DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94N–0155]

RIN 0910–AA19

Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed; and Policy for Data Base Review for Voluntary and Mandatory Nutrition Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the guidelines for voluntary nutrition labeling of raw fruits, vegetables, and fish and revising the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish. This action is in response to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and will make the voluntary nutrition labeling program (hereinafter referred to as the voluntary program) more consistent with mandatory nutrition labeling of other foods regulated by FDA. The agency is also setting out its policy on its review of data bases in both the voluntary and mandatory nutrition labeling programs.

EFFECTIVE DATE: August 18, 1997.

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SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the 1990 amendments (Pub. L. 101–535), FDA published final regulations in the Federal Register of November 27, 1991 (56 FR 60880, and corrected at 57 FR 8174, March 6, 1992), that: (1) Identified the 20 most frequently consumed raw fruits, vegetables, and fish in the United States; (2) established guidelines for the voluntary nutrition labeling of these foods; and (3) set out the criteria for substantial compliance by food retailers with the guidelines for the voluntary nutrition labeling of these foods.

FDA stated in § 101.45(i) (21 CFR 101.45(i)) that it would publish and provide an opportunity for comment on updates of the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish (or a notice that nutrition labeling values have not changed from the previous publication) at least every 2 years. In the preamble to the voluntary nutrition labeling final rule (56 FR 60880 at 60881), FDA advised that once final regulations governing nutrition labeling of processed, packaged foods (except for those foods subject to regulation by the U.S. Department of Agriculture (USDA)) were finalized, it would revise the guidelines for the voluntary program to make them as consistent as possible with those final rules. FDA published the final regulations implementing the 1990 amendments in the Federal Register of January 6, 1993, including regulations on mandatory nutrition labeling of processed, packaged foods (58 FR 2079); reference daily intakes and daily reference values (58 FR 2206); and serving sizes (58 FR 2229). FDA made technical changes in these final rules on August 18, 1993 (58 FR 44020).

FDA published a proposal in the Federal Register of July 18, 1994 (59 FR 36379) (hereinafter referred to as the July 1994 proposal), and a correction notice in the Federal Register of July 21, 1994 (59 FR 37190), to update the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish and to revise the guidelines for the voluntary nutrition labeling of these foods to reflect the January 6, 1993, final rules as modified. Interested persons were given until September 16, 1994, to comment. In the Federal Register of October 17, 1994 (59 FR 52275), FDA reopened the comment period until November 16, 1994, in response to several requests for an extension of the comment period.

FDA received 29 responses to the July 1994 proposal, each of which contained one or more comments. The comments generally supported the July 1994 proposal. A number of comments suggested modification and revision in various provisions of the July 1994 proposal. A summary of the suggested changes and the agency's responses follows.

One comment suggested changes in the definition of ''substantial compliance'' in § 101.43(c) (21 CFR 101.43(c)) and in the study design for the required biennial surveys specified in § 101.43(b) to allow for separate levels of substantial compliance for large and small stores.

FDA did not raise this issue in the July 1994 proposal. It is therefore outside the scope of this rulemaking. Persons interested in this issue may petition the agency in accordance with 21 CFR 10.30.

II. Compliance by Food Retailers

A. Good-Faith Effort/Flexibility

1. One comment encouraged FDA to continue to permit flexibility in providing information to consumers. The comment stated that the most appropriate way for retailers to provide information is dependent on in-store space requirements as well as specific needs of consumers and grocers. The comment stated that the continually changing rules of the voluntary program distort compliance efforts and asked that FDA consider the industry's efforts to comply with ever-changing rules and to adopt a ''good faith effort'' approach in determining substantial compliance. The comment stated that retailers are waiting for the revised nutrition labeling values, that supplies of posters and brochures that display the old nutrition labeling values have dwindled, and that new stores may be unable to obtain display information until sometime after the final rule issues with the new values.

FDA used a good faith effort approach in the survey conducted in November and December 1994 by finding retailers to be in compliance with the guidelines if they followed the November 27, 1991, regulations or used the nutrition labeling values proposed in the July 1994 proposal (59 FR 36379 at 36388 and as corrected at 59 FR 37190).

These final regulations grant retailers flexibility in disseminating the nutrition labeling information to consumers through various means and materials. The regulations allow for the information to be presented in a variety of ways (shelf labels, signs, posters, brochures, notebooks, or leaflets) (§ 101.45(a)(1) (21 CFR 101.45(a)(1))) and provide guidance for retailers who choose to use a chart format (§ 101.45(a)(3)) and for those who use an individual label format (§ 101.45(a)(4)).

In addition, § 101.43(a) recognizes that signs providing nutrition information may be lost or damaged. Thus the regulation provides that retailers will be considered to be in compliance if they provide consumers with at least 90 percent of the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish. Further, § 101.43(a) states that retailers need only provide data for items among those most frequently consumed that are sold in their stores. They need not have nutrition information on items not sold in their stores.

Although the comment refers to ''continuously changing rules,'' the agency does not foresee any additional major changes to the voluntary program

except for the updating of the nutrition labeling values of the most frequently consumed foods. The changes that FDA is making at this time to the guidelines for the voluntary program are primarily to make them as consistent as possible with the January 6, 1993, mandatory nutrition labeling regulations for processed, packaged foods.

B. Use of FDA Data for Compliance

FDA proposed in § 101.43(a)(3) and § 101.45(b) that for retailers to be in compliance with the voluntary program, they must provide customers with the nutrition labeling values developed by FDA in Appendices C and D to part 101 (21 CFR part 101) (except that information on potassium is voluntary). FDA stated that its tentative view was that use of these values will ensure consistency of values among retail stores and thus prevent consumer confusion.

2. One comment supported retailer use of data provided by FDA. Another comment supported the continued revisions to labeling values to reflect newer data and changes in labeling to be consistent with labeling of other foods. This comment endorsed providing consumers with the most accurate and complete information in a consistent format to alleviate customer confusion. However, another comment stated that the proposed requirement that FDA's values be used for the voluntary program was too restrictive. The comment supported the use of more cost-effective, realistic, and workable standards in nutrition labeling and suggested using food composition data from USDA to provide as much information to consumers as possible. The comment said that no one would argue that USDA's data are inaccurate and said that FDA's nutrition labeling regulations are based on food consumption surveys conducted by USDA.

FDA finds that its provision to retailers of the nutrition labeling values for the voluntary program is the most cost-effective method to transmit this information to consumers, and that this method promotes consistency in the information received by consumers. Retailers will incur no costs relating to sampling design, collection procedures, laboratory analysis, or statistical evaluation of data. The costs that will be incurred by retailers participating in the voluntary program will be limited to the purchase or development of the charts, brochures, or other materials for consumer use.

FDA does not agree that mean values from USDA data bases are appropriate for nutrition labeling. The nutrition labeling regulations in § 101.9 (g)(4) and (g)(5) state that FDA will consider a product misbranded if analyzed nutrient levels for naturally occurring vitamins, minerals, protein, total carbohydrate, polyunsaturated fat, monounsaturated fat, and potassium are not at least equal to 80 percent of the value declared on the label, and if analyzed nutrient levels for calories, sugars, total fat, saturated fat, cholesterol, and sodium are more than 20 percent in excess of the value declared on the label. To meet these requirements, the agency encourages manufacturers to use FDA compliance calculations to determine the nutrition labeling values for their products (Ref. 1). Use of mean values (such as those from USDA data bases) for nutrition labeling, as suggested by the comment, is less likely to assure manufacturers of being in compliance with FDA's regulations.

Some of the USDA's food composition data are not truly representative because they are based on small sample sizes or do not take into account specific variables, such as geographic area. Thus, mean food composition values available in various USDA publications are, generally, not suitable for labeling purposes.

FDA has provided nutrition labeling values for the most frequently consumed raw fruits, vegetables, and fish in Appendices C and D. The agency did obtain data for some of these foods from the USDA National Nutrient Databank and other USDA sources. However, where possible, FDA applied compliance calculations to the data obtained from USDA (as well as other data sources) and used the resulting, adjusted values.

It is true, as the comment states, that FDA used information from USDA food consumption surveys to establish reference amounts customarily consumed in § 101.12 (quantities of foods commonly consumed per eating occasions) for use by manufacturers in determining serving sizes for nutrition labeling. However, FDA does not agree with the comment that the use of USDA food consumption data by FDA for that purpose necessitates FDA's use of USDA food composition data for purposes of nutrition labeling if those data are not adequate for those purposes. Based on the foregoing, having fully considered the comments, FDA has adopted §§ 101.43(a)(3) and 101.45(b) as proposed.

III. The 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish

A. Plural Versus Singular Food Names

3. One comment requested latitude in the use of plural versus singular names for fruits and vegetables (e.g., peach versus peaches). The comment stated that FDA was not consistent in the use of plural and singular food names and asked for clarification.

In the July 1994 proposal, FDA used singular food names if the serving was one whole unit (e.g., apple, banana) or part of a whole unit (e.g., salmon, watermelon, avocado) and plural food names if the serving was more than one unit (e.g., grapes, strawberries, green peas, scallops). FDA requests that retailers (and trade associations that provide nutrition labeling information to retailers) use the plural and singular designations for food names for raw fruits, vegetables, and fish provided by FDA in Appendices C and D to part 101 when they provide nutrition labeling information to consumers. However, the agency does not consider the use of singular or plural names to be an issue for the biennial compliance surveys. Noncompliance of a retailer will be judged as failure to provide the nutrition labeling values as specified in this final rule.

B. Food Names

4. One comment requested name changes for three foods. The comment wanted ''lettuce'' to be called ''iceberg lettuce,'' ''sweet cherries'' to be called ''cherries,'' and ''honeydew melon'' to be called ''honeydew.''

FDA notes that ''lettuce'' is specified as ''iceberg lettuce'' in § 101.44(b) and in Appendix C to part 101. FDA mistakenly used the more general term ''lettuce'' in referring to this food in Appendix C of the July 1994 proposal. FDA is not convinced that consumers would be served by changing the name ''sweet cherries'' to ''cherries'' or ''honeydew melon'' to ''honeydew.'' Use of these alternate names for sweet cherries and honeydew melon by retailers will not, however, result in a finding of noncompliance.

C. Changes to the 20 Most Frequently Consumed Fish

FDA received no comments about its proposed changes to the list of the 20 most frequently consumed fish. Therefore, the proposed changes to the fish list (i.e., to list flounder and sole as one entry, to have three subgroups for salmon, and to add swordfish) have been incorporated in § 101.44(c) and Appendix D to part 101.

IV. Presentation of the Nutrition Labeling Values

The July 1994 proposal was designed to make the guidelines for the voluntary program more consistent with the January 6, 1993, nutrition labeling regulations in terms of what information is required (content), and how that information is to be presented (format). The proposed guidelines would allow the information to be presented in a chart format (§ 101.45(a)(3)) as well as in an individual label format (§ 101.45(a)(4)) that is similar to that used for processed, packaged foods.

There was general support among the comments for the proposed content and format for the nutrition labeling of raw fruits, vegetables, and fish. In particular, comments generally agreed that: (1) Labels on produce should be as consistent as possible with those on other foods; (2) saturated fat and cholesterol should be allowed to be listed in a footnote rather than in columns for produce; (3) the entire footnote for Daily Values (DV's) for two calorie levels should not be required to be listed on charts; and (4) if producers and packers label an individual product, they should comply with the format and other regulations that apply to packaged foods.

A. Optional Nutrients

5. One comment requested that the word ''required'' be omitted from proposed § 101.45(a)(2) because it provides that only ''required nutrients'' should be declared in accordance with § 101.9(c) and makes no provision for voluntary inclusion of information on other micronutrients. The comment stated that, as long as it is done accurately, vendors should be allowed to include information for any essential vitamin or mineral listed in § 101.9(c)(8)(iv), not only the required nutrients, to the same extent that they are allowed to do so for the same products in processed form. The comment stated that removing the word ''required'' would allow for the listing of beta-carotene under vitamin A (see § 101.9(c)(8)(vi)), and that fruits and vegetables are a good source of this nutrient.

Two other comments requested that FDA address the use of optional nutrients in the voluntary program. They stated that information about optional nutrients is allowed on processed foods, and that they strongly supported the declaration of optional nutrients as part of the voluntary program. Another comment requested that FDA permit inclusion of data on the vitamin B–6 content of bananas because bananas are an excellent source of this nutrient. The comment stated that inadequate dietary intake of vitamin B–6 is a potential public health issue, and that inclusion of vitamin B–6 on the nutrition label will serve an important public health function.

FDA is persuaded by these comments that providing information on optional nutrients for foods in the voluntary program will be useful. Thus, FDA is providing for the declaration of information on optional nutrients for raw fruits, vegetables, and fish, particularly on labels for individual foods (e.g., on signs, brochures, or food packages). Declarations of optional nutrients included on individual labels should follow the requirements under § 101.9(c). Therefore, FDA is removing the word ''required'' in § 101.45(a)(2), as suggested by the comment.

However, FDA is concerned about the size and readability of charts if they provide information on optional nutrients.

Including optional nutrients on charts will require extra columns and thus make the charts larger. Some comments (discussed in section IV.D. of this document) expressed concern that charts carrying only the required information are too large and unreadable. Therefore, FDA urges retailers to carefully consider the consequences of including optional nutrients in charts.

If optional nutrients are included on charts (see § 101.45(a)(3)), retailers should provide values for the nutrients for all foods and not leave blanks for some foods. FDA fears that consumers might interpret blanks for optional nutrients in charts as zeros. Alternatively, information can be provided on optional nutrients in a footnote outside the column format of the chart (e.g., ''bananas contain 35% of the DV for vitamin B–6'').

B. Use of Individual Labels on Posters

6. One comment stated that posters with horizontal and vertical lines are difficult for consumers to read and provided an alternative poster with 40 individual produce nutrition labels. The comment asked whether the exceptions for chart format posters apply to other poster formats.

In proposed § 101.45(a)(3), FDA stated that when nutrition labeling information is provided for raw fruits, vegetables, and fish on signs, posters, brochures, notebooks, or leaflets, it may be presented in charts in horizontal or vertical columns. This proposed provision would not have required the use of horizontal or vertical columns. However, to clarify that other formats may be used, FDA has modified § 101.45(a)(3) to provide for the optional use of a poster containing a compilation of individual nutrition labels. FDA has also modified the first sentence of § 101.45(a)(3) to clarify that it pertains to materials containing nutrition information for more than one raw fruit, vegetable, or fish, whereas § 101.45(a)(4) pertains to nutrition labeling for individual raw fruits, vegetables, or fish. The exceptions noted in § 101.45 (a)(3)(i) through (a)(3)(iii) for labeling materials containing nutrition information on more than one item will apply to all such materials, i.e., signs, posters, brochures, notebooks, or leaflets.

C. Use of Linear Formats

7. FDA proposed in § 101.45(a)(3) to not permit the use of linear formats in the voluntary program. One comment opposed this restriction. The comment encouraged FDA to find retailers in compliance even if nutrition information is provided in a different format from those specified in § 101.45 and stated that flexibility and creativity should be encouraged. The comment said that alternate formats may be preferable to reach specific populations. The comment stated that the linear format can achieve the desired results as well as the columnar format, and that the retailer should be granted the flexibility to determine what format best suits the needs of its customers. The comment stated that the other labeling requirements regarding highlighting, type size, and other format elements will ensure that the information displayed in a linear format will be visible and readable.

FDA is not persuaded that the linear format (i.e., display) would be useful for providing voluntary nutrition labeling. A linear display is not particularly easy to read, and the difficulties would be exacerbated on posters that a consumer may have to read from a distance. Under § 101.9(j)(13)(ii), linear displays can only be used to present the nutrition label if the food package has less than 40 square inches of space available to bear labeling, and the package shape and size cannot accommodate a standard vertical or tabular display. Posters, brochures, and other means for providing nutrition information under § 101.45(a)(3) are not limited in size and therefore do not meet these criteria. Thus, FDA has retained the restriction on the use of linear displays in § 101.45(a)(3). At the same time, however, the agency modified § 101.45(a)(3) to change ''linear format'' to ''linear display'' to use terminology

consistent with § 101.9(j)(13)(ii)(A)(*2*) and to cross-reference that section.

Linear displays are not precluded under § 101.45(a)(4) for individual labels as long as the labels meet the criteria in § 101.9(j)(13)(ii).

D. Use of Abbreviated Charts

To make the charts containing the nutrition labeling values for raw fruits, vegetables, and fish more readable, FDA proposed in § 101.45(a)(3)(ii) that the full footnote required in § 101.9(d)(9)(i), which lists the DV for six nutrients for two calorie levels, not be required. Because no comments opposed this action, § 101.45(a)(3)(ii) is included in the final rule as proposed.

FDA proposed in § 101.45(a)(3)(iii) to provide the option of omitting the columns for saturated fat and cholesterol for fruits and vegetables, omitting the columns for sugars and fiber for fish, and instead providing the following footnotes: ''Most fruits and vegetables provide negligible amounts of saturated fat and cholesterol; avocados provide 1 gram (g) of saturated fat per ounce,'' and ''Fish provide negligible amounts of dietary fiber and sugars.'' FDA proposed these footnotes to reduce the size of the charts on which nutrition information is presented (to make them more readable) without reducing the amount of information provided to consumers.

8. One comment requested that the portion of the footnote regarding the fat content of raw produce for the voluntary nutrition labeling chart (i.e., ''* * * avocados provide 1 g of saturated fat per ounce'') be changed to ''* * * avocados provide 1 g of saturated fat, 1 g of polyunsaturated fat, and 3 grams of monounsaturated fat per ounce.'' The comment said that this additional information about avocados will be useful for consumers, especially diabetics, because the new diabetes guidelines recommend increasing consumption of monounsaturated fatty acids.

Because information on polyunsaturated and monounsaturated fat may be provided on processed foods, FDA has decided to revise § 101.45(a)(3)(iii) to permit the inclusion of information about the level of these nutrients in avocados (as suggested by the comment) on an optional basis by retailers. To provide the added flexibility, FDA revised § 101.45(a)(3)(iii) to make the subject footnote an example of an appropriate footnote, rather than the required footnote, and added a sentence stating that information about the polyunsaturated and monounsaturated fat content of avocados may be included. In addition, FDA clarified that if the listings of saturated fat and cholesterol are left off of charts or off of individual nutrition labels used on signs, posters, brochures, notebooks, or leaflets, the required information on saturated fat and cholesterol must be included in a footnote.

9. One comment stated that the new charts proposed by FDA will be less readable than the previous ones because there will be 22 columns instead of 10, and that much of the information is repetitious because there are dual listings (i.e., weight amounts and percent DV's) for some nutrients. The comment stated that the new charts will have too much information for consumers to handle. The comment stated that current signs are manageable, but that the new ones will require either smaller type (making it unreadable to consumers) or larger signs (which are impractical to hang). Further, the comment stated that the firm that submitted this comment planned to do away with signs and to use a manual and leaflets if the July 1994 proposal becomes final. The comment requested that FDA allow for the use of abbreviated charts as signs in produce and seafood departments if complete information (e.g., in manuals or leaflets) is available to consumers elsewhere in the store. It stated that a note on the chart could direct consumers to the more detailed information. The comment suggested that abbreviated charts for fruits and vegetables could omit calories from fat, cholesterol, and saturated fat and list only the percent DV's (and not weight amounts) for nutrients, and that for fish, such charts could omit sugars, dietary fiber, and potassium and list only the percent DV's for nutrients. The comment noted that declaration of percent DV's is the most important information on the nutrition label, as reflected in FDA's requirement that it be in bold face.

FDA acknowledges that the new charts containing nutrition labeling for raw produce and fish will contain more information, and thus require larger charts or smaller print, than the old charts. FDA has addressed, in part, the issue of the size of the charts by allowing for the omission of the columns for saturated fat and cholesterol for fruits and vegetables and the columns for dietary fiber and sugars for fish (§ 101.45(a)(3)(iii)). FDA does not feel that it is appropriate to omit the column for calories from fat for fruits and vegetables, as the comment suggests, because seven of these foods have values greater than zero for calories from fat. Information on calories from fat is important for consumers, and a footnote to the chart that specifies the number of calories from fat for seven fruits and vegetables would be lengthy and difficult to read.

In response to the suggestion that the column for potassium be included on the chart for fruits and vegetables but omitted from the chart for fish, FDA notes that the column for potassium is optional on both charts. However, FDA also notes that potassium provided by fish is as important as potassium provided by fruits and vegetables. Several comments agreed that information on potassium is important for consumers, and that it should be optionally provided.

Any inconsistency between abbreviated charts without columns listing the quantitative amounts by weight for nutrients for which percent DV's are declared, as suggested by the comment, and the nutrition labeling of processed, packaged foods could lead to consumer confusion. There was general agreement among the comments that nutrition labeling information for fruits, vegetables, and fish should be as consistent as possible with labeling provided for other foods. Additionally, the quantitative amounts by weight continue to be important to, and used by, many health professionals and consumers. For instance, the results of FDA's 1995 Health and Diet Survey showed that, among respondents who used the Nutrition Facts label to obtain nutrition information on a food product, a majority use the g and milligram (mg) amounts on the label solely or in combination with the percent DV's (69 percent). Few of the respondents in the survey used only the percent DV's (14 percent) (Ref. 4).

Because the size and readability of the charts are important issues, the agency encourages retailers and educators to experiment with various chart formats, to test and determine consumer responses to them, and to share the results of these studies with FDA. However, after considering the information needs of consumers and the comment's expressed concern about chart size, FDA concludes that the requirement that it is adopting strikes an appropriate balance between these potentially competing factors.

E. Nutrient Values on Individual Labels

FDA proposed in § 101.45(a)(4) that individual nutrition labels (e.g., over bins or on packaging) for raw fruits, vegetables, and fish provided by retailers meet the requirements of § 101.9(d). This proposed provision would have required that individual labels carry the full footnote set forth in § 101.9(d)(9), which provides

information about daily values for two calorie levels, rather than the abbreviated footnote permitted for the chart format under § 101.45(a)(3)(ii), unless the package is otherwise exempt under §§ 101.9(f) or 101.9(j)(13) from such a requirement.

10. Several comments disagreed with the need for the full footnote on individual labels provided by retailers above or close to food bins or containers. The comments stated that the modified label, without the lengthy DV's footnote, would be appropriate because of space and readability concerns. One comment stated that the sign could direct the consumer to a source of more complete information in the store. Another comment noted that short, modified labels are allowed on some processed foods and should be allowed for foods in the voluntary program.

FDA is persuaded by the comments that the footnote concerning nutrient requirements at two calorie levels could create concerns about space and readability for individual labels provided by retailers on signs that are over or near food bins or containers for raw fruits, vegetables, and fish. Therefore, FDA has added a sentence to § 101.45(a)(4) that reads, ''For individual labels provided by retailers on signs and posters, the footnote required in § 101.9(d)(9) may be shortened to 'Percent Daily Values are based on a 2,000 calorie diet.' '' The agency also notes that foods that qualify may use the simplified format (see § 101.9(f)). Thus, FDA has provided for the use ′of short, modified nutrition labels with individual raw fruits, vegetables, and fish.

F. Nutrition Labeling Values for a Particular Commodity

11. A commodity group asked whether the nutrition label that was developed and made available by the group in April 1993 could continue to be used on bags and boxes of that commodity.

As discussed in section II.B. of this document, to be in compliance with § 101.45(b) of the guidelines for the voluntary program, retailers must provide consumers with the nutrition labeling values provided by FDA in Appendices C and D to part 101 for the most frequently consumed raw fruits, vegetables, and fish. (As for the date when use of these values must begin, see section VI. of this document.) Individual nutrition labels used on raw fruits, vegetables, and fish that are packaged by a grower, producer, or shipper should provide the information listed in § 101.45(a)(4). If growers, producers, or shippers wish to provide individual nutrition labels on packaging materials for foods included in the voluntary program, they should use the labeling values provided by FDA.

However, if a nutrition label developed by a commodity group is for a specific genus or species, then a more specific name for the product should be used, as stated in § 101.45(c)(1), and the commodity group should have the data to support the labeling values used for the product. The nutrition labeling values in Appendices C and D to part 101 are for generic commodities. If a commodity group wishes to amend the nutrient values for a generic item, FDA encourages the group to submit the values to the agency as specified in § 101.45(b)(1) for consideration for inclusion in the agency's next revision of Appendices C and D. If upon review of the data, FDA decides to use the labeling values for the generic item, those values will be made available for public comment. Any nutrition labeling value for a generic item that the agency decides to incorporate into Appendix C or D will have to be used by retailers for them to be considered to be in compliance.

FDA is agreeable to having its labeling values used on bags of cut raw produce that qualify for the voluntary program (e.g., they have received no further processing or are not packaged with added ingredients such as salad dressing or croutons).

V. Timeframe for Updating Nutrient Values

12. FDA stated in the July 1994 proposal that the nutrition labeling values for the most frequently consumed raw fruits, vegetables, and fish would be revised every 2 years (proposed § 101.45(b)). Several comments thought that this timeframe was too short. One comment expressed concern about retailers keeping up with the 2-year revisions and stated that too frequent changes in the values will result in confusion in the marketplace. The comment stated that changes will require education of retail store operators, and that it is time-consuming and expensive for industry to prepare, obtain, and display new compliance materials. The comment stated that new materials cannot be adequately disseminated to the industry in less than 6 months and asked that FDA consider the administrative and economic burden imposed on the industry.

Four comments recommended updates every 4 years (every other compliance reporting period) rather than every 2 years. Reasons given for extending the time between revisions were: (1) To accommodate the time lag in relaying information to retailers and industry members; (2) to use up old packaging in stock; (3) difficulties for retailers, shippers, and packaging companies in changing packaging materials; (4) cost of printing educational materials; (5) the shelf life of educational materials, which is longer than 2 years; and (6) FDA's inability to complete revisions every 2 years. One comment stated that growers will choose not to put nutrition labeling information on bags of produce if the values are changed on a biennial basis.

FDA agrees that biennial updates of the nutrition labeling values as well as the list of the 20 most frequently consumed raw fruits, vegetables, and fish are difficult for both FDA and retailers, and that updates every 4 years are more reasonable and cost-effective. Accordingly, FDA has revised § 101.45(b) to state that, if necessary, revisions will be proposed every 4 years.

VI. Effective Date for Compliance

13. FDA proposed that any revision that is made in the voluntary program would be effective 30 days after publication of the final rule. A number of comments stated that this time period is too short for retailers and for growers, shippers, and packers. The comments stated that more time is needed to: (1) Finalize the updated charts and have retailers print and distribute their materials throughout their stores; (2) print labels and posters and devise new advertising campaigns; (3) order and receive new packaging; and (4) avoid inventory disposal costs and allow depletion, rather than destruction, of label inventory. Several comments stated that the short effective date would be an economic hardship for growers and shippers with nutrition labeling on packaging materials. Two comments recommended an extended effective date for growers and shippers who voluntarily label produce.

One comment requested that FDA expressly advise that any new nutrient values for raw fish will not have to be used by manufacturers in the nutrition labeling of retail-packaged, single-ingredient raw fish products until, at a minimum, 180 days after publication of the final rule. The comment stated that FDA focused on the effect of voluntary nutrition labeling in retail stores but did not consider manufacturers who use FDA values in nutrition labeling retail-packaged, single-ingredient products. The comment stated that manufacturers of packaged raw fish products must create new label plates, print labels,

package inventory, ship products bearing the new labels, and allow for transit and holding time if the product is exported to the United States.

Several comments noted that FDA allowed considerably more time (16 months and then 19 months as extended) in establishing the effective date for the labeling provisions of the 1990 amendments for processed foods and asked that the produce and fish industries be given more time. Comments requesting a longer time period suggested 4 months (one request), 6 months (one request), 1 year (four requests), 15 months (one request), and 18 months (one request).

FDA agrees that an effective date of 30 days after publication of the final rule is too short for retailers to get new nutrition labeling materials in place. Taking the various suggestions for extended time frames into consideration, FDA has set the effective date of this final rule to be 1 year from the date of publication in the Federal Register. Labeling values in Appendices C and D to part 101 may be and should be used at the retail level as soon as possible, beginning on the date of publication. However, because of the relatively short amount of time before the 1996 FDA Compliance Survey, FDA will consider either the old (1991) or new (1996) labeling values to be acceptable for retail stores to be considered to be in compliance with the voluntary program during the upcoming survey.

Likewise, growers, shippers, and packers who provide nutrition labeling on packages of raw fruits, vegetables, and fish will have 1 year to come into compliance with this document. While growers, shippers, and packers will not be assessed for compliance as a part of the 1996 FDA Compliance Survey for the voluntary program, they will need to be in compliance with § 101.9 (as modified by § 101.45(a)(4)). Accordingly, those who use the generic nutrient values in Appendix C or D to part 101 in nutrition labeling will have 1 year to update nutrient values on the food labels.

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

In the July 1994 proposal, FDA stated that the information that it used to arrive at the proposed nutrition labeling values for raw fruits, vegetables, and fish included data provided by the Produce Marketing Association (PMA), Nutrition Network (on behalf of the International Banana Association), and USDA (for fish and produce). FDA received a few comments in response to the July 1994 proposal that included additional data for some foods from other sources. PMA submitted new labeling values based upon their original raw data that were referenced in the proposal. FDA considered data from all sources and used those data, as appropriate, to calculate the labeling values set forth in this document in Appendices C and D to part 101. In these calculations, to the extent possible, FDA used the statistical methodology that it recommends in the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases'' (i.e., using compliance calculations based on 95 percent prediction intervals) (Ref. 1). Complete documentation for the nutrition labeling values for raw fruits, vegetables, and fish is found in Reference 5.

A. Fat Values for Raw Fruits and Vegetables

14. One comment requested that the fat content of all raw fruits and vegetables containing less than 1 g of fat be listed as zero g.

FDA is not aware of any basis for establishing rules on how nutrient values are determined for raw fruits and vegetables that are different from those for other foods. The nutrition labeling regulations require that the amount of fat be expressed to the nearest 0.5 g increment below 5 g (§ 101.9(c)(2)). However, if the amount of fat is less than 0.5 g, the label value of 0 g may be used. Thus, for fruits and vegetables containing less than 1 g, but more than 0.5 g of fat, FDA rounded to 0.5 g if the amount present was 0.74 g or less, and rounded to 1 g if the amount present was 0.75 g or more. Thus, FDA has not taken the action requested by the comment.

B. Fat Values for Grapefruit, Kiwifruit, Strawberries, and Tomatoes

15. One comment expressed concern about the fat values for grapefruit, kiwifruit, strawberries, and tomatoes. The comment stated that the analytical method (ether extract) that was used to obtain the data overestimates fat when it is present in trace amounts compared to current techniques such as high pressure liquid chromatography (HPLC) or gas chromatography. The comment stated that, consequently, it may be necessary to reanalyze the fat content for those commodities. Five other comments questioned the fat content of grapefruit, and four of those comments suggested that FDA had made an error in rounding. These comments suggested that the fat content of grapefruit is 0 g rather than 0.5 g.

FDA looks forward to receiving new data submissions for raw fruits and vegetables (including grapefruit, kiwifruit, strawberries, and tomatoes) based upon more current analytical methods. The agency will consider those data and will make changes, if appropriate, at the next opportunity for revision of the labeling values for these foods. For the purposes of this final rule, however, FDA determined the fat content of kiwifruit, strawberries, and tomatoes based on the PMA data, using statistical methodology specified in the labeling manual. Revised fat values are listed in Appendix C to part 101 for kiwifruit (1 g, 2 percent DV), strawberries (0 g, 0 percent DV), and tomatoes (0.5 g, 1 percent DV).

FDA acknowledges that it made an error in tentatively assigning a 0.5 g fat value for grapefruit. After reviewing the PMA data, FDA concluded that the fat value for grapefruit is 0 g, 0 percent DV.

C. Fiber Values for 12 Fruits and Vegetables

16. One comment stated that FDA's fiber values in the July 1994 proposal were too low for bananas, cucumbers, and radishes and too high for oranges, grapefruit, tangerines, sweet cherries, kiwifruit, onions, sweet corn, sweet potatoes, and green beans. The comment provided only mean values for dietary fiber for these foods based upon five methods.

FDA reviewed the information on dietary fiber provided by the comment. Unfortunately, the comment did not include raw data, measures of variance (e.g., standard deviations), or the number of samples or composites analyzed, information required for FDA to perform compliance calculations to determine appropriate nutrition labeling values. Because the comment did not provide adequate information for revision of the label values for dietary fiber, FDA will make no changes based upon this comment.

FDA encourages the produce industry to do complete laboratory analyses and welcomes submissions of data for fiber accompanied by detailed information. The agency will consider those data and will make changes, if appropriate, at the next opportunity for revision of the labeling values for these foods. As discussed in sections VII.F. and VII.H. of this document, FDA has revised the fiber values for some foods in this document based on data submitted in other comments.

D. Nutrition Labeling Values for Apples

17. One comment provided FDA with data on the nutrient composition of apples that, the comment claimed,

upgraded the data on file with FDA, which were provided by PMA in 1990. The submission provided data describing the contribution of sugars to total carbohydrate, the levels of saturated and unsaturated fatty acids, and the total fatty acid content. The comment requested that these newer data be included in FDA's revision of the nutrition labeling values for raw apples because they are more complete and accurate and reflect the use of more current analytical methods.

FDA reviewed the newer data for apples (Ref. 6) and used these data, along with other available data, to derive labeling values using compliance calculations based on 95 percent prediction intervals for the levels of calories from fat, total fat, saturated fat, total carbohydrate, and sugars in this final rule. The following summarizes changes to the nutrition labeling values in Appendix C for apples based on the data submitted in the comment:

TABLE 1

Apple nutrient	Proposed values		Final rule values	
Calories from fat	10		0	
Total fat	1 g	2% DV	0 g	0% DV
Total carbohydrate	24 g	8% DV	22 g	7% DV
Sugars	20 g		16 g	

Note: The value for saturated fat remains the same as in the July 1994 proposal at 0 g, 0 percent DV.

FDA made additional changes to the nutrition labeling values for apples based upon another comment, as described in section VII.H. of this document.

E. Nutrition Labeling Values for Avocados

18. One comment provided new data for potassium, protein, and vitamin C in California avocados. Based on the new data, the submission requested that the value for potassium be changed from 105 mg, 3 percent DV to 170 mg, 5 percent DV; that the value for protein be changed from 0 g to 1 g; and that the value for vitamin C be changed from 2 percent DV to 4 percent DV.

FDA reviewed the newer data for avocados (Ref. 7), confirmed that the label values suggested by the comment were correctly derived using compliance calculations based on 95 percent prediction intervals, and used these data in deriving the label values for potassium, protein, and vitamin C for avocados in this final rule. The changes that FDA has made to the nutrition labeling values in Appendix C for avocados based on the comment are summarized below:

TABLE 2

Avocado nutrient	Proposed values		Final rule values	
Potassium	105 mg	3% DV	170 mg	5% DV
Protein	0 g		1 g	
Vitamin C		2% DV		4% DV

FDA made additional changes to the nutrition labeling values for avocados based upon another comment, as described in section VII.H. of this document.

F. Nutrition Labeling Values for Bananas

19. In developing the July 1994 proposal, FDA used data on the composition of bananas that were submitted on behalf of the International Banana Association. Those data were derived from data from a 1982–1983 study by the United Fresh Fruit and Vegetable Association (UFFVA) and from a 1990 PMA study. FDA calculated nutrition labeling values for bananas using compliance calculations based on 95 percent prediction intervals and published these values in Appendix C of the July 1994 proposal.

One comment stated that the 1982–1983 UFFVA data should not be used for fiber and vitamin C, and that the FDA values for these two nutrients in bananas should be revised based only on the PMA data. The comment stated that there are statistically significant differences between the two data sets for dietary fiber and vitamin C, which suggests that only one data set may appropriately be used. The comment stated that the differences are likely attributable to the different analytical methods used in the surveys. The comment said that the 1982–83 UFFVA data were based upon a method of analysis that measured crude fiber, neutral detergent fiber, and pectin, while the 1990 PMA fiber data were based on the AOAC Enzymatic-Gravimetric Method. The 1982–1983 UFFVA vitamin C data were obtained with a titrimetric assay that measures ascorbic acid but not dehydroascorbic acid, while the 1990 PMA data were based on a method that measures both active forms of vitamin C. The comment stated that based on the 1990 PMA data alone, fiber should be 4 g, 15 percent DV, and vitamin C should be 9 mg, 15 percent DV.

FDA accepts the explanation for the data discrepancies for dietary fiber and vitamin C in bananas presented in the comment. The analytical methods used by UFFVA in 1982–1983 to analyze fiber and vitamin C are no longer appropriate for labeling purposes; however, the analytical methods used for the more recent PMA data are appropriate. As a result, FDA recalculated the nutrition labeling values for dietary fiber and vitamin C based on PMA data only. The agency recalculated the nutrition labeling values for bananas for all other nutrients based on both data sources (UFFVA and PMA) (Ref. 8), using compliance calculations based on 95 percent prediction intervals. The following summarizes the differences between the proposed values and the values in Appendix C set forth in this final rule:

TABLE 3

Banana nutrient	Proposed values		Final rule values	
Total fat	0.5 g	1% DV	0 g	0% DV
Potassium	390 mg	11% DV	400 mg	11% DV
Dietary fiber	1 g	4% DV	4 g	16% DV
Vitamin C		0% DV		15% DV
Iron		0% DV		2% DV

G. Nutrition Labeling Values for Tangerines

20. One comment stated that FDA used incorrect values for calories, calories from fat, fat, vitamin C, calcium, and vitamin A in tangerines. It stated that, based on the PMA report on tangerines (Ref. 9), calories should be 45 (not 80), calories from fat should be 5 (not 10), fat should be 1 g (not 2 g), vitamin C should be 40 percent DV (not 35 percent DV), and calcium should be 4 percent DV (not 2 percent DV). The comment disagreed with the proposed value for vitamin A (which FDA derived from PMA data) for tangerines. It stated that PMA only tested for beta-carotene, but that the predominant carotenoid in tangerines is beta-cryptoxanthin. The comment also provided numerous scientific articles containing data, obtained by a variety of methods including newer HPLC methods, for the beta-cryptoxanthin (3-hydroxy beta carotene) content of tangerines. The comment recommended that FDA use the mean vitamin A value from USDA Handbook 8–9 for its derivation of the compliance value.

FDA would first like to note that the proposed value for total fat in tangerines was 1 g, 2 percent DV, and not 2 g of fat, as stated by the comment. For the tangerine values in Appendix C to part 101, FDA derived the label values from raw data provided by a comment, using compliance calculations based on 95 percent prediction intervals. Those data were the only raw data available. The revised values for tangerines are 50 calories; 0 calories from fat; 0.5 g, 1 percent DV total fat; 50 percent DV vitamin C; and 4 percent DV for calcium.

FDA agrees that the method used by PMA measured only beta-carotene and excluded the contribution of beta-cryptoxanthin to the vitamin A activity for tangerines. The agency notes that there is more than one AOAC method for the measurement of carotenes in foods, and that the method that PMA stated that it used is specific for non-hydroxylated carotenes and does not measure mono-hydroxylated carotenes such as beta-cryptoxanthin. However, alternative AOAC methods do permit the measurement of these substances and have been used historically to obtain vitamin A values for food composition tables (Ref. 10). It should be noted that the vitamin A activity of beta-cryptoxanthin has been considered to be about 50 percent of that for beta-carotene (Ref. 11). As discussed in section II.B. of this document, FDA does not consider the use of mean values, such as those in Handbook 8–9, appropriate for labeling purposes.

FDA looks forward to receiving new data submissions for tangerines based upon more comprehensive analytical methodology for vitamin A. The agency will consider those data and will make changes, if appropriate, at the next opportunity for revision of the labeling values. The labeling value for vitamin A remains at 0 percent DV.

H. Statistical Methodology for Deriving Nutrition Labeling Values From PMA Data

Before FDA published the July 1994 proposal, PMA provided the agency with nutrition labeling values for 31 fruits and vegetables that PMA had derived from the raw data it had compiled using 80 percent prediction intervals. FDA included many of these nutrition labeling values in the July 1994 proposal.

21. Several comments expressed concern about the rounding of the nutrition labeling values for fruits and vegetables in the July 1994 proposal, specifically the values obtained from PMA. One comment stated that FDA was inconsistent in rounding labeling values (e.g., in calculating the values for total fat for grapefruit, apples, and tangerines) and requested that FDA be consistent. Other comments specifically questioned how percent DV's were derived from the rounded or unrounded labeling values (e.g., dietary fiber and iron in onions).

FDA recalculated labeling values derived from the raw data that PMA had submitted (described later in this section of this document) and is using those recalculated values in this final rule. With respect to the rounding issues raised by the comments, FDA points out that the nutrition labeling regulations (§ 101.9(d)(7)(ii)) allow percent DV's to be calculated from the original or rounded nutrient values. PMA calculated percent DV's based on the original values. In recalculating the percent DV's, FDA used rounded values. The agency did so to provide consistency in the chart format (i.e., to be sure that the same quantitative amount of a nutrient is associated with the same percent DV). FDA notes that if percent DV's are calculated from original values, it may lead to inconsistencies in the chart that would be confusing to consumers. FDA applied the rounding rules (§ 101.9(c)) consistently to the data used for calculating the values in this final rule. Therefore, FDA has responded fully to these comments.

22. Two comments expressed concern that FDA's use of PMA's nutrition labeling values derived from 80 percent prediction intervals was not consistent with the way the food industry develops nutrition labeling values for processed, packaged foods. The comments stated that fruits and vegetables will be placed at a marketing disadvantage compared to other foods subject to the 1990 amendments, and that consumers will receive less useful and consistent information.

FDA agrees with the comments. The 80 percent prediction values provided by PMA and used in the July 1994 proposal were not entirely appropriate because they were not based on 95 percent prediction intervals. As stated elsewhere in this document, FDA recommends that labeling values be derived from compliance calculations based on 95 percent prediction intervals and be consistent with statistical methodology in the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases'' (Ref. 1).

During the comment period, the agency received data from various sources and considered all of those data in determining the final values. In a comment, PMA submitted a new set of nutrition labeling values for 31 raw fruits and vegetables and asked that those values be used in the final rule. The nutrition labeling values in PMA's comment were derived by using a

different statistical methodology than PMA used in its original submission. Instead of values based upon 80 percent prediction intervals, the nutrition labeling values in the comment were derived by using 95 percent confidence intervals.

When the agency reviewed these values, it found the following concerns with the statistical methodology (Ref. 12) that PMA had used:

(1) PMA used a one-sided 95 percent *confidence* interval to do the compliance calculations rather than the FDA-recommended one-sided 95 percent *prediction* interval. (A confidence interval is used to confidently bracket the true parameters of a population. A prediction interval is associated with confidently bracketing the mean or any number of future samples from the same population. A compliance value based upon FDA laboratory analysis consists of a composite of 12 units. The value is necessarily considered by the industry as the mean of 12 future units, which is expected to be in line with the labeled values. The limit of the prediction interval is lower (or higher, depending on the applications) than the corresponding limit of the confidence interval for a given level of significance (Ref. 1).)

(2) PMA did not always use the minimum of the means and compliance calculations for class II nutrients (naturally occurring vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium) and the maximum of the means and compliance calculations for third group nutrients, as listed in § 101.9(g)(5) (calories, sugars, total fat, saturated fat, cholesterol, and sodium).

(3) In § 101.9(g)(4)(ii), total carbohydrate is defined as a class II nutrient. PMA derived total carbohydrate values under the assumption that total carbohydrate is a third group nutrient (see § 101.9(g)(5)), rather than a class II nutrient.

FDA is grateful to PMA for submitting the nutrition labeling values for 31 fruits and vegetables as a comment, but the agency has decided not to use these values. Instead, FDA recalculated the nutrition labeling values for those raw fruits and vegetables (Ref. 12) using the raw data submitted by PMA, with 95 percent prediction intervals. These nutrition labeling values are presented in Appendix C to part 101.

Additional differences between the nutrition labeling values in this final rule and those provided by PMA in their comment can be attributed to the following factors:

(1) Although PMA submitted revised data for bananas, the agency used other data (described in section VII.F. of this document) that were submitted during the comment period to update the nutrition labeling values for this food.

(2) FDA used data from PMA and from other comments to update nutrition labeling values for apples (described in section VII.D. of this document) and avocados (described in section VII.E. of this document).

(3) PMA calculated percent DV's based on the original values rather than the rounded values. FDA recalculated the percent DV's based on rounded values to avoid consumer confusion (as discussed in section VII.H. of this document).

(4) FDA did not use the values for calories from fat provided by PMA because PMA used 9 calories per g of fat rather than 8.37 calories per g of fat, the appropriate factor to be used for fruits and vegetables (Refs. 13 and 14).

(5) For watermelon, oranges, strawberries, tangerines, and leaf lettuce, FDA adjusted the total carbohydrate value to reflect the sum of dietary fiber and sugars. Total carbohydrate is generally determined ''by difference'' (i.e., it is the weight remaining when the weight of the sum of protein, fat, water, and ash are subtracted from the total weight of the food). In theory, the sum of dietary fiber and sugars should be equal to or less than total carbohydrate because both dietary fiber and sugars are forms of carbohydrate. However, for watermelon, oranges, strawberries, tangerines, and leaf lettuce, the weight of total dietary fiber (values derived from PMA data) and sugars (values obtained from USDA (Ref. 15)) exceeded the weight of total carbohydrate. In the July 1994 proposal, FDA explained that the agency adjusted for this discrepancy in several foods by increasing the weight of total carbohydrate to be at least equal to the sum of dietary fiber and sugars (59 FR 36379 at 36383; Ref. 16). FDA explained that because the values for dietary fiber and sugars are determined by laboratory analysis, they are more accurate than the value for total carbohydrate, which is determined by difference. The agency received no comments expressing disapproval with this adjustment. Therefore, the agency made this adjustment in calculating the values for total carbohydrate in watermelon, oranges, strawberries, tangerines, and leaf lettuce in this final rule.

(6) In order to have calories from fat consistent for a given total fat value, FDA derived calories from fat for fruits and vegetables from the rounded, rather than unrounded, total fat label value. The caloric equivalent for fat is 8.37 calories per g for fruits and vegetables. Thus, 0.5 g of fat is equivalent to 4.19 calories, and according to § 101.9(c)(1)(ii), ''* * * amounts less than 5 calories may be expressed as zero.'' As a result, Appendix C consistently lists 0 calories for 0.5 g of total fat.

The following is a summary of changes from the proposed nutrition labeling values for 30 raw fruits and vegetables that FDA derived from the raw data provided by PMA during the comment period, using compliance calculations based on 95 percent prediction intervals:

TABLE 4

Food nutrient	Proposed values		Final rule values	
Apple:				
Potassium	160 mg		170 mg	
Dietary fiber	4 g	16% DV	5 g	20% DV
Vitamin A		0% DV		2% DV
Vitamin C		6% DV		8% DV
Iron		0% DV		2% DV
Watermelon:				
Calories		90		80
Total carbohydrate	26 g		27 g	
Dietary fiber	1 g	4% DV	2 g	8% DV
Vitamin A		10% DV		20% DV
Calcium		0% DV		2% DV
Iron		2% DV		4% DV

TABLE 4—Continued

Orange:				
Calories		80		70
Potassium	250 mg		260 mg	
Dietary fiber	5 g	20% DV	7 g	28% DV
Vitamin A		0% DV		2% DV
Vitamin C		120% DV		130% DV
Calcium		4% DV		6% DV
Iron		0% DV		2% DV
Cantaloupe:				
Sodium	35 mg		25 mg	
Potassium	210 mg	6% DV	280 mg	8% DV
Total carbohydrate	13 g		12 g	
Vitamin A		80% DV		100% DV
Grapefruit:				
Calories		70		60
Potassium	210 mg	6% DV	230 mg	7% DV
Total carbohydrate	18 g	6% DV	16 g	5% DV
Dietary fiber	5 g	20% DV	6 g	24% DV
Vitamin A		10% DV		15% DV
Vitamin C		80% DV		110% DV
Calcium		4% DV		2% DV
Strawberries:				
Calories		70		45
Total Fat	0.5 g	1% DV	0 g	0% DV
Potassium	220 mg	6% DV	270 mg	8% DV
Total carbohydrate	17 g	6% DV	12 g	4% DV
Dietary fiber	3 g	12% DV	4 g	16% DV
Vitamin C		130% DV		160% DV
Iron		0% DV		4% DV
Honeydew melon:				
Sodium	45 mg	2% DV	35 mg	1% DV
Potassium	290 mg	8% DV	310 mg	9% DV
Total carbohydrate	14 g	5% DV	13 g	4% DV
Vitamin A		0% DV		2% DV
Vitamin C		40% DV		45% DV
Avocado:				
Calories		60		55
Calories from fat		50		45
Total fat	6 g	9% DV	5 g	8% DV
Total carbohydrate	2 g		3 g	
Dietary fiber	1 g	4% DV	3 g	12% DV
Lemon:				
Calories		20		15
Sodium	10 mg		5 mg	
Potassium	65 mg	2% DV	90 mg	3% DV
Total carbohydrate	6 g		5 g	
Vitamin C		35% DV		40% DV
Pineapple:				
Calories		70		60
Potassium	100 mg		115 mg	
Total carbohydrate	17 g	6% DV	16 g	5% DV
Protein	0 g		1 g	
Calcium		0% DV		2% DV
Iron		0% DV		2% DV
Tangerine:				
Calories		80		50
Calories from fat		10		0
Total fat	1 g	2% DV	0.5 g	1% DV
Sodium		5 mg		0 mg
Potassium	120 mg	3% DV	180 mg	5% DV
Total carbohydrate	20 g	7% DV	15 g	5% DV
Protein		0 g		1 g
Vitamin C		35% DV		50% DV
Calcium		2% DV		4% DV
Sweet cherries:				
Calories from fat		10		0
Total fat	1 g	2% DV	0.5 g	1% DV
Potassium	260 mg	7% DV	300 mg	9% DV
Total carbohydrate	23 g	8% DV	22 g	7% DV
Protein	1 g		2 g	
Vitamin A		0% DV		2% DV
Vitamin C		8% DV		15% DV
Iron		0% DV		2% DV

TABLE 4—Continued

Kiwifruit:				
Calories from fat		15		10
Total fat	1.5 g		1 g	
Potassium	450 mg	13% DV	480 mg	14% DV
Total carbohydrate	25 g		24 g	
Vitamin C		200% DV		240% DV
Potato:				
Calories		120		100
Sodium	5 mg		0 mg	
Potassium	680 mg	19% DV	720 mg	21% DV
Total carbohydrate	27 g		26 g	
Dietary fiber	2 g	8% DV	3 g	12% DV
Protein	3 g		4 g	
Vitamin C		40% DV		45% DV
Calcium		0% DV		2% DV
Iceberg lettuce:				
Calories		20		15
Potassium	85 mg	2% DV	120 mg	3% DV
Vitamin A		2% DV		4% DV
Vitamin C		4% DV		6% DV
Calcium		0% DV		2% DV
Iron		0% DV		2% DV
Tomato:				
Calories from fat		10		0
Total fat	1 g	2% DV	0.5 g	1% DV
Potassium	300 mg	9% DV	360 mg	10% DV
Vitamin A		15% DV		20% DV
Vitamin C		35% DV		40% DV
Calcium		0% DV		2% DV
Onion:				
Potassium	200 mg	6% DV	240 mg	7% DV
Total carbohydrate		16 g		14 g
Protein		1 g		2 g
Vitamin C		15% DV		20% DV
Iron		0% DV		2% DV
Carrot:				
Calories		40		35
Sodium		50 mg		40 mg
Potassium	220 mg	6% DV	280 mg	8% DV
Total carbohydrate		9 g		8 g
Vitamin A		220% DV		270% DV
Vitamin C		8% DV		10% DV
Celery:				
Calories		25		20
Sodium	125 mg	5% DV	100 mg	4% DV
Potassium	300 mg	9% DV	350 mg	10% DV
Vitamin C		10% DV		15% DV
Broccoli:				
Calories		50		45
Sodium	70 mg	3% DV	55 mg	2% DV
Potassium	480 mg	14% DV	540 mg	15% DV
Total carbohydrate		9 g		8 g
Dietary fiber	4 g	16% DV	5 g	20% DV
Protein	4 g		5 g	
Vitamin A		10% DV		15% DV
Vitamin C		200% DV		220% DV
Iron		4% DV		6% DV
Green cabbage:				
Sodium	25 mg		20 mg	
Potassium	170 mg		190 mg	
Total carbohydrate	6 g		5 g	
Vitamin C		60% DV		70% DV
Iron		0% DV		2% DV
Cucumber:				
Potassium		160 mg		170 mg
Dietary fiber	0 g	0% DV	1 g	4% DV
Vitamin C		8% DV		10% DV
Bell pepper:				
Potassium	240 mg	7% DV	270 mg	8% DV
Vitamin A		6% DV		8% DV
Vitamin C		150% DV		190% DV
Calcium		0% DV		2% DV
Iron		0% DV		2% DV

TABLE 4—Continued

Cauliflower:				
Sodium	40 mg	2% DV	30 mg	1% DV
Potassium	250 mg	7% DV	270 mg	8% DV
Leaf lettuce:				
Sodium	40 mg	2% DV	30 mg	1% DV
Potassium	210 mg	6% DV	230 mg	7% DV
Total carbohydrate	3 g		4 g	
Dietary fiber	1 g	4% DV	2 g	8% DV
Vitamin A		30% DV		40% DV
Vitamin C		4% DV		6% DV
Calcium		2% DV		4% DV
Mushrooms:				
Potassium	280 mg	8% DV	300 mg	9% DV
Protein	2 g		3 g	
Vitamin C		0% DV		2% DV
Iron		0% DV		2% DV
Green (snap) beans:				
Potassium	190 mg	5% DV	200 mg	6% DV
Vitamin A		2% DV		4% DV
Vitamin C		8% DV		10% DV
Iron		0% DV		2% DV
Radishes:				
Calories		20		15
Sodium	30 mg		25 mg	
Potassium	180 mg	5% DV	230 mg	7% DV
Total carbohydrate	4 g		3 g	
Protein	0 g		1 g	
Calcium		0% DV		2% DV
Summer squash:				
Potassium	240 mg		260 mg	
Dietary fiber	1 g	4% DV	2 g	8% DV
Vitamin A		4% DV		6% DV
Vitamin C		25% DV		30% DV
Asparagus:				
Calories		20		25
Potassium	210 mg	6% DV	230 mg	7% DV
Total carbohydrate	5 g	2% DV	4 g	1% DV
Vitamin C		10% DV		15% DV
Calcium		0% DV		2% DV
Iron		0% DV		2% DV

I. Fat and Calorie Values for Catfish

23. For the July 1994 proposal, FDA used data on catfish obtained from the USDA National Nutrient Databank which included both farmed and wild catfish. Three comments expressed concern that the proposed values for fat (9 g) and calories (170) were too high and did not accurately reflect the farmed catfish available in retail markets in the United States, which constitute the vast majority of the catfish consumed in the United States. The comments stated that the fat content of catfish is affected by species, size of fish, diet of fish, season of year, stocking rate of pond, pond size, and sex of fish. The comments also provided data from Nettleton et al. (Ref. 17) on farmed catfish composition and requested that FDA consider this information in developing revised labeling values for this fish.

Based on the comments, FDA was concerned that the proposed labeling values for catfish did not accurately reflect the farmed catfish available in retail markets. FDA calculated new nutrition labeling values from data for farm-raised catfish available from Nettleton et al. (Ref. 17) and with 95 percent prediction intervals. Although the comments had only pointed to problems with the values for fat and calories, FDA applied compliance calculations to the other nutrients for which information was available in reference 17 to be sure that the full nutritional profile for this fish is accurate and consistent (Ref. 18). The resulting changes in labeling values are summarized below:

TABLE 5

Catfish nutrient	Proposed values		Final rule values	
Calories	170		140	
Saturated fat	1.5 g	8% DV	2 g	10% DV
Cholesterol	55 mg	18% DV	50 mg	17% DV
Potassium	350 mg	10% DV	230 mg	7% DV
Protein	21 g		17 g	

Because FDA confirmed that the consumption of catfish in the United States is predominantly farmed catfish (Ref. 19), the agency concluded that the data from Nettleton et al. provided more accurate label values for catfish and is thus adopting these values in this document. The values for total fat did not change.

J. Fat and Calorie Values for Orange Roughy

24. Because of the lack of acceptable information concerning the total fat content, inclusive of wax esters, of orange roughy, in the July 1994 proposal, FDA used a fat value for this fish that did not include wax esters. FDA requested information on the total fat content of this fish and stated that it would provide a value for total fat in the next revision of the nutrition labeling values if such a value were available. This action would make the listing of total fat in orange roughy consistent with the definition of total fat in § 101.9(c)(2) (i.e., the amount of total lipid fatty acids present expressed as triglycerides).

No comments were received that provided information on the total fat content of orange roughy. One comment questioned why FDA wanted a value for total fat in orange roughy that includes the presence of wax esters because wax esters are not a metabolizable source of energy in humans and have no dietary significance. The comment stated that nutrition labeling should provide consumers with information with which to make dietary choices, and that it is misleading to add nonmetabolizable fat to the value for fat in orange roughy. The comment stated that the elevated levels of fat that would result from the addition of wax esters would falsely suggest to consumers that orange roughy was contributing a substantial amount of metabolizable fat to daily intake. The comment said that providing such levels in the nutrition label would be a disservice to consumers who are seeking foods, such as orange roughy, that contribute a minimum amount of fat to their diet. The comment recommended that FDA retain the fat value for orange roughy presented in the July 1994 proposal.

Because FDA did not receive any data on the total fat content of orange roughy, the agency will continue to use values for fat that do not include the wax esters despite the fact that the labeling of total fat for orange roughy remains an exception to the definition of total fat in § 101.9(c)(2). FDA continues to request information that would provide a basis for revising the declaration of total fat to reflect the presence of wax esters in orange roughy but that would not be misleading to the consumer.

The agency understands the point made in the comment. It intends to address the issue of declaration of available fat in a separate rulemaking.

K. Saturated Fat Value for Atlantic/Pacific Mackerel

25. One comment stated that FDA's proposed value for saturated fat for Atlantic/Pacific mackerel is 6 g, while USDA's mean value for 84 g of cooked Atlantic mackerel is 3.5 g, and asked that this discrepancy be examined.

The proposed value for saturated fat in Atlantic and Pacific mackerel was based upon data obtained from the USDA National Nutrient Databank. However, in response to the comment, FDA reviewed the data for saturated fat. After consulting with USDA, FDA discovered that the saturated fat data that FDA received were not in the units indicated in the data file. The saturated fat data were actually presented as percentages of the total fat content, rather than as g amounts. After converting the saturated fat values to g, FDA applied compliance calculations to the data (Ref. 20). As a result, the agency found that the labeling value for saturated fat for Atlantic/Pacific mackerel is 1.5 g with 8 percent DV. Appendix D has been modified accordingly.

L. Sodium and Cholesterol in Ocean Perch

26. One comment disagreed with FDA's proposed values for sodium (200 mg) and cholesterol (75 mg) for ocean perch. It stated that USDA's mean sodium value for raw ocean perch from the National Nutrient Databank is 78.80 mg, with a range of 59 to 109.02 mg, and that using the 75 percent retention factor would result in a mean value of 88.26 and a range of 66.08 to 122.10 mg. This comment suggested that FDA set the sodium value for ocean perch at 90 mg, the rounded mean value. The comment said that USDA's mean value for cholesterol in ocean perch is 47.05 mg, with a range of 32.48 to 60.93 mg, and suggested that FDA use a rounded value of 45 mg for this nutrient.

FDA applied compliance calculations based upon 95 percent prediction intervals to data obtained from the USDA National Nutrient Databank to develop the sodium and cholesterol values of ocean perch that it included in Appendix D in the July 1994 proposal. In response to this comment, FDA compared the statistical parameters (mean, standard error, and sample size) in Handbook 8 to those derived from data provided by USDA from the National Nutrient Databank.

After discovering these parameters did not match, FDA asked USDA to review the data that it had sent to FDA. In its review, USDA discovered that the data file sent to FDA contained entries for species of fish other than ocean perch. Because this data file was incorrectly labeled, FDA used inappropriate nutrient data to derive the nutrition labeling values for ocean perch.

After consulting with USDA, FDA identified and extracted the nutrient data for ocean perch from the data file and rederived nutrition labeling values for this document (Ref. 21). In table 6 of this document is a summary of changes to the nutrition labeling values for ocean perch that FDA derived from these data, with compliance calculations based on 95 percent prediction intervals.

TABLE 6

Ocean perch nutrient	Proposed values		Final rule values	
Calories from fat		25		20
Total fat	3.5 g	5% DV	2.0 g	3% DV
Cholesterol	75 mg	25% DV	50 mg	17% DV
Sodium	200 mg	8% DV	95 mg	4% DV
Potassium	330 mg	9% DV	290 mg	8% DV
Protein	20 g		21 g	
Vitamin C		4% DV		0% DV
Calcium		4% DV		10% DV
Iron		2% DV		6% DV

M. Calories From Fat for Lobster

27. In the July 1994 proposal, FDA made an error in the determination of calories from fat for lobster. Lobster contains 0.5 g total fat, and the calories from fat should have been zero ((9.02 calories per g)(0.5 g fat)) = 4.51 calories, which rounds to zero according to § 101.9(c)(1)(ii)), instead of 5 calories as indicated in the July 1994 proposal. FDA has corrected this error in Appendix D of this document.

VIII. Nutrient Content Claims and Health Claims for Raw Fruits, Vegetables, and Fish

28. One comment expressed concern about nutrient content and health claims for raw fruits, vegetables, and fish and asked that FDA clarify two points. The comment asked whether labeling information on a chart in a retail store for a raw fruit or vegetable in the voluntary program would suffice for a packaged commodity that has a claim on the package. The comment also asked whether a nutrient content claim or health claim for a raw fruit or vegetable not among the 20 most frequently consumed follows the same rules applicable to produce within the voluntary program (i.e., if point-of-purchase nutrition labeling suffices for packaged commodities).

FDA addressed the question of the need for nutrition labeling for packaged raw fruits and vegetables that bear a claim in a publication on frequently asked questions that it issued in August 1993 (Ref. 22). At that time it stated: ''Claims subject the food to nutrition labeling in accordance with § 101.45, which means that nutrition information will have to be available at point of purchase although not necessarily on the package.''

FDA encourages processors and packers of raw fruits, vegetables, and fish who put nutrient content or health claims on their packaging to also include nutrition label information because it is not possible to predict whether the products will be sold in stores where retailers make the nutrition information available to consumers. Even if processors and packers are able to control the flow of their products into specific retail stores, they will have no control over retailers' decisions to display (or to continue to display) nutrition labeling information for these products. Depending upon retailers to provide nutrition labeling values to justify nutrient content or health claims would be a gamble for the processors and packers, who assume liability for their products with claims. FDA encourages processors and packers who provide nutrient content or health claims on the packaging of these foods to also include the nutrition information.

For raw fruits, vegetables, and fish that are not among the 20 most frequently consumed, it is even less likely that nutrition information for that particular commodity will be available in retail stores. Therefore, FDA encourages processors and packers who provide nutrient content or health claims on the packaging of these foods to also include the nutrition information.

IX. FDA Review of Submitted Data Bases

FDA encourages industry to submit data for raw produce and raw fish to the agency for consideration for the next revision of nutrition labeling information for raw commodities. In addition, FDA continues to request food manufacturers and trade associations representing products falling under mandatory nutrition labeling regulations to submit proposed studies to collect nutrient data for nutrition labeling data base compilation. In the July 1994 proposal for the voluntary program, the agency acknowledged that problems existed in the process for data base review and sought feedback on how to improve upon that process (59 FR 36379 at 36387). The agency specifically solicited comments regarding evaluation criteria related to: (1) The nature and rigor of the evaluation process and (2) the policy of interim approvals, as well as followup procedures and time frames to ensure long-term interest in continued data collection.

In response, FDA received comments regarding all aspects of the data base review process. Most comments expressed general support for a modification of the data base review process. In addition, some comments commended FDA for attempting to provide industry with a nutrient data base policy that would reduce the costs of labeling their products.

29. Several comments cited the enormous effort and expense needed to abide by the requirements in the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases'' (Ref. 1). One comment stated that if the manual's requirements serve as the gold standard, and companies will never be able to meet that standard, then the standard must be changed into one that is more cost-effective, realistic, and workable. Another comment recommended that FDA scale back its evaluation criteria. It stated that the current manual's evaluation criteria require enormous effort and expense for data base development, primarily because the number of samples required for a single raw commodity may be in the thousands. The number of samples selected for analysis directly relates to the total cost of the nutrition labeling of products.

Several comments presented estimates of the cost of analyzing commodities based on the requirements in the manual. They argued that these high costs were so burdensome to small businesses that the manufacturers would opt not to nutrition label their products and thus defeat the purpose of the 1990 amendments. Comments also argued that if manufacturers could not afford nutrition labeling, they would have a strong marketing disadvantage in selling their products. Another comment suggested that if historical information indicates that the level of a particular mandatory nutrient is zero, and it is generally accepted as such, then no individual analyses should be necessary (e.g., fiber in milk). Still another comment stated that sample sizes need not be as large as the manual suggests to be statistically valid, and that smaller sample sizes would reduce the total costs of analyses. The comment stated that FDA did not balance the cost of a nutrient analysis with the marginal increase in accuracy that may come from doing more analyses.

FDA continues to acknowledge the potential usefulness of data bases to reduce costs associated with nutrition labeling. A data base compiled and submitted by a trade association representing a large number of members would represent less cost than would be required if each member company were to analyze its own products and submit its own individual data base. The agency wishes to emphasize that submission of a data base to FDA for the purpose of nutrition labeling is voluntary. Each manufacturer, however, is responsible for ensuring the validity of the nutrient values that appear on its label.

The manual provides generic guidelines for industry to use in preparing and developing data bases. Industry may choose to follow these guidelines or may use alternative procedures even though they are not provided for in the manual. If industry wishes to submit a data base to FDA, but chooses to use alternative procedures, the organization preparing the data base may wish to discuss those procedures with the agency to prevent expenditure of money and effort on activities that the agency may later find unacceptable. The agency recognizes that everything recommended in the manual cannot be achieved at the present time for most

commodities, even by some of the larger trade associations. FDA does expect, however, that all planned studies will continue to be based upon consideration of the statistical random sampling, methodology, design, and treatment of data that are described in the manual. The agency has stated that analysis is not needed for nutrients where reliable data bases or scientific knowledge establish that a nutrient is not present in the product (58 FR 2109, January 6, 1993).

A great deal of information already exists for some foods regarding factors that influence nutrient variability (e.g., variety, season, species). As a result, it may be possible to reduce the number of samples to be assayed on the basis of data and knowledge of which nutrients vary with changing parameters. In addition, information describing the effect of various factors on nutrient content of foods may be obtained through the completion of experimental pilot studies. These data in turn may provide information on nutrient variability that will also provide a basis for reducing the number of samples necessary for a valid data base.

30. Questions continue to arise over the issue of whether data base submitters may use USDA Handbook 8 data, data obtained through literature searches, or historical data with limited quality assurance from manufacturers. Several comments were in favor of FDA allowing data base developers to use USDA Handbook 8 values in their data base submissions. Other comments suggested that the use of historical data would add depth and broad coverage and would, therefore, provide a positive aspect to the data bases. They argued that such allowances would lessen the number of nutrient analyses needed to arrive at an appropriate label value while reducing the total cost of conducting nutrient analyses.

FDA continues to acknowledge the value of data available from USDA Handbook 8 and from the scientific literature, but as stated in response to comment 2, mean composition values derived from those sources are generally not suitable for labeling purposes. The agency's policy is to recommend that products be labeled according to nutrient composition based upon laboratory analysis.

In response to the comments, FDA reassessed how best to consider historical data submitted for review. The agency has decided to review and to allow the use of historical data submitted for labeling purposes, as long as those data are accompanied by a planned study to collect additional data for updating the label values. FDA will evaluate the historical data for completeness and reasonableness. If analytical methods have changed substantially from those used in gathering the data, or if it is obvious that the sampling design used to develop the data is incorrect, the agency may choose not to accept the historical data. Otherwise, if FDA determines that the historical data are complete and reasonable, the agency will allow use of the data, as long as the manufacturer plans to collect additional data to update those values.

31. One comment suggested that data should be presented on a per 100-g basis as well as the reference amount.

FDA agrees with the suggestion and recommends that industry submitting data bases to FDA provide those data on both the 100 g and the reference amount bases. The agency continues to encourage industry to submit data not only to FDA but also to USDA for use in compilations such as Handbook 8. Data submitted for inclusion in Handbook 8 should be provided on a mean 100-g basis and not as label values that have been derived by FDA compliance algorithms.

32. One comment urged FDA to revise the analytical methods section of the manual to make the text compatible with nutrition labeling regulations in § 101.9(g)(2). The comment noted that this regulation allows for non-AOAC analytical methods if AOAC methods are neither available nor appropriate. The comment further suggested that there would be improvement in the accuracy of the data as a result of using diverse analytical methods. Another comment suggested that FDA require companies or trade associations to submit a table of proposed analytical methods with accompanying information concerning specific validation of the method used by the on-site or commercial lab for the matrix of interest.

The manual's recommendations are consistent with § 101.9(g)(2), wherein the agency advises companies or associations to use non-AOAC methods where no AOAC method is available or appropriate. The manual recommends the use of non-AOAC methods only in the absence of AOAC-validated methods. The agency agrees that the process of refining methods of analysis will reduce variability in nutrient levels but does not agree that use of diverse analytical methods will reduce variability. FDA respects the worldwide consensus surrounding the applicability, specificity, sensitivity, accuracy, precision, and detectability of methods validated by AOAC International and continues to recommend the use of those methods in obtaining measures of nutrient content.

The agency agrees with the comment that suggested that data base developers should submit a table delineating proposed analytical methods for each nutrient, with accompanying information concerning specific validation of the method used by the onsite or commercial lab for the matrix of interest. In fact, in response to FDA's requests for such data, several submissions to FDA have already included a table of the analytical methods used and accompanying documentation validating the use of the method.

33. One comment suggested that manufacturers should be able to send data in an electronic format. The comment noted that if software were developed in the form of a template, then FDA would greatly improve its review process.

FDA strongly agrees with this comment and will consider use of electronic methods for data collection as it continues to assess and improve its data base submission and review process.

34. FDA received the greatest number of comments regarding interim approvals for nutrient data bases. This issue relates specifically to data bases for products having mandatory labeling. The comments addressed the following three primary issues: (1) Whether submitters should receive interim approvals; (2) if so, at what point in the process; and (3) for what time period. All comments on the subject expressed support for the issuance of interim approvals. Some comments suggested that an interim approval should be granted if the submitter has made a good faith effort to abide by the guidelines, as discussed in the nutrition labeling manual. Several comments proposed various criteria for granting interim approvals. One comment suggested a grading scale for data bases that would also take into account the length of time for an interim approval. Another comment proposed that FDA create a checklist to serve as the basis for interim approvals and thus expedite the review process. Suggested time periods for interim approval ranged from 1 to 10 years.

FDA has carefully examined and fully considered the thoughtful comments submitted in response to this issue. Based on its review of the comments, FDA has decided to modify its approach to data bases that are submitted to the agency for review. The new policy directly addresses concerns relevant to interim review and approval of data bases. FDA implemented a new

discretionary enforcement strategy for those manufacturers who submit interim data to the agency for approval. Interim data in the form of nutrition label values should be accompanied by raw data. If there are data that the manufacturer has determined to be unsuitable, they should also be submitted with explanation. FDA will continue to evaluate interim data (i.e., historical or newly collected) submitted for review if those data are accompanied by a plan to collect additional data for the purpose of updating label values. However, in order to facilitate the use of the developing nutrient data base and to limit the uncertainty that could result from an unforeseen delay in agency review of the data base, firms are free upon submission to begin use of the nutrient label values and to initiate the planned studies to collect and update nutrient values. During this interim period, FDA does not anticipate that it will take action against a product bearing label values included in a data base submitted to the agency for review. If any product is identified through FDA compliance activities as including label values that are out of compliance, contingent on the company's willingness to come into compliance, the agency intends to work with both the manufacturer and the data base developer to understand and correct the problem label values.

When FDA receives the interim data and planned studies referred to above, it will first evaluate the label values relative to the raw data. FDA will recalculate label values based solely on the raw data that have been submitted. The agency will derive label values using compliance calculations based upon 95 percent prediction intervals and, when appropriate, will use weighting procedures, as recommended in the nutrition labeling manual. FDA will evaluate the data for completeness and reasonableness, e.g., it will consider whether or not there are enough samples, and whether all nutrients are included. FDA requests that supporting documentation, such as analytical methodology and a sampling plan, accompany interim data. The agency acknowledges, however, that a large amount of the interim data available from manufacturers and trade associations are based upon historical data, where the analytical methodology and sampling plan are not available. Hence, FDA will not refuse to accept data solely on the basis that it is not accompanied by comprehensive documentation, so long as the reason such documentation is not provided is fully explained and is acceptable to the agency.

FDA will review the accompanying planned studies to collect additional data, concentrating on analytical methodology and on the reasonableness of the factors that could account for nutrient variability (e.g., style, region), rather than on the rigor of sampling design or statistical treatment of the data. FDA cautions, however, that data base submitters should follow FDA's recommendations regarding sampling strategies, weighting procedures, and statistical treatment of data that are described in the nutrition labeling manual.

FDA will respond in writing after review of the data and the planned studies. FDA will address the nutrient label values that were submitted and will indicate whether it has any objection to continuing the planned studies or to continued use of the label values for 2 years from the date of the agency response.

After those 2 years, manufacturers will be expected to provide the agency with a summary update that reassesses the interim label values based upon completion of the planned laboratory analyses. The agency will evaluate how the study findings bear on the interim label values and will consider whether it would have any objection to continued use of the updated interim values for up to an additional 5 years. At the same time, however, the agency may suggest modifications to the ongoing plan of study. If after review of data and planned studies, FDA determines that the label values or studies are not appropriate, as indicated above, the agency will notify the manufacturer of that decision.

Please note that a primary focus of FDA's compliance review of product labels is on nutrient content claims (e.g., ''high fiber'', ''low fat'') that are used. FDA will continue to closely monitor products making such claims and expects that the manufacturer, packer, or distributor will have sufficient data to support the validity of such claims.

X. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) 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.

XI. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. sections 601 and 612). 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).

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of a rule on small entities. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866, and finds under the Regulatory Flexibility Act, that the final rule will not have a significant impact on a substantial number of small entities.

A. Costs of the Regulation

The costs of a labeling regulation are the incremental administrative, analytical, redesign, and label inventory disposal costs associated with the regulatory action. Because FDA is requiring that retailers use the nutrition values provided by FDA, there are not expected to be any analytical costs or other costs of obtaining the information. FDA has information that the typical sign, which is the most frequently used form of labeling of raw products, has an expected useful life of 6 months. Therefore, there will be no label inventory disposal costs because existing signs normally would have been replaced during the compliance period. However, FDA does not believe that signs normally would have been redesigned during that period. Therefore, the costs of the regulation are administrative and redesign costs.

In the July 1994 proposal, FDA estimated that the average cost of redesigning signs to label raw fruits, vegetables, and fish is $100 per year per store. There are approximately 31,000 chain stores and 68,000 independent grocery stores that fall under the compliance guidelines. Therefore, if those stores currently complying with the guidelines continue to do so, annual costs of compliance will be approximately $7.5 million. Because these regulations require that the nutrition values for raw fruits, vegetables, and fish be readdressed and possibly revised every 4 years, FDA anticipates that stores may need to incur these redesign costs as frequently as once every 4 years.

B. Costs Incurred by the Federal Government

Executive Order 12866 requires agencies also to estimate costs to Government. The 1990 amendments require that FDA determine every 2 years whether there is substantial compliance with the labeling guidelines. If substantial compliance does not exist, FDA must make compliance mandatory. FDA estimates that the costs incurred by Government are approximately $150,000 every 2 years to establish a contract to survey food retailers, oversee the contract, and publish a report on the status of voluntary compliance. Total costs incurred by Government, discounted to infinity at 7 percent are $1 million.

If compliance with the guidelines becomes mandatory, costs incurred by the Government would not significantly change because the costs associated with determining whether there is substantial compliance would be replaced by enforcement costs. Also, if FDA were to make compliance mandatory, costs incurred by retailers would increase to $9.9 million in the first year and recurring every 4 years as values are modified, or $42 million discounted to infinity at 7 percent.

Total costs of this regulation are $7.5 million in the first year, or $32 million discounted to infinity at 7 percent.

C. Benefits of this Regulation

In the Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations (56 FR 60856, November 27, 1991), FDA stated that the benefit of labeling raw fruits, vegetables, and fish is a change in purchase behavior that would happen if the information presented was new to some consumers and was important to their consumption decision. At present, however, the majority of consumers have been exposed to the labeling on these products. Based on results of the 1992 survey, 76 percent of retailers (representing 77 percent of annual sales) of raw fruits and vegetables were in compliance with current nutrition labeling guidelines. In addition, 73 percent of retailers (representing 74 percent of annual sales) of raw fish were in compliance. Results from the 1994 survey establish that compliance is 75 percent for raw produce (representing 81.4 percent of annual sales) and 75 percent for raw fish (representing 77 percent of annual sales).

The actions in this document are designed to produce consistency between voluntary nutrition labeling of raw fruits, vegetables, and fish and the nutrition labeling of processed, packaged foods. Similarly, FDA is specifying that compliance requires that retailers use the nutrition values provided by FDA for the 20 most frequently consumed raw fruits, vegetables, and fish, thus providing consistency among retailers. FDA has concluded that the flexibility of allowing manufacturers to use other values does not outweigh the consumer confusion caused by different values for the same food in different stores. However, FDA is allowing commodity groups to develop a nutrition label for a specific genus or species provided that they have the data to support the labeling values presented to the consumer, and they use a more specific name for the product. Therefore, the agency intends to avoid a tradeoff between consistency and accuracy.

35. Comments supporting the proposed rules stated that making the guidelines for the labeling of raw fruits, vegetables, and fish consistent with the labeling of processed, packaged foods will reduce opportunities for consumer confusion caused by the current inconsistencies between retailers who use different nutrient values for the same commodities. The comments stated that the rules will permit meaningful comparisons between raw products and other foods. However, FDA also received one comment that stated that the reduced confusion that would result will not benefit consumers. The comment stated that these costs would be borne by consumers for little or no benefit. Using potatoes as an example, the comment stated that the new rounding rules provide a disservice for consumers looking for reasonably priced, readily available, well-liked foods high in potassium. The comment argued that the new rules would prevent nutrient content claims on potatoes, thus making it necessary for consumers to scrutinize the label for information about the potassium content of potatoes.

The nutrition labeling values for potatoes presented in Appendix C to part 101 are based on PMA data. The revised values for potassium for potatoes would not preclude a ''high potassium'' claim, as stated by the comment. Therefore, FDA notes that the comment's concerns that the new rounding rules would reduce benefits to consumers by prohibiting nutrient content claims is unwarranted.

D. Regulatory Flexibility

36. One comment stated that FDA should have prepared an initial regulatory flexibility analysis for the July 1994 proposal and asks that FDA do so prior to issuing a final rule. The comment stated that the proposed regulations represent a significant restructuring of food labeling of new commodities, and that businesses complying with the regulations confront a number of economic hurdles. Finally, the comment alleged that the failure of FDA to consider both the effects of the short phase in period and less burdensome alternatives are inconsistent with the requirements of the Regulatory Flexibility Act.

The nutrition labeling of raw fruits, vegetables, and fish is a voluntary program. Retailers may decide whether they wish or do not wish to participate in the program. However, the comment was concerned that, in order for the program to remain voluntary, a number of small retailers must choose to participate in the program.

For the purposes of this analysis, FDA defines a grocery store as small if its annual sales are under $20 million. This definition is consistent with the Small Business Administration's size standards (61 FR 3280, January 31, 1996). According to Dun and Bradstreet, as of June 1996, there are approximately 196,000 grocery stores in the United States. Sales data were available for 183,000 stores. Of these, 99 percent (or 180,500 stores) meet the definition of a small grocery store. Congress exempted stores with annual sales less than $500,000, or 109,000 stores with sales data available. There are 71,000 grocery stores for which data are available with annual sales between $500,000 and $20 million.

For purposes of determining substantial compliance, FDA samples 2,000 grocery stores weighted by size (above and below $2 million annual sales). The sample is also distributed by sales, region/state, and chain versus independent. Chain stores with less than $2 million annual sales are not included in the sample because the majority are convenience stores. FDA also does not include either fish markets or fruit and vegetable markets. Substantial compliance was achieved in the 1992 and 1994 surveys without compliance by the smallest stores as a group (sales under $2 million) because these stores constitute a small percent of total sales. FDA notes, however, that in order for substantial compliance to be achieved, many small grocery stores with annual sales between $2 million and $20 million will have to continue to comply with these regulations. Therefore, FDA finds that this rule will impact on a substantial number of small entities. However, FDA has determined that the cost of compliance per store is $100. This amount is sufficiently small that it will not cause either a significant increase in costs or a significant

decrease in revenues. Therefore, FDA concludes that this rule will not result in a significant impact on a substantial number of small entities.

As explained elsewhere in this document, FDA has been convinced by the comment that it is not feasible for all the materials containing nutrition labeling information on raw fruits, vegetables, and fish to be changed before the next compliance survey of the industry. Thus, for the purpose of determining substantial compliance, FDA will consider a retail store to be in compliance if the nutrition labeling information complies with either current (1996) values or values previously published in the Federal Register (56 FR 60856 at 60880).

Therefore, the short compliance period should not result in any undue burden.

37. One comment objected to the cost estimates presented in the analysis of the July 1994 proposal. The comment stated that, although the voluntary program only applies to the 20 most frequently consumed raw fruits, vegetables, and fish for which FDA is providing data, the producers of the other 150+ retail produce items offered would be required to bear the cost of analyzing their products if they attempted to provide the same type of information as required of the top 20 fruits and top 20 vegetables. The comment further stated that producers of commodities not sold in large quantities, most of which are small entities, cannot afford the cost associated with an analysis that would be acceptable under FDA's data base review process. These producers would be at a marketing disadvantage as compared with producers of the top 20 fruits and vegetables.

FDA agrees that some producers of commodities not listed in the top 20 most frequently consumed fruits, vegetables, or fish may be placed at a competitive disadvantage as retailers currently shift the costs of determining the nutrient values of products to producers. However, FDA is unaware of the extent to which this is a problem for small businesses. Furthermore, FDA has no data to indicate the importance of a nutrition profile in marketing these products. However, the more important these profiles are, the more likely that increased sales could cover the costs of analysis. FDA also notes that acceptable nutrient data is available for many of these products through USDA's Handbook 8 and other databases.

XII. The Paperwork Reduction Act of 1995

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

XIII. 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.

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16. Pennington, J. A. T., ''FDA Voluntary Nutrition Labeling Program for Raw Fruits, Vegetables, and Fish: Documentation for the Proposed Nutrition Labeling Values,'' CFSAN, FDA, Washington, DC, October 1993.

17. Nettleton, J. A., W. H. Allen, L. V. Klatt, W. M. N. Ratnayake, and R. G. Ackman, ''Nutrients and Chemical Residues in One- to Two-Pound Mississippi Farm-raised Channel Catfish (Ictalurus punctatus),'' *Journal of Food Science*, 55(4):954–958, 1990.

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20. O'Neill, K. R., ''Results of Atlantic/Pacific Mackerel Nutritional Analyses for Appendix D to Part 101: Nutritional Facts for Cooked Fish (Revised),'' CFSAN, FDA, Washington, DC, March 15, 1996.

21. O'Neill, K. R., ''Results of Ocean Perch Nutritional Analyses for Appendix D to Part 101: Nutritional Facts for Cooked Fish,'' CFSAN, FDA, Washington, DC, March 7, 1996.

22. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Labeling, ''Food Labeling Questions and Answers,'' p. 21, Washington, DC, August 1993.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

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

PART 101—FOOD LABELING

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

Authority: 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 101.43 is amended by revising paragraphs (a)(1), (a)(2), and (a)(3) to read as follows:

§ 101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish.

(a) * * *

(1) Be presented in the store or other type of establishment in a manner that is consistent with § 101.45(a)(1);

(2) Be presented in content and format that are consistent with § 101.45(a)(2), (a)(3), and (a)(4); and

(3) Include data that have been provided by FDA in Appendices C and D to part 101 of this chapter, except that the information on potassium is voluntary.

* * * * *

3. Section 101.44 is amended by revising paragraph (c) to read as follows:

§ 101.44 Identification of the 20 most frequently consumed raw fruits, vegetables, and fish in the United States.

* * * * *

(c) The 20 most frequently consumed raw fish are: Shrimp, cod, pollock, catfish, scallops, salmon (Atlantic/Coho, chum/pink, sockeye), flounder/sole, oysters, orange roughy, Atlantic/Pacific mackerel, ocean perch, rockfish, whiting, clam, haddock, blue crab, rainbow trout, halibut, lobster, and swordfish.

4. Section 101.45 is revised to read as follows:

§ 101.45 Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish.

(a) Nutrition labeling for raw fruits, vegetables, and fish listed in § 101.44 should be presented to the public in the following manner:

(1) Nutrition labeling information should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(2) Serving sizes should be determined, and nutrients declared, in accordance with § 101.9 (b) and (c), respectively, except that the nutrition labeling data should be based on the raw edible portion for fruits and vegetables and on the cooked edible portion for fish. The methods used to cook fish should be those that do not add fat, breading, or seasoning (e.g., salt or spices).

(3) When nutrition labeling information is provided for more than one raw fruit, vegetable, or fish on signs, posters, brochures, notebooks, or leaflets, it may be presented in charts with horizontal or vertical columns or as a compilation of individual nutrition labels. Nutrition labeling that is presented in a linear display (see § 101.9(j)(13)(ii)(A)(*2*)) will not be considered to be in compliance. The heading ''Nutrition Facts'' must be in a type size larger than all other print in the nutrition label. The required information (i.e., headings, serving sizes, list of nutrients, quantitative amounts by weight (except for vitamins and minerals), and percent of Daily Values (DV's) (except for sugars and protein) must be clearly presented and of sufficient type size and color contrast to be plainly legible, with numeric values for percent of DV highlighted in contrast to the quantitative amounts by weight and hairlines between all nutrients.

(i) Declaration of the number of servings per container need not be included in the nutrition labeling of raw fruits, vegetables, and fish.

(ii) Except for the statement ''Percent Daily Values are based on a 2,000 calorie diet,'' the footnote required in § 101.9(d)(9) is not required. However, when labeling is provided in brochures, notebooks, leaflets, or similar types of materials, retailers are encouraged to include the footnote.

(iii) When the nutrition labeling information for more than one raw fruit or vegetable is provided on signs, posters, brochures, notebooks, or leaflets, the listings for saturated fat and cholesterol may be omitted from the charts or individual nutrition labels so long as the fact that most fruits and vegetables provide negligible amounts of these nutrients, but that avocados contain 1 gram (g) of fat per ounce, is stated in a footnote (e.g., ''Most fruits and vegetables provide negligible amounts of saturated fat and cholesterol; avocados provide 1 g of saturated fat per ounce''). The footnote may also contain information about the polyunsaturated and monounsaturated fat content of avocados. When the nutrition labeling information for raw fish is provided on a chart, the listings for dietary fiber and sugars may be omitted if the following footnote is used, ''Fish provide negligible amounts of dietary fiber and sugars.''

(4) When nutrition labeling is provided for individual raw fruits, vegetables, or fish on packages or on signs, posters, brochures, notebooks, or leaflets, it should be displayed in accordance with § 101.9, except that the declaration of the number of servings per container need not be included. For individual labels provided by retailers on signs and posters, the footnote required in § 101.9(d)(9) may be shortened to ''Percent Daily Values are based on a 2,000 calorie diet.''

(b) Nutrition label values provided by the Food and Drug Administration (FDA) in Appendices C and D to part 101 for the 20 most frequently consumed raw fruits, vegetables, and fish listed in § 101.44 shall be used to ensure uniformity in declared values. FDA will publish proposed updates of the 20 most frequently consumed raw fruits, vegetables, and fish and nutrition label data for these foods (or a notice that the data sets have not changed from the previous publication) at least every 4 years in the Federal Register.

(1) The agency encourages the submission of data bases with new or additional nutrient data for any of the most frequently consumed raw fruits, vegetables, and fish to the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, for review and evaluation. FDA may incorporate these data in the next revision of the nutrition labeling information for the top 20 raw fruits, vegetables, and fish.

(i) Guidance in the development of data bases may be found in the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases,'' available from the FDA Office of Food Labeling.

(ii) The submission to FDA should include, but need not be limited to, information on the following: Source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, and statistical treatment of the data. Proposed quantitative label declarations may be included. The proposed values for declaration should be determined in accordance with the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases.''

(2) [Reserved]

(c) Data bases of nutrient values for raw fruits, vegetables, and fish that are not among the 20 most frequently consumed may be used to develop nutrition labeling values for these foods. This includes data bases of nutrient values for specific varieties, species, or cultivars of raw fruits, vegetables, and fish not specifically identified among the 20 most frequently consumed.

(1) The food names and descriptions for the fruits, vegetables, and fish should clearly identify these foods as distinct from foods among the most frequently consumed list for which FDA has provided data.

(2) Guidance in the development of data bases may be found in the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases.''

(3) Nutrition labeling values computed from data bases are subject to the compliance provisions of § 101.9(g).

(i) Compliance with the provisions of § 101.9(g) may be achieved by use of a data base that has been developed following FDA guideline procedures and approved by FDA.

(A) The submission to FDA for approval should include but need not be limited to information on the following: Source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The values for declaration should be determined in accordance with the ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases.''

(B) FDA approval of a data base and nutrition labeling values shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices (e.g., a change occurs in a predominant variety produced). FDA will take steps to revoke its approval of the data base and nutrition labeling values if FDA monitoring suggests that the data base or nutrition labeling values are no longer representative of the item sold in this country. Approval requests shall be submitted in accordance with the provision of § 101.30 of this chapter.

(ii) [Reserved]

5. Appendices C and D are added to part 101 to read as follows:

APPENDIX C TO PART 101.—NUTRITION FACTS FOR RAW FRUITS AND VEGETABLES

Nutrition facts[1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total fat		Saturated fat		Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	(%)	(g)	(%)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Banana, 1 medium (126 g/4.5 oz)	110	0	0	0	0	0	0	0	0	0	400	11	29	10	4	16	21	1	0	15	0	2
Apple, 1 medium (154 g/5.5 oz)	80	0	0	0	0	0	0	0	0	0	170	5	22	7	5	20	16	0	2	8	0	2
Watermelon, 1/18 medium melon; 2 cups diced pieces (280 g/10.0 oz)	80	0	0	0	0	0	0	0	10	0	230	7	27	9	2	8	25	1	20	25	2	4
Orange, 1 medium (154 g/5.5 oz)	70	0	0	0	0	0	0	0	0	0	260	7	21	7	7	28	14	1	2	130	6	2
Cantaloupe, 1/4 medium (134 g/4.8 oz)	50	0	0	0	0	0	0	0	25	1	280	8	12	4	1	4	11	1	100	80	2	2
Grapes, 1 1/2 cups (138 g/4.9 oz)	90	10	1	2	0	0	0	0	0	0	270	8	24	8	1	4	23	1	2	25	2	2
Grapefruit, 1/2 medium (154 g/5.3 oz)	60	0	0	0	0	0	0	0	0	0	230	7	16	5	6	24	10	1	15	110	2	0
Strawberries, 8 medium (147 g/5.3 oz)	45	0	0	0	0	0	0	0	0	0	270	8	12	4	4	16	8	1	0	160	2	4
Peach, 1 medium (98 g/3.5 oz)	40	0	0	0	0	0	0	0	0	0	190	5	10	3	2	8	9	1	2	10	0	0
Pear, 1 medium (166 g/5.9 oz)	100	10	1	2	0	0	0	0	0	0	210	6	25	8	4	16	17	1	0	10	2	0
Nectarine, 1 medium (140 g/5.0 oz)	70	0	0.5	1	0	0	0	0	0	0	300	9	16	5	2	8	12	1	4	15	0	2
Honeydew Melon, 1/10 medium melon (134 g/4.8 oz)	50	0	0	0	0	0	0	0	35	1	310	9	13	4	1	4	12	1	2	45	0	2
Plums, 2 medium (132 g/4.7 oz)	80	10	1	2	0	0	0	0	0	0	220	6	19	6	2	8	10	1	6	20	0	0
Avocado, California, 1/5 medium (30 g/1.1 oz)	55	45	5	8	1	5	0	0	0	0	170	5	3	1	3	12	0	1	0	4	0	0
Lemon, 1 medium (58 g/2.1 oz)	15	0	0	0	0	0	0	0	5	0	90	3	5	2	1	4	1	0	0	40	2	0
Pineapple, 2 slices, 3″ diameter, 3/4″ thick (112 g/4 oz)	60	0	0	0	0	0	0	0	10	0	115	3	16	5	1	4	13	1	0	25	2	2
Tangerine, 1 medium (109 g/3.9 oz)	50	0	0.5	1	0	0	0	0	0	0	180	5	15	5	3	12	12	1	0	50	4	0
Sweet cherries, 21 cherries; 1 cup (140 g/5.0 oz)	90	0	0.5	1	0	0	0	0	0	0	300	9	22	7	3	12	19	2	2	15	2	2
Kiwifruit, 2 medium (148 g/5.3 oz)	100	10	1	2	0	0	0	0	0	0	480	14	24	8	4	16	16	2	2	240	6	4
Lime, 1 medium (67 g/2.4 oz)	20	0	0	0	0	0	0	0	0	0	75	2	7	2	2	8	0	0	0	35	0	0
Potato, 1 medium (148 g/5.3 oz)	100	0	0	0	0	0	0	0	0	0	720	21	26	9	3	12	3	4	0	45	2	6
Iceberg lettuce, 1/6 medium head (89 g/3.2 oz)	15	0	0	0	0	0	0	0	10	0	120	3	3	1	1	4	2	1	4	6	2	2
Tomato, 1 medium (148 g/5.3 oz)	35	0	0.5	1	0	0	0	0	5	0	360	10	7	2	1	4	4	1	20	40	2	2
Onion, 1 medium (148 g/5.3 oz)	60	0	0	0	0	0	0	0	5	0	240	7	14	5	3	12	9	2	0	20	4	2
Carrot, 7″ long, 1 1/4″ diameter (78 g/2.8 oz)	35	0	0	0	0	0	0	0	40	2	280	8	8	3	2	8	5	1	270	10	2	0
Celery, 2 medium stalks (110 g/3.9 oz)	20	0	0	0	0	0	0	0	100	4	350	10	5	2	2	8	0	1	2	15	4	2
Sweet corn, kernels from 1 medium ear (90 g/3.2 oz)	80	10	1	2	0	0	0	0	0	0	240	7	18	6	3	12	5	3	2	10	0	2
Broccoli, 1 medium stalk (148 g/5.3 oz)	45	0	0.5	1	0	0	0	0	55	2	540	15	8	3	5	20	3	5	15	220	6	6
Green cabbage, 1/12 medium head (84 g/3.0 oz)	25	0	0	0	0	0	0	0	20	1	190	5	5	2	2	8	3	1	0	70	4	2
Cucumber, 1/3 medium (99 g/3.5 oz)	15	0	0	0	0	0	0	0	0	0	170	5	3	1	1	4	2	1	4	10	2	2
Bell pepper, 1 medium (148 g/5.3 oz)	30	0	0	0	0	0	0	0	0	0	270	8	7	2	2	8	4	1	8	190	2	2
Cauliflower, 1/6 medium head (99 g/3.5 oz)	25	0	0	0	0	0	0	0	30	1	270	8	5	2	2	8	2	2	0	100	2	2
Leaf lettuce, 1 1/2 cups shredded (85 g/3.0 oz)	15	0	0	0	0	0	0	0	30	1	230	7	4	1	2	8	2	1	40	6	4	0
Sweet Potato, medium, 5″ long, 2″ diameter (130 g/4.6 oz)	130	0	0	0	0	0	0	0	45	2	350	10	33	11	4	16	7	2	440	30	2	2
Mushrooms, 5 medium (84 g/3.0 oz)	20	0	0	0	0	0	0	0	0	0	300	9	3	1	1	4	0	3	0	2	0	2
Green onion, 1/4 cup chopped (25 g/0.9 oz)	10	0	0	0	0	0	0	0	5	0	70	2	2	1	1	4	1	0	2	8	0	0
Green (snap) beans, 3/4 cup cut (83 g/3.0 oz)	25	0	0	0	0	0	0	0	0	0	200	6	5	2	3	12	2	1	4	10	4	2
Radishes, 7 radishes (85 g/3.0 oz)	15	0	0	0	0	0	0	0	25	1	230	7	3	1	0	0	2	1	0	30	2	0
Summer squash, 1/2 medium (98 g/3.5 oz)	20	0	0	0	0	0	0	0	0	0	260	7	4	1	2	8	2	1	6	30	2	2
Asparagus, 5 spears (93 g/3.3 oz)	25	0	0	0	0	0	0	0	0	0	230	7	4	1	2	8	2	2	10	15	2	2

[1] Raw, edible weight portion. Percent (%) Daily Values are based on a 2,000 calorie diet.

APPENDIX D TO PART 101.—NUTRITION FACTS FOR COOKED FISH

Nutrition facts[1] fish (84 g/3 oz)	Calories	Calories from fat	Total fat		Saturated fat		Cholesterol		Sodium		Potassium		Total carbohydrate		Dietary fiber		Sugars (g)	Protein (g)	Vitamin A (%)	Vitamin C (%)	Calcium (%)	Iron (%)
			(g)	(%)	(g)	(%)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)						
Shrimp	80	10	1	2	0	0	165	55	190	8	140	4	0	0	0	0	0	18	0	0	2	15
Cod	90	0	0.5	1	0	0	45	15	60	3	450	13	0	0	0	0	0	20	0	0	2	2
Pollock	90	10	1	2	0	0	80	27	110	5	360	10	0	0	0	0	0	20	0	0	0	2
Catfish	140	80	9	14	2	10	50	17	40	2	230	7	0	0	0	0	0	17	0	0	0	0
Scallops, about 6 large or 14 small	120	10	1	2	0	0	55	18	260	11	280	8	2	1	0	0	0	22	0	0	2	2
Salmon, Atlantic/Coho	160	60	7	11	1	5	50	17	50	2	490	14	0	0	0	0	0	22	0	0	0	4
Salmon, Chum/Pink	130	35	4	6	1	5	70	23	65	3	410	12	0	0	0	0	0	22	2	0	0	2
Salmon, Sockeye	180	80	9	14	1.5	8	75	25	55	2	320	9	0	0	0	0	0	23	4	0	0	2

APPENDIX D TO PART 101.—NUTRITION FACTS FOR COOKED FISH—Continued

Nutrition facts[1] fish (84 g/3 oz)	Calories	Calories from fat	Total fat		Saturated fat		Cholesterol		Sodium		Potassium		Total carbohydrate		Dietary fiber		Sugars (g)	Protein (g)	Vitamin A (%)	Vitamin C (%)	Calcium (%)	Iron (%)
			(g)	(%)	(g)	(%)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)						
Flounder/sole	100	14	1.5	2	0.5	3	60	20	90	4	290	8	0	0	0	0	0	21	0	0	2	2
Oysters, about 12 medium	100	35	3.5	5	1	5	115	38	190	8	390	11	4	1	0	0	0	10	0	0	6	45
Orange roughy	80	10	1	2	0	0	20	7	70	3	330	9	0	0	0	0	0	16	0	0	0	0
Mackerel, Atlantic/Pacific	210	120	13	20	1.5	8	60	20	100	4	400	11	0	0	0	0	0	21	0	0	0	5
Ocean perch	110	20	2	3	0	0	50	17	95	4	290	8	0	0	0	0	0	21	0	0	10	6
Rockfish	100	20	2	3	0	0	40	13	70	3	430	12	0	0	0	0	0	21	4	0	0	2
Whiting	110	25	3	5	0.5	3	70	23	95	4	320	9	0	0	0	0	0	19	2	0	6	0
Clams, about 12 small	100	15	1.5	2	0	0	55	18	95	4	530	15	0	0	0	0	0	22	10	0	6	60
Haddock	100	10	1	2	0	0	80	27	85	4	340	10	0	0	0	0	0	21	0	0	2	6
Blue crab	100	10	1	2	0	0	90	30	320	13	360	10	0	0	0	0	0	20	0	0	8	4
Rainbow trout	140	50	6	9	2	10	60	20	35	1	370	11	0	0	0	0	0	21	4	4	6	2
Halibut	110	20	2	3	0	0	35	12	60	3	490	14	0	0	0	0	0	23	2	0	4	4
Lobster	80	0	0.5	1	0	0	60	20	320	13	300	9	1	0	0	0	0	17	0	0	4	2
Swordfish	130	35	4.5	7	1	5	40	13	100	4	310	9	0	0	0	0	0	22	2	2	0	4

[1] Cooked, edible weight portion. Percent (%) Daily Values are based on a 2,000 calorie diet.

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Dated: July 31, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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