingredients would be nutritionally comparable to the raw version and can be used interchangeably in the diet with raw versions. On the one hand, the addition of oils, sodium, sauces, syrups, and other ingredients that could change the level of nutrients, as compared to raw foods, could increase the consumption of undesirable nutrients beyond that of the raw version, as well as imply that these products have nutritional profiles comparable to the raw version, when in fact they do not. Consequently, the agency finds no basis on which fruit and vegetable products with added oils, sauces, sodium, and syrups should be exempt from the 10 percent requirement. On the other hand, fruit and vegetable products that have nonnutritive added ingredients (such as water, spices, or flavors) maintain comparable nutrient profiles to the raw versions, and, therefore, should be permitted to bear the claim under the same conditions as the raw versions. Accordingly, the agency is amending § 101.65(d)(2)(iv) from the proposal to clarify that foods comprised solely of fruits and vegetables may have added ingredients such as water, spices, flavors or other additives that do not change the level of nutrients in the food. This change from the proposal substantially lengthens the description of the exemption for frozen and canned single ingredient fruits and vegetables. The agency has therefore placed the exemptions to the 10 percent nutrient contribution requirement at the end of § 101.165(d)(2)(iv), paragraphs A through C. In addition, the agency has deleted the phrase ''per labeled serving,'' an error in the proposed codified language, from the final codified language so that the description of the 10 percent nutrient contribution itself conforms to the preexisting codified description in § 101.165(d)(2)(iv).)

6. A few comments opposed exempting canned fruits and vegetables from the 10 percent nutrient contribution requirement because, the comments argued, some canned fruits and vegetables are high in sugar and salt and should not bear the term ''healthy.''

While the agency appreciates the concerns raised in the comments, the agency notes that it is not, in this rulemaking, providing an exemption for foods containing ingredients that would increase the amount of sugar or salt beyond that occurring in the raw version of the fruit or vegetable. The agency points out, however, that not granting an exemption to these foods would not prohibit fruits and vegetables with added sugar or salt from bearing the ''healthy'' claim because such foods that contain 10 percent or more of one of the six listed nutrients, and otherwise meet the requirements for the claim, are not precluded from bearing the claim.

E. Enriched Cereal Grain Products

In the 1996 healthy proposal, FDA proposed to amend the definition of ''healthy'' in § 101.65 to exempt enriched cereal-grain products that conform to a standard of identity in part 136, 137, or 139 from the 10 percent nutrient contribution requirement. This exemption is justified because foods made in accordance with these standards are precluded from meeting the 10 percent nutrient contribution requirement and because they are the types of food that meet the basis of the ''healthy'' definition and are recommended in dietary guidelines. Foods labeled with the term ''healthy'' should be those that can be used to achieve a total diet that conforms to current dietary recommendations (see 58 FR 2944 at 2946, January 6, 1993). Current dietary guidelines recommend 6 to 11 servings of breads, cereals, rice, and pasta per day. Because most Americans do not achieve 6 to 11 servings per day, increased consumption of grain products is also recommended in dietary guidelines. The appearance of a ''healthy'' claim on enriched cereal-grain products would likely encourage consumers to select these products as part of a healthy diet. Furthermore, precluding standardized enriched cereal-grain products from bearing the term ''healthy'' may confuse consumers because they might incorrectly regard such products as not particularly beneficial in achieving diets consistent with dietary guidelines.

Comments responding to this issue (with the exception of comment 7, in section II.E of this document) supported FDA's proposal, and stated that permitting a ''healthy'' claim on enriched cereal-grain products would likely encourage consumers to select these products as part of a healthy diet. Accordingly, FDA is amending the definition of the term ''healthy'' in § 101.65(d)(2)(iv) as proposed to exempt enriched grain products that conform to a standard of identity in part 136, 137, or 139 from the 10 percent nutrient contribution requirement.

7. Two comments opined that the healthy claim should be reserved only for breads that contain flour that is 50 percent whole grain. The comments contended that breads that are made from enriched flour and do not contain at least 50 percent whole grain flour should not be labeled as ''healthy.'' The comments further contended that valuable nutrients such as the B-vitamins, vitamin E, dietary fiber, and minerals are not adequately supplied in enriched flour.

The agency disagrees with these comments. While the agency recognizes that during the milling process of wheat, the B-vitamins, vitamin E, dietary fiber and certain minerals may be lost, the enrichment requirement in the standards of identity restores several of these nutrients. Moreover, as discussed previously in section II.E of this document, standardized enriched cereal-grain products are the types of products that are consistent with the basis of the ''healthy'' claim and should not be precluded from bearing the claim. The comments are asking the agency to base the requirement to bear the ''healthy'' claim on the presence and percentage of a particular ingredient in a food rather than on the presence and percentage of particular nutrients that are important to the food's overall nutritional profile. Such an approach would require the agency to change the underlying principles of the ''healthy'' claim, which focuses on the food's overall nutritional profile. Further, it would require the agency to develop a list of ingredients that could qualify a food to bear a ''healthy'' claim. The agency believes that such an approach is neither equitable nor feasible. Consequently, the agency is not granting the comments' request that only breads containing 50 percent whole grain flour be labeled as ''healthy.''

8. Another comment stated that all breakfast cereals should be exempt from the 10 percent nutrient contribution requirement. The comment opined that the presence of the term ''healthy'' on breakfast cereals would increase their consumption that, in turn, would increase consumption of cereal-grain products. Such consumption, the comment argued, would be entirely consistent with, and supportive of, the

government's current dietary recommendations and the intent of the NLEA. The comment provided no other rationale for exempting breakfast cereals from the 10 percent requirement.

While the agency agrees that increased consumption of breakfast cereals would mean increased consumption of cereal-grain products, the agency is not persuaded that breakfast cereals should be exempt from the nutrient contribution requirement. There is no evidence to suggest that breakfast cereals as a category of foods are precluded from bearing the term because of the food's inability to meet the 10 percent requirement. On the contrary, breakfast cereals that meet the other requirements of the claim generally are a ''good source'' of at least one of the listed nutrients. Furthermore, breakfast cereals are not governed by a standard of identity and have the flexibility of modifying their formulation to meet the requirements of the claim. Consequently, FDA is not establishing an exemption for breakfast cereals.

9. A number of comments urged the agency to allow cereal-grain products that are eligible to bear a health claim to also bear the term ''healthy.'' The comments stated that these products play a major role in a healthful diet and precluding these products would confuse consumers and undermine the ability of health claims to assist consumers in making appropriate dietary choices.

The agency strongly disagrees with these comments. The agency would like to reiterate and clarify its position on this subject. The fundamental concerns that underlie a health claim are different from those that underlie the definition of ''healthy.'' FDA's goal is to define ''healthy'' in such a way that it will highlight foods that, because of their nutrient content, will be most helpful to consumers in constructing a diet that is consistent with all of the dietary recommendations. The purpose of a health claim, by contrast, is to highlight scientifically valid nutrient-disease relationships as well as foods that have a level of the substance in question such that consumption of the food may help to affect the risk of developing the disease in question. In some cases these purposes overlap, in others they do not.

Because a health claim is based on the relationship of a substance to a specific disease or health-related condition (59 FR 24232 at 24233), a product that bears a health claim may not necessarily be particularly helpful in assisting consumers in lowering their daily intake of those nutrients that are not the subject of the claim, but of which reduced daily intake has been recommended. For example, a food must be ''low fat'' to bear the claim ''healthy,'' whereas some health claims do not require the food to be ''low fat.'' The agency therefore acknowledges that there are foods that will be eligible to bear a health claim that will not be eligible to bear the term ''healthy.'' This fact is not an inconsistency in FDA's regulations because, as described above, these two claims are different and have different functions.

The comments have not persuaded the agency that FDA's goal in defining the term ''healthy'' would be met if the agency permitted a food to bear the term ''healthy'' just because it qualifies for a health claim. Therefore, FDA is not amending the definition of ''healthy'' to permit foods to bear the term simply because the food qualifies to bear a health claim. The agency notes, however, that foods that bear health claims and that meet the requirements for ''healthy'' may also bear the term ''healthy.''

III. Economic Analysis

A. Benefit/Cost Analysis

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this final rule is neither economically significant nor a significant regulatory action as defined by Executive Order 12866.

In addition, FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 requiring cost-benefit and other analyses. A significant rule is defined in Section 1531(a) as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year * * *''.

Finally, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this final rule is not a major rule for the purpose of Congressional review.

FDA is proposing to permit certain processed fruits and vegetables, and enriched cereal-grain products that conform to a standard of identity to bear the term ''healthy.'' FDA has determined that these products are particularly helpful in assisting consumers to achieve dietary goals.

In the benefit/cost analysis for the proposed rule, FDA stated that the benefit of this rule is to provide more beneficial information to consumers. FDA received comments stating that the rule will have a positive impact on the demand for fruits and vegetables if it helps people to understand the relative nutritiousness of fresh versus frozen or canned produce. Several comments also stated the rule would result in health benefits if it caused consumption of fruits and vegetables to increase.

Although it is possible that this rule will have some marginal impact on the overall demand for fruits and vegetables, it is unlikely that any increase in demand that might occur would be significant. It is likely, however, that demand will shift from products that are higher in fat, sugars, and sodium, such as multi-ingredient vegetable products with added oils, to products that are lower in fat, sugars, and sodium irrespective of whether the switching that may occur is within or between product types. The real benefit of use of the term ''healthy'' depends not on whether it favors one type of product over another, but on whether it provides consumers with a tool with which they can select foods that will help to achieve dietary goals.

The costs of this regulation will be incurred only by those manufacturers desiring to take advantage of the opportunity to use the term ''healthy.'' FDA cannot predict the number of manufacturers who will take advantage of this opportunity. Therefore, the agency cannot estimate the number of labels that will be revised as a result of this rule. FDA estimates however, that, the cost of revising a label to include a ''healthy'' claim is approximately $3,000 per label.

B. Small Entity Analysis

FDA has examined the impacts of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a

substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), FDA certifies that this final rule will not have a significant impact on a substantial number of small entities.

FDA received one comment to the analysis of the proposed rule regarding the potential impact on small entities. The comment suggested that if consumption shifts from raw to processed produce as a result of this rule, the impact on small farmers would be detrimental.

The comment did not provide any data with which FDA could evaluate the potential for shifts in consumption from raw to processed produce or any resulting impact on small farmers. FDA notes, however, that it is unlikely that this rule would cause consumption to shift from raw to processed produce. As stated previously, the likely substitution is from those fruits and vegetables that are too high in fat or sodium to qualify for the term ''healthy'' to those raw or processed fruits and vegetables that do qualify as ''healthy.''

FDA further notes that, even if demand for processed produce increased relative to raw produce, the impact on small farmers should not be detrimental. There is no reason to expect that small farmers would not be able to sell their produce to processors if the demand for processed produce increases.

Only those processed products that would meet the current definition of the term ''healthy'' other than the minimum nutrient contribution requirement will be affected by this rule. Because there is no change in the definition as it applies to those products currently using the term, only those entities desiring to take advantage of the new exemption will bear any cost of this regulation. No firm of any size will voluntarily bear the cost of changing a label to bear the term ''healthy'' unless doing so will be advantageous to the firm. Therefore, FDA concludes that no small entity will be adversely affected by this rule.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (61 FR 5349, February 12, 1996; corrected May 21, 1996 (61 FR 25421)). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

In the 1996 healthy proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling or other third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling provisions in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320(c)(2)).

VI. References

1. Karmas, E., and R. S. Harris, ''Nutritional Evaluation of Food Processing, 3d Ed.,'' Van Nostrand Reinhold Co., Inc., New York, chapters 3, 4, and 11, 1988.

2. Satchell, F. B., Division of Programs and Enforcement Policy (HFS–158), Center for Food Safety and Applied Nutrition, memorandum to file, September 22, 1995, Modification of USDA's Nutrient Data Base for National Nutrient Databank Release No. 9, ''Processed Fruit and Vegetable Products that Qualify to Bear the Term 'Healthy','' June 17, 1994, and July 17, 1995.

3. University of Illinois at Urbana-Champaign, Department of Food Science and Human Nutrition, ''Nutrient Conservation in Canned, Frozen and Fresh Foods,'' October 1997.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, 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: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.65 is amended by revising paragraph (d)(2)(iv) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) * * *

(2) * * *

(iv) The food contains at least 10 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed of vitamin A, vitamin C, calcium, iron, protein, or fiber, except for the following:

(A) Raw fruits and vegetables;

(B) Frozen or canned single ingredient fruits and vegetables and mixtures of frozen or canned single ingredient fruits and vegetables, except that ingredients whose addition does not change the nutrient profile of the fruit or vegetable may be added;

(C) Enriched cereal-grain products that conform to a standard of identity in part 136, 137, or 139 of this chapter.

* * * * *

Dated: March 18, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–7667 Filed 3–24–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 75N–0339]

Human and Veterinary Drugs; Current Good Manufacturing, Processing, Packaging, or Holding; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the current good manufacturing practice regulations for human and veterinary drug products to correct a typographical error. This action is being taken to ensure accuracy and clarity in the agency's regulations.

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has become incorporated into the agency's current good manufacturing practice regulations for human and veterinary drug products. In an amendment to 21 CFR 211.84, published on September 29, 1978 (43 FR 45014), the word ''date'' was inadvertently misspelled as ''data''. This document corrects that error. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has