b. Would U.S. Customs regulations pose any impediment to an amendment of Commission rules to allow abbreviations of country names?

11. Should the Commission amend the Textile Rules to allow a symbol to be used to mean ''made in'' or ''product of,'' or other similar phrases, in country of origin labeling?

a. What would be the advantages and disadvantages of allowing the use of a symbol?

b. If the Commission decides to allow the use of a symbol, which symbol should be used?

c. What benefits and costs would allowing a symbol have for purchasers of the products affected by the Textile Rules?

d. What actions can be taken to ensure that consumers understand what the symbol means?

e. How would the use of a symbol work when manufacturers wish to distinguish between the country of origin of an unfinished textile product and the country where another phase of the manufacturing process takes place, as in ''Made in the Dominican Republic of United States components''?

12. How can the apparent conflict between the Commission's country of origin labeling requirements and the new marking requirements imposed by U.S. Customs, with regard to household furnishings and apparel accessories, be resolved in a manner that will be consistent with statutory requirements, provide meaningful information to consumers, and not be burdensome to U.S. businesses?

13. Are there additional conflicts between Commission and Customs regulations on country of origin labeling for textile products? If so, what is the specific nature of the conflict, and how can it be resolved in the best interests of both businesses and consumers?

Procedures for Establishing New Generic Names for Manufactured Fibers

14. Should the Commission amend the Textile Rules to allow the use of new generic names for manufactured fibers if the name and fiber are recognized by an international standards-setting organization?

a. If the Commission decided to amend the Textile Rules in this manner, what international standards-setting organization(s) should the Commission follow?

b. Is the proposed amendment language set out in this Notice appropriate? If not, what amendment language should be used?

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–11, requires an analysis of the anticipated impact of the proposed amendments to the Textile Rules on small businesses. The analysis must contain, as applicable, a description of the reasons why action is being considered, the objectives of and legal basis for the proposed actions, the class and number of small entities affected, the projected reporting, recordkeeping and other compliance requirements being proposed, any existing federal rules which may duplicate, overlap or conflict with the proposed actions, and any significant alternatives to the proposed actions that accomplish their objectives and, at the same time, minimize their impact on small entities.

A description of the reasons why the proposed amendments are being considered and the objectives of the proposed amendments to the Rules have been explained elsewhere in this Notice. The proposed amendments do not appear to have a significant economic impact on a substantial number of small businesses. To the extent they do have an effect on such entities, the effect should be to reduce the costs of compliance with Textile Act requirements.

Therefore, based on available information, the Commission certifies, pursuant to section 605 of RFA, 5 U.S.C. 605, that, if the Commission amends the Textiles Rules as proposed, that action will not have a significant impact on a substantial number of small entities. To ensure that no substantial economic impact is being overlooked, however, the Commission requests comments on this issue. After reviewing any comments received, the Commission will determine whether it is necessary to prepare a final regulatory flexibility analysis.

V. Paperwork Reduction Act

The Textile Rules contain various collection of information requirements for which the Commission has current clearance under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, pursuant to Office of Management and Budget (OMB) Control Number 3084–0101.

In addition, the amendments proposed in this notice would lower the paperwork burden associated with the current Rules. The proposed amendments would eliminate the functional significance disclosure requirement of Rule 3(b) and the ''Fiber Content on Reverse Side'' disclosure requirement of Rule 16(b). They would allow abbreviations for generic fiber names and the use of new generic names for manufactured fibers if the name and fiber are recognized by an international standards-setting organization.

VI. Additional Information for Interested Persons

A. Motions or Petitions

Any motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

B. Communications by Outside Parties to Commissioners or Their Advisors

Pursuant to Rule 1.18(c) of the Commission Rules of Practice, 16 CFR 1.18(c), communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor during the course of this rulemaking shall be subject to the following treatment. Written communications, including written communications from members of Congress, shall be forwarded promptly to the Secretary for placement on the public record. Oral communications, not including oral communications from members of Congress, are permitted only when such oral communications are transcribed verbatim or summarized at the discretion of the Commissioner or Commissioner's advisor to whom such oral communications are made, and are promptly placed on the public record, together with any written communications relating to such oral communications. Memoranda prepared by a Commissioner or Commissioner's advisor setting forth the contents of any oral communications from members of Congress shall be placed promptly on the public record. If the communication with a member of Congress is transcribed verbatim or summarized, the transcript or summary will be placed promptly on the public record.

List of Subjects in 16 CFR Part 303

Textile fiber products identification; Trade practices.

Authority: 15 U.S.C. 70 et seq.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–2935 Filed 2–9–96; 8:45 am]

BILLING CODE 6750–01–P

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise 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 intended to provide consumers with information that will assist them in achieving their dietary goals and is in response 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).

DATES: Written comments by April 29, 1996. FDA proposes that any final rule that may issue based on this proposal become effective on the date of publication in the Federal Register.

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: Felicia B. Satchell, 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 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 constructing 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 or Daily Reference Value of one 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 the six listed nutrients). The definition provides that a food can be fortified to meet the requirement that the food be a ''good source'' of one or more of these nutrients if the fortification is done in accordance with the agency's fortification policy in § 104.20 (21 CFR 104.20).

FDA provided one narrow exception to the requirement that a food bearing the term ''healthy'' be a ''good source'' of one or more of the six listed nutrients. The agency stated that the claim can be used on raw fruits and vegetables that do not meet the nutrient contribution requirement but that meet all other aspects of the definition. As FDA stated in the healthy final rule (59 FR 24232 at 24244), increased consumption of raw fruits and vegetables can contribute significantly to a healthy diet and to achieving compliance with dietary guidelines, even if particular items, such as celery and cucumbers, do not contain 10 percent of the daily value of one of the six identified nutrients. However, the agency also stated that it was not prepared to extend this exemption to all fruit and vegetable products because it did not have an adequate basis to evaluate the effects of processing (i.e., exposure to liquid packing medium, freezing, canning, cooking, and other procedures) on these foods. In addition, the agency sought information on whether to propose changes in the 10 percent nutrient contribution requirement to allow other foods to bear the term that did not meet this aspect of the definition but may also be particularly useful in assisting consumers to achieve dietary goals.

II. Petitions

A. Description of Petitions

Following publication of the healthy final rule, two trade associations submitted petitions to FDA that requested that the agency reconsider its decision regarding the nutrient contribution exemption for raw fruits and vegetables. A third trade association submitted a citizens petition requesting that FDA amend the ''healthy'' definition to exempt certain enriched cereal-grain products from the 10 percent nutrient contribution requirement.

Both of the petitions for reconsideration requested that FDA revise the definition of ''healthy'' to extend this exemption to processed fruits and vegetables. The petition submitted by AFFI (Docket No. 91N–384H/PRC1) disagreed with FDA's assertion that it did not have an adequate basis to evaluate the effects of the freezing process on the nutritional profile of fruits and vegetables. AFFI contended that it had provided the agency with extensive nutrition information for frozen fruits and vegetables, in conjunction with the development of AFFI's nutrient data base for frozen fruits and vegetables. AFFI also stated that the nutrient profile information for frozen products submitted in its data base proposal shows that the nutrient profile information on frozen vegetables does not differ significantly from the nutrient profile information for fresh products, and that in some cases the nutrient levels in frozen products exceed the nutrient levels in fresh products. Consequently, AFFI argued that, contrary to FDA's assertion, the agency already had extensive information in its possession regarding the effects of the freezing process on the nutrient profile of frozen fruits and vegetables, and that precluding use of the term ''healthy'' on frozen fruits and vegetables while permitting use of the term on fresh fruits and vegetables implies a distinction in nutritional value that does not exist.

AFFI requested that FDA reconsider its position and revise its definition of ''healthy'' to permit frozen fruits and vegetables that do not meet the ''good source'' requirement, but otherwise meet the requirements of the claim, to bear the term. In addition to the petition, AFFI also submitted supplemental comments to the administrative record for the ''healthy'' final rule containing data that compare the nutrient profiles of various raw and frozen fruits and vegetables.

NFPA also petitioned (Docket No. 91N–384H/PRC2) the agency to reconsider its position regarding the exemption for raw fruits and vegetables. In its petition, NFPA contended that the exemption for raw fruits and vegetables established in the final rule was not a logical outgrowth of the proposal because FDA failed to give adequate

notice and opportunity for comment to the public on the different labeling requirement for raw and processed fruits and vegetables in its healthy proposal. Consequently, the petition argued, interested parties were not allowed to participate in the rulemaking in a meaningful and informed manner on the issue of establishing such an exemption.

Furthermore, NFPA asserted that FDA incorrectly drew a distinction in the nutritional benefit between raw and processed fruits and vegetables, and that such a distinction has no logical basis in fact or law. It contended that the administrative record before the agency fails to provide any justification for this distinction, and that such a distinction is contrary to prior FDA positions and regulations. Thus, NFPA requested that § 101.65(d)(2)(iv) be revised to eliminate the word ''raw'' so that processed fruits and vegetables, as well as raw fruits and vegetables, will be exempt from the nutrient contribution requirement for food labeled ''healthy.''

The third citizen petition (Docket No. 95P–0241), submitted by ABA, requested that FDA amend the definition of ''healthy'' to permit enriched cereal-grain products that conform to the standards of identity in parts 136, 137, or 139 (21 CFR parts 136, 137, or 139), and bread that conforms to the standard of identity for enriched bread in § 136.115 except that it contains whole wheat or other grain products not permitted under that standard, to bear the term ''healthy.'' ABA contended that while some enriched breads might meet the 10 percent nutrient contribution requirement for fiber, most enriched grain products cannot meet the 10 percent nutrient contribution requirement for any of the six listed nutrients because they are precluded by the standards of identity from containing 10 percent of the six listed nutrients. In other words, under the food standards and FDA's fortification policy, the nutrients and levels required by the standards of identity cannot be altered. Moreover, ABA argued that most nutritional authorities agree that grain products have a central role in a healthy diet because they are excellent sources of complex carbohydrates. In fact, ABA argued, most nutritional authorities recommend that Americans increase their consumption of grain products as alternative sources of energy to replace dietary fat. The petitioner contended that these foods are, therefore, precisely the kinds of foods that FDA intended to permit to bear the term ''healthy.''

ABA further argued that the 10 percent nutrient contribution requirement was obviously not intended to apply to foods that conformed to the standards of identity for enriched grain products because it precludes virtually all enriched grain products from bearing a ''healthy'' claim. ABA contended that this exclusion is 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. The petition notes that the Food Guide Pyramid recommends that 6 to 11 servings of grain products be consumed per day. ABA contended that this recommendation demonstrates the importance of including these foods in the diet. ABA argued that the 10 percent nutrient contribution requirement has had the unintended effect of precluding foods that FDA intended to be labeled ''healthy'' from bearing that term. Thus, ABA requested that the agency amend § 101.65 to exempt: (1) Enriched grain products that conform to a standard of identity in part 136, 137, or 139, and (2) bread that conforms to the standard of identity for enriched bread in § 136.115 (except that it contains whole wheat or other grain products not permitted under that standard) from the 10 percent nutrient contribution requirement.

In the alternative, ABA suggested that the agency expand the list of nutrients that must be present at 10 percent to include complex carbohydrates, niacin, or thiamin. Such action would permit enriched grain products to bear health claims because these products are a significant source of such nutrients.

A second alternative suggested in the petition would be to amend the 10 percent nutrient contribution requirement to allow it to apply to a daily consumption of grain products rather than to the nutrient profile of a specific food.

B. Response to Petitions

FDA has fully evaluated both petitions for reconsideration and reviewed the administrative record to determine whether, in light of the arguments raised in the petitions, the agency would have reached a different decision regarding the exemption from the nutrient contribution requirement for raw fruits and vegetables in the definition of ''healthy.'' The agency has determined that based on the administrative record at the time of publication of the healthy final rule, FDA made the correct decision. While FDA acknowledges that AFFI had submitted nutrient profile information on frozen fruits and vegetables, this information was presented as an acceptable nutrient data base for nutrition labeling of frozen fruits and vegetables and did not contain information comparing nutrient profiles between raw fruits and vegetables and frozen fruits and vegetables. Moreover, the data base was not submitted, or referenced, as part of the administrative record for the healthy final rule and therefore was not before the agency in that rulemaking.

Although the information relied on in AFFI's petition may serve as grounds for revising FDA's regulations concerning ''healthy'' (as discussed in section III.C. of this document), because the information was not part of the administrative record in the initial rulemaking, AFFI has not met the standard in § 10.33(d)(1) (21 CFR 10.33(d)(1)) for granting a petition for reconsideration. AFFI failed to demonstrate that relevant information or views contained in the administrative record were not previously or not adequately considered during that rulemaking. Accordingly, the agency is denying AFFI's petition for reconsideration.

In response to the arguments raised in NFPA's petition, FDA acknowledges that the issue of nutrient content requirements specifically for raw and processed fruits and vegetables was not directly addressed in the proposal. However, the agency did discuss and solicit comment on the appropriateness of requiring foods bearing the term ''healthy'' to meet a nutrient contribution requirement in the proposal that FDA published in the Federal Register of January 6, 1993 (58 FR 2944 at 2948). This discussion alerted interested parties to the possibility that the agency could modify the proposal and include a nutrient contribution requirement in the ultimate final rule.

In response to this discussion, the agency did receive several comments that addressed the impact of imposing such a requirement on raw fruits and vegetables. Some of these comments asserted that, compared to other foods, all raw fruits and vegetables are inherently healthy and should not be required to meet a nutrient contribution requirement. The agency considered the merits of these comments and the other comments that it received and determined that it was appropriate to: (1) Include a nutrient contribution criterion in the ''healthy'' definition, and (2) exempt raw fruits and vegetables from this requirement (59 FR 24232 at 24244).

Because this issue was addressed in the healthy proposal of January 6, 1993, the agency finds that its decision to

include a nutrient contribution requirement in the ''healthy'' definition, and to define its application to various foods, was a logical outgrowth of the proposal. Thus, FDA finds that it acted in accordance with the provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553) and rejects the assertion by NFPA that the agency violated the procedural requirements of the APA. Consequently, FDA is also denying NFPA's petition for reconsideration.

III. The Proposal

Although the agency has decided under § 10.33 not to grant the petitions for reconsideration, FDA has been persuaded by the concerns raised in the petitions and the information submitted in the supplemental comments to consider whether some fruit or vegetable products are being inappropriately excluded from bearing the ''healthy'' claim because the food cannot meet the nutrient contribution requirement.

In the healthy final rule, FDA stated that it was not prepared to extend the exemption from the nutrient contribution requirement to all fruits and vegetables because it did not have an adequate basis to evaluate the effects of various processing techniques on the food. The agency was concerned that precluding raw fruits and vegetables from bearing a ''healthy'' claim could confuse consumers and undermine an important element of current dietary guidance that emphasizes consumption of fruits and vegetables. For processed fruits and vegetables, however, the agency was not sure that processing did not have a significant effect on the nutritional profile of the food. The agency sought information on whether to propose changes in the nutrient contribution requirement for processed fruits and vegetables, as well as for other foods that may be useful in achieving dietary guidelines but did not meet the nutrient contribution requirement.

A. All Fruit and Vegetable Products

The agency has carefully considered whether all fruit and vegetable products should be exempt from the nutrient contribution requirement, and whether simply revising the ''healthy'' definition to remove the term ''raw'' from § 101.65(d), as requested by NFPA, would assist consumers in maintaining healthy dietary practices. As the agency discussed in the healthy final rule (59 FR 24232 at 24239), for this implied claim to be useful, foods that are able to bear the term should be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations. The agency would consider it inappropriate if the requirements in the definition of this term, specifically the nutrient contribution requirement, precluded use of the claim for such a large number of fruit and vegetable products that the ''healthy'' claim was no longer useful for this category of foods, or for consumers wishing to rely on the ''healthy'' claim to select fruit and vegetable products that are particularly useful in constructing diets that conform with current dietary recommendations.

A survey of fruit and vegetable products available in the local supermarket and a review of the U.S. Department of Agriculture's (USDA's) nutrient data base for fruit and vegetable products reveal that out of a total of over 700 fruit and vegetable products reviewed, 65 percent are eligible to bear the ''healthy'' claim (Refs. 1 and 2). The agency notes that these products comply with all the criteria of the definition for the term ''healthy,'' including the nutrient contribution requirement. Therefore, FDA tentatively concludes that a general exemption for all fruit and vegetable products is not warranted because a significant number and variety of products currently on the market are eligible to bear the claim.

In fact, FDA is concerned that if it were to propose to extend this exemption to all fruit and vegetable products, the utility of the ''healthy'' claim for this category of foods would be greatly diminished. If the claim were permitted on virtually all fruit and vegetable products, it could not be used to highlight those fruit and vegetable products that meet the requirements of the definition without an exemption. In addition, the agency points out that permitting the claim to appear on virtually all products would mean that it would appear on some formulated, multi-ingredient products that include fruits or vegetables but that have added ingredients that raise the level of certain nutrients, i.e., fat, saturated fat, cholesterol, and sodium, above levels found in raw or single ingredient versions of the same fruit or vegetable. The appearance of a ''healthy'' claim on such foods would represent them as being particularly useful in constructing diets that conform to current dietary guidelines. Such a representation would not necessarily be valid. While the agency recognizes that these foods have an appropriate place in the diet, the higher fat, saturated fat, cholesterol, or sodium levels in these products would make it misleading to represent them as products whose nutrient profiles would lend themselves to such use.

Furthermore, fruit and vegetable products that contain other ingredients are not precluded from bearing the term ''healthy,'' provided that the finished food meets all the criteria for the claim. Such foods can be formulated and fortified in accordance with the agency's policy on rational fortification in § 104.20 if they fail to contribute 10 percent of one of the subject nutrients. Therefore, FDA tentatively concludes that there is no reason to exempt such foods from the 10 percent requirement. Accordingly, the agency is not proposing to extend the exemption to all fruit and vegetable products.

B. Tentative Determination To Broaden Exemption

While the agency is not persuaded to extend the exemption to all fruit and vegetable products, it is persuaded that it may well be appropriate to broaden the exemption to include fruit and vegetable products other than raw fruits and vegetables and to include enriched cereal-grain products that conform to a standard of identity. In determining whether to broaden this exemption, FDA has to consider several questions similar to those raised when it first defined ''healthy.'' For example, does the nutrient contribution requirement, FDA's policy on rational fortification, or other FDA regulations preclude the use of the ''healthy'' claim on certain foods that play an important role in the diet and that dietary guidelines recommend be included in a healthy diet? Does the appearance of a ''healthy'' claim on raw fruits and vegetables and the absence of the claim on processed versions of the same fruits and vegetables, such as frozen vegetables or canned mushrooms packed in water, confuse and mislead consumers to believe that fruits and vegetables must be raw to be considered healthy? Moreover, does the absence of the claim on processed fruits and vegetables and standardized enriched cereal-grain products reduce the opportunity for encouraging consumption of these foods at a time when FDA and other government agencies have stated specifically that increased consumption of fruits, vegetables, and grain products can contribute significantly to a healthy diet?

Regarding fruits and vegetables, it is unlikely that most consumers are aware of the narrow exemption for raw fruits and vegetables provided in the ''healthy'' definition because, generally, most consumers are not familiar with the specific requirements of the nutrient content claim definitions. However, consumers are familiar with the overall concepts governing claims, that is, that

the claim be used consistently from food to food, that the claim be defined by FDA, and that the food bearing the claim meet the definition of the term being used. Foods bearing the term ''healthy'' will inform consumers that the food, because of its nutrient profile, is particularly useful in constructing diets that conform to current dietary guidelines.

Because of the likelihood that most consumers are unaware of the exemption for raw fruits and vegetables, consumers will likely not recognize that there are alternative fruit and vegetable products that are precluded from bearing the claim but that are just as useful as raw fruits or vegetables in assisting consumers in meeting dietary goals. Furthermore, it was not the intent of the agency to suggest that the goal of increasing fruits and vegetables in the diet could only be achieved by consuming raw products, or that raw products are necessarily superior to all other fruit and vegetable products. FDA acknowledges that there are processed fruit and vegetable products, like frozen fruits and vegetables, that can be used to assist consumers in constructing a diet that is consistent with dietary recommendations; but those foods are currently ineligible to bear the ''healthy'' claim because they do not meet the 10 percent nutrient contribution requirement.

C. Single Ingredient Fruit and Vegetable Products

FDA reviewed the data presented in AFFI's supplemental comments comparing nutrient profiles of selected raw fruits and vegetables and frozen, single ingredient versions of the same fruits and vegetables. While only preliminary, the data do support AFFI's argument that blanching and freezing do not significantly change the nutrient profile of the fruits and vegetables. These data provide examples of similar or higher nutrient levels of one or more of the six required nutrients in single ingredient, frozen fruit and vegetable products when compared to the raw version of the same fruit and vegetable. The higher nutrient levels found in the frozen version of the food are likely attributable to the fact that unprocessed fruits and vegetables may lose some of their nutrients over time or under certain storage conditions (Ref. 3).

Considering these data, the agency tentatively concludes that, like raw fruits and vegetables, single ingredient frozen fruits and vegetables 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 tentatively concludes that in cases where the nutrient profile of a single ingredient, frozen fruit or vegetable product is comparable to the nutrient profile of the raw version of the same fruit or vegetable, the single ingredient, frozen fruit or vegetable product would likely have the same effects, and could be used interchangeably in the diet to achieve dietary goals, as the raw version of the fruit or vegetable. Precluding such foods from being termed ''healthy'' could undermine an important element of current dietary guidance.

The agency tentatively concludes that such foods should not be barred from bearing the term ''healthy,'' especially when the foods are comparable to, and are just as useful as, raw fruits and vegetables in assisting consumers in structuring diets that achieve dietary goals. Furthermore, consumers should be informed that these foods serve as appropriate and useful alternatives to raw fruits and vegetables in constructing diets consistent with current dietary recommendations. Accordingly, FDA is proposing 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.

However, FDA does not have information comparable to that submitted by AFFI to support extending this exemption to all single ingredient, processed fruit and vegetable products. The agency solicits comment and data on the effects of other types of processing, e.g., drying and canning, and how these processes affect the nutritional profile. If appropriate data are submitted, the agency is prepared to extend this exemption to other single ingredient, processed fruit and vegetable products in any final rule that issues in this proceeding.

D. Multi-Ingredient Fruit and Vegetable Products

In deciding to extend this exemption beyond raw fruits and vegetables, the agency must ensure that the claim is permitted only on those foods that contain nutrients in amounts that are consistent with the basis of the claim. As discussed above, FDA tentatively concludes that frozen, single ingredient fruit and vegetable products and mixtures of these foods are consistent with the basis of the ''healthy'' claim and should be permitted to bear the term, even if the food does not contain 10 percent of one of the six listed nutrients. However, FDA has not been persuaded that multi-ingredient products that are composed of ingredients other than fruits or vegetables and that meet all other aspects of the claim should be exempt from the 10 percent requirement. Many of these multi-ingredient fruit and vegetable products can have added ingredients that increase the content of fat, saturated fat, cholesterol, or sodium beyond that for the raw version. Considering that one reason that fruits and vegetables are helpful in achieving a diet consistent with dietary guidelines is that they can replace foods, such as snack foods and desserts, that contain higher levels of fat, saturated fat, cholesterol, and sodium, FDA tentatively concludes that providing an exemption for such multi-ingredient fruit and vegetable products would be inconsistent with current dietary recommendations and, consequently, inconsistent with the basis of the ''healthy'' claim.

Furthermore, 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 these multi-ingredient fruit and vegetable products are just as helpful as raw or frozen, single ingredient fruits and vegetables in achieving dietary goals, when in fact, they would increase dietary intake of less desirable nutrients and could decrease intake of micronutrients. Consumers could be motivated to select these multi-ingredient products rather than products comprised solely of fruits and vegetables. In the agency's opinion, a claim that could motivate consumers to choose fruit and vegetable products containing added ingredients that increase the content of fat, saturated fat, cholesterol, or sodium beyond that for the raw version as alternatives to the raw version or to the frozen, single ingredient version would not be beneficial for consumers and would undermine current dietary guidelines.

Moreover, FDA tentatively concludes that fruit and vegetable products composed of ingredients other than fruit or vegetable can be formulated and fortified in accordance with § 104.20 to meet the 10 percent contribution requirement, and, therefore, there is no reason to exempt such foods from the 10 percent requirement. Accordingly, FDA is not proposing to extend the exemption to multi-ingredient fruit and vegetable products composed of ingredients other than fruit or vegetable that do not contain 10 percent of one of the six listed nutrients.

E. Enriched Cereal-Grain Products

FDA finds merit in the arguments raised in the ABA petition. The agency

acknowledges that the requirements of the standards of identity for enriched cereal-grain products preclude reformulation and fortification to qualify the food to meet the 10 percent nutrient contribution requirement. As a result of the restrictions established in the standards, manufacturers of these products are not afforded the opportunity to reformulate and fortify the food to qualify the food to bear a ''healthy'' claim. Consequently, any action short of exempting such products from the 10 percent requirement or amending the standards of identity to increase the amount of enrichment nutrients that could be added to cereal-grain products, would mean that these foods could not bear a ''healthy'' claim. The agency does not have information on which to base a change in the individual standards, and the petitioner did not provide any.

Moreover, the agency acknowledges that increased consumption of grain products is recommended in current dietary guidelines, and that the appearance of a ''healthy'' claim on enriched cereal-grain products would encourage consumers to select these products as part of a healthy diet. The agency agrees with the arguments raised in the ABA petition that even though these foods do not contain at least 10 percent of one of the six listed nutrients, they are recommended in dietary guidance and can be particularly helpful in assisting consumers to achieve dietary goals. Thus, the agency tentatively concludes that enriched cereal-grain products that conform to a standard of identity are consistent with the basis and intent of the ''healthy'' definition and should not be precluded from bearing the term because they do not meet the 10 percent nutrient contribution requirement. Further, the agency tentatively concludes that precluding such foods from bearing the term ''healthy'' would be inconsistent with current dietary recommendations and not beneficial for consumers. Accordingly, FDA is proposing 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.

However, the agency is not persuaded that bread that does not conform to the standard of identity should be exempt from the 10 percent nutrient contribution requirement. Like other nonstandardized foods, nonstandardized bread can be formulated and fortified in accordance with § 104.20 to meet the 10 percent nutrient contribution requirement (see § 104.20(b)). Therefore, there is no reason to exempt these foods from the 10 percent requirement. Accordingly, FDA is not proposing to extend the exemption to bread that conforms to the standard of identity for enriched bread in § 136.115, except that it contains whole wheat or other grain products not permitted under that standard.

The approach that FDA is taking in this proposal is similar to the approach that it took in establishing the definition of ''healthy'' for seafood and game meats. In the healthy final rule (FR 59 24232 at 24249), 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, in part, because 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 addition, these provisions are consistent with the provisions adopted by the USDA for use of the term ''healthy'' on meat and poultry products. However, FDA did not establish different provisions for seafood and game meat products that are composed of more than one ingredient because such foods can be reformulated to reduce the fat, saturated fat, and cholesterol levels inherently found in these foods. In this document, FDA is relying on the same general concept that it based its decision on in providing alternative criteria for raw, single ingredient seafood and game meats, namely that the agency would consider it inappropriate if the requirements in the definition of ''healthy'' precluded use of the claim for foods that play 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 to bear the claim.

The agency's primary goal in extending this exemption to other fruit and vegetable products and to enriched cereal-grain products that conform to a standard of identity is to permit the ''healthy'' claim on products that are particularly helpful in assisting consumers to achieve dietary goals yet are precluded from bearing the claim because they do not contain at least 10 percent of the subject nutrients, and they can not be reformulated to do so. The agency believes that the action that it is proposing in this document is fully responsive to the concerns raised by the petitioners and is appropriate because it will permit the ''healthy'' claim on fruit and vegetable products and on enriched cereal-grain products that are currently unfairly precluded from bearing the claim, yet prevent other products from inappropriately bearing the claim.

Accordingly, FDA is proposing to amend the definition of the term ''healthy'' by revising § 101.65(d)(2)(iv) 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.

FDA tentatively concludes that the action that it is proposing is equitable and will provide consumers with information that will assist them in constructing diets that conform to all aspects of current dietary recommendations. The agency requests comment on its proposed rule and on whether such an extension of the exemption is necessary to ensure that consumers are not misled or confused by the current requirement that all foods except raw fruits and vegetables provide 10 percent of one of the six listed nutrients.

IV. Analysis of Impacts

FDA has examined the economic implications of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this proposed rule is not an economically significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

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

proposed rule is to provide more useful information to consumers.

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 which will be revised as a result of this rule. However, FDA estimates that the cost of revising a label to include a ''healthy'' claim is approximately $3,000 per label.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has determined 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.

VI. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling or other third party disclosure requirements; thus there is no ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is seeking comment on whether this proposed rule to amend the definition for the implied nutrient content claim ''healthy'' imposes any paperwork burden.

VII. Effective Date

FDA is proposing to make these regulations effective on the date of publication in the Federal Register.

VIII. Comments

Interested persons may, on or before April 29, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above, between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. 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 9, ''Processed Fruit and Vegetable Products that Qualify to Bear the Term 'Healthy,''' June 17, 1994, and July 17, 1995.

2. Satchell, F. B., Division of Programs and Enforcement Policy (HFS–158), Center for Food Safety and Applied Nutrition, memorandum to file,'' Nutrient Profiles of Marketplace Fruit and Vegetable Products that Qualify to Bear the Term 'Healthy,''' October 10, 1995.

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

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, it is proposed that 21 CFR part 101 be 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 101.65 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) Except for raw or frozen fruit or vegetable products comprised solely of fruits and vegetables and for enriched grain products that conform to a standard of identity in parts 136, 137, or 139 of this chapter, the food contains at least 10 percent of the RDI or DRV per reference amount customarily consumed, per labeled serving of vitamin A, vitamin C, calcium, iron, protein, or fiber;

* * * * *

Dated: January 26, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–2980 Filed 2–9–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC33

Shenandoah National Park, Recreational Fishing

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) is proposing to remove the special fishing regulations for Shenandoah National Park. The general NPS fishing regulations and the regulations on closures and public use limits are sufficient to allow for the proper management of fishing at Shenandoah National Park. This duplication of regulations is often confusing and unnecessary.

DATES: Written comments will be accepted through April 12, 1996.

ADDRESSES: All comments should be addressed to: Superintendent, Shenandoah National Park, Route 4 Box 348, Luray, VA 22835.

FOR FURTHER INFORMATION CONTACT: Greg Stiles, Leader, Resource and Visitor Protection Services, Shenandoah National Park, Route 4 Box 348, Luray, VA 22835, Telephone (540) 999–3401.

SUPPLEMENTARY INFORMATION:

Background

The fishing regulations that are currently in use for Shenandoah National Park are codified at 36 CFR 7.15(a). These regulations: (1) Permit recreational fishing in selected streams of the Park as designated by the Superintendent; (2) establish seasons, creel and size limits; and (3) establish licensing requirements. This proposed rulemaking will delete subsection 7.15(a) of 36 CFR pertaining to recreational fishing in Shenandoah National Park and exclusively adopt the general regulations found at 36 CFR 1.5 (Closures and public use limits) and 2.3 (Fishing). Inherent to this proposal is the need to provide for protection and management of the Park's fisheries resources and to encourage partnerships with state agencies through regulatory review.

Section-by-Section Analysis

1. *Open Waters and Applicability.* The general regulations for Fishing, found at 36 CFR 2.3, establish that fishing in the parks, except in designated areas, will be in accordance with nonconflicting State laws and regulations within whose exterior