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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2001N-0548] (formerly Docket No. 01N-0548)

Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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SUMMARY: The Food and Drug Administration (FDA) is amending the voluntary nutrition labeling regulations by updating the names and the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States and clarifying guidelines for the voluntary nutrition labeling of these foods. Availability of the updated nutrition labeling values in retail stores and on individually packaged raw fruits, vegetables, and fish will enable consumers to make better purchasing decisions to reflect their dietary needs.

EFFECTIVE DATE: January 1, 2008.

FOR FURTHER INFORMATION CONTACT: Mary Brandt, Center for Food Safety and Applied Nutrition (HFS-840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1788.

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## I. Background

In response to requirements of the Nutrition Labeling and Education Act of 1990 (``the 1990 amendments'') (Public Law 101-135), which amended the Federal Food, Drug, and Cosmetic Act (the act), FDA (we) published final regulations in the Federal Register of November 27, 1991 (56 FR 60880) (hereinafter identified as ``the 1991 final rule''), and corrections in the Federal Registers of March 6, 1992 (57 FR 8174), and March 26, 1992 (57 FR 10522), that: (1) Identified the 20 most frequently consumed raw fruits, vegetables, and fish in the United States, which are those varieties purchased raw but not necessarily

consumed raw; (2) established guidelines for the voluntary nutrition labeling of these foods; and (3) set the criteria for food retailers to meet substantial compliance with these guidelines. The 1991 final rule also required FDA to publish proposed updates of the nutrition labeling data for the 20 most frequently consumed raw fruits, vegetables, and fish (or a notice

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that the data sets have not changed) at least every 2 years (56 FR 60880 at 60888 and 60891).

Next, FDA published a proposed rule on the voluntary nutrition labeling program in the Federal Register of July 18, 1994 (59 FR 36379) (hereinafter identified as ``the 1994 proposed rule''), a correction in the Federal Register of July 21, 1994 (59 FR 37190), and a final rule in the Federal Register of August 16, 1996 (61 FR 42742) (hereinafter identified as ``the 1996 final rule''). In the 1996 final rule, among other actions, FDA revised the following: (1) The nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States and (2) the guidelines for the voluntary nutrition labeling of these foods. FDA also modified the guidelines in Sec. 101.45(b) (21 CFR 101.45(b)), in response to comments, to state that FDA would publish every 4 years (rather than 2 years) proposed updates of the nutrition data or a notice that the data sets have not changed from the previous publication (comment 12, 61 FR 42742 at 42746 and 42760).

FDA then published a proposed rule on the voluntary nutrition labeling program in the Federal Register of March 20, 2002 (67 FR 12918) (hereinafter identified as ``the 2002 proposed rule''), and a correction to the Docket number and extension of the comment period in the Federal Register of June 6, 2002 (67 FR 38913). The 2002 proposed rule: (1) Updated the names and nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States and (2) clarified the guidelines for the voluntary nutrition labeling of these foods. Subsequently, FDA again reopened the comment period until June 3, 2005 (70 FR 16995, April 4, 2005) (hereinafter identified as ``the 2005 reopening of the comment period''), to allow all interested parties the opportunity to review its tentative nutrition labeling values based upon data FDA received within and after the comment period for the 2002 proposed rule, and to comment on the additional nutrient data for some of the 20 most frequently consumed raw fruits, vegetables, and fish. FDA also stated that it would evaluate any new data submissions during the reopened comment period and would consider use of those data in a final rule.

## II. Comments on the 2002 Proposed Rule and 2005 Reopening of the Comment Period

FDA received 21 responses to the 2002 proposed rule and 30 responses to the tentative nutrition labeling values set forth in its 2005 reopening of the comment period document, each of which contained one or more comments. New data also were submitted in response to the 2005 reopening of the comment period. Comments generally supported the

2002 proposed rule, including the new values set forth in the 2005 reopening of the comment period document. A number of comments that were received are not considered here because they are beyond the scope of this regulation, including those comments on labeling of meat, poultry, and pork products; labeling of possible positive or ill side effects of consuming raw produce and fish; expiration dating; physical exercise; inclusion of additional nutrients and amino acids; protection of the public from profiteers; genetically modified products; pesticide residues, chemicals, and processes; and monosodium glutamate (MSG). Several comments suggested modification and revision in various provisions of the 2002 proposed rule, as revised by the 2005 reopening of the comment period. These latter comments are discussed in detail in this section of the document.

To make it easier to identify comments and FDA's responses to the comments, the word ``Comment'' will appear in parenthesis before the description of the comment, and the word ``Response'' will appear in parenthesis before FDA's response. We have also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

#### A. General Comments

(Comment 1) One comment, which supported the agency's efforts to establish accurate, meaningful nutrition information, requested that FDA post this information on its Web site and permit retailers who have developed Web sites to incorporate links from the retailer Web site to the FDA nutrition information.

(Response) FDA agrees with this suggestion and has posted the nutrition labeling values on the Internet at <http://www.cfsan.fda.gov>. We

encourage retailers, industry, trade associations, academia, and other government agencies to provide links to that information.

#### B. Consistency Among Government Agencies in Providing Nutrient Information

(Comment 2) Several comments expressed concern that the proposed changes to some of the nutrient values appear inconsistent from the U.S. Department of Agriculture (USDA) Nutrient Database for Standard Reference (SR) (Ref. 1) and from its data source, the USDA National Nutrient Data Bank (NNDB) (Ref. 2). One comment suggested that whenever possible, FDA should consider SR values in addition to the agency's own 95 percent prediction limit when determining label values.

(Response) FDA agrees that some of its nutrient values differ from data found in the USDA SR and NNDB. As we explained in the 1996 final rule (61 FR 42742 at 42743), FDA does not agree that mean values from USDA databases are appropriate for nutrition labeling.

We support use of the USDA NNDB and associated USDA SR for many nutritional purposes and recognize the USDA SR as the most comprehensive nutrient database in the United States and the basis of much nutrition software. For this reason, we have used all data

submitted by USDA to update the nutrition labeling values for raw fruits and vegetables, including the data from its 2001-2002 nationwide sampling study of fruits and vegetables for 16 of the 20 most frequently consumed raw fruits and 12 of the 20 most frequently consumed raw vegetables that it submitted in response to the 2002 proposed rule (see <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080602/01n-0548-c000006-voll.pdf>) and (see <http://www.fda.gov/OHRMS/>

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mushrooms in response to the 2005 reopening of the comment period, as well as data from other sources, as described later in this final rule. In addition, we used data from the USDA NNDB to establish nutrient levels for Chinook salmon in response to comments to the 2002 proposed rule. Raw nutrient data (individual analytical data points) from the USDA NNDB also provide the basis of the nutrient levels for most of the raw fish. Because of the lack of data for vitamin A and vitamin C in raw fish, we have based the values for most fish in the voluntary nutrition labeling program on data published in the USDA SR, which are mean values.

As stated in the 1996 final rule (61 FR 42742 at 42743), some of USDA's food composition data published in the SR are not fully representative because they are based on small sample sizes or do not take into account specific variables, such as geographic area. We obtained data for many of the raw fruits, vegetables, and fish from the USDA NNDB and SR, but, where possible, instead of using the mean values, we

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applied compliance calculations based on 95 percent prediction intervals to those data (as well as to other data sources) and used the resulting adjusted values that account for variability in the nutrient.

To meet the requirements for compliance in Sec. 101.9(g)(4) and (g)(5) (21 CFR 101.9(g)(4) and (g)(5)), the agency encourages manufacturers to use FDA compliance calculations based on 95 percent prediction intervals to determine the nutrition labeling values for their products. We provide guidance explaining this calculation and for industry to use to develop nutrition labeling values in the ``FDA Nutrition Labeling Manual--A Guide for Developing and Using Databases'' (the Nutrition Labeling Manual) (Ref. 3). The Nutrition Labeling Manual more fully explains the rationale and process for conducting and using compliance calculations based upon 95 percent prediction intervals.

(Comment 3) Several comments stated that it is important to have consistency in the nutrition information that is communicated to the public and that FDA should do more to bring greater harmony among the government's nutrition information, including ensuring that nutrient values are consistent with the nutrition messages publicized by the 2005 Dietary Guidelines for Americans.

(Response) We believe it is important to have consistency in the nutrition information that is communicated to the public; however,

there are some fundamental differences in the nutrient values being established in this final rule and the nutrition messages publicized by the 2005 Dietary Guidelines for Americans. The Dietary Guidelines for Americans (Ref. 4) recommends the increased intake of fruits, vegetables, and fish and cites nutrient data from the USDA SR in the report that they released January 12, 2005. The data provided by the 2005 Dietary Guidelines for Americans were mean values per 100 gram (g) of product and were not on the same metric as the nutrition labeling values in Appendices C and D to part 101 (21 CFR part 101), which are provided on a serving size basis and are required in Sec. 101.45(b) for labeling of the 20 most frequently consumed raw fruits, vegetables, and fish to ensure uniformity in declared values. Thus, some differences in nutrient levels are likely to be noted.

### C. Need for Additional Research and Data

(Comment 4) Five comments requested that the final rule not be finalized at this time because they needed an additional 12 months to plan, execute, and evaluate additional nutrient research so that nutrient data are as complete and extensive as possible. The comments asserted that this additional time will allow for sampling products at different times of the year which will give them a more accurate reflection of the seasonal impact on nutrient content values. One of the comments stated the additional time also would allow the industry to establish more data points and thus increase the sample size of analytical values, which may help in calculating a more reliable mean value and improving the standard deviation, both factors needed to calculate the one-sided 95 percent prediction interval.

(Response) The data submitted to FDA in response to the 2002 proposed rule were available for public review for almost 3 years. We believe that this is more than an adequate amount of time for interested persons to complete nutrient analyses, provide additional data and information on market shares, determine the seasonal impact on nutrient content values, and establish more data points for calculating a more reliable nutrient value. We therefore have concluded that the requested additional time is not warranted. However, we do encourage the produce and fish industries to continue to conduct research on nutrient values and to submit new data to FDA for consideration in future updates, in accord with Sec. 101.45(b).

(Comment 5) One comment urged that FDA utilize all credible data available and not a limited set of data from one study.

(Response) FDA agrees that it should utilize all credible data available in developing its nutritional values for raw fruit, vegetables, and fish. We recognize that additional nutrient data are needed to support the voluntary nutrition labeling of raw produce and fish because some of the current values are based on small sample sizes or older data and should be updated. However, many of the commodity groups and organizations that represent the produce and fish industries have not submitted new data to support the updating and refinement of the nutrient levels. We therefore can only use the data we have in updating and refining these nutrient levels. As stated in the response to comment 4 of this document, we encourage and will continue to encourage the produce and fish industries to conduct additional

nutrient analyses to support the labeling of these foods and to submit those data to FDA for consideration in updating the nutrient levels in the next review of the voluntary nutrition labeling of raw produce and fish.

#### D. Consumer Support for Labeling of Raw Fruits, Vegetables, and Fish

(Comment 6) One comment recommended that FDA establish nutrition labeling values for more than just the 20 most frequently consumed raw products identified in the proposal.

(Response) Section 403(q)(4)(B) of the act (21 U.S.C. 343(q)(4)(B)) provides that FDA establish by regulation a list of the 20 varieties of vegetables, fruits, and raw fish most frequently consumed in a year. Therefore, we are not granting the comment's request in this final rule. However, we have provided for the nutrition labeling of raw fruits, vegetables, and fish that are not among the 20 most frequently consumed in Sec. 101.45(c). In that regulation, FDA states that databases of nutrient values may be used to develop nutrition labeling values for specific varieties, species, or cultivars of those foods not among the 20 most frequently consumed raw fruits, vegetables, and fish. The food names and descriptions for the fruits, vegetables, and fish in nutrition labeling or in databases developed and submitted to FDA under this regulation should clearly identify these foods as distinct from foods among the most frequently consumed list for which we have provided data. Guidance in the development of databases for these foods may be found in the FDA Nutrition Labeling Manual (Ref. 3).

(Comment 7) Two comments requested that FDA make the voluntary guidelines mandatory and require retailers to provide nutrition information for raw fruits, vegetables, and fish products.

(Response) FDA disagrees with the comments. The compliance surveys we conducted in 1992, 1994, and 1996 (Ref. 5) do not support taking such action at this time. These surveys found that retailers exceeded the 60 percent substantial compliance standard set in Sec. 101.43(c) by a large enough margin to provide confidence that the levels were not invalidated by statistical error. Levels of compliance for 1992, 1994, and 1996 were 76.9 percent, 81.4 percent, and 77.8 percent for raw produce and 74.3 percent, 76.8 percent, and 74.0 percent for raw fish. As our surveys have found substantial compliance over several years, we have no reason to evaluate the marketplace differently than we have in past years because there is no evidence that substantial compliance does not continue at the present time. Absent information suggesting otherwise, our evaluation of the available compliance

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data and our projections based on those data indicate that compliance remains substantial at this time. Thus, at this time, we continue to encourage retailers to provide quantitative nutrition information for raw fruits, vegetables, and fish but will not publish regulations to make the provision of nutrition information mandatory.

#### E. Allowable Nutrient Content Claims

(Comment 8) One comment expressed concern that changing the

existing nutrition label values for several key fruits and vegetables will weaken their perceived nutrient values (e.g., a fruit or vegetable that was previously an ``excellent source'' would now be considered a ``good source'') and some micronutrient claims would have to be dropped altogether because these fruits and vegetables will not be able to bear the same nutrient content claims that they once did under Sec. 101.54. This situation could cause only fortified processed foods to be able to use the claim ``excellent source'' for some nutrients. The comment stated that the changes the agency is making would mean the loss of positive nutrition content claims for several vegetables and fruits that are currently considered to be the ``gold standard'' of nutrition among consumers.

(Response) We recognize and agree that based upon new data, some of the fruits and vegetables may no longer be able to bear the same nutrient content claims. We want to clarify, however, that as described in Sec. 101.54, nutrient content claims must be based on the reference amounts customarily consumed (RACCs) and not on the serving sizes of products, which are derived from the RACCs. Specifically, Sec. 101.54(b) states the provisions for ``high claims'' (``high,'' ``rich in,'' or ``excellent source of''), and Sec. 101.54(c) provides those for ``good source claims'' (``good source,'' ``contains,'' or ``provides'').

Section 101.12(b) states that reference amounts shall be used as the basis for determining serving sizes for specific products. The RACCs shown in Table 2 of Sec. 101.12 for fruits, vegetables, and fish in the voluntary nutrition labeling program include 140 g for fresh fruits, 30 g for avocado, 280 g for watermelon, 55 g for lemon and lime, 30 g for green onion, 110 g for fresh potatoes, 85 g for fresh vegetables, and 85 g for cooked, plain fish and shellfish. The serving sizes of raw produce displayed in Appendix C to part 101, while based on the RACCs, are generally not equivalent to the RACCs, which are listed in grams only, but are provided on the basis of a ``household measure'' of a food as well as in g and ounces (oz), such as 1 medium banana (126 g per (/) 4.5 oz) or 5 asparagus spears (93 g/3 oz). The serving size for all raw fish displayed in Appendix D to part 101 is 84 g/3 oz.

#### F. Declaration of ``Vitamin A'' or ``Carotenoid''

(Comment 9) One comment stated that fruits and vegetables contain carotenoid, which is the precursor of vitamin A, but not vitamin A itself, so the term ``vitamin A'' for fruits and vegetables should be changed to ``carotenoid''.

(Response) We believe it would be inaccurate to change the term ``Vitamin A'' to ``carotenoids'' for fresh fruit and vegetables given the understanding of the term ``Vitamin A'' and the relatively limited understanding of the functions of the hundreds of naturally occurring carotenoids. Vitamin A comprises a family of molecules containing a 20-carbon structure with a methyl substituted cyclohexenyl ring and a tetraene side chain with a hydroxy group (retinol), aldehyde group (retinal), carboxylic acid group (retinoic acid) or ester group (retinyl ester) at carbon 15. The term ``Vitamin A'' includes provitamin A carotenoids that are dietary precursors of retinol. The



term ``retinoids'' refers to retinol, its metabolites, and synthetic analogues that have a similar structure. Carotenoids are polyisoprenoids, of which more than 600 forms exist. Of the many carotenoids in nature, several have provitamin A nutritional activity. Food composition data are available for only three (alpha-carotene, beta-carotene, and beta-cryptoxanthin). Because the term ``Vitamin A'' typically encompasses pro-vitamin A carotenoids, and most carotenoids have no food composition data available at this time, the suggested change would be inaccurate.

#### G. Updating of Reference Amounts

(Comment 10) One comment recommended that FDA not revise nutrient values for the 20 most frequently consumed raw fruits, vegetables, and fish until we finalized the April 4, 2005 (70 FR 17010) Advanced Notice of Proposed Rulemaking (ANPRM) (the April 2005 ANPRM), that requested comments on, among other issues, whether we should update the RACCs, the basis for serving size. The comment was of the view that we should wait until the reference amounts are revised to reflect what is currently available in the U.S. market.

(Response) FDA disagrees with the comment. We believe we should publish this final rule at this time and not wait until completion of the rulemaking process that we initiated by the April 2005 ANPRM. We are currently reviewing comments submitted in response to the ANPRM and have not determined whether or when we will update the RACCs. If we do decide to go forward with that rulemaking and revise the RACCs, we will then update the serving sizes of raw fruits, vegetables, and fish to reflect those revisions in future rulemaking for the voluntary nutrition labeling program.

#### H. Inclusion of Magnesium in Nutrition Labeling

(Comment 11) One comment suggested that FDA include the magnesium content of seafood in the voluntary nutrition labeling regulations. Cooked fish, the comment noted, can provide substantial amounts of magnesium in the U.S. diet, which would provide health benefits to American consumers. Another comment requested that magnesium be added to the banana's nutrition labeling profile in Appendix C to part 101. The latter comment noted that the 2005 Dietary Guidelines for Americans recommend that both adults and children increase their intake of magnesium from food sources.

(Response) FDA is not granting either of these requests. We note that the 2005 Dietary Guidelines state that based on dietary intake data or evidence of public health problems, intake levels of magnesium may be of concern for both adults and children (Ref. 4). However, none of the comments included nutrient data for magnesium for any of the fish in the voluntary nutrition labeling program, and we do not have access to magnesium data for any of the fish or the raw fruits and vegetables. Thus we cannot grant the request in the comment without such supporting data.

However, we consider magnesium an optional nutrient for both mandatory nutrition labeling and the voluntary nutrition labeling of raw fruits, vegetables, and fish. In the 1996 final rule, we noted that

providing information on optional nutrients for foods in the voluntary program will be useful, and declarations of optional nutrients included on individual labels should follow the requirements under Sec. 101.9(c).

## I. Guidelines for Presentation of the Nutrition Labeling Values

### 1. Clarity in Guidelines for Raw Fruits and Vegetables and for Raw Fish

To provide clarity and consistency in the voluntary nutrition labeling of raw

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fruits, vegetables, and fish, FDA proposed in Sec. 101.45(a)(3) to: (1) Divide current Sec. 101.45(a)(3)(iii) into two parts (i.e., into Sec. 101.45(a)(3)(iii) and (a)(3)(iv)) so that Sec. 101.45(a)(3)(iii) pertains only to raw fruits and vegetables and Sec. 101.45(a)(3)(iv) pertains only to raw fish and (2) revise the wording for consistency and increased readability. No comments were received, and therefore these guidelines were adopted as proposed.

### 2. Trans Fatty Acid Labeling

FDA stated in the 2002 proposed rule that trans fatty acids would not be expected to be present in raw produce and that the footnote required in proposed Sec. 101.45(a)(3)(iii) should be revised to state: ``Most fruits and vegetables provide negligible amounts of saturated fat, trans fat, and cholesterol \* \* \*.''' Comments supported FDA's proposed revisions to Sec. 101.45(a)(3)(iii), and therefore we have adopted it as proposed.

Also, FDA requested comments that provide data on the trans fat content of raw fish (or cooked fish without the addition of any ingredients, e.g., fat, breading, or seasoning).

(Comment 12) Several comments requested that FDA revise Sec. 101.45(a)(3)(iv) to state that fish provide only negligible amounts of trans fat, or no trans fat. A comment from the fish industry noted that, unlike some animals, fish do not typically accumulate measurable levels of trans fat as a result of their metabolized food sources, and it is particularly true of wild-caught fish.

(Response) FDA agrees with the comments and has revised Sec. 101.45(a)(3)(iv) to read as follows: ``When retailers provide nutrition labeling information for more than one raw fish on signs or posters or in brochures, notebooks, or leaflets, the listings for trans fat, dietary fiber and sugars may be omitted from the charts or individual nutrition labels if the following footnote is used, `Fish provide negligible amounts of trans fat, dietary fiber, and sugars'.'' Appendices C and D to part 101 will show 0 g of trans fat for all varieties of raw fruits, vegetables, and fish.

## J. Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish in the United States

### 1. Fruits and Vegetables

There were no comments that recommended changing the top 20 most frequently consumed raw fruits and the top 20 most frequently consumed raw vegetables. For ease of use and to be consistent with the food

names in Appendix C to part 101, we revised Sec. 101.44(a) and (b) by listing the items in alphabetical order and by using the plural form of the food name when the serving size is more than one unit. Revised Sec. 101.44(a) reads as follows: ``The 20 most frequently consumed raw fruits are: Apple, avocado (California), banana, cantaloupe, grapefruit, grapes, honeydew melon, kiwifruit, lemon, lime, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, tangerine, and watermelon.'' Revised Sec. 101.44(b) reads as follows: ``The 20 most frequently consumed raw vegetables are: Asparagus, bell pepper, broccoli, carrot, cauliflower, celery, cucumber, green (snap) beans, green cabbage, green onion, iceberg lettuce, leaf lettuce, mushrooms, onion, potato, radishes, summer squash, sweet corn, sweet potato, and tomato.''

## 2. Fish

(Comment 13) Two comments requested that FDA revise Sec. 101.45(a)(3)(iv) to add Chinook salmon to the salmon species. One comment stated that the vast majority of Chinook salmon is sold raw to the U.S. consumer, and the nutrient profile is most similar to the proposed category for the values for Atlantic/coho/sockeye salmon.

(Response) We agree with this suggestion and have revised 101.45(a)(3)(iv) to combine Atlantic, coho, Chinook and sockeye into one subgroup of salmon based upon similarity in nutrient values.

(Comment 14) One comment requested that FDA report information for farmed salmon separately from that for wild salmon because food supply and water quality greatly affect nutrition value of the food whether it is raised or caught.

(Response) We are not granting this request because there were no nutrient data submitted that supported providing nutrition information separately for farmed versus wild species of salmon or other types of fish.

## K. Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish

### 1. FDA Analysis of the Data

FDA considered the data from all of the sources identified in sections II.K.2 and II.K.3 of this final rule and used these data as the basis for deriving the updated nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in Appendices C and D to part 101. Reference 6 of this document provides complete documentation of the derivation of each nutrition labeling value for the raw fruits, vegetables, and fish covered in this final rule. The documentation also includes the actual (unrounded) values for total fat, total carbohydrate, and protein used to calculate calories and calories from fat for each food.

To the extent possible (i.e., for those nutrients for which sufficient data were available), we used the statistical methodology recommended in the FDA Nutrition Labeling Manual to produce the nutrition labeling values. The recommended statistical methodology uses compliance calculations that take into account the variation of nutrients in foods, as described in greater detail in the 2002 proposed rule.

#### a. 95 Percent Prediction Intervals.

(Comment 15) One comment stated that proposed values appear to be imprecise and not representative when calculating for the one-sided 95 percent prediction interval. As a solution, the comment recommended that FDA use predicted values that fall within the range of the actual data points.

(Response) We agree with the comment that the 95 percent predicted value should fall within the range of the interval of all raw data points and have reviewed all nutrient data for all foods. If the 95 percent predicted value falls within the interval of all raw data points, then it is reasonable that it represent the nutrient level of the product. If for any reason, the 95 percent predicted value shows an invalid complete absence of a nutrient, if it is a negative value, or if it does not fall within the interval of all raw data points, it is likely that the mean will provide a better estimate of the nutrient than the predicted value. We also noted in the 2002 proposed rule that we frequently find that the mean and the predicted value round to the same value. In addition, we found that when the sample size was small (e.g., three or fewer analytical data points), the values derived from compliance calculations (using 95 percent prediction intervals) were less likely than the mean to represent the nutrient level. Thus, after a careful review of statistical and analytical data and considering all criteria listed in section II.K.1 of this document, we selected those values that more appropriately represent the nutrient level in the food.

(Comment 16) One comment asked that FDA provide clarification of the agency's compliance with the Data Quality Act in issuing the proposed nutrient labeling values.

(Response) In the Information Quality Act (IQA), Public Law No. 106-554,

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section 515 (2000), see 44 U.S.C. 2516 note, Congress directed the Office of Management and Budget (OMB) to issue governmentwide guidelines designed to ensure and maximize the ``quality, objectivity, utility, and integrity of information \* \* \* disseminated by Federal agencies,' and in turn required agencies to issue their own guidelines concerning information quality and to establish administrative mechanisms to allow affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comport with the agency's guidelines. OMB's guidelines were published in the Federal Register of February 22, 2002 (67 FR 8452); HHS's guidelines were announced in the Federal Register of September 30, 2002 (67 FR 61343), and can be found at <http://aspe.hhs.gov/infoquality/guidelines/fda.shtml>.

(FDA has verified the Web site address, but we

are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.)

The nutrition labeling values that we provide in the voluntary nutrition labeling program are developed using a transparent process that provides data that are reproducible and are otherwise in compliance with FDA's IQA guidelines and the IQA. The process of

setting and updating these values is identified in Sec. 101.45(b) and (c) and in the FDA Nutrition Labeling Manual, described in Sec. 101.45(b) and (c). The manual provides the general methodology that we recommend and follow to determine nutrition labeling values based on 95 percent prediction intervals, and FDA has provided detailed explanations of its methodology in the proposed rule and in response to comments in this preamble. In addition to the FDA Nutrition Labeling Manual, FDA staff members are available to answer questions and to provide further direction on the analytical, statistical, and methodological questions that arise concerning determination of nutrition labeling values. Stakeholders with new or additional nutrient data for any of the most frequently consumed raw fruits, vegetables, and fish are encouraged in Sec. 101.45(b) and (c) to submit data to the agency for review and evaluation by the agency, and these data may be incorporated into subsequent revisions of the nutrition labeling information.

b. Precision in Estimates.

(Comment 17) One comment suggested that USDA and FDA emphasize in the regulation that the [serving] sizes given for produce items are expressed for the edible portion even though, as another comment noted, consumers buy foods in ``as purchased'' quantities. For example, a consumer buying a fruit with a large amount of inedible content (e.g., cantaloupe or peach), would likely believe that they are getting more nutrients than they are. The comment stated that having yield conversion factors would be necessary to make the nutrient information truly usable to the consumer.

(Response) We do not believe the emphasis requested is necessary, as we are not aware of consumer research that describes consumers' perceptions of the size of fruits and vegetables they purchase with respect to interpretation of nutrient information available on signs in retail outlets, which is based on a serving size set by FDA and reflects the amount customarily consumed. We are therefore not convinced that most consumers will require the precision in knowing at the point of purchase the yield information of the raw fruits and vegetables they purchase.

(Comment 18) One comment expressed concern that the proposed changes in nutrient levels mislead the public because listing the weight of any fruit or vegetable in unrounded numbers gives an impression of an unwarranted level of accuracy, when in fact fruits and vegetables vary in size.

(Response) FDA agrees that fruits and vegetables vary in size but disagrees that listing the weight in unrounded numbers gives an impression of an unwarranted level of accuracy. The nutrition labeling values in Appendix C to part 101 provide serving sizes for each fruit and vegetable that is expressed in a visual unit of measure (e.g., 1 medium apple; 2 slices pineapple; 5 spears asparagus; 1/2 medium summer squash; 1 medium, 5' long, 2' diameter sweet potato), as well as the gram and ounce equivalent. Visual units of measure vary and are not intended to be precise. We expect that consumers will treat them as an approximation but will also have the option of referring to the gram and ounce serving size measures if greater precision is needed.

c. Adjusting Values for Total Carbohydrate.

(Comment 19) One comment objected to FDA adjusting the total

carbohydrate values where the sum of sugars and dietary fiber exceeded the value for total carbohydrate. The comment stated that the sugar value should be adjusted when sugars and fibers exceed total carbohydrate, and the sugar values are from a different source than the proximate, fiber, and other nutrient values. This, the comment stated, would more accurately represent the sugar and carbohydrate content, as well as the caloric value, of the samples from which most of the nutrition labeling values have been derived.

(Response) We disagree that the sugars value should be adjusted. The sum of the sugars and dietary fiber values, which were derived from analytical data submitted by USDA, exceeded the value for total carbohydrate for cantaloupe, honeydew melon, and watermelon. For these foods only, we adjusted the value for total carbohydrate to reflect the sum of sugars and dietary fiber. As stated in the 2002 proposed rule, we consider this adjustment to be appropriate because the values for sugars and dietary fiber are determined by laboratory analysis, and therefore, are more accurate than the value for total carbohydrate, which is determined ``by difference'' (i.e., the weight remaining after subtracting the sum of the protein, fat, moisture, and ash from the total weight of the food (Sec. 101.9(c)(6))).

## 2. Nutrition Labeling of Raw Fruits and Vegetables

In the 2002 proposed rule, FDA updated nutrition labeling values for 12 of the 20 raw fruits and 9 of the 20 raw vegetables. We used new data for six of the fruits from the California Avocado Commission (CAC); the California Table Grape Commission; the California Tree Fruit Agreement (CTFA) for peach, plums, and nectarine; and the California Cherry Advisory Board for fat in sweet cherries. We also used new data for four vegetables from the National Potato Protection Board and the USDA NNDB for green onion, sweet corn, and sweet potatoes. In other nutrition label changes, we corrected slight errors in sugars, total carbohydrate, calories, and calories from fat values in a few fruits and vegetables (cantaloupe, orange, strawberries, sweet cherries, tangerine, watermelon, asparagus, celery, green (snap) beans, and tomato) and corrected the serving size for grapefruit, carrot, and sweet potato.

As indicated in section II.B of this final rule, USDA submitted data in response to the 2002 proposed rule from its 2001-2002 nationwide sampling study of fruits and vegetables, which it incorporated into its NNDB and SR, for 16 of the 20 most frequently consumed raw fruits (apple, avocado (California), banana, cantaloupe, grapefruit, honeydew melon, kiwifruit, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, and watermelon) and 12 of the 20 most frequently consumed raw vegetables (bell pepper, broccoli, carrot, celery, cucumber, iceberg lettuce, leaf lettuce, onion, potato, radish, sweet potato, and

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tomato). At the time USDA submitted the comment, the data results for vitamin C, sodium, and potassium were not yet available, and the analysis of carotenoids for carrots, sweet potatoes, cucumbers, onions, and sweet peppers had not been completed. In June and July of 2003, after the close of the comment period, USDA provided sodium, potassium,

and some carotenoid values that it did not submit earlier, including vitamin C values for pineapple. In other comments to the 2002 proposed rule, the Citrus Research Board and Food Research, Inc., provided nutrient data from 1998 for oranges, grapefruit, tangerines (Mandarin oranges), and lemons. We used all of the new data to update the nutrition labeling values in the 2005 reopening of the comment period.

In response to the 2005 reopening of the comment period, the Pear Bureau Northwest submitted market share data for four varieties of pears; USDA submitted data for raw mushrooms; Food Research, Inc., submitted data for total fat in kiwifruit; and the California Strawberry Commission (CSC) submitted data for sugars, calcium, and iron in strawberries. After the close of the comment period, the U.S. Apple Association (USApple) submitted data for fiber and new serving size information. We considered all data submitted in response to the 2005 reopening of the comment period and used those data to update the nutrition labeling values for raw fruits and vegetables in this final rule. The following will address individual fruits and vegetables for which we received data in response to the 2005 reopening of the comment period.

a. Apple.

(Comment 20) USApple requested that FDA use its new serving size information and new data for dietary fiber for five varieties of apples (Red Delicious, Golden Delicious, Granny Smith, Gala, and Fuji) in updating the nutrient values for apples. USApple stated that based on current market data, retailers are selling significantly larger apples than those represented by the existing serving size of 154 g or 5.5 oz edible portion, which is based on 1975 market data. They noted that the 154 g serving size for apples does not reflect the majority of apples for sale in the retail market and that a large apple (264 g whole, 242 g edible portion) is customarily consumed in the United States. They stated apple growers have adapted to consumers' tastes and preferences by growing and marketing larger apples, and, as a result, apple production and the apple market have changed significantly. In addition, only small and large apple sizes exist in today's marketplace. There is no inventory management or price look-up (PLU) sticker that designates a ``medium'' size apple at the retail level, and smaller apples typically go to processing. USApple recommended that a large apple (242 g edible portion) should be listed as the serving size.

(Response) We agree with the USApple request. We are convinced by the data submitted by USApple that ``1 large (242 g/8 oz)'' better represents the serving size for apple. Thus, we combined the data for dietary fiber from the USApple research study (n=8) with data provided by USDA for the same five varieties of apples in response to the 2002 proposed rule (n=15) and conducted weighted compliance calculations of all nutrients based on market share using 95 percent prediction intervals (Ref. 7). Based upon our analysis of the data, we determined that there would be changes in nutrition labeling values for calories (130 from 80), potassium (260 milligrams (mg), 7 percent daily value (DV), from 160 mg, 5 percent DV), total carbohydrate (34 g, 11 percent DV, from 21 mg, 7 percent DV), dietary fiber (5 g, 20 percent DV, from 3 g, 12 percent DV), sugars (25 g from 16 g), protein (1 g from 0 g), calcium (2 percent DV from 0 percent DV), and iron (2 percent DV from 0

percent DV). Table 1 of this document includes changes in nutrition labeling values for apples, and Appendix C to part 101 provides the listing of all values.

Table 1.--Changes to the Nutrition Labeling Information for Raw Fruits and Vegetables

Period Values	Food and Nutrient	Final Rule Values	2005 Reopening Comment
% DV		% DV	
<hr/>			
Apples (242 g)		(242 g)	(154 g)
.....		.....	.....
Calories			80
.....		130	.....
Potassium			160 mg
5%	260 mg	7%	
Total Carbohydrate			21 mg
7%	34 mg	11%	
Dietary Fiber			3 g
12%	5 g	20%	
Sugars			16 g
.....		25 g	.....
Protein			0 g
.....		1 g	.....
Calcium			.....
0%	.....	2%	.....
Iron			.....
0%	.....	2%	.....
<hr/>			
Avocado (30 g)			.....
.....			.....
Calories from Fat			45 g
.....		35	.....
Total Fat			5 g
8%	4.5 g	7%	
Saturated Fat			1 g
5%	0.5 g	3%	
Total Carbohydrate			2 g
1%	3 g	1%	
Iron			.....
0%	.....	2%	.....
<hr/>			
Banana (126 g)			.....
.....			.....
Sodium			5 mg



0%	0 mg	0%	
Dietary Fiber			2 g
8%	3 g	12%	
Vitamin A		.....	
0%	.....	2%	

---

Cantaloupe (134 g)		.....	
.....		.....	
Calcium		.....	
0%	.....	2%	

---

Honeydew melon (134 g)		.....	
.....		.....	
Calcium		.....	
0%	.....	2%	

---

Kiwifruit (148 g)		.....	
.....		.....	

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Total Fat			1.5 g
2%	1 g	2%	

---

Lemon (58 g)		.....	
.....		.....	
Dietary Fiber			1 g
4%	2 g	8%	

---

Nectarine (140 g)		.....	
.....		.....	
Dietary Fiber			1 g
4%	2 g	8%	

---

Orange (154 g)		.....	
.....		.....	
Vitamin A		.....	
0%	.....	2%	

---

Pear (166 g)		.....	
.....		.....	
Potassium			180 mg
5%	190 mg	5%	
Total Carbohydrate			25 g
8%	26 g	9%	

Dietary Fiber			4 g
16%	6 g	24%	
Protein			0 g
.....	1 g	.....	
Calcium		.....	
0%		2%	

---

Pineapple (112 g)			
.....			
Iron		.....	
0%		2%	

---

Plums (151 g)			
.....			
Dietary Fiber			1 g
4%	2 g	8%	
Iron		.....	
0%		2%	

---

Strawberries (147 g)			
.....			
Sugars			6 g
.....	8 g	.....	
Calcium		.....	
0%		2%	
Iron		.....	
0%		2%	

---

Tangerine (109 g)			
.....			
Sodium			5 mg
0%	0 g	0%	

---

Broccoli (148 g)			
.....			
Total Carbohydrate			10 g
3%	8 g	3%	
Protein			2 g
.....	4 g	.....	
Iron		.....	
4%		6%	

---

Carrot (78 g)			
.....			
Iron		.....	
0%		2%	

---

---

Celery (110 g) .....

.....

Dietary Fiber 1 g

4% 2 g 8%

---



---

Cucumber (99 g) .....

.....

Calories 15

..... 10 .....

Total Carbohydrate 3 g

1% 2 g 1%

Sugars 2 g

..... 1 g .....

Protein 0 g

..... 1 g .....

---



---

Green Onion (25 g) .....

.....

Iron .....

0% 2%

---



---

Leaf Lettuce (85 g) .....

.....

Calcium .....

4% 2%

---



---

Mushrooms (84 g) .....

.....

Sodium 0 g

0% 15 g 0%

---



---

Onion (148 g) .....

.....

Potassium 160 mg

5% 190 g 5%

Calcium .....

2% 4%

---



---

Radishes (85 g) .....

.....

Potassium 160 mg

5% 190 mg 5%

---



---

Tomato (148 g) .....

.....

---

Sodium

35 mg

1% 20 mg

1%

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## b. Avocado.

(Comment 21) In comments submitted in response to the 2005 reopening of the comment period, CAC requested that FDA establish a nutrition labeling value of 0.5 g for saturated fat, 2 g for dietary fiber, and 150 mg for potassium.

CAC also submitted a comment in response to the 2002 proposed rule stating that it is well established that the fat content of an avocado varies and increases throughout the season and asked that we consider seasonal data in determining the content of fat. To support their request, CAC also noted that the State of California regulates the percent oil (fat) that must be present in an avocado before it can be sold. Not only does the fat content vary throughout the season, but as with many fruit crops, avocado sales start slow, build and then decline at the end of the season. Seasons and corresponding market share for avocado include: Primary season (January through September), 93 percent of crop; pre-season (November and December), 2.4 percent of crop; and post-season (October), 4.6 percent of crop.

(Response) We agree with the comment on the seasonal variation of fat in avocados and reevaluated the total fat and saturated fat levels for this final rule. We used the seasonal market share data that CAC provided along with their nutrient data, combined these data with those provided by USDA in response to the 2002 proposed rule, and conducted weighted compliance calculations based on 95 percent prediction intervals (Ref. 8). The resulting nutrition labeling value for saturated fat is 0.5 g. In addition, we found that other nutrient levels changed from those we published in the reopening of the comment period for total fat (4.5 g, 7 percent DV, from 5 g, 8 percent DV), calories from fat (35 from 45), total carbohydrate (3 g, 1 percent DV, from 2 g, 1 percent DV), and iron (2 percent DV from 0 percent DV).

We have also provided a correction in this final rule in Sec. 101.45(a)(3)(iii) that ``\* \* \* avocados contain 1 gram (g) of fat per ounce'' should read ``\* \* \* avocados contain 0.5 gram (g) of saturated fat per ounce.'' In addition, we have revised the footnote that follows in Sec. 101.45(a)(3)(iii) that states ``avocados provide 1 g of saturated fat per ounce'' to read ``avocados provide 0.5 g of saturated fat per ounce.''

We will make no changes to the nutrition labeling values for dietary fiber and potassium. We completed weighted compliance calculations based on 95 percent prediction intervals with nutrient data submitted by CAC and USDA, and determined that the 95 percent predicted value for dietary fiber fell outside the interval of the raw data points. We selected the mean value for dietary fiber, with a resulting nutrition labeling value of 1 g. For potassium, the 95 percent predicted value of 142.9 mg fell within the interval of the raw data points, so we selected the rounded value of 140 mg for nutrition

labeling. Thus, FDA calculated final values for dietary fiber and potassium, in accord with the statistical methods described in the 2002 proposed rule, the 2005 reopening of the comment period, and in response to comments in this final rule. Table 1 of this document includes all changes in nutrition labeling values for avocado, and Appendix C to part 101 provides the listing of all values.

c. Banana.

(Comment 22) The International Banana Association (IBA), in response to the 2005 reopening of the comment period, questioned the accuracy of FDA's calculations for the 95 percent prediction intervals for bananas. Specifically, IBA recommended that the nutrition labeling values for sodium, dietary fiber, and sugars be 0 mg, 3 g, and 16 g, respectively.

(Response) We agree that the nutrition labeling values for sodium and dietary fiber in banana should be changed to the levels recommended by IBA (0 mg from 5 mg for sodium, and 3 g, 12 percent DV, from 2 g, 8 percent DV for dietary fiber) (Ref. 9). Based upon our review of the USDA data submitted in response to the 2002 proposed rule and reassessment of 95 percent prediction intervals, as discussed in section II.K.3 of this document, we determined that there would be changes in the values for sodium, fiber, and vitamin A (2 percent DV from 0 percent DV). However, we did not find reason to change the nutrition labeling value for sugars and have not changed the 19 g listed in Appendix C to part 101. Table 1 of this document provides changes in nutrition labeling values for banana, and Appendix C to part 101 lists all values.

d. Kiwifruit.

(Comment 23) Food Research Inc., on behalf of kiwifruit growers that combined represent an estimated 98.75 percent of all kiwifruit sold in the United States, recommended that FDA label total fat as 0.5 g (1 percent DV) per serving. The comment stated that because a large coefficient of variation due to two high values in the USDA data raise uncertainties, and because so much of the sample information, country of origin, and method of analysis were not reported, it would be more appropriate to use the results of the Food Research Inc., study for the basis of labeling total fat. In support of their request, the comment provided nutrient data for total fat in kiwifruit from three of the countries they represent, which account for 88 percent of the kiwifruit sold in the United States (Chile, the United States (California), and New Zealand).

(Response) We do not agree with the 0.5 g (1 percent DV) total fat value recommended by the comment. We combined the data for total fat from the kiwifruit research study (n=6) to data provided by USDA in response to the 2002 proposed rule (n=8) and conducted weighted compliance calculations based on 95 percent prediction intervals (Ref. 10). The resulting nutrition labeling values for total fat are 1 g, 2 percent DV, a change from the 1.5 g, 2 percent DV published in the 2005 reopening of the comment period (see table 1 of this document). Appendix C to part 101 provides the listing of all nutrition labeling values for kiwifruit.

e. Pear.

(Comment 24) The Pear Bureau Northwest (Pear Bureau) submitted market share data for four varieties of pears and requested that FDA

use these data to weight the nutrient data submitted by USDA in response to the 2002 proposed rule. The varieties and market share include Bartlett (37 percent), Bosc (17 percent), Green Anjou (2 percent), and Red Anjou (28 percent), accounting for 84 percent of fresh pears sold domestically. The Pear Bureau requested nutrition labeling values for dietary fiber and total carbohydrate be updated to 5 g and 26 g, respectively.

(Response) We agree that the market share data submitted by the Pear Bureau should be used to weight the nutrient data for pears. We reviewed the market share data for pears submitted by the Pear Bureau and used their market share percentages to weight USDA nutrient data for the four varieties of pears and derive nutrition labeling values using compliance calculations based on 95 percent prediction intervals (Ref. 11). The resulting nutrition labeling values include changes for potassium (190 mg from 180 mg, both 5 percent DV), total carbohydrate (26 g, 9 percent DV, from 25 g, 8 percent DV), dietary fiber (6 g, 24 percent DV, from 4 g, 16 percent DV), protein (1 g from 0 g), and calcium (2 percent DV from 0 percent DV). Table 1 of this document includes changes in nutrition labeling values for pear, and Appendix C to part 101 provides the listing of all values.

f. Strawberries.

(Comment 25) CSC requested nutrition labeling values of 8 g for sugars and 2 percent DV for calcium and iron. In support of their request, CSC submitted the results of analytical

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research conducted by Food Research, Inc., to determine the sugars, calcium, and iron content of fresh strawberries. Twelve 16-oz containers or six 32-oz containers of four brands of strawberries were purchased in May 2005 and delivered on the same day to the laboratory for analysis.

(Response) We agree with the changes recommended by CSC. We have evaluated the CSC nutrient data, combined those data with the data USDA submitted in response to the 2002 proposed rule, and conducted weighted compliance calculations based on 95 percent intervals (Ref. 12). The resulting nutrition labeling value for sugars is 8 g (from 6 g) and for calcium and iron is 2 percent DV (from 0 percent DV). Table 1 of this document includes changes in nutrition labeling values for strawberries, and Appendix C to part 101 provides the listing of all values.

g. Potato.

(Comment 26) The U.S. Potato Board (USPB) commented, in response to the 2002 proposed rule, that the 2000 market basket data that Ketchum (a public relations firm) submitted to FDA on their behalf and that FDA used in proposing to update the nutrition labeling values for potatoes in the 2002 proposed rule should not be used because the data contain inaccuracies due to unusually high moisture content and did not represent the average potato that a consumer would eat. USPB recommended that FDA use the preliminary data that USDA submitted in response to the 2002 proposed rule, as those data were more in line with the nutrition labeling values for potato. USPB also noted that the data in the current USDA SR are more appropriate for labeling purposes

than the data that they submitted and that we used in the 2002 proposed rule. USPB also, in response to the 2005 reopening of the comment period, requested that FDA retain the current nutrition labeling and not use the values that FDA published in the 2005 reopening of the comment period document, which were derived from the new data that USDA submitted in response to the 2002 proposed rule. USPB said they saw no compelling reason to have one set of data negatively impact a nutrition label that has been acceptable to FDA for the past 10 years.

(Response) We disagree with the comment. We have determined that the Produce Marketing Association nutrient data we used to support the nutrition labeling values for potato in the 1996 final rule were based upon nutrient data analyzed in 1983 and 1984 and are not likely to be valid because they are outdated. In the 2005 reopening of the comment period, we used new nutrient data for four types of potatoes that USDA submitted in response to the 2002 proposed rule, and conducted compliance calculations based on 95 percent prediction intervals to determine nutrition labeling values (Ref. 13). Having received no additional nutrient data for potato, we are using these nutrition labeling values in Appendix C to part 101 to replace the nutrient data that are more than 20 years old.

### 3. Changes to Nutrition Labeling Values Based Upon Reassessment of 95 Percent Prediction Intervals

As indicated in section II.K.1.a of this final rule, upon completion of all statistical analyses to calculate compliance calculations based on 95 percent prediction intervals (Refs. 7 through 19), we reviewed all nutrient data for all foods to determine if the 95 percent predicted value fell within the range of the interval of all raw data points for each nutrient and food. If the nutrient level derived from the 95 percent prediction interval was selected as the more appropriate nutrient value (versus the mean), and that level fell within the interval of all raw data points, then we determined it would be a reasonable choice to represent the nutrient for the raw food. However, if the nutrient level based on the 95 percent prediction interval did not fall within the interval of all raw data points, we determined the mean would be a better estimate of the nutrient level for the raw food. As a result of the reassessment of all nutrient levels based on 95 percent prediction intervals, we updated the nutrient values for 11 of the raw fruits and 9 of the raw vegetables: Avocado (iron), banana (sodium, dietary fiber, vitamin A), cantaloupe (calcium), honeydew melon (calcium), lemon (dietary fiber), nectarine (dietary fiber), orange (vitamin A), pineapple (iron), plums (dietary fiber, iron), strawberries (calcium, iron), tangerine (sodium), broccoli (total carbohydrate, protein, iron), carrot (iron), celery (dietary fiber), cucumber (calories, total carbohydrate, protein), green onion (iron), mushrooms (sodium), onion (potassium, calcium), radishes (potassium), and tomato (sodium). These changes are listed among changes to nutrition labeling values in table 1 of this document.

### 4. Summary of Changes for Fruits and Vegetables

Table 1 of this document shows a summary of the changes from the nutrition labeling values for 25 raw fruits and vegetables for this final rule versus those published in the 2005 reopening of the comment period.

## L. Nutrition Labeling of Raw Fish

For the 2002 proposed rule, we obtained new data from USDA NNDB for cooked Atlantic salmon and rainbow trout and for the following raw fish: Catfish (only on fat content), flounder/sole, orange roughy, coho and sockeye salmon, shrimp, swordfish, tilapia, and tuna. We also obtained new information on the cooking yield for mollusks, discovered a slight error in the raw weight used to calculate the nutrient values for finfish and crustaceans, and obtained new data on nutrient retention factors. Therefore, in addition to updating the nutrient values based on new data, we reanalyzed the data from USDA NNDB for the remaining fish and adjusted the nutrient values accordingly (Ref. 20).  
Chinook Salmon

(Comment 27) As indicated in section II.J.2 of this document, two comments recommended that FDA include Chinook salmon along with Atlantic, coho, and sockeye salmon and use USDA nutrient data to support nutrition labeling.

(Response) We obtained data for Chinook salmon (raw) from the USDA NNDB and added those data to the USDA NNDB data we already had for Atlantic salmon (cooked, farmed); coho salmon (raw, farmed); sockeye salmon (raw). We subjected the data to FDA compliance calculations where possible using 95 percent prediction intervals and used the data in deriving the nutrition labeling values for these fish (Ref. 20).

There were no changes in nutrition labeling values for fish in this final rule as compared with those in the 2005 reopening of the comment period. Appendix D to part 101 contains a comprehensive listing of all raw fish and all nutrients in the voluntary nutrition labeling program.

## M. Effective Date

(Comment 28) One comment opposed the proposed changes because they will result in unnecessary reprinting costs to industry and those producing nutrition education materials.

(Response) FDA periodically establishes, by final rule in the Federal Register, uniform effective dates for compliance with food labeling regulations (see, e.g., the Federal Register of December 23, 1998 (63 FR 71015)). This final rule will become effective in accordance with the uniform effective date for compliance with food labeling requirements, which is January 1, 2008. However, we will not object to voluntary compliance immediately upon publication of the final rule. We

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believe that the effective date should allow industry and nutrition educators adequate time to update nutrition labeling information.

## III. Final Regulatory Impact Analysis

FDA has examined the impacts of the 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, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

Option 1 of this document is for no new regulatory action, and provides the baseline with which all other options are compared. Option 2 of this document is for the provision of updated nutrition information based on the current data and methodology for computation.

#### Option 1: No New Regulatory Action

There would be no costs or benefits if no new regulatory action were taken to update the nutrition information for the 20 most frequently consumed raw fruits, vegetables, and fish.

#### Option 2: Costs of Updated Guidelines

We anticipate, as a result of these guidelines, that some firms will expend resources to redesign signs near produce items at retail outlets. These expenditures will be voluntary, and we assume that no firms will make them if they do not judge that it is in their best interests to do so. These are considered in this analysis in order to quantify the extent to which nutrition updates likely influence resource expenditures.

While there were no comments on the estimate costs in the proposed guidelines, we used 2003 County Business Pattern (CBP) data (Ref. 21) collected by the U.S. Census Bureau to update estimates of the number of firms that will voluntarily change signs because of these guidelines. There are approximately 67,000 supermarkets under the North American Industry Classification System (NAICS) code 44511, approximately 2,000 fish and seafood markets under NAICS 44522, approximately 3,000 fruits and vegetables markets under NAICS 44523, and approximately 15,000 other specialty markets under NAICS 44529. We assume that many of the markets in NAICS codes 44522, 44523, and 44529 have annual sales of less than \$500,000 and therefore have been exempted by Congress from coverage by these guidelines. We use the number of supermarkets in NAICS 44511 as a low estimate of the number of establishments under consideration, and all establishments in NAICS codes 44522, 44523, and 44529 as well as 44511 as an upper bound. Based on the most recent survey of adoption of our guidelines, we assume that 72 percent of establishments (between 48,000 and 63,000 establishments) will continue to choose to follow these guidelines.

We estimated the total voluntary expenditures using the revised number of establishments, and the assumptions of expenditure per establishment. Consistent with the methodology used in the 2002 proposed rule, we assume a normal cycle for retailers to redesign their labels to be once every 3 years, and that one-half of the 48,000 to 68,000 stores would redesign after the third year following publication of these guidelines. The updating cost expenditures for a partial redesign, incurred in the first and second years, are assumed to be \$50 per store, and the updating costs of a full redesign, incurred in the third year, are assumed to be \$100 per store. Table 2 of this document shows these assumptions and estimates. We compute the present value of total expenditures for each year using both a 7 percent and 3 percent discount rate. The present value of the total of voluntary expenditures is between \$3,257,000 for the low estimate assuming a 7 percent discount rate, and \$4,593,000 for the high assuming a 3 percent discount rate (i.e., the sum of the present values of the expenditures

in rows (e) and (f) of table 2 of this document for 2006, 2007, and 2008).

Table 2.--Adoption Schedule and

## Voluntary Expenditures

Schedule and Voluntary Expenditures		Adoption
(a) Adoption Year		2006
2007	2008	
(b) Number of Stores 12,000 to 16,000	24,000 to 32,000	12,000 to 16,000
(c) Expenditures per Store \$50	\$100	\$50
(d) Total Expenditures \$600,000 to \$800,000	\$2,400,000 to \$3,200,000	\$600,000 to \$800,000
(e) Present Value (assuming a 7% discount rate) \$561,000 to \$736,000	\$2,096,000 to \$2,800,000	\$600,000 to \$800,000
(f) Present Value (assuming a 3% discount rate) \$582,000 to \$761,000	\$2,262,000 to \$2,970,000	\$600,000 to \$800,000

## Option 2: Benefits of the Updated Guidelines

The benefits from updating nutrition information on the 20 most frequently consumed raw fruits, vegetables, and fish derive from maintaining the accuracy of the information over the long term, and giving consumers current information to use in making healthful dietary choices. The larger the difference between the updated information and the current information, the more likely that consumption behavior will change if consumers are aware of the changes made in this final rule. A greater change in behavior is likely to provide greater potential for improved dietary choices.

The potential for this particular update to improve dietary choices is likely to be small since modest changes in the nutrient profile of a food are likely to have a small influence on the demand for that food. Table 3 of this document summarizes the extent of changes in foods and the nutrient profiles in the proposed and final rules.

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Table 3.--Changes to Guidelines in

Proposed Rule and Final Rule

Proposed Rule\1\		Changes to Guidelines in Final Rule\2\	
		Fruits and Vegetables	
Fish		Fruits and Vegetables	
No. of foods with changes			21
21		20	
No. of nutrients with changes			40
107		38	

\1\Computed from values in tables 1 and 2 of the 2002 proposed rule.

\2\Computed from the values in this final rule.

The substantial changes made in this final rule to the current nutrition information indicate the importance of updates in nutrition information. We proposed changes for approximately one-half of all of the most frequently consumed varieties of fruits, vegetables, and fish, with an average number of revisions to nutrient information per food item of approximately two for fruits and vegetables (i.e., 40 nutrients / 21 whole food items) and approximately five for fish (i.e., 107 nutrients / 21 whole food items). The guidelines in this final rule contain additional revisions for one-half of all of the most frequently consumed fruits and vegetables, with an average of approximately 2 revised nutrients per revised food item (i.e., 38 nutrients / 20 whole food items).

Consumers may use this updated information in making their dietary choices. If they use it, the updated information will allow them to be more effective at achieving the results that they intend than if they were using outdated information. We are not able to quantify the benefit that having this updated information will provide.

Because only substantial compliance with these guidelines is mandated by the statute, aggregate costs may be less than would occur if they were mandatory for all establishments. Moreover, confusion on the part of consumers may arise during the transition period as retail stores adopt these guidelines at different times. Confusion may arise, for example, if one store displayed an updated set of nutrient values while another store displayed an out-dated set of nutrient values for otherwise identical raw fruits, vegetables, or fish. Any such confusion will reduce the benefit of updating the values in these guidelines.

As discussed previously in this document, the unquantified benefits

of providing accurate information for consumers to use in making their dietary choices are believed to outweigh the costs associated with this rule.

#### IV. Final Regulatory Flexibility Analysis

FDA has examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601-612). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Although many of the estimated 48,000 to 63,000 stores that may choose to update their nutrition displays are small entities, because these guidelines are voluntary, no small entity would be required to display the information set forth here. Consequently, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

#### V. Unfunded Mandates

FDA has examined the impacts of the final rule under the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, that includes any ``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 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

#### VI. Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)

SBREFA (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is not a major rule for the purpose of congressional review.

#### VII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collection of information. Therefore clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

#### VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant

effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ``construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a)(4) of the act provides that ``no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce-- \* \* \* (4) any requirement for the voluntary nutrition labeling of food that is not identical to the requirement of section 403(q).''

Currently, this provision operates to preempt States from imposing nutrition labeling requirements for raw fruits, vegetables, and fish because no such requirement had been imposed by FDA

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under section 403(q) of the act. This final rule amends existing food labeling regulations by updating the names and the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States and by revising the guidelines for further clarity and consistency. Although this rule would have a preemptive effect, in that it would preclude States from issuing any nutrition labeling requirements for raw fruits, vegetables, and fish that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties.

FDA believes that the preemptive effect of the final rule would be consistent with Executive Order 13132. Section 4(e) of the Executive Order provides that ``when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the Federal Register of March 20, 2002 (67 FR 12918), and the reopening of the comment period on April 4, 2005 (70 FR 16995). FDA received no comments from any States on the proposed rulemaking.

In addition, on May 16, 2006, FDA's Division of Federal and State Relations provided notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel of

FDA's intended final rule to update the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish. The notice provided the States with further opportunity for input on the rule. It advised the States of the publication of the final rule and encouraged State and local governments to review the notice and to provide any comments to the docket (Docket No. 2001N-0548) by June 28, 2006, or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the above numbered docket.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

## X. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. U.S. Department of Agriculture, Agricultural Research Service, USDA Nutrient Database for Standard Reference, Release 18, 2005. Available on the Internet at USDA's Nutrient Data Laboratory Home Page, [http://www.ars.usda.gov/main/site\\_main.htm?modecode=12354500](http://www.ars.usda.gov/main/site_main.htm?modecode=12354500)

2. U.S. Department of Agriculture, National Nutrient Data Bank, maintained at the Nutrient Data Laboratory, Agricultural Research Service, Beltsville Human Nutrition Research Center, Beltsville, MD.

3. Bender, M. M., J. I. Rader, and F. D. McClure, ``Guidance for Industry, FDA Nutrition Labeling Manual--A Guide for Developing and Using Databases,' ' Center for Food Safety and Applied Nutrition, FDA, 1998. Available on the Internet at <http://vm.cfsan.fda.gov/dms/nutrguid.html>

4. U.S. Department of Health and Human Services and U.S. Department of Agriculture, Dietary Guidelines for Americans, 2005, 6th ed. Washington DC: U.S. Government Printing Office, January, 2005. Available on the Internet at <http://www.healthierus.gov/dietaryguidelines/>

5. Retail Diagnostics, Inc., Food and Drug Administration Nutrition Labeling Information Study December 1996, Oradell, NJ, March 10, 1997.

6. Brandt, M. M. ``Documentation for the Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish,' ' Center for Food Safety and Applied Nutrition, FDA, January 2006.

7. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Apples from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data

Laboratory (NDL) Data and U.S. Apple Association Data for Raw Red Delicious, Golden Delicious, Granny Smith, Gala, and Fuji Apples by Weighting by Market Share,' Center for Food Safety and Applied Nutrition, FDA, 2006.

8. O'Neill, K. R., ``Statistical Derivation of Raw Avocado Nutrition Label for Appendix C to Part 101: Nutrition Facts for Raw Fruits and Vegetables,' Center for Food Safety and Applied Nutrition, FDA, 2005.

9. O'Neill, K. R., ``Statistical Derivation of Nutrition Labels for Raw Banana, Raw Cantaloupe, Raw Sweet Cherries, Raw Honeydew Melon, and Raw Watermelon from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data under the Assumption of Simple Random Sample (SRS),' Center for Food Safety and Applied Nutrition, FDA, 2005.

10. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Kiwifruit from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) and 2005 Food Research Institute, Inc. (FRI) Data Weighted by Variability,' Center for Food Safety and Applied Nutrition, FDA, 2005.

11. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Pears from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data for Raw Bartlett, Bosc, Red Anjou, and Green Anjou Pears by Weighting by Market Share,' Center for Food Safety and Applied Nutrition, FDA, 2005.

12. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Strawberries from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) and 1999-2000 California Strawberry Commission (CSC) Data Weighted by Variability,' Center for Food Safety and Applied Nutrition, FDA, 2005.

13. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Potatoes from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data for Raw Russet, White, and Red Potatoes by Weighting by Market Share,' Center for Food Safety and Applied Nutrition, FDA, 2005.

14. O'Neill, K. R., ``Statistical Derivation of Nutrition Labels for Raw Broccoli, Raw Carrots, Raw Celery, Raw Cucumber, Raw Green Pepper, Raw Iceberg Lettuce, Raw White Mushrooms, Raw Yellow Onions, Raw Radishes, Raw Sweet Potatoes, and Raw Tomatoes Derived from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data under the Assumption of Simple Random Sample (SRS),' Center for Food Safety and Applied Nutrition, FDA, 2005.

15. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Yellow Nectarines, Raw Yellow Peaches, and Raw Plums from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data and 1999-2000 California Tree Fruit Agreement (CTFA) Data Weighted by Variability,' Center for Food Safety and Applied Nutrition, FDA, 2005.

16. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Pineapples from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data by Weighting by Market Share,'' Center for Food Safety and Applied Nutrition, FDA, 2005.

17. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Leaf Lettuce from 2001-2002 United States Department of Agriculture (USDA) Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) Data for Raw Red and Green Leaf Lettuce Weighted by Variability,'' Center for

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Food Safety and Applied Nutrition, FDA, 2005.

18. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Lemons and Tangerines from 1989-1991 Produce Marketing Association (PMA) and 1998 Citrus Research Board (CRB) Data under the Assumption of Simple Random Sample (SRS),'' Center for Food Safety and Applied Nutrition, FDA, 2005.

19. O'Neill, K. R., ``Statistical Derivation of Nutrition Label for Raw Red Grapefruit and Naval and Valencia Oranges from 2001-2002 United States Department of Agriculture (USDA) and 1998 Citrus Research Board (CRB) Data under the Assumption of Simple Random Sample (SRS),'' Center for Food Safety and Applied Nutrition, FDA, 2005.

20. O'Neill, K. R., ``Statistical Derivation of Nutrition Labeling from USDA Data for Appendix D to Part 101: Nutrition Facts for Cooked Seafood,'' Center for Food Safety and Applied Nutrition, FDA, 2005.

21. U.S. Census Bureau, 2002 Economic Census, American FactFinder, Geographic Area Series: Summary Statistics. Available on the Internet at [http://factfinder.census.gov/home/saff/main.html?\\_lang=en](http://factfinder.census.gov/home/saff/main.html?_lang=en)

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

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

PART 101--FOOD LABELING

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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; 42 U.S.C. 243, 264, 271.

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## 2. Section 101.44 is revised to read as follows:

Sec. 101.44 What are the 20 most frequently consumed raw fruits, vegetables, and fish in the United States?

(a) The 20 most frequently consumed raw fruits are: Apple, avocado (California), banana, cantaloupe, grapefruit, grapes, honeydew melon, kiwifruit, lemon, lime, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, tangerine, and watermelon.

(b) The 20 most frequently consumed raw vegetables are: Asparagus, bell pepper, broccoli, carrot, cauliflower, celery, cucumber, green (snap) beans, green cabbage, green onion, iceberg lettuce, leaf lettuce, mushrooms, onion, potato, radishes, summer squash, sweet corn, sweet potato, and tomato.

(c) The 20 most frequently consumed raw fish are: Blue crab, catfish, clams, cod, flounder/sole, haddock, halibut, lobster, ocean perch, orange roughy, oysters, pollock, rainbow trout, rockfish, salmon (Atlantic/coho/Chinook/sockeye, chum/pink), scallops, shrimp, swordfish, tilapia, and tuna.

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## 3. Amend Sec. 101.45 by revising paragraph (a)(3)(iii) and adding paragraph (a)(3)(iv) to read as follows:

Sec. 101.45 What are the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish?

(a) \* \* \*

(3) \* \* \*

(iii) When retailers provide nutrition labeling information for more than one raw fruit or vegetable on signs or posters or in brochures, notebooks, or leaflets, the listings for saturated fat, trans fat, and cholesterol may be omitted from the charts or individual nutrition labels if a footnote states that most fruits and vegetables provide negligible amounts of these nutrients, but that avocados contain 0.5 gram (g) of saturated fat per ounce (e.g., ``Most fruits and vegetables provide negligible amounts of saturated fat, trans fat, and cholesterol; avocados provide 0.5 g of saturated fat per ounce''). The footnote also may contain information about the polyunsaturated and monounsaturated fat content of avocados.

(iv) When retailers provide nutrition labeling information for more than one raw fish on signs or posters or in brochures, notebooks, or leaflets, the listings for trans fat, dietary fiber, and sugars may be omitted from the charts or individual nutrition labels if the following footnote is used, ``Fish provide negligible amounts of trans fat, dietary fiber, and sugars.''

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## 4. Appendices C and D to part 101 are revised to read as follows:

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[GRAPHIC] [TIFF OMITTED] TR25JY06.009

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[GRAPHIC] [TIFF OMITTED] TR25JY06.010

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[GRAPHIC] [TIFF OMITTED] TR25JY06.011

Dated: July 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-6436 Filed 7-24-06; 8:45 am]

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