Authority: 26 U.S.C. 3304(a)(9)(B); Secretary's Order No. 3–2007, April 3, 2007 (72 FR 15907).

§ 616.5 [Removed]

2. Remove § 616.5.

3. Revise paragraph (e) of § 616.6 to read as follows:

§ 616.6 Definitions.

* * * * *

(e) *Paying State.* A single State against which the claimant files a Combined-Wage Claim, if the claimant has wages and employment in that State's base period(s) and the claimant qualifies for unemployment benefits under the unemployment compensation law of that State using combined wages and employment.

* * * * *

4. Add paragraph (f) to § 616.7 to read as follows:

§ 617.7 Election to file a Combined-Wage Claim.

* * * * *

(f) If a State denies a Combined-Wage Claim, it must inform the claimant of the option to file in another State in which the State finds that claimant has wages and employment during that State's base period(s).

§ 616.8 [Amended]

5. In § 616.8(a) remove the words '', even if the Combined-Wage Claimant has no earnings in covered employment in that State''.

Signed at Washington, DC, this 29th day of October 2007.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. E7–21513 Filed 11–1–07; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

RIN 0910–ZA30

[Docket No. 2006N–0168]

Food Labeling: Revision of Reference Values and Mandatory Nutrients

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on what new reference values the agency should use to calculate the percent daily value (DV) in the Nutrition Facts and Supplement Facts labels and what factors the agency should consider in establishing such new reference values. In addition, FDA requests comments on whether it should require that certain nutrients be added or removed from the Nutrition Facts and Supplement Facts labels. Comments on what factors should be considered to update the agency's reference values will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by January 31, 2008.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0168, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2579, or e-mail: *Paula.Trumbo@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background[1]

On November 8, 1990, the Nutrition Labeling and Education Act (NLEA) of 1990 (Public Law No. 101–535) was signed into law (the 1990 amendments) amending the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments made the most significant changes in the act and had a direct bearing on FDA's revision of nutrition labeling in 1993. The 1990 amendments added section 403(q) (21 U.S.C. 403(q)) to the act which specified, in part, that: (1) With certain exceptions, a food is to be considered misbranded unless its label or labeling bears nutrition labeling; (2) certain nutrients and food components are to be included in

[1] A list of the acronyms cited in this ANPRM are defined in Appendix A.

nutrition labeling, although the Secretary of Health and Human Services can add or delete nutrients by regulation if it is found necessary to assist consumers in maintaining healthy dietary practices; (3) nutrition labeling is to be provided for the most frequently consumed varieties of raw produce (fruits and vegetables) and raw fish according to voluntary guidelines or, if necessary, regulations; (4) a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients; and (5) FDA is to develop regulations governing labeling of foods to which section 411 of the act (21 U.S.C. 350) applies (i.e., vitamin and minerals).

In response to the NLEA, FDA, in 1993, issued several rules to modify how nutrition information is presented on food labels. When the agency issued those rules to modify the nutrition label information, it considered the diet and health information that was current at that time, including the National Academy of Sciences (NAS) Recommended Dietary Allowances (RDAs) (Refs. 1 to 3), the NAS Diet and Health Report (Ref. 4), the Surgeon General's Report on Nutrition and Health (Ref. 5), and the 1990 Dietary Guidelines for Americans (Ref. 6). New information has since become available on nutrient values that the agency believes may impact what nutrients it should consider requiring to be listed on the food label and what nutrient values it should use as a basis for the DVs on the food label. The new information includes revisions to the Dietary Guidelines for Americans (Ref. 7), the Institute of Medicine's (IOM's) published reports on the Dietary Reference Intakes (DRIs) that update recommendations for the intake of vitamins, minerals, and macronutrients (Refs. 8 to 14), the IOM report on the application of the DRIs (Ref. 15), and the IOM report on ''Guiding Principles for Nutrition Labeling and Fortification'' that provides recommendations on the use of the new DRIs in nutrition labeling (Ref. 16). The latter reports stimulated extensive discussion in the scientific community (e.g. at nutrition and food science conferences and in publications (Refs. 17 to 19); FDA and the IOM recognize that the approach to setting a DV in the labeling report (Ref. 16) represents a new approach that requires evaluation. At the IOM's 2007 workshop on ''The Development of DRI's 1994–2004: Lessons Learned and New Challenges,'' there was discussion about the limitations of the framework that was used to set the DRIs, as well as recommendations for future consideration. For all of these reasons, FDA finds it important to seek comment on the recommendations made in these reports (Refs. 7 to 16). In addition, the agency is considering changes to the food label in more recently published ANPRMs concerning prominence of calories and the labeling of *trans* fats. The agency discusses, below, the 1993 rules on food labeling, these ANPRMs, and publications and reports available since 1993, to provide background for the questions the agency is asking in this ANPRM related to a future proposed rule to update the presentation of nutrients and content of nutrient values on food labels.

A. Development of Current DVs

In the final rule on Food Labeling; Reference Daily Intakes and Daily Reference Values (the 1993 RDI/DRV final rule) (58 FR 2206, January 6, 1993), FDA amended its regulations to establish two sets of label reference values: Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs) for use in declaring the nutrient content of a food on its label or labeling. These two reference values were used to establish a single set of label reference values known as the DVs, which were intended to assist consumers in both understanding the relative significance of nutritional information in the context of a total daily diet and in comparing the nutritional values of food products.

1. RDIs

In the **Federal Register** of July 19, 1990 (55 FR 29476), FDA proposed to replace the U.S. Recommended Daily Allowances (U.S. RDAs) as the reference values for certain vitamins and minerals used in nutrition labeling of foods with updated and expanded reference values (the 1990 proposal). The U.S. RDAs set in 1973 were based primarily on the NAS 1968 RDA values for vitamins and minerals (Ref. 1). However, the U.S. RDAs for certain vitamins and minerals for which no RDA had been identified (biotin, pantothenic acid, copper, and zinc) were based on information cited in the NAS's ''Recommended Dietary Allowances,'' 7th edition (Ref. 1). The NAS RDAs were updated in 1974 and 1980, and again in 1989 along with revised values for the listing known as ''Estimated Safe and Adequate Daily Dietary Intakes'' (ESADDIs).[2] In 1990, FDA decided that it needed to update the U.S. RDA values, in part, due to the revisions of the 1989 NAS RDA and ESADDI values. FDA proposed to redesignate ''U.S. RDAs'' as ''RDIs,''[3] and to establish five sets of RDIs for different developmental groups, i.e., adults and children 4 or more years of age (excluding pregnant or lactating women), children less than 4 years of age, infants, pregnant women, and lactating women. FDA also proposed using a population-weighted average of the relevant NAS RDAs and ESADDIs to establish the RDIs because it would ''serve the purpose of providing an overall reference value for food labeling more appropriately than a highest value'' and ''because of decreasing public health concern with nutritional deficiencies, it makes less sense to use maximum values as the basis for these reference values'' (55 FR 29476 at 29478).

In the 1993 RDI/DRV final rule, FDA redesignated the U.S. RDA values in part 101 (21 CFR part 101) for vitamins and minerals as RDIs. In addition, FDA established, under 21 CFR part 104, a single set of label reference values for adults and children 4 or more years of age, in part, because of space constraints on the food label and the fact that children over the age of 4 years consume the same foods that the rest of the population consumes (58 FR 2206 at 2213). These RDIs were based on the NAS RDAs set in 1968. Although FDA proposed in 1990 to base the RDIs on a population-weighted average of the RDAs and ESADDIs, in the 1993 RDI/DRV final rule FDA used the highest RDA for adults and children 4 or more years of age (excluding values for pregnant and lactating women) to serve as label reference values (58 FR 2206 at 2210 to 2213). FDA found that there was considerable and uniform support in the comments for continuing to select the highest nutrient value from this group and that vulnerable or at-risk groups would be sufficiently covered by electing the highest value. FDA referred to this approach as the ''population-coverage approach.''

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 that, in section 203, instructed FDA to not issue regulations before November 8, 1993, that would revise the U.S. RDAs (redesignated as RDIs) for vitamins or minerals (other than existing regulations that established the U.S. RDAs specified in § 101.9(c)(7)(iv) that were in effect prior to October 6, 1992). Thus, FDA did not codify new nutrient values in the 1993 RDI/DRV final rule. In the **Federal Register** of December 28, 1995 (60 FR 67164) (the 1995 final rule), FDA amended certain

[2]The ESADDIs are nutrient values set by NAS for essential nutrients for which data are available to estimate a range of requirements, but insufficient for developing a specific RDA (Ref. 3).

[3]In 1993, FDA redesignated the term U.S. RDA to RDI because the term U.S. RDA was easily confused with the term RDA (58 FR 2206 at 2207).

RDIs based on the 1989 NAS RDAs and ESADDIs.

In the 1995 final rule, FDA amended its regulations to establish RDIs for vitamin K and selenium based on the 1989 NAS RDAs, and for manganese, chromium, molybdenum, and chloride based on the 1989 ESADDIs (Ref. 3). FDA did not establish a DV for fluoride in the 1995 final rule because the 1989 NAS RDA report stated that published studies ''do not justify a classification of fluorine[4] as an essential element, according to accepted standards'' (Ref. 3 at p. 235) and because the primary sources of dietary fluoride (e.g., community water supplies, toothpastes, mouth rinses) are not required to bear nutrition labeling (60 FR 67164 at 67168). FDA concluded that the declaration of percent DV of fluoride within nutrition labeling on a limited number of foods that are relatively minor sources of the nutrient would be of little use in assisting consumers in maintaining healthy dietary practices (60 FR 67164 at 67168).

In addition, a notification was submitted under section 403(r)(2)(G) of the act (21 U.S.C. 343(r)(2)(G)) in 2001 for the use of certain nutrient content claims for choline. These statements identify the daily value for choline as 550 milligrams (mg).[5] This value is based on the Adequate Intake (AI) set by the Institute of Medicine (IOM) of the NAS in 1998 (Refs. 9 and 20).

2. DRVs

The 1993 RDI/DRV final rule also identified DRVs for those nutrients that are important to diet and health (e.g., total fat, saturated fat, cholesterol, total carbohydrate (CHO), protein, dietary fiber, sodium, and potassium). The DRVs are based on the NAS Diet and Health Report (sodium, potassium, fat, saturated fat, cholesterol, carbohydrate, and dietary fiber) (Ref. 4), the Surgeon General's Report on Nutrition and Health (dietary fiber) (Ref. 5), and the 1990 Dietary Guidelines for Americans (Ref. 6). The DRV for protein (50 grams per day (g/d)) was set at 10 percent of 2,000 calories based on an adjusted average of the 1989 RDA (Ref. 3). The use of ''calories'' to mean ''kilocalories'' (kcals) is commonly accepted and more readily understood by consumers.

The DRVs in the 1993 RDI/DRV final rule (58 FR 2206) were based on a 2,000 calorie reference diet. In the 1990 proposal (55 FR 29476 at 29482), FDA proposed using a 2,350 calories reference diet based on a population adjusted mean of recommended calorie allowances for persons 4 or more years of age (excluding pregnant and lactating women) (from table 3–5 of the 10th edition of ''Recommended Dietary Allowances'' (Ref. 3)). However, FDA received several comments opposing the 2,350 reference values because of concerns that this value was too high, especially among women (58 FR 2206 at 2217). In addition, several comments suggested that using 2,000 calories as a reference diet would be easier for consumers to use in calculations and closer to caloric requirements of older women who are ''at risk for excessive calories and fat'' (*id.*). The 2,000 calorie reference diet FDA adopted was consistent with the ''population-coverage approach'' as it selected a lower calorie basis for the DRVs for the group at risk (i.e., older women).

B. Nutrient Content Final Rule

In the **Federal Register** of January 6, 1993 (58 FR 2079), FDA published a final rule entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (the 1993 nutrient content final rule). The 1993 nutrient content final rule: (1) Requires nutrition labeling on most foods that are regulated by FDA, (2) revises the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, (3) specifies a new format for declaring nutrition information, (4) allows specified products to be exempt from nutrition labeling, and (5) prescribes a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling can be used. An example of a Nutrition Facts label can be found in appendix B.

1. Required and Voluntary Labeling of Nutrients on Food Products (§ 101.9(c))

With respect to nutrition labeling of foods, the 1993 nutrient content final rule declared that nutrition information on the label and in labeling of foods shall contain information about the level of the following nutrients: (1) Calories or total calories; (2) calories from fat; (3) calories from saturated fat (voluntary); (4) total fat; (5) saturated fat; (6) polyunsaturated fat (voluntary); (7) monounsaturated fat (voluntary); (8) cholesterol; (9) sodium; (10) potassium (voluntary); (11) total carbohydrate (including sugars (mono- and disaccharides), oligosaccharides, starch, fiber, and organic acids); (12) dietary fiber; (13) soluble fiber (voluntary); (14) insoluble fiber (voluntary); (15) sugars; (16) sugar alcohol (voluntary); (17) other carbohydrate (voluntary); (18) protein; and (19) vitamins and minerals (see § 101.9(c)(1) through (c)(8)). However, those nutrients that can be declared voluntarily, as described previously in this document, must be declared when a nutrient content or health claim is made (§ 101.9(c)). In the **Federal Register** of July 11, 2003 (68 FR 41434), FDA amended its regulations on nutrition labeling to require *trans* fatty acids be declared in grams per serving in the nutrition label of conventional foods and dietary supplements (see section G).

Nutrient information for both mandatory and any voluntary nutrients that are to be declared in the nutrition label, except vitamins and minerals, shall be declared with the name of each nutrient, and the quantitative amount by weight for that nutrient (i.e. g or mg) (see § 101.9(d)(7)(i)). A listing of the percent DRV as established in § 101.9(c)(7)(iii) and (c)(9) (see table 1 of this document for reference values) is required under the heading percent DV for each nutrient for which a DRV was established, except that the percent for protein may be omitted (see § 101.9(d)(7)(ii)).

The regulations require that information about these nutrients be declared on the nutrition label and that no nutrients or food components, other than those listed, may be included on the nutrition label (§ 101.9(c)).

A statement about the percent of the RDI, expressed as the percent of the DV for vitamin A, vitamin C, calcium, and iron, in that order, is required (see table 1 of this document for reference values) (§ 101.9(c)(8)(ii)). These four vitamin and mineral nutrients are required to be declared because of public health concerns relative to inadequate intake of these nutrients by specific portions of the population, as well as the possible association between the lack of several of these nutrients in the diet and the risk of chronic disease (58 FR 2079 at 2106). The declaration of other vitamins and minerals that have an RDI is required when they are added as a nutrient supplement or when a claim is made about them (§ 101.9(c)(8)(ii)). If the amount of the vitamin or mineral is present at less than 2 percent of the RDI, declaration of an amount is not required or the content may be expressed as zero (§ 101.9(c)(8)(iii)).

[4]Fluoride is the ionized form of the element fluorine.

[5]FDA has not acted to prohibit or modify the claims, and therefore, manufacturers may use the specified claims on the label and in the labeling of any food or dietary supplement product that qualifies for the claims described in the notification.

TABLE 1.—REFERENCE VALUES FOR NUTRITION LABELING (BASED ON A 2,000 CALORIE INTAKE; FOR ADULTS AND CHILDREN 4 OR MORE YEARS OF AGE)

Nutrient[1]	Unit of Measure	Daily Values
Total Fat	g	65
Saturated fatty acids	g	20
Cholesterol	mg	300
Sodium	mg	2,400
Potassium	mg	3,500
Total carbohydrate	g	300
Fiber	g	25
Protein	g	50
Vitamin A	International Units (IU)	5,000
Vitamin C	mg	60
Calcium	mg	1,000
Iron	mg	18
Vitamin D	IU	400
Vitamin E	IU	30
Vitamin K	micrograms (µg)	80
Thiamin	mg	1.5
Riboflavin	mg	1.7
Niacin	mg	20
Vitamin B6	mg	2.0
Folate	µg	400
Vitamin B12	µg	6.0
Biotin	µg	300
Pantothenic acid	mg	10
Phosphorus	mg	1,000
Iodine	µg	150
Magnesium	mg	400
Zinc	mg	15
Selenium	µg	70
Copper	mg	2.0
Manganese	mg	2.0
Chromium	µg	120

TABLE 1.—REFERENCE VALUES FOR NUTRITION LABELING (BASED ON A 2,000 CALORIE INTAKE; FOR ADULTS AND CHILDREN 4 OR MORE YEARS OF AGE)—Continued

Nutrient[1]	Unit of Measure	Daily Values
Molybdenum	µg	75
Chloride	mg	3,400

[1]Nutrients in this table are listed in the order in which they are required to appear on a label in accordance with § 101.9(c). This list includes only those nutrients for which a DRV has been established in § 101.9(c)(9) or a RDI in § 101.9(c)(8)(iv).

The declaration of other vitamins and minerals with an RDI need not be declared if: (1) Neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and (2) the vitamins and minerals are required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and included in a food solely for technological purposes and declared only in the ingredient statement (§ 101.9(c)(8)(ii)). Foods that are represented or purported to be for use by infants (up to 12 months of age), children 1 to 4 years of age, pregnant women, or lactating women must use the RDIs that are specified for the intended group (§ 101.9(c)(8)(i)). However, FDA has not codified RDI values to use for these various groups. FDA stated, in the 1995 final rule, that it intended to address the issue of RDIs for all nutrients for the various age groups in a future rulemaking but was not doing so in that rule due to the continuing questions about how to arrive at such values. FDA noted that, for conventional foods, there could be no declaration on labels of foods represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women for vitamin K, selenium, chloride, manganese, chromium, and molybdenum until such time as RDIs are established for such groups (60 FR 67164 at 67171). FDA stated that these six nutrients could be specified in mg or µg amounts in dietary supplements under § 101.36 with an asterisk in the percent DV column that refers to a footnote stating ''Daily Value not established.''

Prior to the 1995 final rule, FDA noted in the 1993 RDI/DRV final rule that manufacturers have continued to use the nutrient values that were contained in 21 CFR 105.3(b) (FDA deleted this paragraph on March 16, 1979 (44 FR 16005)), as label reference values for use on foods purported or represented to be for use by infants, children under 4 years of age, or pregnant or lactating women, without objection from FDA (58 FR 2206 at 2213). The RDIs for the vitamins and minerals for these groups are listed in a table in the 1993 RDI/DRV final rule as guidance (58 FR 2206 at 2213). Such table does not include the seven nutrients that FDA stated could not be on conventional food labeling for these specific groups in the 1995 final rule. Section 101.9(c)(8)(i) states that all other foods must use the RDI for adults and children 4 or more years of age.

2. Application of DVs

Section 403(q) of the act provides discretion to the agency to require information about nutrients on the food label when the agency determines such information will ''assist consumers in maintaining healthy dietary practices.'' Section 2(b)(1)(A) of the 1990 amendments states that nutrition labeling must ''be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in context of a total daily diet.'' In the 1993 nutrient content final rule, FDA stated that ''the nutrition label can and should help consumers make informed food choices, and that it can also contribute to consumers maintaining healthy dietary practices'' (58 FR 2079 at 2114). While the DVs do not represent dietary goals for individuals, their intended use is to provide an overall population reference value on the food label for the consumer (55 FR 29476 at 29481).

In order to determine a nutrition labeling format that could be used most effectively by consumers, FDA conducted consumer research and evaluated research conducted by others in considering requirements for the nutrition label format in the 1993 nutrient content final rule (58 FR 2079 at 2115–2121). Based on the results of several consumer studies that evaluated the ability of nutrition label formats to enable consumers to understand the relative significance of product nutrition information in the context of a total daily diet, FDA concluded the following: (1) The declaration of nutrient amount information as percentages of DV or the placement of adjectives (e.g., high, medium, or low) next to the nutrient amount information are effective ways to help consumers understand the significance of product nutrition information in the context of the total daily diet; (2) the percent DV declarations moderate dietary judgments about a food; and (3) other format elements, such as a list of DRVs

for important macronutrients, highlighting, or grouping nutrients according to Dietary Guidelines for Americans, did not help consumers to make better dietary judgments (58 FR 2079 at 2118). Upon reviewing the results of several studies that evaluated the consumer's use of the nutrition label, the two most reported uses identified by FDA were to evaluate nutrition characteristics of single products and to assist in making choices between products (58 FR 2079 at 2121 and references cited therein).

Informed choices include making judgments about a food product's contribution to the total diet and making comparisons between the nutritional quality of different food products. Findings from the FDA Food Label Use and Nutrition Education Surveys (FLUNES) conducted in 1994 and 1995 showed that more than half of consumers used the Nutrition Facts label to make a judgment about the overall nutritional quality of a food product, especially the fat content (Ref. 21).

3. Uses of the DVs in Nutrient Content and Health Claims

The DVs are used to determine, in part, whether a food or dietary supplement is eligible to bear nutrient content claims or health claims. For nutrient content claims, a food or dietary supplement must contain 10 to 19 percent of the DV per Reference Amount Customarily Consumed (RACC) in order to be labeled as a good source of a particular nutrient and must contain 20 percent or more of the DV per RACC in order to be labeled as an excellent source of a particular nutrient (§ 101.54(b) and (c)). When a health claim is about the effects at decreased dietary intake levels (i.e., low claim), the levels must meet the definition for use of the term low that has been established for that substance, unless a specific alternative level has been established (§ 101.14(d)(2)(vi)). If no definition for low has been established, the level of the substance must meet the level established in the regulation authorizing the claim. For health claims, when a claim is about the effects of consuming the substance at other than decreased dietary levels (i.e. not a low claim), a food must meet the definition of high (20 percent of the DV) for the substance that is the subject of the claim, if the agency has established a definition for the use of the term ''high'' for that substance and the agency has not established an alternative level for that nutrient in the health claim regulation (§ 101.14(d)(2)(vii)). For a few health claims authorized in §§ 101.76, 101.78, and 101.79, an eligibility requirement is based upon meeting the definition for a good source (10 percent) of the DV for a particular nutrient. The specific eligibility requirements for each authorized health claim are set forth in subpart E, §§ 101.70 to 101.83. In addition, foods bearing health claims, other than dietary supplements or where otherwise provided for in regulations, must contain 10 percent or more of the DV, prior to any nutrient addition, for one of the following nutrients: Vitamins A, vitamin C, iron, calcium, protein, or fiber (§ 101.14(e)(6)).

C. Labeling of Dietary Supplements

As part of the implementation of the Dietary Supplement Health and Education Act of 1994, FDA issued final regulations in the **Federal Register** of September 23, 1997 (62 FR 49826), requiring that a Supplement Facts label appear on the label or labeling of all dietary supplements. The Supplement Facts label is similar to the Nutrition Facts label in both content and format. Examples of Supplement Facts labels can be found in appendix B. The Supplement Facts label must include the amount and percent DV of the same nutrients that are required for conventional foods if the nutrients are present in the supplement, as well as the amount of other dietary ingredients present (§ 101.36(b)). Nutrients that have established DVs are listed first, followed by a horizontal line that separates these nutrients from dietary ingredients that have no DVs (e.g., botanicals). The Supplement Facts label must state that percent DVs have not been established for these dietary ingredients and must indicate these ingredients clearly with an asterisk (*) (§ 101.36(b)(3)(iv)).

D. IOM DRIs and Acceptable Macronutrient Distribution Ranges

Beginning in 1997, the IOM began publishing a series of reports on reference intake values (Refs. 8 to 14), collectively known as the DRIs. The DRIs are defined intake levels and include the AI, estimated average requirement (EAR), RDA, and the tolerable upper intake level (UL). DRIs were set for those vitamins, minerals, and macronutrients that are essential in humans and/or provide a beneficial role in human health. While many of the RDAs were revised for nutrients that had an existing RDA (e.g., iron and vitamin A), some nutrients that had RDAs now have an AI (e.g., calcium and vitamin K). Those nutrients that had an ESADDI, now have either an RDA (copper and molybdenum) or an AI (manganese, fluoride, and chromium). Although not considered to be a DRI that provides a defined intake level, the IOM also set acceptable macronutrient distribution ranges (AMDRs) for carbohydrate (i.e., sugars (mono-, di- and oligosaccharides) and starch), total fat, *n*-3 and *n*-6 polyunsaturated fatty acids, and protein (Ref. 13 and Ref. 16 at p. 93). The DRIs and AMDRs were set for the following life stage groups: Infants (0 to 6 and 7 to 12 months); toddlers (1 to 3 years); boys and girls (4 to 8 years); adolescent boys and girls (9 to 13 and 14 to 18 years); adult men and women (19 to 30, 31 to 50, 51 to 70, and greater than 70 years); and pregnant and lactating women.

1. EAR

The EAR for a nutrient is defined as the daily intake value that is estimated to meet the requirement for that nutrient, as defined by a specific criterion of adequacy or optimal health, in half of the apparently healthy individuals in a specific life stage and gender group. This definition of the EAR implies a median, rather than a mean or average. The median and mean would be the same if the distribution of requirements followed a symmetrical distribution.

In the case of energy, the IOM set an estimated energy requirement (EER) to represent the average dietary energy intake that is predicted to maintain energy balance in a healthy adult of a defined age, gender, weight, height, and physical activity level (PAL). PAL is the ratio of total energy expenditure (TEE) divided by the basal rate of energy expenditure. The EER equations use one of the four PAL categories: Sedentary, low active, active, and very active. In children and pregnant and lactating women, the EER meets the needs associated with the deposition of tissues or secretion of milk at rates consistent with good health.

The EAR and the EER are used for assessing nutrient intakes of groups. For nutrients with an EAR and for the EER, the prevalence of inadequacy in the population group for the nutrient or energy level evaluated is usually the approximate percentage of the population evaluated whose intakes fall below the EAR for the nutrient or the EER (Ref. 22). The EAR for the nutrient and the EER can also be used to plan for an acceptably low prevalence of inadequate intakes within a group. The EAR for a nutrient and the EER should not be used as an intake goal for the individual. Examples of planning for groups include planning diets in an assisted-living facility for senior citizens

or planning menus for a school nutrition program (Ref. 15).

2. RDAs

The RDA is an estimate of the daily average intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group and assuming a normal distribution of requirements (Ref. 8). An RDA cannot be set without an EAR. For all nutrients, except iron, the RDA was set based on the EAR plus 2–times the standard deviation (SD) of the EAR : RDA = EAR + 2 x $SD_{requirement}$. If data about the variability in the EAR for a nutrient were insufficient to calculate the SD_{EAR}, then a coefficient of variation (CV) of 10 percent was assumed.

If individual intakes have been observed for a large number of days and are at the RDA, or observed intakes for fewer days are well above the RDA, there can be a high level of confidence that the intake is adequate. Under these conditions, RDAs can be used for assessing intakes of individuals for nutritional adequacy. The RDA can also be used to plan for intakes of individuals. The RDA should not be used to plan intakes of groups. The RDA is not used to plan intakes of groups because the median of a target intake distribution for a group will usually exceed the RDA because the variance in usual intakes exceeds the variance in requirements. Thus, the selection of the RDA as the median of the target usual intake distribution for groups is not recommended as it results in a greater percentage of inadequacy. The IOM report on the application of the DRIs in planning diets for individuals provided several examples of nutrient-based food guidance systems that could be used by individuals for planning diets, including food and supplement labels (e.g., the Nutrition Facts label) (Ref. 15).

3. AI

If there is insufficient scientific evidence to calculate the EAR and therefore insufficient evidence on which to establish an RDA for an essential nutrient or a nutrient that is beneficial for human health, then an AI is determined. AIs are based on the following: (1) Scientific evidence for requirements that is insufficient to set an EAR (e.g., calcium, vitamin D, choline, biotin, fluoride, sodium); (2) experimental data on risk reduction of chronic disease that are insufficient to set an EAR (e.g., dietary fiber, potassium); or (3) median intakes of a nutrient usually using national nutrition intake survey data, provided there is no evidence of a deficiency of the nutrient in the United States (e.g., pantothenic acid, vitamin K, chromium, manganese, linoleic acid, and α-linolenic acid). There is much less certainty about an AI value than about an RDA value. The AI for a nutrient is expected to exceed the RDA for that nutrient, and therefore it should cover the needs of more than 97 to 98 percent of individuals. The IOM set most AIs for young infants (0 to 6 months of age) based on the average intake of the nutrient consumed exclusively from breastfed infants, provided that breast milk provides a sufficient amount of a nutrient to meet the needs of the infant. The AIs for older infants (7 to 12 months) were set based on: (1) The average intake of the nutrient consumed exclusively from breastfed infants and, if data were available, average intakes of a nutrient provided by complimentary weaning foods; and/or (2) extrapolated from the AI of younger infants; and/or (3) extrapolated from adult AIs; and/or (4) clinical data. The AIs for iron and zinc for older infants could not be set using intake from breast milk because the level of iron and zinc in human milk is not sufficient to meet their needs. For iron, zinc, and protein; EARs and RDAs for older infants 7 to 12 months were set based upon data regarding daily requirements.

Usual individual intakes that are equal to or above the AI can be assumed adequate. The likelihood of inadequacy of usual intakes below the AI cannot be determined since there is insufficient information of the distribution of requirements. The AI can also be used to plan for intakes of individuals (Ref. 15).

4. UL

The UL is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the specific life stage group. As intake increases above the UL, there is a potential for an increased risk of adverse effects. The UL is not intended to be a recommended level of intake, as there is no established benefit for healthy individuals if they consume a nutrient in amounts exceeding the RDA or AI.

The UL can be used to estimate the percentage of the population at potential risk of adverse effects from excess nutrient intake. The UL can also be used to plan for usual intakes below this level for an individual or in planning to minimize the proportion of the population at risk of excess nutrient intake (Ref. 15).

5. AMDR

An AMDR is a range of intakes for a particular energy source (e.g., fat, fatty acids, carbohydrate, and protein) that is associated with reduced risk of chronic disease while providing adequate intakes of essential nutrients. The AMDR of a macronutrient (e.g., fat) is expressed as a percentage of total energy intake because its requirement is dependent on other energy sources (e.g., carbohydrate and protein). If an individual consumes below or above this range, there is a potential for increasing the risk of chronic diseases shown to affect long-term health, as well as increasing the risk of insufficient intakes of essential nutrients.

6. DRIs Set for Macronutrients and Micronutrients

Based on the review of all macronutrients and micronutrients that are known to be essential and/or beneficial in humans, the IOM set the DRIs that are listed for each nutrient in tables 2 to 10 of this document. As can be seen from tables 11a and 11b of this document, the population-coverage and population-weighted AIs for fluoride and the population-coverage RDAs for synthetic niacin exceed the UL for children 4 to 8 years.

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Table 2.--Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Vitamins

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Vit A (μg/d)[a]	Vit C (mg/d)	Vit D (μg/d)[b,c]	Vit E (mg/d)[d]	Vit K (μg/d)	Thiamin (mg/d)	Riboflavin (mg/d)	Niacin (mg/d)[e]	Vit B_6 (mg/d)	Folate (μg/d)[f]	Vit B_{12} (μg/d)	Pantothenic Acid (mg/d)	Biotin (μg/d)	Choline[g] (mg/d)
Infants														
0–6 mo	400*	40*	5*	4*	2.0*	0.2*	0.3*	2*	0.1*	65*	0.4*	1.7*	5*	125*
7–12 mo	500*	50*	5*	5*	2.5*	0.3*	0.4*	4*	0.3*	80*	0.5*	1.8*	6*	150*
Children														
1–3 y	**300**	**15**	5*	**6**	30*	**0.5**	**0.5**	**6**	**0.5**	**150**	**0.9**	2*	8*	200*
4–8 y	**400**	**25**	5*	**7**	55*	**0.6**	**0.6**	**8**	**0.6**	**200**	**1.2**	3*	12*	250*
Males														
9–13 y	**600**	**45**	5*	**11**	60*	**0.9**	**0.9**	**12**	**1.0**	**300**	**1.8**	4*	20*	375*
14–18 y	**900**	**75**	5*	**15**	75*	**1.2**	**1.3**	**16**	**1.3**	**400**	**2.4**	5*	25*	550*
19–30 y	**900**	**90**	5*	**15**	120*	**1.2**	**1.3**	**16**	**1.3**	**400**	**2.4**	5*	30*	550*
31–50 y	**900**	**90**	5*	**15**	120*	**1.2**	**1.3**	**16**	**1.3**	**400**	**2.4**	5*	30*	550*
51–70 y	**900**	**90**	10*	**15**	120*	**1.2**	**1.3**	**16**	**1.7**	**400**	**2.4**[i]	5*	30*	550*
> 70 y	**900**	**90**	15*	**15**	120*	**1.2**	**1.3**	**16**	**1.7**	**400**	**2.4**[i]	5*	30*	550*
Females														
9–13 y	**600**	**45**	5*	**11**	60*	**0.9**	**0.9**	**12**	**1.0**	**300**	**1.8**	4*	20*	375*
14–18 y	**700**	**65**	5*	**15**	75*	**1.0**	**1.0**	**14**	**1.2**	**400**[j]	**2.4**	5*	25*	400*
19–30 y	**700**	**75**	5*	**15**	90*	**1.1**	**1.1**	**14**	**1.3**	**400**[j]	**2.4**	5*	30*	425*
31–50 y	**700**	**75**	5*	**15**	90*	**1.1**	**1.1**	**14**	**1.3**	**400**[j]	**2.4**	5*	30*	425*
51–70 y	**700**	**75**	10*	**15**	90*	**1.1**	**1.1**	**14**	**1.5**	**400**	**2.4**[h]	5*	30*	425*
> 70 y	**700**	**75**	15*	**15**	90*	**1.1**	**1.1**	**14**	**1.5**	**400**	**2.4**[h]	5*	30*	425*
Pregnancy														
14–18 y	**750**	**80**	5*	**15**	75*	**1.4**	**1.4**	**18**	**1.9**	**600**[j]	**2.6**	6*	30*	450*
19–30 y	**770**	**85**	5*	**15**	90*	**1.4**	**1.4**	**18**	**1.9**	**600**[j]	**2.6**	6*	30*	450*
31–50 y	**770**	**85**	5*	**15**	90*	**1.4**	**1.4**	**18**	**1.9**	**600**[j]	**2.6**	6*	30*	450*
Lactation														
14–18 y	**1,200**	**115**	5*	**19**	75*	**1.4**	**1.6**	**17**	**2.0**	**500**	**2.8**	7*	35*	550*
19–30 y	**1,300**	**120**	5*	**19**	90*	**1.4**	**1.6**	**17**	**2.0**	**500**	**2.8**	7*	35*	550*
31–50 y	**1,300**	**120**	5*	**19**	90*	**1.4**	**1.6**	**17**	**2.0**	**500**	**2.8**	7*	35*	550*

NOTE: This table (taken from the DRI reports, see www.nap.edu) presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy breastfed infants, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

[a] As retinol activity equivalents (RAEs). 1 RAE = 1 μg retinol, 12 μg β-carotene, 24 μg α-carotene, or 24 μg β-cryptoxanthin. The RAE for dietary provitamin A carotenoids is twofold greater than retinol equivalents (RE), whereas the RAE for preformed vitamin A is the same as RE.

[b] As cholecalciferol. 1 μg cholecalciferol = 40 IU vitamin D.

[c] In the absence of adequate exposure to sunlight.

[d] As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of α-tocopherol (*RRR*-, *RSR*-, *RRS*-, and *RSS*-α-tocopherol) that occur in fortified foods and supplements. It does not include the *2S*-stereoisomeric forms of α-tocopherol (*SRR*-, *SSR*-, *SRS*-, and *SSS*-α-tocopherol), also found in fortified foods and supplements.

[e] As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan; 0–6 months = preformed niacin (not NE).

[f] As dietary folate equivalents (DFE). 1 DFE = 1 μg food folate = 0.6 μg of folic acid from fortified food or as a supplement consumed with food = 0.5 μg of a supplement taken on an empty stomach.

[g] Although AIs have been set for choline, there are few data to assess whether a dietary supply of choline is needed at all stages of the life cycle, and it may be that the choline requirement can be met by endogenous synthesis at some of these stages.

[h] Because 10 to 30 percent of older people may malabsorb food-bound B_{12}, it is advisable for those older than 50 years to meet their RDA mainly by consuming foods fortified with B_{12} or a supplement containing B_{12}.

[i] In view of evidence linking folate intake with neural tube defects in the fetus, it is recommended that all women capable of becoming pregnant consume 400 μg from supplements or fortified foods in addition to intake of food folate from a varied diet.

[j] It is assumed that women will continue consuming 400 μg from supplements or fortified food until their pregnancy is confirmed and they enter prenatal care, which ordinarily occurs after the end of the periconceptional period—the critical time for formation of the neural tube.

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Table 3.--Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Elements

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Calcium (mg/d)	Chromium (µg/d)	Copper (µg/d)	Fluoride (mg/d)	Iodine (µg/d)	Iron (mg/d)	Magnesium (mg/d)	Manganese (mg/d)	Molybdenum (µg/d)	Phosphorus (mg/d)	Selenium (µg/d)	Zinc (mg/d)	Potassium (g/d)	Sodium (g/d)	Chloride (g/d)
Infants															
0–6 mo	210*	0.2*	200*	0.01*	110*	0.27*	30*	0.003*	2*	100*	15*	2*	0.4*	0.12*	0.18*
7–12 mo	270*	5.5*	220*	0.5*	130*	**11**	75*	0.6*	3*	275*	20*	**3**	0.7*	0.37*	0.57*
Children															
1–3 y	500*	11*	**340**	0.7*	**90**	**7**	**80**	1.2*	**17**	**460**	**20**	**3**	3.0*	1.0*	1.5*
4–8 y	800*	15*	**440**	1*	**90**	**10**	**130**	1.5*	**22**	**500**	**30**	**5**	3.8*	1.2*	1.9*
Males															
9–13 y	1,300*	25*	**700**	2*	**120**	**8**	**240**	1.9*	**34**	**1,250**	**40**	**8**	4.5*	1.5*	2.3*
14–18 y	1,300*	35*	**890**	3*	**150**	**11**	**410**	2.2*	**43**	**1,250**	**55**	**11**	4.7*	1.5*	2.3*
19–30 y	1,000*	35*	**900**	4*	**150**	**8**	**400**	2.3*	**45**	**700**	**55**	**11**	4.7*	1.5*	2.3*
31–50 y	1,000*	35*	**900**	4*	**150**	**8**	**420**	2.3*	**45**	**700**	**55**	**11**	4.7*	1.5*	2.3*
51–70 y	1,200*	30*	**900**	4*	**150**	**8**	**420**	2.3*	**45**	**700**	**55**	**11**	4.7*	1.3*	2.0*
> 70 y	1,200*	30*	**900**	4*	**150**	**8**	**420**	2.3*	**45**	**700**	**55**	**11**	4.7*	1 2*	1.8*
Females															
9–13 y	1,300*	21*	**700**	2*	**120**	**8**	**240**	1.6*	**34**	**1,250**	**40**	**8**	4.5*	1.5*	2.3*
14–18 y	1,300*	24*	**890**	3*	**150**	**15**	**360**	1.6*	**43**	**1,250**	**55**	**9**	4.7*	1.5*	2.3*
19–30 y	1,000*	25*	**900**	3*	**150**	**18**	**310**	1.8*	**45**	**700**	**55**	**8**	4.7*	1.5*	2.3*
31–50 y	1,000*	25*	**900**	3*	**150**	**18**	**320**	1.8*	**45**	**700**	**55**	**8**	4.7*	1.5*	2.3*
51–70 y	1,200*	20*	**900**	3*	**150**	**8**	**320**	1.8*	**45**	**700**	**55**	**8**	4.7*	1.3*	2.0*
> 70 y	1,200*	20*	**900**	3*	**150**	**8**	**320**	1.8*	**45**	**700**	**55**	**8**	4.7*	1.2*	1.8*
Pregnancy															
14–18 y	1,300*	29*	**1,000**	3*	**220**	**27**	**400**	2.0*	**50**	**1,250**	**60**	**12**	4.7*	1.5*	2.3*
19–30 y	1,000*	30*	**1,000**	3*	**220**	**27**	**350**	2.0*	**50**	**700**	**60**	**11**	4.7*	1.5*	2.3*
31–50 y	1,000*	30*	**1,000**	3*	**220**	**27**	**360**	2.0*	**50**	**700**	**60**	**11**	4.7*	1.5*	2 3*
Lactation															
14–18 y	1,300*	44*	**1,300**	3*	**290**	**10**	**360**	2 6*	**50**	**1,250**	**70**	**13**	5.1*	1.5*	2.3*
19–30 y	1,000*	45*	**1,300**	3*	**290**	**9**	**310**	2.6*	**50**	**700**	**70**	**12**	5.1*	1.5*	2.3*
31–50 y	1,000*	45*	**1,300**	3*	**290**	**9**	**320**	2.6*	**50**	**700**	**70**	**12**	5.1*	1.5*	2.3*

NOTE: This table presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy breastfed infants, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

SOURCES: *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride* (1997); *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline* (1998); *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids* (2000); *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (2001); and *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate* (2004). These reports may be accessed via http://www.nap.edu.

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Table 4.--Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels (UL[a]), Vitamins

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Vitamin A (μg/d)[b]	Vitamin C (mg/d)	Vitamin D (μg/d)	Vitamin E (mg/d)[c,d]	Vitamin K	Thiamin	Ribo-flavin	Niacin (mg/d)[d]	Vitamin B_6 (mg/d)	Folate (μg/d)[d]	Vitamin B_{12}	Pantothenic Acid	Biotin	Choline (g/d)	Carote-noids[e]
Infants															
0–6 mo	600	ND[f]	25	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
7–12 mo	600	ND	25	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Children															
1–3 y	600	400	50	200	ND	ND	ND	10	30	300	ND	ND	ND	1.0	ND
4–8 y	900	650	50	300	ND	ND	ND	15	40	400	ND	ND	ND	1.0	ND
Males, Females															
9–13 y	1,700	1,200	50	600	ND	ND	ND	20	60	600	ND	ND	ND	2.0	ND
14–18 y	2,800	1,800	50	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–70 y	3,000	2,000	50	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
> 70 y	3,000	2,000	50	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
Pregnancy															
14–18 y	2,800	1,800	50	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–50 y	3,000	2,000	50	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
Lactation															
14–18 y	2,800	1,800	50	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–50 y	3,000	2,000	50	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND

[a] UL = The maximum level of daily nutrient intake that is likely to pose no risk of adverse effects. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to lack of suitable data, ULs could not be established for vitamin K, thiamin, riboflavin, vitamin B_{12}, pantothenic acid, biotin, carotenoids. In the absence of ULs, extra caution may be warranted in consuming levels above recommended intakes.

[b] As preformed vitamin A only.

[c] As α-tocopherol; applies to any form of supplemental α-tocopherol.

[d] The ULs for vitamin E, niacin, and folate apply to synthetic forms obtained from supplements, fortified foods, or a combination of the two.

[e] β-Carotene supplements are advised only to serve as a provitamin A source for individuals at risk of vitamin A deficiency.

[f] ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

SOURCES: *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride* (1997); *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline* (1998); *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids* (2000); and *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (2001). These reports may be accessed via http://www.nap.edu.

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Table 5.--Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels (UL[a]), Elements

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Arsenic[b]	Boron (mg/d)	Calcium (g/d)	Chromium	Copper (µg/d)	Fluoride (mg/d)	Iodine (µg/d)	Iron (mg/d)	Magnesium (mg/d)[c]	Manganese (mg/d)	Molybdenum (µg/d)	Nickel (mg/d)	Phosphorus (g/d)	Potassium	Selenium (µg/d)	Silicon[d]	Sulfate	Vanadium (mg/d)[e]	Zinc (mg/d)	Sodium (g/d)	Chloride (g/d)
Infants																					
0–6 mo	ND[f]	ND	ND	ND	ND	0.7	ND	40	ND	ND	ND	ND	ND	ND	45	ND	ND	ND	4	ND	ND
7–12 mo	ND	ND	ND	ND	ND	0.9	ND	40	ND	ND	ND	ND	ND	ND	60	ND	ND	ND	5	ND	ND
Children																					
1–3 y	ND	3	2.5	ND	1,000	1 3	200	40	65	2	300	0.2	3	ND	90	ND	ND	ND	7	1.5	2 3
4–8 y	ND	6	2 5	ND	3,000	2.2	300	40	110	3	600	0 3	3	ND	150	ND	ND	ND	12	1.9	2.9
Males, Females																					
9–13 y	ND	11	2 5	ND	5,000	10	600	40	350	6	1,100	0.6	4	ND	280	ND	ND	ND	23	2 2	3 4
14–18 y	ND	17	2.5	ND	8,000	10	900	45	350	9	1,700	1.0	4	ND	400	ND	ND	ND	34	2 3	3.6
19–70 y	ND	20	2 5	ND	10,000	10	1,100	45	350	11	2,000	1 0	4	ND	400	ND	ND	1 8	40	2.3	3.6
>70 y	ND	20	2 5	ND	10,000	10	1,100	45	350	11	2,000	1.0	3	ND	400	ND	ND	1.8	40	2.3	3 6
Pregnancy																					
14–18 y	ND	17	2 5	ND	8,000	10	900	45	350	9	1,700	1.0	3.5	ND	400	ND	ND	ND	34	2 3	3.6
19–50 y	ND	20	2 5	ND	10,000	10	1,100	45	350	11	2,000	1.0	3 5	ND	400	ND	ND	ND	40	2.3	3 6
Lactation																					
14–18 y	ND	17	2.5	ND	8,000	10	900	45	350	9	1,700	1 0	4	ND	400	ND	ND	ND	34	2 3	3 6
19–50 y	ND	20	2 5	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	ND	400	ND	ND	ND	40	2.3	3 6

[a] UL = The maximum level of daily nutrient intake that is likely to pose no risk of adverse effects. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to lack of suitable data, ULs could not be established for arsenic, chromium, silicon, potassium, and sulfate. In the absence of ULs, extra caution may be warranted in consuming levels above recommended intakes.

[b] Although the UL was not determined for arsenic, there is no justification for adding arsenic to food or supplements.

[c] The ULs for magnesium represent intake from a pharmacological agent only and do not include intake from food and water.

[d] Although silicon has not been shown to cause adverse effects in humans, there is no justification for adding silicon to supplements.

[e] Although vanadium in food has not been shown to cause adverse effects in humans, there is no justification for adding vanadium to food and vanadium supplements should be used with caution. The UL is based on adverse effects in laboratory animals and this data could be used to set a UL for adults but not children and adolescents.

[f] ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

SOURCES: *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride* (1997); *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline* (1998); *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids* (2000); *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (2001); and *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate* (2004). These reports may be accessed via http://www.nap.edu

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Table 6.--Dietary Reference Intakes (DRIs): Estimated Energy Requirements (EER) for Men and Women 30 Years of Age[a]

Food and Nutrition Board, Institute of Medicine, National Academies

Height (m [in])	PAL[b]	Weight for BMI[c] of 18.5 kg/m^2 (kg [lb])	Weight for BMI of 24.99 kg/m^2 (kg [lb])	EER, Men[d] (kcal/day)		EER, Women[d] (kcal/day)	
				BMI of 18.5 kg/m^2	BMI of 24.99 kg/m^2	BMI of 18.5 kg/m^2	BMI of 24.99 kg/m^2
1.50 (59)	Sedentary	41.6 (92)	56.2 (124)	1,848	2,080	1,625	1,762
	Low active			2,009	2,267	1,803	1,956
	Active			2,215	2,506	2,025	2,198
	Very active			2,554	2,898	2,291	2,489
1.65 (65)	Sedentary	50.4 (111)	68.0 (150)	2,068	2,349	1,816	1,982
	Low active			2,254	2,566	2,016	2,202
	Active			2,490	2,842	2,267	2,477
	Very active			2,880	3,296	2,567	2,807
1.80 (71)	Sedentary	59.9 (132)	81.0 (178)	2,301	2,635	2,015	2,211
	Low active			2,513	2,884	2,239	2,459
	Active			2,782	3,200	2,519	2,769
	Very active			3,225	3,720	2,855	3,141

[a] For each year below 30, add 7 kcal/day for women and 10 kcal /day for men. For each year above 30, subtract 7 kcal/day for women and 10 kcal/day for men.

[b] PAL = physical activity level.

[c] BMI = body mass index.

[d] Derived from the following regression equations based on doubly labeled water data:

Adult man: $EER = 662 - (9.53 \times age\ [y]) + PA \times (15.91 \times wt\ [kg] + 539.6 \times ht\ [m])$

Adult woman: $EER = 354 - (6.91 \times age\ [y]) + PA \times (9.36 \times wt\ [kg] + 726 \times ht\ [m])$

Where PA refers to coefficient for PAL

PAL = total energy expenditure ÷ basal energy expenditure

PA = 1.0 if PAL ≥ 1.0 < 1.4 (sedentary)

PA = 1.12 if PAL ≥ 1.4 < 1.6 (low active)

PA = 1.27 if PAL ≥ 1.6 < 1.9 (active)

PA = 1.45 if PAL ≥ 1.9 < 2.5 (very active)

Table 7.--Dietary Reference Intakes (DRIs): Acceptable Macronutrient Distribution Ranges

Food and Nutrition Board, Institute of Medicine, National Academies

Macronutrient	Range (percent of energy)		
	Children, 1–3 y	Children, 4–18 y	Adults
Fat	30–40	25–35	20–35
n-6 polyunsaturated fatty acids[a] (linoleic acid)	5–10	5–10	5–10
n-3 polyunsaturated fatty acids[a] (α-linolenic acid)	0.6–1.2	0.6–1.2	0.6–1.2
Carbohydrate	45–65	45–65	45–65
Protein	5–20	10–30	10–35

[a] Approximately 10 percent of the total can come from longer-chain *n*-3 or *n*-6 fatty acids.

SOURCE: *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002).

Table 8.--Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Macronutrients
Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Total Water[a] (L/d)	Carbohydrate (g/d)	Total Fiber (g/d)	Fat (g/d)	Linoleic Acid (g/d)	α-Linolenic Acid (g/d)	Protein[b] (g/d)
Infants							
0–6 mo	0.7*	60*	ND	31*	4.4*	0.5*	9.1*
7–12 mo	0.8*	95*	ND	30*	4.6*	0.5*	**11.0**[c]
Children							
1–3 y	1.3*	**130**	19*	ND	7*	0.7*	**13**
4–8 y	1.7*	**130**	25*	ND	10*	0.9*	**19**
Males							
9–13 y	2.4*	**130**	31*	ND	12*	1.2*	**34**
14–18 y	3.3*	**130**	38*	ND	16*	1.6*	**52**
19–30 y	3.7*	**130**	38*	ND	17*	1.6*	**56**
31–50 y	3.7*	**130**	38*	ND	17*	1.6*	**56**
51–70 y	3.7*	**130**	30*	ND	14*	1.6*	**56**
> 70 y	3.7*	**130**	30*	ND	14*	1.6*	**56**
Females							
9–13 y	2.1*	**130**	26*	ND	10*	1.0*	**34**
14–18 y	2.3*	**130**	26*	ND	11*	1.1*	**46**
19–30 y	2.7*	**130**	25*	ND	12*	1.1*	**46**
31–50 y	2.7*	**130**	25*	ND	12*	1.1*	**46**
51–70 y	2.7*	**130**	21*	ND	11*	1.1*	**46**
> 70 y	2.7*	**130**	21*	ND	11*	1.1*	**46**
Pregnancy							
14–18 y	3.0*	**175**	28*	ND	13*	1.4*	**71**
19–30 y	3.0*	**175**	28*	ND	13*	1.4*	**71**
31–50 y	3.0*	**175**	28*	ND	13*	1.4*	**71**
Lactation							
14–18 y	3.8*	**210**	29*	ND	13*	1.3*	**71**
19–30 y	3.8*	**210**	29*	ND	13*	1.3*	**71**
31–50 y	3.8*	**210**	29*	ND	13*	1.3*	**71**

NOTE: This table presents Recommended Dietary Allowances (RDAs) in **bold** type and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy infants fed human milk, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover the needs of all individuals in the group, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

[a] *Total* water includes all water contained in food, beverages, and drinking water.

[b] Based on 0.8 g/kg body weight for the reference body weight.

[c] Change from 13.5 in prepublication copy due to calculation error.

Table 9.--Dietary Reference Intakes (DRIs): Additional Macronutrient Recommendations
Food and Nutrition Board, Institute of Medicine, National Academies

Recommendation
As low as possible while consuming a nutritionally adequate diet
As low as possible while consuming a nutritionally adequate diet
As low as possible while consuming a nutritionally adequate diet
Limit to no more than 25 percent of total energy

SOURCE: *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002).

Table 10.--Dietary Reference Intakes (DRIs): Estimated Average Requirements for Groups
Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	CHO (g/d)	Protein (g/d)[a]	Vit A (μg/d)[b]	Vit C (mg/d)	Vit E (mg/d)[c]	Thiamin (mg/d)	Ribo-flavin (mg/d)	Niacin (mg/d)[d]	Vit B_6 (mg/d)	Folate (μg/d)[b]	Vit B_{12} (μg/d)	Copper (μg/d)	Iodine (μg/d)	Iron (mg/d)	Magnes-ium (mg/d)	Molyb-denum (μg/d)	Phos-phorus (mg/d)	Sele-nium (μg/d)	Zinc (mg/d)
Infants																			
7–12 mo		9*												6.9					2.5
Children																			
1–3 y	100	11	210	13	5	0.4	0.4	5	0.4	120	0.7	260	65	3.0	65	13	380	17	2.5
4–8 y	100	15	275	22	6	0.5	0.5	6	0.5	160	1.0	340	65	4.1	110	17	405	23	4.0
Males																			
9–13 y	100	27	445	39	9	0.7	0.8	9	0.8	250	1.5	540	73	5.9	200	26	1,055	35	7.0
14–18 y	100	44	630	63	12	1.0	1.1	12	1.1	330	2.0	685	95	7.7	340	33	1,055	45	8.5
19–30 y	100	46	625	75	12	1.0	1.1	12	1.1	320	2.0	700	95	6	330	34	580	45	9.4
31–50 y	100	46	625	75	12	1.0	1.1	12	1.1	320	2.0	700	95	6	350	34	580	45	9.4
51–70 y	100	46	625	75	12	1.0	1.1	12	1.4	320	2.0	700	95	6	350	34	580	45	9.4
> 70 y	100	46	625	75	12	1.0	1.1	12	1.4	320	2.0	700	95	6	350	34	580	45	9.4
Females																			
9–13 y	100	28	420	39	9	0.7	0.8	9	0.8	250	1.5	540	73	5.7	200	26	1,055	35	7.0
14–18 y	100	38	485	56	12	0.9	0.9	11	1.0	330	2.0	685	95	7.9	300	33	1,055	45	7.3
19–30 y	100	38	500	60	12	0.9	0.9	11	1.1	320	2.0	700	95	8.1	255	34	580	45	6.8
31–50 y	100	38	500	60	12	0.9	0.9	11	1.1	320	2.0	700	95	8.1	265	34	580	45	6 8
51–70 y	100	38	500	60	12	0.9	0.9	11	1.3	320	2.0	700	95	5	265	34	580	45	6.8
> 70 y	100	38	500	60	12	0.9	0.9	11	1.3	320	2.0	700	95	5	265	34	580	45	6.8
Pregnancy																			
14–18 y	135	50	530	66	12	1.2	1.2	14	1.6	520	2.2	785	160	23	335	40	1,055	49	10.0
19–30 y	135	50	550	70	12	1.2	1.2	14	1.6	520	2.2	800	160	22	290	40	580	49	9.5
31–50 y	135	50	550	70	12	1.2	1.2	14	1.6	520	2.2	800	160	22	300	40	580	49	9.5
Lactation																			
14–18 y	160	60	885	96	16	1.2	1.3	13	1.7	450	2.4	985	209	7	300	35	1,055	59	10.9
19–30 y	160	60	900	100	16	1.2	1.3	13	1.7	450	2.4	1,000	209	6.5	255	36	580	59	10.4
31–50 y	160	60	900	100	16	1.2	1.3	13	1.7	450	2.4	1,000	209	6.5	265	36	580	59	10.4

NOTE: This table presents Estimated Average Requirements (EARs), which serve two purposes: for assessing adequacy of population intakes, and as the basis for calculating Recommended Dietary Allowances (RDAs) for individuals for those nutrients. EARs have not been established for vitamin D, vitamin K, pantothenic acid, biotin, choline, calcium, chromium, fluoride, manganese, or other nutrients not yet evaluated via the DRI process.

[a] For individual at reference weight (Table 1-1). *indicates change from prepublication copy due to calculation error.

[b] As retinol activity equivalents (RAEs). 1 RAE = 1 μg retinol, 12 μg β-carotene, 24 μg α-carotene, or 24 μg β-cryptoxanthin. The RAE for dietary provitamin A carotenoids is two-fold greater than retinol equivalents (RE), whereas the RAE for preformed vitamin A is the same as RE.

[c] As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of α-tocopherol (*RRR*-, *RSR*-, *RRS*-, and *RSS*-α-tocopherol) that occur in fortified foods and supplements. It does not include the *2S*-stereoisomeric forms of α-tocopherol (*SRR*-, *SSR*-, *SRS*-, and *SSS*-α-tocopherol), also found in fortified foods and supplements.

[d] As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan.

[e] As dietary folate equivalents (DFE). 1 DFE = 1 μg food folate = 0.6 μg of folic acid from fortified food or as a supplement consumed with food = 0.5 μg of a supplement taken on an empty stomach.

SOURCES: *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride* (1997); *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline* (1998); *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids* (2000); *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (2001), and *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002). These reports may be accessed via www.nap.edu.

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BILLING CODE 4160–01–C

E. IOM Report on Guiding Principles for Nutrition Labeling

In 2003 the IOM committee on nutrition labeling (the IOM Committee) considered how the DRIs can be used to develop appropriate reference values for nutrition labeling (Ref. 16). The IOM Committee's report recommended the following 10 guiding principles for nutrition labeling:

• *Nutrition information in the Nutrition Facts label should continue to be expressed as percent DV*. The concept of percent DV was developed by FDA in response to NLEA to help consumers better comprehend the nutritional value of food and to understand its relative significance in the context of a daily diet. The percent DV concept was modeled after the ''percent of U.S. RDAs'' used in 1973 labeling. The use of the percent DV concept has been supported by consumer studies (58 FR 2079). The IOM Committee concluded that the rationale to use percent DV was compelling and suggested no alternative approach.

• *The DVs should be based on a population-weighted reference value using census data and proportions of each life stage and gender group*. The IOM Committee's rationale for using a population-weighted approach was that the DRIs for the various age and gender groups should be represented by the DV of the population in the same proportions. A DV defined this way would represent a central value of the requirement of the base population, with individual requirements varying around this value.

As discussed previously in this document, the population-weighted approach is one of two approaches for setting one DV for all individuals 4 years of age and older. Currently, FDA uses the population-coverage approach for setting a single DV which represents the highest recommended intake level among all life stage and gender groups, excluding pregnant and lactating women. Although the degree of change will differ for each nutrient, the DV would be lower using the population-weighted approach for most nutrients when compared to a DV derived using the population-coverage approach (see tables 11a and 11b of this document). Note that if the DV for a nutrient is increased, then a serving of food would have a lower percent DV on the Nutrition Facts label.

TABLE 11A. COMPARISON OF THE CURRENT DVS WITH THE EAR, RDA, AND UL USING THE POPULATION-COVERAGE OR POPULATION-WEIGHTED APPROACH

Nutrient	Unit of Measure	Current DV	Highest RDA	Weighted RDA[1]	Highest EAR	Weighted EAR[1]	UL 4 to 8 years[2]
Nutrients Assigned an EAR and RDA							
Copper	mg	2.0	0.9	0.8	0.7	0.7	3
Folate	µg	400	400	378	330	304	400
Iodine	µg	150	150	144	95	91	300
Iron	mg	18	18	11	8	6	40
Magnesium	mg	400	420	341	350	283	110
Molybdenum	µg	75	45	42	34	32	600
Niacin	mg	20	16	14	12	11	15
Phosphorus	mg	1,000	1,250	769	1,055	640	3,000
Protein	g	50	56	47	46	39	-
Riboflavin	mg	1.7	1.3	1.1	1.1	0.9	—
Selenium	µg	70	55	52	45	43	150
Thiamin	mg	1.5	1.2	1.1	1.0	0.9	—
Vitamin A	IU	5,000	3,000	2,511	2,100	1,768	—
	µg	1,500 RE	900 RAE	754 RAE	630 RAE	531 RAE	900
Vitamin B_6	mg	2.0	1.7	1.3	1.4	1.1	40
Vitamin B_{12}	µg	6.0	2.4	2.3	2.0	1.9	—
Vitamin C	mg	60	90	74	75	61	650
Vitamin E	IU	30 IU	—	—	—	—	—
	mg α-tocopherol		15	14	12	11	300

TABLE 11A. COMPARISON OF THE CURRENT DVS WITH THE EAR, RDA, AND UL USING THE POPULATION-COVERAGE OR POPULATION-WEIGHTED APPROACH—Continued

Nutrient	Unit of Measure	Current DV	Highest RDA	Weighted RDA[1]	Highest EAR	Weighted EAR[1]	UL 4 to 8 years[2]
Zinc	mg	15	11	9.1	9.4	7.7	12

[1]Population-weighted means of life-stage and gender specific RDAs, EARs, AIs, and ULs were computed for adults and children 4 or more years of age, using 2005 Middle Series Data from Annual Projections of the Resident Population by Age, Sex, Race, and Hispanic Origin: Lowest, Middle, Highest, and Zero International Migration Series, 1999 to 2100 (NP-D1-A), (*http://www.census.gov/population/www/projections/natdet-D1A.htm*), U.S. Census Bureau, Population Projection Program , accessed July 19, 2006. Life-stage and gender specific RDAs, EARs, AIs, and ULs were multiplied by the population projection for the corresponding life-stage and gender group (e.g., children 4 to 8 years old, males 9 to 13 years old). Sum of these values were divided by the total population projection for adults and children 4 or more years of age.

[2]The ULs for vitamin E, niacin, and folate apply to synthetic forms obtained from supplements, fortified foods, or a combination of the two. The ULs for vitamin A apply only to preformed vitamin A. The ULs for magnesium represent intake from a pharmacological agent only and do not include intake from food and water.

RE=retinol equivalents, RAE=retinol activity equivalents

TABLE 11B. COMPARISON OF THE CURRENT DVS WITH THE AIS AND ULS USING THE POPULATION-COVERAGE OR POPULATION-WEIGHTED APPROACH

Nutrient	Unit Of Measure	Current DV	Highest AI	Weighted AI[1]	Highest UL	Weighted UL[1]	UL 4 to 8 years
Nutrients Assigned an AI							
Biotin	µg	300	30	28	—	—	—
Calcium	mg	1,000	1,300	1,091	—	—	2,500
Chloride	mg	3,400	2,300	2,150	3,600	3,536	2,900
Choline	mg	550[2]	550	460	—	—	1,000
Chromium	µg	120	35	27	—	—	—
Fiber	g	25	38[3]	29[3]	—	—	—
Linoleic acid	g	—	17	13	—	—	—
α-Linolenic acid	g	—	1.6	1.3	—	—	—
Manganese	mg	2.0	2.3	1.9	—	—	3
Pantothenic acid	mg	10	5	5	—	—	—
Potassium	mg	3,500	4,700	4,622	—	—	—
Sodium	mg	2,400[4]	1,500	1,410	2,300	2,265	1,900
Vitamin D	IU	400	600	280	—	—	—
	µg	10	15	7			50
Vitamin K	µg	80	120	95	—	—	—
Fluoride	mg	—	4	3	—	—	2.2

[1]Population-weighted means of life-stage and gender specific RDAs, EARs, AIs, and ULs were computed for adults and children 4 or more years of age, using 2005 Middle Series Data from Annual Projections of the Resident Population by Age, Sex, Race, and Hispanic Origin: Lowest, Middle, Highest, and Zero International Migration Series, 1999 to 2100 (NP-D1-A), (*http://www.census.gov/population/www/projections/natdet-D1A.htm*), U.S. Census Bureau, Population Projection Program , accessed July 19, 2006. Life-stage and gender specific RDAs, EARs, AIs, and ULs were multiplied by the population projection for the corresponding life-stage and gender group (e.g., children 4 to 8 years old, males 9 to 13 years old). Sum of these values were divided by the total population projection for adults and children 4 or more years of age.

[2]A notification was submitted under section 403(r)(2)(G) of the act (21 U.S.C. 343(r)(2)(G)) in 2001 for the use of certain nutrient content claims for choline. These statements identify the daily value for choline as 550 mg (see footnote 5 of this document). This value is based on the AI set by the IOM of the NAS in 1998 (Refs. 9 and 20).

[3]Based on AI of 14g/1,000 calories.

[4]Daily reference value to not be exceeded.

• *A population-weighted EAR should be the basis for DVs for those nutrients for which EARs have been identified.* The Committee's rationale for using an EAR, rather than the RDA, to set the DV was the Committee's belief that the EAR represents the most accurate representation of the true contribution of food to total nutrient needs in the general population.

Currently, the RDIs are based on RDAs, when available. There are 16 nutrients for which the DV is currently based on an RDA and now have a new EAR and RDA.[6] Because the RDA is 2 standard deviations greater than the

[6]Currently there are DVs that were based on RDAs for vitamin A, vitamin C, iron, vitamin E, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, phosphorous, iodine, magnesium, zinc, selenium, and protein.

EAR, a DV based on an EAR would be lower than when based on the RDA (see table 11a of this document). The population-weighted EAR yields the lowest values compared to population-coverage RDA, population-weighted RDA, or population-coverage EAR (see table 11a of this document). The population-weighted EAR can vary from as little as 21 percent lower than the population-coverage RDA for vitamin B_{12}, to 41 percent lower for vitamin A, to as much as 67 percent lower for iron.

• *If no EAR has been set for a nutrient, then a population-weighted AI should be used as the basis for a DV.*

An AI is a proxy for an RDA, however, the AI is not the equivalent of an EAR. Thus, when an AI is set for a nutrient, there is no other recommended intake level that is set for that nutrient. AIs were determined for 15 nutrients (tables 2 and 3 of this document). As can be seen in table 11b of this document, a reference value for labeling based on a population-weighted AI is lower for most nutrients than a reference value that is derived based on the population-coverage approach that uses the highest AI. As discussed previously in this document, AIs for children and adults were based on experimental data that were not sufficient for setting an EAR or were based on median intake levels. The IOM labeling report did not address the issue of whether AIs based on either approach should or should not be considered in setting a DV. The IOM labeling report did not address the AIs set for sodium and potassium because the IOM DRI report on electrolytes and water was not completed (Ref. 14).

• *The AMDR should be the basis for the DVs for protein, total carbohydrate, and total fat.* The IOM labeling committee recommended that using the AMDRs to set reference values for protein, total carbohydrate, and total fat is appropriate to promote healthful dietary practices and nutritionally adequate diets and would provide consistency. Because the IOM set AMDRs (percent of energy) for all three macronutrients, the IOM Committee recommended setting the DV based on the following: (1) The midpoint of the AMDR for carbohydrate (starch and sugars), (2) a population-weighted midpoint of the AMDR for total fat since AMDRs varied for age, and (3) the difference (100 percent of energy - (DV_{fat} + $DV_{carbohydrate}$)) for protein. The IOM Committee stated that using the midpoint of the AMDR values avoids extreme values from the upper or lower boundaries and is an approach that focuses on moderation. The IOM Panel on Macronutrients did not set a UL for total or added sugars, but identified a suggested maximum intake level of no more than 25 percent of energy from added sugars. However, the IOM Committee recommended against using this value for nutrition labeling because it could be misrepresented as a desirable intake level. Although the IOM panel on macronutrients set an AMDR for protein, they also set EARs and RDAs for protein (see tables 11a and 12 of this document).

Currently, the DV for protein is based on 10 percent of 2,000 calories using an adjusted average of the 1989 RDA (Ref. 3). Although protein has a DV, the declaration of a percent DV for protein on the label is optional unless a claim is being made. The declaration of a percent DV for protein is optional due, in part, to the cost consideration of determining the protein digestibility-corrected amino acid score which is necessary to calculate the percent DV of protein (58 FR 2079 at 2102).

TABLE 12.—COMPARISON OF THE CURRENT DVS IN GRAMS TO THE LOWER, MIDPOINT, AND UPPER ACCEPTABLE MACRONUTRIENT DISTRIBUTION RANGES FOR A 2,000 CALORIE DIET

Nutrient	Current DV		AMDR			AMDR		
	Percent of Energy	Grams (for 2,000 calories per day)	Percent of energy			Grams (for 2,000 calories per day)[1]		
			Low	Midpoint	High	Low	Midpoint	High
Adults								
Protein	10	50	10	22.5	35	50	112.5	175
Fat	30[2]	65	20	27.5	35	44.4	61.1	77.7
Linoleic acid	—	—	5	7.5	10	11	17	22
α-Linolenic	—	—	0.6	0.9	1.2	1.3	2	2.7
Carbohydrate	60	300[3]	45	55.0	65	225[4]	275[4]	325[4]
Protein by difference				17.5			87.5	
Total energy	100			100				
Children Age 4 to 18 Years								
Protein	10	50	10	20	30	50	100	150
Fat	30[2]	65	25	30	35	55.6	66	77.7
Linoleic acid	—	—	5	7.5	10	11	17	22
α-Linolenic	—	—	0.6	0.9	1.2	1.3	2	2.7
Carbohydrate	60	300[3]	45	55	65	225[4]	275[4]	325[4]
Protein by difference				15			75	
Total energy	100			100				

TABLE 12.—COMPARISON OF THE CURRENT DVS IN GRAMS TO THE LOWER, MIDPOINT, AND UPPER ACCEPTABLE MACRONUTRIENT DISTRIBUTION RANGES FOR A 2,000 CALORIE DIET—Continued

Nutrient	Current DV		AMDR			AMDR		
	Percent of Energy	Grams (for 2,000 calories per day)	Percent of energy			Grams (for 2,000 calories per day)[1]		
			Low	Midpoint	High	Low	Midpoint	High
Age 4 Years and Older (Weighted per IOM Labeling Report, Table B–4)								
Fat[5]	30[2]	65	21	28	35	46.7	62	77.7
Linoleic acid	—	—	5	7.5	10	11	17	22
α-Linolenic	—	—	0.6	0.9	1.2	1.3	2	2.7
Carbohydrate[6]	60	300[3]	45	55	65	225[4]	275[4]	325[4]
Protein by difference[7]			34	17	0	170	85	0
Total energy				100				

[1]Derived by converting percent energy to g/d using Atwater factors 4 calories/g for carbohydrates and protein and 9 calories/d for fat for a 2,000 calories diet.
[2]Based on a Dietary Guideline recommendation of no more than 30 percent of energy from fat.
[3]Carbohydrate represents sugars, starch, fiber, and organic acids.
[4]Carbohydrate represents starch and sugars.
[5]The AMDR for total fat is comprised of population-weighted values computed based on U.S. Census Bureau estimates of the U.S. population in 2005.
[6]No weighting was done for this group.
[7]Calculated using the difference (100 percent of energy - (DV_{fat} + $DV_{carbohydrate}$)) for protein.

For the purpose for food labeling, total carbohydrate in food is currently calculated by subtraction of the sum of crude protein, total fat, moisture, and ash from the total weight of the food and includes starch, sugars, sugar alcohols, and fiber (§ 101.9(c)(6)). The current DV for total carbohydrate is based on the 100 percent of energy minus the sum of the DV for fat (30 percent) plus the DV for protein (10 percent). Thus, the DV is 60 percent of a 2,000 calorie diet (300 g) for total carbohydrate. In contrast to the calculation of total carbohydrates (§ 101.9(c)(6)), the IOM panel on macronutrients set an AMDR for carbohydrates and also set an EAR and RDA for carbohydrate that specifically represents starch and sugars, but does not include sugar alcohols or fiber (see tables 8, 10, and 12 of this document). Therefore, the recommendation by the IOM Committee to use the AMDR for setting a DV for total carbohydrate would limit the definition and corresponding DV to sugars and starch.

The current DV for fat (65 g) is based on the NAS Diet and Health Report (Ref. 4) which recommended no more than 30 percent of energy from fat and represents triglyceride content (§ 101.9(c)(2)). The IOM panel on macronutrients set AMDRs for total fat and fatty acids linoleic and α-linolenic acid (see table 12 of this document). The IOM panel on macronutrients also set AIs for linoleic and α-linolenic acid (see table 11b of this document).

Table 12 of this document shows the current DV, the lowest, the midpoint, and the highest value for each AMDR set by the IOM DRI panel on macronutrients, and the AMDRs adjusted using the population-weighted approach. As can be seen in table 12 of this document for fat, linoleic acid, α-linolenic acid, and carbohydrate, the lowest, the midpoint, and the highest AMDR values are similar to the values obtained using the population-weighted AMDRs. The approach that was recommended by the IOM Committee, i.e., using the midpoint of the AMDR for fat and carbohydrate as the basis for label reference values, would yield values of 62 g/d of fat, 85 g/d protein, and 275 g/d carbohydrate.

- *Two thousand calories should be used, when needed, as the basis for expressing energy intake when developing DVs.* Although EERs were set for all life-stage groups (Ref. 13), the IOM Committee recognized that the EERs are dependent upon height, weight, and physical activity level. In addition, the EER equations are based on normal weight individuals, and the United States has a high prevalence of obese and overweight individuals (64 percent of adults and 15 percent of children) (Ref. 16). The IOM Committee found that the data necessary to use the EER to derive a calorie reference value is incomplete. Therefore, the IOM Committee recommended retaining the current 2,000 calorie reference level (Ref. 16).
- *The DVs for saturated fatty acids, trans fatty acids, and cholesterol should be set at a level that is as low as possible in keeping with an achievable health-promoting diet.* The rationale for this recommendation is based on the DRI macronutrient report (Ref. 13) which did not set ULs but recommended that saturated fatty acid, *trans* fatty acid and cholesterol intakes should be as low as possible while consuming a nutritionally adequate diet. The current DV for saturated fat (not more than 10 percent of energy (20 g/d) and cholesterol (300 mg/d)) is based on the NAS Diet and Health Report (Ref. 4).

For FDA to establish a DV for *trans* fatty acids, saturated fat, and cholesterol, the IOM Committee suggested that FDA use food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes consistent with nutritionally adequate and health-promoting diets for diverse populations. In April of 2004, FDA held a meeting of the Nutrition Subcommittee of the Food Advisory Committee on total fat and *trans* fat (the subcommittee) (Ref. 23). The subcommittee concluded that currently there is not enough scientific evidence to recommend a specific acceptable daily intake for *trans* fatty acids.

- *While the general population is best identified as all individuals 4 years of age and older, four distinctive life stages were identified for developing separate DVs: Infants (< 1 year), toddlers (1 to 3 years), pregnancy, and lactation.* Because infants, toddlers, and pregnant women and lactating women have specific nutritional needs, the IOM Committee stated that a single DV for the entire population could over- or underestimate the nutrient contribution

of foods for these four groups. Therefore, the IOM Committee recommended that separate DVs for foods manufactured specifically for these four groups be used for that specific life-stage group.

See discussion in section I.B.1 of this document on requirements for foods that are represented or purported to be for the use of infants (up to 12 months of age) or children 1 to 4 years of age, and pregnant women or lactating women.

• *The Supplement Facts label should use the same DVs as the Nutrition Facts label.* The IOM Committee recommended that all other guiding principles should apply to dietary supplement labeling. The IOM Committee came up with this recommendation because the Supplement Facts label requires the inclusion of the percent DVs for the nutrients that are mandated for conventional food (21 U.S.C. 321(ff)). Therefore, the comparisons that are shown for the Nutrition Facts label in tables 11a and 11b of this document are the same for the Supplement Facts label.

• *Absolute amounts should be included in the Nutrition Facts and Supplement Facts labels for all nutrients.* The IOM Committee concluded that including absolute amounts (e.g., mg/serving) would assist consumers who want nutrient information but are yet unable to understand the percent DVs. Furthermore, absolute amounts for macronutrients are already required on the Nutrition and Supplement Facts labels. Therefore, the IOM Committee stated that adding absolute amounts for micronutrients would make the labeling consistent. The IOM Committee also recommended that the units used for vitamin A (IU), vitamin D (IU), vitamin E (IU), folate (µg), copper (mg), sodium (mg), potassium (mg) and chloride (mg) be changed to be consistent with the units in the new DRI reports (vitamin A (µg Retinol Activity Equivalents), vitamin D (µg), vitamin E (mg α-tocopherol), folate (µg dietary folate equivalents), copper (µg), sodium (g), potassium (g), and chloride (g)).

F. IOM Report on the Definition of Fiber

1. Definitions

Because there is not a formal definition for dietary fiber, dietary fiber is the material isolated using AOAC INTERNATIONAL Enzymatic-Gravimetric Method 985.29 (Ref. 12). This method includes lignin and nonstarch polysaccharides and some resistant starch, inulin, chitin, chitosan, chondroitin sulfate, and noncarbohydrate material. This method does not include oligosaccharides, polydextrose, or resistant maltodextrins. Currently, dietary fiber is indented under ''Total Carbohydrates'' in the Nutrition Facts label (§ 101.9(c)(6)(i)).

In 2001 the IOM Panel on the Definition of Dietary Fiber (the IOM Panel) responded to FDA's request to provide definitions for dietary fiber based on its role in human physiology and health. The IOM Panel developed two categories of definitions of fiber: ''Dietary Fiber'' and ''Functional Fiber'' (Ref. 12). See table 13 of this document from the IOM Report on the Definition of Dietary Fiber, which lists the characteristics of dietary fiber currently determined by FDA and by the IOM definitions for dietary and functional fibers.

TABLE 13.—CHARACTERISTICS OF VARIOUS DIETARY FIBER DEFINITIONS[1]

Reference	Nondigestible Animal CHOs[2]	CHOs Not Recovered by Alcohol Precipitation[3]	Nondigestible Mono- and Disaccharides	Lignin	Resistant Starch	Intact, Naturally Occurring Food Sources Only	Resistant to Human Enzymes	Specifies Physiological Effect
U.S. Food and Drug Administration (USFDA), 1987[4]	Yes	Some inulin	No	Yes	Some	No	No	No
Institute of Medicine (IOM) (Proposed), 2001								
Dietary Fiber	No	Yes	No	Yes	Some	Yes	Yes	No
Added Fiber	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes

[1]All definitions are assumed to include nonstarch polysaccharides.
[2]CHO = carbohydrate.
[3]Includes inulin, oligosaccharides (3–10 degrees of polymerization), fructans, polydextrose, methylcellulose, resistant maltodextrins, and other related compounds.
[4]Method-based definition.
Source: Adapted from the IOM, ''Dietary Reference Intakes: Proposed Definition of Dietary Fiber,'' Washington, DC: National Academy Press, 2001.

a. *The IOM Panel defined ''Dietary Fiber'' as nondigestible carbohydrates and lignin that are intrinsic and intact in plants.* Nondigestible means that the material is not digested and absorbed in the human small intestine. Fractions of plant foods are still considered ''Dietary Fiber'' if the plants' cells and their three dimensional interrelationships remain largely intact. Examples of ''Dietary Fiber'' include cereal brans; resistant starch that is naturally occurring; naturally occurring oligosaccharides such as raffinose, stachyose, verbacose; and low molecular weight fructans. The known physiological benefits of foods containing ''Dietary Fiber,'' such as attenuation of postprandial blood glucose and cholesterol levels and improved laxation, are recognized.

b. *The IOM Panel defined ''Functional Fiber'' as isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.* ''Functional Fibers'' can be isolated or extracted nondigestible carbohydrates, using chemical, enzymatic, or aqueous procedures or synthetically manufactured. Provided that one or more beneficial physiological effects are demonstrated in humans, examples of ''Functional Fiber'' would include isolated nondigestible animal carbohydrates, pectins or gums, resistant starch formed during processing, and synthetic fibers such as resistant maltodextrin and fructooligosaccharides. At this time, current FDA regulations have not established formal criteria for establishing the beneficial physiological effects of potential ''Functional Fibers.''

c. *The IOM Panel defined ''Total Fiber'' as the sum of ''Dietary Fiber''*

and ''Functional Fiber.'' Thus, while there is currently one category of dietary fiber in the Nutrition Fact label, the Panel has provided three definitions of fiber for potential use. The AI set by the IOM is for ''Total Fiber.''

2. Soluble and Insoluble Fiber

The IOM Panel recommended that the terms soluble and insoluble fiber be phased out and replaced with an appropriate physicochemical property (e.g., viscous or fermentable fiber) of the specific fiber as these become standardized. This recommendation is based on scientific findings that suggest that the physiological benefit of a fiber (e.g., attenuation of blood glucose and cholesterol concentration and improved laxation) is not related to the solubility of a fiber. There is evidence indicating that viscous fibers and fibers that are slowly, incompletely, or not fermented can provide beneficial physiological effects. The IOM Panel recommended that viscosity or fermentability of a fiber be considered as characteristics to distinguish ''Dietary Fibers'' and ''Functional Fibers'' that modulate gastric and small bowel function from those that provide substantial stool bulk which is affected by fiber solubility and may or may not affect gastric and small bowel function.

Currently, a statement of the number of grams of soluble (§ 101.9(c)(6)(i)(A)) and insoluble (§ 101.9(c)(6)(i)(B)) dietary fiber can be voluntarily declared and indented under dietary fiber and both are identified and quantified using AOAC INTERNATIONAL methods.

3. Analytical Issues

The IOM Panel recognized that adoption of the two definitions for fiber would challenge the currently available analytical methods, requiring changes to the current analytical methods. Particularly, separating out ''Dietary'' and ''Functional Fibers,'' of which there could be a potential overlap (e.g., resistant starch and dietary fibers that are extracted, concentrated, and added to foods (gums, cellulose, pectin)). The IOM Panel proposed modifications to the current methods. While further refinement of these methods is made, the IOM Panel indicated that it would be more practical to determine ''Total Fiber'' using the current methods.

G. Current Regulations on Trans Fat

In the **Federal Register** of July 11, 2003 (68 FR 41434), FDA amended its regulations on nutrition labeling to require *trans* fatty acids be declared in grams per serving in the nutrition label of conventional foods and dietary supplements (the 2003 *trans* fat final rule). No DV was established for *trans* fatty acids. Required labeling became effective on January 1, 2006.

In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA published an ANPRM (the 2003 *trans* fat ANPRM) to solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fatty acids; to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fatty acids and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. FDA also requested comments on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts label or as a disclosure statement in conjunction with claims to enhance consumer understanding about cholesterol-raising lipids and how to use the information to make healthy food choices.

On March 1, 2004 (69 FR 9559), FDA reopened the comment period for the 2003 *trans* fat ANPRM to receive comments that considered the information in the 2003 IOM report on nutrition labeling (Ref. 16) that addressed the labeling of *trans* fat (see section II.E of this ANPRM). In addition to the questions raised in the 2003 *trans* fat ANPRM, FDA sought comments on the 2003 IOM labeling report's approach to establish a DV using food composition data, menu modeling, and dietary survey data to estimate a minimum *trans* fat intake within a nutritionally adequate diet. FDA also sought comment on whether the IOM approach of using food composition data, menu modeling, and dietary survey data should be used to revise the DV for saturated fat. Public comments were also sought on the IOM recommendation to list saturated fat and *trans* fat on separate lines of the Nutrition Facts label, but have one numerical value for the percent DV for these two nutrients together. In addition, if FDA were to use one numerical value for the percent DV for both *trans* fat and saturated fat together, the agency asked for comment about whether such value should be determined by adding a new DV established for saturated fat to the DV for *trans* fat, or, alternatively, whether the agency should establish a joint DV for saturated and *trans* fats that would then be used to calculate one numerical value as the percent DV for both fats.

On April 19, 2004 (69 FR 20838), FDA extended the comment period for the 2003 *trans* fat ANPRM to receive comments that considered the information in the 2004 subcommittee meeting (Ref. 23) that addressed whether the available scientific evidence supports listing the percent DV for saturated fat and *trans* fat together or separately on the Nutrition Facts label and what the maximal daily intake of *trans* fat may be.

Because of their relevance to the Nutrition Facts label, FDA intends to consider, as comments to this ANRPM, the comments to the 2003 *trans* fat ANPRM on the IOM approach for calculating a DV for saturated fat and *trans* fat and listing of saturated and *trans* fats on separate lines of the Nutrition Facts label with one numerical value for the percent DV for both, and how to calculate the percent DV as one numerical value. Comments to the 2003 *trans* fat ANPRM on the outcome of the subcommittee meeting will also be considered. Public comments on these issues are being asked again in this ANPRM so that these issues can be considered in the context of the entire Nutrition Facts and Supplement Facts labels along with other questions being asked in this ANPRM.

H. ANPRM on Prominence of Calories

In the **Federal Register** of April 4, 2005 (70 FR 17008), FDA published an ANPRM on the prominence of calories on the food label (the 2005 ANPRM). The 2005 ANPRM was issued in response to recommendations from the Obesity Working Group (OWG) created by the Commissioner of Food and Drugs to develop an action plan to address the growing incidence of obesity in the United States. The 2005 ANPRM, in part, requested comments on whether giving more prominence to the declaration of calories per serving would increase consumer awareness of the caloric content of the packaged food. FDA also sought comment of whether providing a percent DV for total calories would help consumers understand the caloric content of the packaged food in the context of a 2,000 calorie diet. In addition, FDA also requested comments on questions posed concerning the declaration of ''calories from fat'' (70 FR 17008 at 17010). Because of their relevance to the Nutrition Facts label, FDA intends to consider, as comments to this ANRPM, comments to the 2005 prominence of calories ANPRM related to questions posed on a percent DV for total calories and calories from fat. Public comments on the specific question about establishing a percent

DV for total calories and the questions posed concerning ''calories from fat'' are being requested in this ANPRM so that these questions can be considered in the context of the entire Nutrition Facts and Supplement Facts labels along with other questions being asked in this ANPRM.

I. Carbohydrate Content of Food

FDA received nine citizen petitions that requested, among other things, that the agency amend our nutrition labeling requirements related to the declaration of total carbohydrate content of foods.[7] With respect to carbohydrate labeling, the agency is requesting comment in this ANPRM on questions related to the label declaration of carbohydrate in the Nutrition Facts and Supplement Facts labels (see section II.C.10 of this document).

J. ''2005 Dietary Guidelines for Americans''

The ''2005 Dietary Guidelines for Americans'' (the 2005 Dietary Guidelines) developed jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture provide several key numerical recommendations with respect to micronutrients and macronutrients, of which most are based on the DRI reports (Ref. 7). These recommendations are as follows:

- Consume less than 10 percent of calories from saturated fat and less than 300 mg/d of cholesterol. These recommendations are the same as the current DRVs for saturated fat and cholesterol.
- Keep total fat intake between 20 and 35 percent of calories, the AMDR for total fat.
- Consume less than 2,300 mg/d of sodium, the UL for sodium.

The 2005 Dietary Guidelines also identified nutrients of concern based on dietary intake data or evidence of public health problems. The nutrients of concern are identified for:

- Adults: Calcium, potassium, fiber, magnesium, and vitamins A (as carotenoids), C, and E;
- Children and adolescents: Calcium, potassium, fiber, magnesium, and vitamin E.

The 2005 Dietary Guidelines also identified nutrients of concern for specific populations groups. Vitamin B12 was identified as a nutrient of concern for people over the age of 50. Iron was identified as a nutrient of concern for women of childbearing age who may become pregnant. Folic acid was also identified as a nutrient of concern for women of childbearing age who may become pregnant and those in the first trimester of pregnancy. Vitamin D was identified as a nutrient of concern for older adults, people with dark skin, and people exposed to insufficient ultraviolet band radiation (i.e., sunlight).

[7]The nine citizen petitions can be found in Docket Nos. 2004P–0105/CP1, 2004P–0107/CP1, 2004P–0110/CP1, 2004P–0297/CP1, 2004P–0298/CP1, 2004P–0299/CP1, 2004P–0293/CP1, 2004P–0473/CP1, 2004P–0542/CP1.

II. Agency Request for Information

FDA has not updated or set new DVs since 1995. In 2003, the IOM completed its first review of nutrients using the DRI process. This review has generated discussion in the scientific community. FDA plans to revise the reference values used for the Nutrition Facts and Supplement Facts labels. FDA requests comments on the following questions. As part of the comments, FDA requests that scientific justification be submitted in support of the response. FDA recognizes that an individual commenter may choose to respond to all of the questions or only a subset, based on his/her area of expertise.

A. Approach to Setting DVs

As discussed in section I.D of this document, beginning in 1997, the IOM began publishing a series of reports on reference intake levels, collectively known as the DRIs. The DRIs provided revised RDAs and three new reference intakes for nutrients (AI, EAR, and UL). The IOM also reported on AMDRs for macronutrients. FDA requests comments on the following questions on which DRIs and AMDRs should be used for setting DVs.

- Should the DV be based on an EAR for those nutrients for which an EAR has been set? Explain why or why not.
- If EARs are used to set DVs, should they be set based on population-coverage or population-weighted EAR? Explain why you have chosen a particular approach and why it is preferable to the other approach. Explain why or why not.
- Should the DV be set based on an RDA for those nutrients for which an RDA has been set? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- If RDAs are used to set DVs, should they be set based on population-coverage or population-weighted RDA? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- Should any or all AIs, regardless of how they are derived, be used to set DVs? Explain why or why not. Or, should only those AIs based on experimental data be used to set DVs (i.e., from intervention studies that are designed to evaluate nutrient requirements rather than dietary intake data from national surveys)? Explain why or why not.
- If AIs are used to set DVs, should they be set based on population-coverage or population-weighted AI? Explain why you have chosen a particular approach and why it is preferable to the other approach.

B. Populations for Which the DVs are Intended

Currently the DVs are for persons 4 years of age and older. FDA requests comments on the following questions on the populations for which the DVs should be intended.

- Should the DVs continue to be used for persons 4 years of age and older? Explain why or why not.
- Should DVs for different life stage groups be developed for labeling of food products specific to these groups, as recommended in the IOM labeling report (i.e., separate DVs: Infants (< 1 year), toddlers (1 to 3 years), pregnancy, and lactation)? Explain why or why not.

If so,

- Should DVs for infants (< 1 year) be set based on the EARs, RDAs, or AIs for older infants (7 to 12 months)? Explain why you have chosen a particular approach and why it is preferable to the other approaches.
- Should DVs for toddlers (1 to 3 years) be set based on the EARs, RDAs, or AIs for toddlers (1 to 3 years)? Explain why you have chosen a particular approach and why it is preferable to the other approaches.
- Should DVs for pregnant women be set based on the population-weighted or population-coverage EARs, RDAs, or AIs for all DRI pregnancy groups (i.e. 14 to 18 years, 19 to 30 years, 31 to 50 years)? Explain why you have chosen a particular approach and why it is preferable to the other approaches.
- Should DVs for lactating women be set based on the population-weighted or population-coverage EARs, RDAs, or AIs for all DRI lactation groups (i.e. 14 to 18 years, 19 to 30 years, 31 to 50 years)? Explain why you have chosen a particular approach and why it is preferable to the other approaches.

C. Labeling of Individual Nutrients

FDA requests comments on the following questions on individual nutrients:

1. Calories

- Should 2,000 calories continue to be used to express reference energy intake, as recommended in the IOM

labeling report? Explain why or why not.

- Should 2,500 calories also be kept on the label footnote? Explain why or why not.
- Should the EER (Estimated Energy Requirements) be used to express reference energy intake? Explain why or why not.
- If a population-weighted EER or a population-coverage EER should be used, which PAL (sedentary, low active, active, very active) should be used to calculate the EER? Explain why you have chosen a particular approach and why it is preferable to the other approaches.
- Would providing for a percent DV disclosure for total calories assist consumers in understanding the caloric content of the packaged food in the context of a 2,000 calorie diet? Explain why or why not.

2. Calories From Fat

- What data are there on how consumers use the listing of ''Calories from fat?''
- How does the listing ''Calories from fat'' adjacent to ''Calories'' affect consumers' focus on the total calories of a food?
- What are the advantages or disadvantages of eliminating the listing for ''Calories from fat'' from the nutrition label?
- What data would be needed to determine whether the listing of ''Calories from fat'' is or is not necessary to assist consumers in maintaining healthy dietary practices?

3. Calories From Saturated Fat

- Should calories from saturated fat continue to be voluntary or should it be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.

4. Total Fat

- Should a population-weighted midpoint of the AMDR (e.g. 28 percent for adults) be used, as suggested in the IOM labeling report? Explain why or why not.

Note: 28 percent of 2,000 calories/d is 560 calories/d. 560 calories/d divided by 9 calories/g is 62 g/d.

- Should the upper range of AMDR of 35 percent be used? Explain why or why not.

Note: This would increase the DRV from 65g/d to 78 g/d for 2,000 calorie diet. 35 percent of 2,000 calories is 700 calories. 700 calories divided by 9 calories/g is ~ 78g.

5. Saturated Fat

- Should the current DRV of 20g/d from saturated fat remain, as recommended by the 2005 Dietary Guidelines? Explain why or why not.
- Should food composition data, menu modeling, and data from dietary surveys be used to establish a DRV for saturated fat that is as low as possible while consuming a nutritionally adequate diet, as recommended in the IOM labeling report? Explain why or why not.

6. *Trans* Fat

- Should food composition data, menu modeling, and data from dietary surveys be used to establish a DRV for *trans* fat that is as low as possible while consuming a nutritionally adequate diet, as recommended in the IOM labeling report? Explain why or why not.
- Should saturated fat and *trans* fat be listed on separate lines of the Nutrition Facts label, but have one numerical value for the percent daily value for these two nutrients together, as recommended in the IOM labeling report? Explain why or why not.
- If one numerical value is used for the percent DV for both *trans* fat and saturated fat together, should such value be determined by adding the DV for saturated fat to the DV for *trans* fat, or, alternatively, should the agency directly establish a joint DV for saturated and *trans* fats that would then be used to calculate one numerical value as the percent DV for both fats?

7. Polyunsaturated Fat

- Should polyunsaturated fat continue to be voluntary or should it be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- Should a DRV for polyunsaturated fat (*n*-3 plus *n*-6) be established using the AMDRs for *n*-6 (5–10 percent) and *n*-3 (0.6–1.2 percent) of total calories? If so, should the midpoint be used? Explain why or why not.

Note: 7.5 percent (midpoint) for n-6 and 0.9 percent (midpoint) for n-3 of 2,000 calories =19g/d polyunsaturated fat.

- Should a DRV for polyunsaturated fat be derived based upon AIs for linoleic acid (*n*-6 polyunsaturated fat) plus α-linolenic acid (*n*-3 polyunsaturated fat)? Explain why or why not.
- Should separate DRVs for linoleic acid (*n*-6 polyunsaturated fat) and α-linolenic acid (*n*-3 polyunsaturated fat) be established? Explain why or why not.
- If separate DRVs for linoleic acid (*n*-6 polyunsaturated fat) and α-linolenic acid (*n*-3 polyunsaturated fat) are established should they be voluntary or should they be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.

8. Monounsaturated Fat

- Should monounsaturated fat continue to be voluntary or should it be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.

9. Cholesterol

- Should the current cholesterol DRV of 300 mg/d remain, as recommended by the ''2005 Dietary Guidelines for Americans''? Explain why or why not.
- Should food composition data, menu modeling, and data from dietary surveys be used to establish a DRV for cholesterol that is as low as possible while consuming a nutritionally adequate diet, as recommended in the IOM labeling report? Explain why or why not.

10. Carbohydrate

- Should the current approach for calculating grams of total carbohydrate by difference (see section I.E of this document) continue to be used? Explain why or why not. If not, what other approach or method do you recommend? If so, what should be included or excluded in the current calculation of ''total carbohydrate''?
- The 2005 Dietary Guidelines recommends consuming fiber-rich foods. Would the separation of dietary fiber from the ''total carbohydrate'' declaration in nutrition labeling affect consumer understanding of label information and its application to dietary guidelines and what would be the impact, if any, on fiber consumption?
- Should ''sugars'' continue to be included in the Nutrition Facts label?
- Should additional types of carbohydrate (e.g., starch) be listed separately in the Nutrition Facts label? Explain why or why not.
- Should carbohydrates be classified and declared in nutrition labeling based on their chemical definition or on their physiological effect? Explain why you have chosen a particular approach and why it is preferable to the other approach. If based on a physiologic effect, should the DV for carbohydrate (i.e., sugars and starch) be based on the midpoint of the AMDR (i.e., 55 percent)? Explain why or why not.

Note: 55 percent of 2,000 calories/d is 1,100 calories. 1,100 calories divided by 4 calories/g would be 275 g/d.

11. Dietary Fiber

- Should FDA continue to use the AOAC INTERNATIONAL methods to determine dietary fiber? If not, what other or additional methods should be used?
- Should the IOM dietary fiber and/or functional fiber definitions replace the current FDA definition for dietary fiber? Explain why or why not.
- Do you recommend another name for functional fiber? If so, what do you recommend and why?
- Until FDA identifies functional fibers and analytical methods are established for distinguishing functional fiber from dietary fiber, should total fiber be used on the label to represent dietary fiber? Explain why or why not.

12. Soluble and Insoluble Fiber

- Should soluble and insoluble fiber continue to be voluntary or should they be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- Should the terms soluble fiber and insoluble fiber be changed to viscous and nonviscous fiber, as suggested by the IOM? Explain why or why not.

13. Sugar Alcohols

- Should sugar alcohols continue to be voluntary or should they be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- How should the energy contribution of sugar alcohols be represented on the label since energy values vary (e.g., from 0.2 calories/g for erythritol to 3.0 calories/g for hydrogenated starch hydrolysates)?
- FDA has not defined how it would determine available energy from sugar alcohols. What analytical methods could be used to determine the energy contribution of sugar alcohols?

14. Protein

- Should the DRV be based on the approach recommended in the IOM labeling report (100 percent—(DV_{fat} + $DV_{carbohydrate}$))? Explain why or why not.
- Should the DRV be based on the midpoint of the AMDR for protein (i.e., 17 percent)? Explain why or why not. *Note: Based on 2,000 calories/d, the DRV would be 85 g/d.*
- Should the DRV for protein be based on the EAR or RDA for protein? Explain why you have chosen a particular approach and why it is preferable to the other approach.

15. Sodium

- Should the DRV for sodium be based on the UL for sodium (2,300 mg/d) as suggested by the 2005 Dietary Guidelines for Americans or should it be based on the AI (1,500 mg/d using the population-coverage approach)? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- If the UL should be used, should it be adjusted using the same approach (population-weighted or population-coverage) as the other DRIs? Explain why or why not.

16. Chloride

The IOM set an AI and UL for chloride on an equi-molar basis to that of sodium since most sodium is consumed in the form of sodium chloride.

- Should the DV for chloride continue to be an RDI, or should it be a DRV like sodium? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- Should the DV for chloride be based on the same DRI (AI versus UL) as used to set a DV for sodium? Explain why or why not.

17. Vitamins and Minerals

Currently vitamin A, vitamin C, calcium, and iron are mandatory on the food label because they were considered to be of public health concern.

- Are vitamin A, vitamin C, calcium, and iron still considered to be of public health concern? Explain why or why not.
- Are there other micronutrients that should be of public health concern? Please be specific in describing what, if any, other micronutrients are of public health concern and why.
- For those nutrients given an AI under the DRI process, but currently have a DV based on an earlier RDA (e.g., calcium, vitamin K, vitamin D, pantothenic acid, biotin), should the current DV be retained or should the newer AI be used to develop a new DV? Explain why you have chosen a particular approach and why it is preferable to the other approach.
- Currently there is no DV for fluoride. Since the IOM established an AI for fluoride, should there be a DV for fluoride? Explain why or why not.

D. Other Questions

- Should the IUs that are currently used for the DVs for vitamins A, D, and E be changed to µg RAE (retinol activity equivalents), µg, and mg α-tocopherol, respectively? Explain why or why not.
- Should the current DV units for folate (µg), copper (mg), chloride (mg), potassium (mg), and sodium (mg) be changed to be consistent with the units in the IOM DRI reports (folate (µg dietary folate equivalents), copper (µg), chloride (g), potassium (g), and sodium (g))? Explain why or why not.
- Should the Supplement Facts label use the same DVs as the Nutrition Facts label, as suggested in the IOM labeling report? Explain why or why not.
- Should absolute amounts (e.g., grams or milligrams) be included in the Nutrition Facts and Supplement Facts labels for mandatory and voluntary nutrients? Explain why or why not.

E. Process Questions

The following question seeks information on the process issues related to the Nutrition and Supplement Facts labels.

- If FDA includes functional fiber in the Nutrition Facts labels, should FDA develop criteria for identifying fibers that meet the definition of functional fiber (i.e., demonstrates a physiological benefit)? If so, what should those criteria be?

F. Questions on Consumer and Producer Use and Understanding of DVs

To help determine which regulatory options might address problems associated with food package labels reflecting current DVs, we request comments including available data on the following questions:

- In the 2002 Health and Diet Survey (Ref. 24), respondents were asked how they use the Nutrition Facts label. The most common answers were as follows: (1) To see if the product was high or low in a specific nutrient, (2) to get a general idea of the nutritional content of food, and (3) to decide which brand to purchase and to compare different food items. Do you have information indicating how the percent DV found in the Nutrition Facts label facilitates any of these uses by consumers? For which food products and nutrients?
- Currently, a percent DV is required for most nutrients listed in the Nutrition Facts label. Do you have any information indicating that there are nutrients for which consumers would value percent DV information, but such nutrients are not currently found in the Nutrition Facts label?
- Do you have information suggesting the degree to which the percent DV is helpful for making purchases? For which food products? For which nutrients?
- Do you have information suggesting differences between the degree to which the percent DV is helpful for making

purchases intended for consumers 4 years of age and older, children younger than 4 years of age, infants, and pregnant women and lactating women? For which food products? For which nutrients?

The following questions address information needed by FDA to analyze the implications of changes in the percent DVs on consumer and producer behavior.

- Do you have any information suggesting that changes in percent DV (higher or lower), for a nutrient per serving, would cause consumers to reduce their consumption of some products or product categories and increase their consumption of other products or product categories? If so, changes in the percent DVs of which nutrients would cause changes in the consumption of which products or product categories? Why?
- If changes in the percent DVs of some nutrients would alter the eligibility of some products or product categories to make nutrient content claims or health claims, do you have any information suggesting that manufacturers would reformulate or re-label some of their products in order to make a nutrient content claim or a health claim? If so, changes in the percent DVs of which nutrients would cause which products or product categories to be reformulated in order to make a nutrient content claim or health claim?
- If changes in the percent DVs of some nutrients would cause some products or product categories to be reformulated or re-labeled in order to make a nutrient content claim or a specific health claim, do you have any information suggesting that there are public health effects from changes in nutrient intakes and consumption behavior of newly reformulated or re-labeled products or product categories that make these claims? If so, what are the public health effects from changes in nutrient intakes and from changes in the consumption behavior of which newly reformulated products or product categories?
- The length of time to comply with any regulation requiring revision to product labels may introduce confusion on the part of consumers during a transition period in which two different percent DVs would be reflected on labels of otherwise identically formulated products. Do you have information suggesting the extent to which such confusion might exist for compliance periods of 6 months, 12 months, and 24 months? For which food products?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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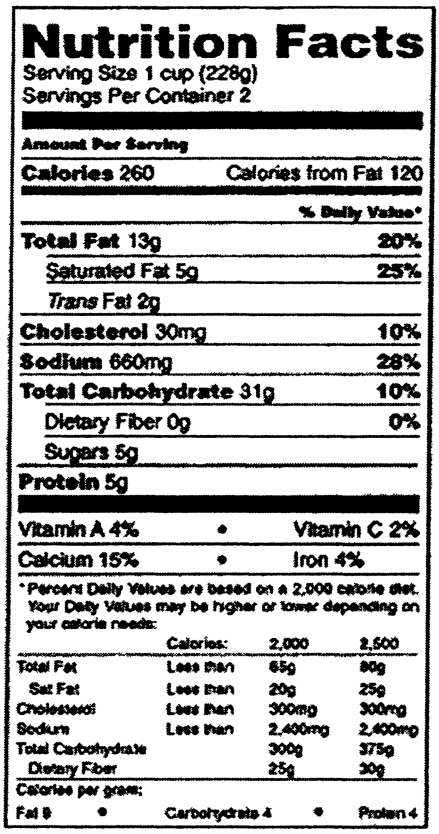
This ANPRM is issued under section 201 et al. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et al.) and under authority of the Commissioner of Food and Drugs.

APPENDIX A

ACRONYMS USED IN THIS DOCUMENT

AI	Adequate Intake
AMDRs	Acceptable Macronutrient Distribution Ranges
ANPRM	Advance Notice of Proposed Rulemaking
CV	Coefficient of Variation
DRIs	Dietary Reference Intakes
DRV	Daily Reference Value
DV(s)	Daily Value(s)
EAR	Estimated Average Requirement
EER	Estimated Energy Requirement
ESADDIs	Estimated Safe and Adequate Daily Dietary Intakes
FDA	Food and Drug Administration
FLUNES	Food Label Use and Nutrition Education Surveys
IOM	Institute of Medicine
IU	International Units
NAS	National Academy of Sciences
NLEA	Nutrition Labeling and Education Act of 1990
OWG	Obesity Working Group
PAL	Physical Activity Level
RACC	Reference Amount Customarily Consumed
RDA	Recommended Dietary Allowance
RDI	Reference Daily Intakes
SD	Standard Deviation
TEE	Total Energy Expenditure
U.S. RDA	U.S. Recommended Daily Allowance
UL	Tolerable Upper Intake Level

Appendix B
Examples of Nutrition Facts and Supplement Facts Labels



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% •	Vitamin C 2%
Calcium 15% •	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

Supplement Facts

Serving Size 1 Packet

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	5,000 IU	100%
Vitamin C (as ascorbic acid)	250 mg	417%
Vitamin D (as ergocalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	150 IU	500%
Thiamin (as thiamin mononitrate)	75 mg	5000%
Riboflavin	75 mg	4412%
Niacin (as niacinamide)	75 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	75 mg	3750%
Folic Acid	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	1667%
Biotin	100 mcg	33%
Pantothenic Acid (as calcium pentothenate)	75 mg	750%
Calcium (from oystershell)	100 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%
Magnesium (as magnesium oxide)	60 mg	15%
Zinc (as zinc oxide)	15 mg	100%
Selenium (as sodium selenate)	25 mcg	36%
Copper (as cupric oxide)	1 mg	50%
Manganese (as manganese sulfate)	5 mg	250%
Chromium (as chromium chloride)	50 mcg	42%
Molybdenum (as sodium molybdate)	50 mcg	67%
Potassium (as potassium chloride)	10 mg	< 1%
Choline (as choline chloride)	100 mg	*
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established

Other ingredients: Cellulose, stearic acid and silica.

BILLING CODE 4160–01–C

Dated: October 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–5440 Filed 11–1–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–0AR–2007–0510; FRL–8485–8]

Federal Implementation Plans for the Clean Air Interstate Rule: Automatic Withdrawal Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the Federal Implementation Plans (FIPs) for the Clean Air Interstate Rule (CAIR) to provide for automatic withdrawal of the CAIR FIPs in a State upon the effective date of EPA's approval of a full State implementation plan (SIP) revision meeting the CAIR requirements. EPA believes it is appropriate for the FIP withdrawal to be automatic because to the extent EPA approves the State's full CAIR SIP, this corrects the deficiency that provided the basis for EPA's promulgation of the FIPs in that State.

In the ''Rules'' section of this **Federal Register**, we are issuing this action as a direct final rule without a prior proposed rule. If we receive no adverse comment, we will not take further action on this proposed rule.

DATES: Written comments must be received by December 17, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0510, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-Docket@epa.gov*. Attention Docket ID No. EPA–HQ–OAR–2007–0510.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2007–0510.
- *Mail:* EPA Docket Center, EPA West (Air Docket), Attention Docket ID No. EPA–HQ–OAR–2007–0510, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center (Air Docket), Attention Docket ID No. EPA–HQ–OAR–2007–0510, Environmental Protection Agency, 1301 Constitution Avenue, NW., Room 3334; Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0510. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the EPA Docket Center EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

Rulemaking actions related to the CAIR and the CAIR FIPs are also available at the EPA's CAIR Web site at *www.epa.gov/cair*.

FOR FURTHER INFORMATION CONTACT: Carla Oldham, Air Quality Planning Division, Office of Air Quality Planning and Standards, mail code C539–04, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: 919–541–3347; fax number: 919–541–0824; e-mail address: *oldham.carla@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Why Is EPA Issuing This Proposed Rule?

This document proposes to amend the CAIR FIPs to provide for automatic withdrawal of the CAIR FIPs in a State upon the effective date of EPA's approval of a full SIP revision meeting the CAIR requirements. We have published a direct final rule making such amendments in the ''Rules'' section of this **Federal Register** because we view this as a noncontroversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule and it will not take effect. We would address all public comments in any subsequent final rule based on this proposed rule. We do not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time.

The regulatory text for this proposal is identical to that for the direct final rule published in the ''Rules'' section of this **Federal Register**. For further information and the detailed rationale for this proposal, see the information provided in the direct final rule.

II. Does This Action Apply to Me?

This action does not propose any control requirements. It proposes to amend the CAIR FIPs to provide for automatic withdrawal of the CAIR FIPs in a State upon the effective date of EPA's approval of the CAIR SIP for the State. EPA promulgated the CAIR FIPs on April 28, 2006 (71 FR 25328). Categories and entities potentially regulated by the CAIR FIPs include the following: