

**DOCKET NO. FDA-2012-N-1210**

**BEFORE**

**THE UNITED STATES OF AMERICA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**FOOD AND DRUG ADMINISTRATION**

**COMMENTS OF THE**

**AMERICAN HERBAL PRODUCTS ASSOCIATION**

**ON**

**PROPOSED RULE on**

**FOOD LABELING: REVISION OF THE NUTRITION AND  
SUPPLEMENT FACTS LABELS**

**August 1, 2014**

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## **Prefatory remarks**

The Food and Drug Administration (FDA or the Agency) on March 3, 2014 issued a proposed Rule titled Food Labeling: Revision of the Nutrition and Supplement Facts Labels (the proposed Rule).<sup>1</sup> FDA states in its March 2014 notice that it is proposing to amend the current labeling regulations for conventional foods and dietary supplements “to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices.” The agency also states that this updated nutrition information “is consistent with current data on the associations between nutrients and chronic diseases or health-related conditions, reflects current public health conditions in the United States, and corresponds to new information on consumer behavior and consumption patterns.”

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

Numerous AHPA members market conventional foods and dietary supplements and so are engaged in activities that would be directly covered by the proposed Rule. AHPA’s members therefore have an interest in the proposed Rule and these comments are submitted on their behalf.

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<sup>1</sup> 79 FR 11880.

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## **1. AHPA generally agrees with many of FDA's proposals**

AHPA is in general agreement with much of what FDA proposes, in particular the items mentioned below.

### **1.1 AHPA supports use of the RDA approach**

AHPA strongly agrees with FDA's decision to retain the Recommended Daily Allowance (RDA) approach to setting Daily Values (DVs) for nutrients where RDAs exist. Use of the RDA ensures that the corresponding DV will meet the nutritional needs of the vast majority of the population, whereas use of Estimated Average Requirement (EAR) for the nutrient would lead to DVs that are insufficient for approximately half of the population. This would be contrary to public health goals, especially since significant portions of the population already consume diets that are deficient in key nutrients<sup>2</sup> and AHPA expects that a significant reduction in DVs, as would result from revising them based on EARs, would serve only to worsen this problem. Furthermore, use of DVs based on EARs would be extremely misleading to consumers, who have come to expect that consuming a diet that provides 100% of the DVs will provide 100% of the nutrients they require.

### **1.2 AHPA supports use of recordkeeping to verify compliance**

FDA proposes to require manufacturers to make and keep written records, such as analyses of databases, recipes, formulations, or batch records, to verify the declared amount of certain nutrients for which it is not practical to verify the content in the finished food through analytical testing. FDA believes this will be an accurate and practical method to determine compliance with the nutrient content labeling requirements. AHPA strongly agrees.

### **1.3 AHPA supports many of the proposed formatting changes**

AHPA generally supports the proposed changes to the format of the nutrition label. In particular, AHPA finds the readability of the label to be significantly improved by (a) increasing the prominence for "Calories" and "Serving size" and (b) positioning the %DV column to the left of the nutrient name. AHPA strongly supports the exemption of small package labels from the revised requirements to the maximum extent possible. AHPA also agrees with FDA that changes to "Serving Size" and "Servings Per Container" are not necessary for dietary supplement labels, and that moving the %DV to the left of the nutrient name would not be appropriate for supplements.

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<sup>2</sup> See Table 1 in the preamble to the proposed Rule.

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## **2. The provisions for labeling of protein content should be updated and clarified**

AHPA believes that the provisions (both current and proposed) for determination and labeling of protein content on Nutrition/Supplements Facts panels are confusing to both industry and consumers, and that these provisions should be clarified.

### **2.1 Proposed protein labeling provisions do not reflect current science**

AHPA notes that the proposed Rule would continue to require use of the Protein Digestibility-Corrected Amino Acid Score (PDCAAS) for foods marketed to adults and children over 1 year of age. The use of PDCAAS in determining the nutritional value of protein was recommended in the 1991 report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation<sup>3</sup> to replace other methods. The use of PDCAAS has since been widely implemented.

However, significant criticisms of the PDCAAS method have been raised<sup>4</sup>; as a result, the 2013 report of the 2011 FAO Expert Consultation on Dietary Protein Quality Evaluation in Human Nutrition (hereinafter "the 2013 FAO report") recommends the PDCAAS method be replaced with the Digestible Indispensible Amino Acid Score (DIAAS), which takes into account the digestibility of individual essential amino acids.<sup>5</sup>

AHPA therefore recommends that FDA consider changing the requirement in revised 21 CFR § 101.9(c)(7) from use of PDCAAS to use of DIAAS, since the latter is believed to be a more accurate method of evaluating protein quality. Admittedly, DIAAS should optimally be based on known values of ileal amino acid digestibility for human foods, and such data are currently lacking; however, until such data become available the 2013 FAO report recommends use of DIAAS with the currently available values for fecal crude protein digestibility (i.e. DIAAS values should be calculated by applying fecal crude protein digestibility values to dietary amino acid contents).<sup>6</sup> Thus, a transition to use of DIAAS is currently possible.

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<sup>3</sup> FAO/WHO. "Protein Quality Evaluation: Report of the Joint FAO/WHO Expert Consultation." FAO Food and Nutrition Paper 51. (1991) Rome: FAO.

<sup>4</sup> WHO/FAO/UNU. Chapter 6.2 in "Protein and Amino Acid Requirements in Human Nutrition." Report of a joint WHO/FAO/UNU Expert Consultation, WHO Tech. Rep. Ser. no. 935. (2007) Geneva: WHO.

<sup>5</sup> FAO. "Dietary protein quality evaluation in human nutrition." Report of an FAO Expert Consultation 31 March - 2 April 2011, Auckland, New Zealand. (2013) Rome: FAO.

<sup>6</sup> Furthermore, since it may be several more years before the revised Nutrition Labeling Rule goes into effect, it is possible that authoritative values for ileal amino acid digestibility will be available before the Rule is finalized.

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Since AHPA does not know whether FDA will make the change to use of DIAAS in the final Rule, the remainder of AHPA's comments in this section assume continued use of PDCAAS; but they would be similarly applicable to DIAAS in the event that method is chosen.

## **2.2 Non-protein nitrogen compounds should not be included in the declared quantity of protein**

21 CFR § 101.9(c)(7) provides that the label must declare the number of grams of protein in a serving, and that protein content *may* (emphasis added) be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate AOAC method of analysis except when the official procedure for a specific food requires another factor.

The optional nature of this provision can lead to use of various practices in calculating protein for the labeling of foods (e.g., breakfast cereal, meal replacement products, dietary supplements, etc.) that contain protein combined with non-protein sources of nitrogen such as free amino acids and non-proteinogenic nitrogen compounds (L-carnitine, creatine, D-phenylalanine, adenosine, niacinamide, etc.). Companies may calculate the declared protein content as described in the rule (i.e., measuring the total nitrogen content and multiplying by the appropriate factor), or may instead determine the amount of nitrogen, calculate an "apparent" total protein content, and subtract the known quantities of non-protein nitrogen compounds (e.g., free proteinogenic amino acids; non-proteinogenic amino acids; other nitrogen-containing compounds such as nucleotides, vitamins, or alkaloids when present in appreciable quantities) to arrive at the declared protein content. Alternately, the protein content may be determined by measuring the total amino acid content and subtracting the free amino acid content; this method is often preferable for complex matrices and foods containing a wide variety of nitrogen sources.

As FDA notes in the preamble to the proposed Rule, consumers need "a consistent basis on which to compare products." AHPA believes it is not desirable to have the protein content of foods labeled using widely divergent approaches by different companies.<sup>7</sup> To address this concern, AHPA and the Council for Responsible Nutrition (CRN) recently developed guidelines for industry recommending that the declared content of protein in grams should represent only actual protein (i.e., free proteinogenic amino acids, free non-proteinogenic amino acids, and other non-proteinogenic nitrogen compounds should be excluded). In addition, NSF International is in the process of revising the ANSI standard for dietary

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<sup>7</sup> AHPA acknowledges that the declared %DV is required to be adjusted using protein digestibility corrections. However, based on input from members engaged in the retail sale of protein and meal replacement products, AHPA believes that many consumers who care about protein content are guided primarily by the declared grams of protein rather than the %DV.

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supplements to require that the declared content of protein in grams should represent only actual protein.

AHPA and CRN arrived at this recommendation after year-long discussions among experts and marketers of foods that contain added protein and amino acids, including both companies that declare protein on the basis of total nitrogen and companies that subtract non-protein nitrogen compounds. The companies came to a consensus that, in the interest of maximum label consistency, non-protein nitrogen sources (including free proteinogenic amino acids) should be excluded from the declared content of protein.<sup>8</sup>

AHPA recommends that FDA revise the regulation to provide that the declared content of protein in grams shall not include non-protein nitrogen sources, with protein being defined as "a chain of amino acids connected by peptide bonds."

Under this scenario, there are two means by which the appropriate label declaration for protein may be determined: (a) by subtracting the quantity of non-protein nitrogen sources from the total "protein" calculated based on the nitrogen content; (b) by measuring the total amino acids in the food and subtracting the free amino acids present. There are a number of analytical methods available for analysis of total and free amino acids in foods, including a few AOAC methods.<sup>9</sup> According to the 2013 FAO report, "no one method of analysis is necessarily the best, with a variety of approaches being acceptable....[T]here is a diversity of food matrices, such that most laboratories adapt methods to best suit their applications." AHPA agrees with this view. In addition, methods for analysis of various non-protein nitrogen sources may not exist or may not be valid in a given matrix. Therefore, AHPA believes it

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<sup>8</sup> With respect to proteinogenic amino acids, recent science indicates that free amino acids are not necessarily as biologically effective in meeting dietary protein requirements as are bound amino acids. Studies show that PCDAAS can overestimate the quality of proteins supplemented with limiting amino acids. (Sarwar G. "The Protein Digestibility-Corrected Amino Acid Score Method Overestimates Quality of Proteins Containing Antinutritional Factors and of Poorly Digestible Proteins Supplemented with Limiting Amino Acids in Rats." *J. Nutr.* (1997) 127(5): 758-764.) This may be due to the fact that postprandial oxidative losses are significantly higher for free amino acids compared to the same amino acids consumed in protein form. (Nolles J.A. "Postprandial fate of amino acids; adaptation to molecular forms." Thesis (2006) Wageningen University and Research Center, Wageningen, The Netherlands.) As one author states, "The assumption that amino acid supplementation can completely restore biological efficiency of the protein source is incorrect, since the kinetics of digestion and absorption between supplemented amino acids and amino acids present in dietary proteins, are different." (Schaafsma G. "Advantages and limitations of the protein digestibility-corrected amino acid score (PDCAAS) as a method for evaluating protein quality in human diets." *British J Nutr.* (2012) 108: S333-S336.)

<sup>9</sup> See Rutherford S.M. and Sarwar-Gilani G. "Amino acid analysis" (Chapter 11.9) in *Current Protocols in Protein Science*. (2009) Wiley as well as Otter D. "Standardized methods for amino analysis of food." *British J Nutr.* (2012) 108: S230-237.



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necessary that the Rule allow maximum flexibility for manufacturers to select an appropriate test method or to rely on recordkeeping to determine the quantities of non-protein nitrogen sources.

### **2.3 All products containing no protein should be precluded from declaring "protein"**

21 CFR §101.36(b)(2) states "Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids."

Technically, this does not preclude foods containing non-amino acid nitrogen compounds as the only source of nitrogen (e.g., a dietary supplement containing vitamins or nucleotides but no amino acids) from being labeled as containing protein.

AHPA is not aware of any such products that are labeled as containing protein; non-amino acid nitrogen-containing ingredients are generally used in products at low levels compared to the threshold for declaring protein. However, it is not impossible that such a product would contain sufficient nitrogen to merit a declared quantity of protein. AHPA believes for the sake of clarity the regulations should explicitly preclude such an eventuality.

### **2.4 The value of low-PDCAAS proteins should not be entirely discounted in nutrition labeling**

21 CFR § 101.9(c)(7) states that food labeling must include "A statement of the number of grams of protein in a serving...When the protein in foods [under one set of circumstances] has a [PDCAAS] of less than 20 expressed as a percent, or when the protein in a food [under another set of circumstances] has a [PDCAAS] of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement 'not a significant source of protein,' or a listing aligned under the column headed 'Percent Daily Value' of the corrected amount of protein per serving...calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as Percent of Daily Value."

As a result of this provision, the label for a product that contains 10 g of protein per serving (i.e., nominally 20% of the DRV for adults) from low-PDCAAS proteins such as gelatin or collagen as the sole source of amino acids will often<sup>10</sup> declare "10 g of protein" and "not a significant source of protein." This is both confusing and misleading: confusing because these statements are, at least on their face, self-

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<sup>10</sup> The "not a significant source of protein" statement is required unless the product manufacturer labels the product with the %DV calculated based on the corrected PDCAAS.

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contradictory, and misleading because these foods are, in fact, sources of protein (and can be significant sources depending on the serving size and protein content).

Furthermore, any amino acids deficient in one food or meal can be supplied by another, so that dietary needs are met over the course of a day.<sup>11</sup> Therefore, foods with a low PDCAAS are a valuable source of protein in the context of the overall diet, and the labeling regulations should not completely discount their value.

AHPA realizes that there is no way to reduce the complexities of protein nutrition to a simple statement that will fit on a product label and be readily comprehensible to consumers. However, AHPA believes the current and proposed labeling requirements would be improved by changing "not a significant source of protein" to "not a source of complete protein" for products that supply a non-trivial amount of protein but which have a low PDCAAS. AHPA believes that many consumers, especially vegetarians, are familiar with the concept of complete vs. incomplete protein and, even for consumers who are unfamiliar with the concept, the statement "not a source of complete protein" provides notice that the food in question cannot be relied upon as the sole source of protein in the diet.<sup>12</sup>

## **2.5 Protein labeling provisions should be reorganized for clarity**

Current and proposed 21 CFR § 101.9(c)(7) are written in a manner that is convoluted and confusing, such that many readers have a hard time parsing its requirements. For example, readers are often confused as to when, how, and to what the PDCAAS correction is to be applied in labeling, and when declaration of the %DV is required, prohibited, or optional. There is also, as discussed above, confusion regarding the most appropriate method to determine the declared quantity of protein.

AHPA suggests this portion of the Rule be reorganized so that the regulated industry can more easily understand its provisions.

## **2.6 AHPA's recommendations regarding protein labeling provisions**

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<sup>11</sup> It is not necessary to consume complementary proteins at the same time; their consumption can be separated among meals over the course of a day. (Young V.R. and Pellett P.L. "Plant proteins in relation to human protein and amino acid nutrition." Am J Clin Nutr. (1994) 59: 1203S-1212S.)

<sup>12</sup> AHPA believes this statement to be appropriate for foods marketed for use by adults and children over 4. In view of the much lower protein intakes recommended for infants and young children, AHPA believes it wise to continue labeling products with low protein quality marketed to infants and children under 4 with "not a significant source of protein" in order to ensure adequate consumption of all essential amino acids.

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In view of the above, AHPA recommends the following changes to proposed 21 CFR § 101.9(c)(7):

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. (The quantity of protein in grams shall not be corrected based on protein quality values as described in paragraph (c)(7)(vii) of this section.)

(i) For foods in which the only significant source of nitrogen is from protein (i.e., chains of amino acids linked by peptide bonds), protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be inspected at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(ii) For foods containing non-protein sources of nitrogen (including but not limited to free amino acids of any type) at levels which would elevate the declared content of protein, the quantity of non-protein nitrogen sources shall not be included in the declared quantity of protein. The declared quantity of protein may be determined by subtracting the quantity of non-protein nitrogen sources from the total "protein" determined as per paragraph (c)(7)(i) of this section, or may be determined by measuring the total amino acids in the food and subtracting the free amino acids present. The quantities of non-protein nitrogen sources may be determined by testing or by recordkeeping; in the latter case, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (g)(11) of this section to verify the quantities of non-protein nitrogen sources used to calculate the declared amount of protein.

(iii) When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score (PDCAAS) of less than 20 expressed as a percent when determined as per paragraph (c)(7)(vii) of this section, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a source of complete protein," or a listing aligned under the column headed "Percent Daily Value"

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of the corrected amount of protein per serving, as determined in paragraph (c)(7)(vii) of this section, calculated as a percentage of the Daily Reference Value (DRV) for protein and expressed as a Percent of Daily Value.

~~(iv) or w~~When the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a ~~protein~~ digestibility-corrected amino acid score PDCAAS of less than 40 expressed as a percent when determined as per paragraph (c)(7)(vii) of this section, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(vii) of this section, calculated as a percentage of the ~~Daily Reference Value (DRV)~~ or Reference Daily Intake (RDI), as appropriate, for protein and expressed as a Percent of Daily Value.

(v) When the protein quality in a food represented or purported to be specifically for infants 7 through 12 months has a protein quality value as measured by the Protein Efficiency Ratio (PER) that is less than 40 percent of the reference standard (casein) for a food represented or purported to be specifically for infants 7 through 12 months when determined as per paragraph (c)(7)(vii) of this section, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content, and the percentage of the RDI for protein (expressed as Percent of Daily Value) shall not be declared. Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be inspected at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(vi) A Except as provided in paragraphs (c)(7)(iii) through (v) of this section, a statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(vii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be specifically for infants 7 through 12 months or children

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1 through 3 years of age. When such a declaration is provided, it should be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. ~~However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be specifically for infants 7 through 12 months and the protein quality value is less than 40 percent of the reference standard.~~

(vii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1991, except that when official AOAC procedures described in this paragraph (c)(7) require a specific food factor other than 6.25, that specific factor shall be used. The "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" as published by the Food and Agriculture Organization of the United Nations/World Health Organization is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be inspected at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202-741-6030, or go to:

[http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). For foods represented or purported to be specifically for infants 7 through 12 months, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(viii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants 7 through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant and lactating women.

AHPA furthermore recommends the following changes to proposed 21 CFR § 101.36(b)(2)(i):

Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only ~~individual~~<sup>13</sup> free amino acids or other non-protein nitrogen sources.

AHPA recommends the following changes to proposed 21 CFR § 101.36(b)(2)(iii)(B), for clarity:

The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent for protein may or shall be omitted as provided in §101.9(c)(7).

AHPA also recommends the following changes to proposed 21 CFR § 101.36(b)(2)(iii)(B) for clarity:

The percent of Daily Value shall be calculated by dividing the quantitative amount by weight of each (b)(2)-dietary ingredient by the RDI as established in §101.9(c)(8)(iv) or the DRV as established in §101.9(c)(9) for the specified dietary ingredient and multiplying by 100, except that the percent of Daily Value for protein, when present, shall be calculated using the corrected amount of protein as specified in §101.9(c)(7)(vii).

Finally, AHPA also recommends the following be inserted as 21 CFR § 101.9(g)(10)(vi), and that current paragraphs (vi) and (vii) be renumbered (vii) and (viii):

For foods that declare an amount of protein and contain non-protein sources of nitrogen (including but not limited to free amino acids of any type) at levels which would elevate the declared content of protein, and for which the quantities of non-protein nitrogen sources are not determined through testing, the manufacturer must make and keep written records necessary to verify the quantities of non-protein nitrogen sources in the food.

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<sup>13</sup> Use of the word "individual" leaves some ambiguity as to whether products containing mixtures of free amino acids (as opposed to a single amino acid) are permitted to declare protein in the absence of actual protein.

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### **3. Botanicals in dietary supplements should be named as per the current edition of *Herbs of Commerce***

Current 21 CFR §101.4(h) provides that botanical ingredients in dietary supplements shall be labeled using names that are "consistent with the names standardized in *Herbs of Commerce*, 1992 edition, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, 8484 Georgia Ave., suite 370, Silver Spring, MD 20910, 301-588-1171, FAX 301-588-1174, e-mail: [ahpa@ahpa.org](mailto:ahpa@ahpa.org)....The listing of these names on the label shall be followed by statements of...[t]he Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: *Herbs of Commerce* for the common or usual name listed on the label...."

Since the time this provision was written into the regulations, AHPA has relocated its office and has published an updated and expanded 2nd edition of *Herbs of Commerce* ("HOC"), which includes nearly 1500 more botanicals than the 1st edition. In the dietary supplement marketplace today, companies commonly follow the naming conventions in HOC 2nd Ed.

Official recognition of nearly 1500 new standard common names will provide a level playing field for dietary supplement companies and additional clarity and convenience for consumers, healthcare practitioners, and regulators alike. As FDA notes in the preamble to the proposed Rule, consumers need "a consistent basis on which to compare products." It is to everyone's benefit for FDA to maximize consistency and simplicity in naming botanical ingredients and discourage or preclude use of "common" names that are idiosyncratic, uncommon, nonstandard, confusing, or actively misleading.

Establishment of these new standard common names will also reduce the need to use Latin binomials in labeling, which will benefit both consumers (who often find Latin names to be confusing or intimidating) and regulated firms (who often struggle to fit Latin names into limited label space).

Furthermore, AHPA is currently in the process of finalizing HOC 3rd Ed. In the preamble to the proposed Rule, FDA states that it will consider referencing the most current version of the Official Methods of Analysis of the AOAC International at the time the final rule is published; AHPA encourages FDA to do the same with HOC.

AHPA therefore suggests that FDA should update the regulation to refer to HOC 2nd Ed. or 3rd Ed. (depending on which edition is current at the time of publication of a final Rule). In addition, the contact information for AHPA should be updated. AHPA proposes the following changes to 21 CFR §101.4(h):

(h) The common or usual name of an ingredients of dietary supplements that ~~are~~ is a botanicals (including fungi and algae) shall be consistent with the Standardized

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Common<sup>14</sup> ~~Names standardized established~~ in *Herbs of Commerce*, 1992 20XX<sup>15</sup> edition (where an entry for the botanical exists in that reference),<sup>16</sup> which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, ~~8484 Georgia Ave., suite 370,~~ 8630 Fenton St., Suite 918, Silver Spring, MD 20910, 301-588-1171, FAX 301-588-1174, e-mail: [ahpa@ahpa.org](mailto:ahpa@ahpa.org)....

In addition, AHPA suggests the following changes to the remainder of 21 CFR §101.4(h), for clarity and currency:

(1) The listing of these names on the label shall be followed by statements of:

(i)~~(1)~~ The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., “Garlic bulb” or “Garlic (bulb)”), except that this designation is not required for algae. The name of the part of the plant shall be expressed in English (e.g., “flower” rather than “flos”);

(ii)~~(2)~~ The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: *Herbs of Commerce* for the ~~common or usual name~~ Standardized Common Name listed on the label, ~~and, w~~When required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of ~~Botanical~~ Nomenclature for algae, fungi, and plants* and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence. The *International Code of ~~Botanical~~ Nomenclature for algae, fungi, and plants* (~~Tokyo~~ Melbourne Code), ~~1994~~ 2012 edition, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the *International Code of ~~Botanical~~ Nomenclature for algae, fungi, and plants* may be obtained from Koeltz Scientific Books, D-61453 Königstein, Germany,

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<sup>14</sup> HOC includes various types of names, including Standardized Common Names, Latin names, pinyin names, Ayurvedic names, and other common names. Therefore, for clarity and accuracy, the regulation should specify that it is the Standardized Common Names that shall be used in labeling.

<sup>15</sup> The year should correspond to the publication date of the HOC edition current at the time the final rule is published.

<sup>16</sup> This qualification is necessary since not all botanicals have a Standardized Common Name established in HOC.



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~~and University Bookstore, Southern Illinois University, Carbondale, IL 62901-4422, 618-536-3321, FAX 618-453-5207,~~<sup>17</sup> or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

~~(2)(3)~~ On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when ~~needed~~required, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

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<sup>17</sup> Based on a search of the Southern Illinois University Bookstore website ([http://www.bkstr.com/southernillinoisstore/home/en?cm\\_mmc=Redirect\\_-\\_VanityURL\\_-\\_siu.bkstr.com\\_-\\_10728](http://www.bkstr.com/southernillinoisstore/home/en?cm_mmc=Redirect_-_VanityURL_-_siu.bkstr.com_-_10728), accessed 07/29/14), it does not appear this publication is currently available from that source.

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## 4. Comments regarding declaration of the amount of "added sugar" in foods

AHPA generally supports the mandatory declaration of "added sugar" in foods as would be required by proposed 21 CFR §101.9(c)(6)(iii), and agrees that maintenance and review of the manufacturer's records is an effective and practical means to determine compliance with the values declared on the product label. However, AHPA believes a number of clarifications and adjustments are necessary to the proposed requirements.

### 4.1 Adjustment for moisture content and other constituents

AHPA notes that many sources of "added sugar" contain significant amounts of water or moisture. For example, glucose commonly occurs as a monohydrate in which water represents around 9% of the ingredient. Similarly, ingredients such as syrups and fruit juice concentrates often contain significant amounts of water (e.g., 30%). Furthermore, these ingredients may contain a range of naturally occurring constituents besides sugars (e.g., polysaccharides, anthocyanins, vitamins, minerals, etc.).

Therefore, in order to avoid overstating the amounts of added sugars, it is important to take into account the actual "sugars" content of these ingredients, because the quantity of added ingredient may not equal the amount of added sugars. However, the current language of the provision appears to equate "added sugars" with the ingredient itself; for example, the definition equates "added sugars" with "syrups" and "fruit juice concentrates." AHPA suggests language should be added to clarify that the quantity of "added sugars" declared in labeling will include only the actual "sugars" portion of the ingredient.

In the absence of this adjustment, AHPA strongly opposes the inclusion of syrups and fruit juice concentrates (as well as honey, if FDA intends honey to be included) in the category of "added sugars." Without a correction to account for the actual sugars content of the ingredients, the declared quantity of honey, syrup, or fruit juice concentrate will grossly overstate the actual amount of added sugars. This will be misleading to the consumer. It will also be contrary to good public health, because it will put chemically complex "added sugars" (which are often healthier sources of sweetening since they can provide nutrients other than sugars<sup>18</sup>) at an unwarranted disadvantage to "added sugars" that consist

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<sup>18</sup> For example, a serving of honey provides 8% of the DV for riboflavin, 8% of the DV for iron and 14% of the DV for manganese (<http://nutritiondata.self.com/facts/sweets/5568/2>, accessed 05/03/14), and a serving of apple juice concentrate supplies 11% of the DV for iron, 12% of the DV for vitamin B6, 24% of the DV for manganese, and 27% of the DV for potassium (<http://nutritiondata.self.com/facts/fruits-and-fruit-juices/1823/2>, accessed 05/04/14).

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only of pure sugars (which are often used in smaller quantities and thus will have a less unfavorable "added sugars" declaration).

#### 4.2 Changes in "added sugars" content due to fermentation

In the preamble to the proposed Rule, FDA acknowledges that fermentation may reduce the amount of added sugars present in the final food. FDA proposes that, in certain narrowly-defined cases, manufacturers of fermented foods will have the option to either (a) declare the amount of sugars added to the food, so long as that amount does not exceed the amount of total sugars present in the finished food, or (b) rely upon data and information to determine what quantity of added sugars should be declared.

AHPA generally supports these options for industry, but believes adjustments to the proposed Rule are required to account for the broad variety of products and manufacturing processes in the food industry.

FDA states in the preamble, "[W]e tentatively conclude that the amount of added sugars present in foods prior to undergoing fermentation, with the exception of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a 'malt beverage' as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)) with sugars added during the fermentation process, will not be significantly affected by virtue of the food having undergone fermentation."

AHPA strongly disagrees with this statement. There are a wide variety of fermented food products to which sugars (in the form of sucrose, honey, jaggery, molasses, etc.) are or may be<sup>19</sup> added in which the content of sugars can be significantly affected by the fermentation process.<sup>20</sup> These include, for example, various fermented vegetables (e.g., kimchi, pickled cucumbers, olives), beverages (e.g., kombucha, fermented sodas), fruits (e.g., mango pickle, lime pickle), condiments (e.g., fermented sriracha,

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<sup>19</sup> Some fermented foods are routinely made with sugars added to the fermentation culture (e.g., yogurt made from almond milk). In other cases the decision to add sugars depends on the desired sensory qualities of the finished food (e.g., degree of sweetness or acidity) and/or technical factors (e.g., use of added sugars in the fermentation of olives that have insufficient levels of natural sugars to support adequate microbial growth, due to low sugars content at harvest and/or due to loss of sugars during preliminary leaching steps).

<sup>20</sup> In most cases the sugars are added at the beginning of fermentation, but in some cases sugars are added partway through fermentation or after initial fermentation but prior to final fermentation.

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fermented ketchup), products made with grains and/or pulses (e.g., sweet idli, sweet dosa), dairy replacement products (e.g., non-dairy yogurt), and fermented meat products (e.g., salami).<sup>21</sup>

The effect of fermentation on the content of sugars is variable. In many cases, the sugars present in the culture are consumed by the fermentative microorganisms and the decrease in sugars content is significant. For example, the content of reducing sugars has been shown to drop by half in one type of kimchi when optimally ripened,<sup>22</sup> and the content of mannose, fructose, and glucose has been shown to drop by 80-100% during fermentation of other kimchis.<sup>23</sup> Many fermentations exhibit significant and consistent reductions in sugar content.<sup>24,25</sup> In other fermented foods the results are more variable; for example in grain fermentations the content of sugars often initially increases due to digestion of poly- or oligosaccharides before later decreasing due to microbial metabolism,<sup>26</sup> which means the sugar content of the finished product will depend on the extent to which fermentation is allowed to proceed. The net effect can depend on details of the starting materials, fermentation process, and length of fermentation used.<sup>27</sup>

There are also various food ingredients such as vinegars, enzymes, vitamins, and amino acids in pure form or in mixtures produced through fermentation, for which the culture medium may include pure sugars (e.g., sucrose, glucose) or other sources of sugars (e.g., molasses); these ingredients are sometimes be sold in retail packaged form where the "added sugars" declaration would be required under the proposed Rule. In many of these cases, the added sugars will be significantly diminished or entirely removed by microbial digestion and/or post-fermentation purification steps.

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<sup>21</sup> AHPA believes there are probably many other fermented meat, fish, and dairy food products to which sugars are or may be added before or during fermentation, but does not have extensive knowledge regarding such products.

<sup>22</sup> Rhee S.J. et al. "Importance of lactic acid bacteria in Asian fermented foods." *Microb. Cell Fact.* (2011) 10(Suppl 1): S5.

<sup>23</sup> Yun J.W. et al. "Mannitol accumulation during fermentation of kimchi." *J. Fermentation and Bioengineering.* (1996) 81(3): 279-280.

<sup>24</sup> Fleming H.P. et al. "Storage stability of vegetables fermented with pH control." *J. Food Sci.* (1983) 48: 975-981.

<sup>25</sup> Hughes A. and Lindsay R.C. "Liquid chromatographic analysis of sugars and mannitol in cabbage and fermenting sauerkraut." *J. Food Sci.* (1985) 50(6): 1662-1667.

<sup>26</sup> See for example Osman M. "Effect of traditional fermentation process on the nutrient and antinutrient contents of pearl millet during preparation of Lohoh." *J. Saudi Soc. Ag. Sci.* (2011) 10(1): 1-6.

<sup>27</sup> McFeeters R.F. "Effects of fermentation on the nutritional properties of food" in *Nutritional Evaluation of Food Processing.* (1988) 423-446.

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### 4.3 Changes in "added sugars" content due to chemical reactions

In the preamble to the proposed Rule, FDA states "Sugars in some foods may undergo chemical changes mediated by chemical reactions from non-enzymatic browning (i.e., Maillard reactions and caramelization)...During these reactions, some sugars are...transformed and converted into compounds that are no longer recognizable or detectable as sugars through conventional analytical methods (Ref. 77). We expect that the amount of added sugars transformed during non-enzymatic browning reactions is insignificant relative to the initial levels of sugars (Ref. 78)."

AHPA disagrees that the amount of added sugars transformed by chemical reactions will necessarily be insignificant relative to the initial levels of sugars. For example, the manufacture of caramel converts sugars into thousands of new chemical compounds that include oligomers, dehydration and hydration products, disproportionation products, and colored aromatic products.<sup>28</sup> AHPA believes these and other transformations of sugars occur to a significant extent in a wide variety of foods. The extent of the decrease in added sugars may depend on the ingredients, moisture levels, presence of acids or bases, exposure to heat, etc., but it is not wise to assume the decrease is uniformly "insignificant."

Proposed § 101.9(g)(10)(v) would permit manufacturers of a few types of fermented foods to make and keep records of scientific data and information to demonstrate the amount of added sugars remaining in the finished food, when that amount is less than the initial amount of added sugars. AHPA believes this provision should be extended to all food manufacturers that are required to declare "added sugars" in the labeling of their products. AHPA believes this provision may be necessary to enable accurate "added sugars" labeling for many types of food, and it is not possible for FDA to anticipate in advance all of the types of food for which this provision will be necessary and appropriate. Furthermore, AHPA can see no reason this option should not be provided to all food manufacturers rather than limited to a select few cases.

### 4.4 The amount of "added sugars" may vary

AHPA notes that the quantity of added sugars may vary from batch to batch or from time period to time period for a particular food product. Such variations may be necessary to achieve the desired flavor

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<sup>28</sup> Golon A. and Kuhnert N. "Unraveling the chemical composition of caramel." J. Agric. Food Chem. (2012) 60: 3266-3274.

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profile,<sup>29</sup> texture, fermentability,<sup>30</sup> or other qualities in the food. Factors related to agriculture (e.g., availability of soil nutrients and water; variety or strain of crop used; heat and sun exposure; stage of development at time of harvest), season (e.g., early- vs. late-season harvest), and post-harvest handling of raw agricultural commodities (e.g., storage conditions or drying method) can affect the chemical composition of the starting materials used in food production, which may then necessitate adjustments in the recipe (e.g., changes in the amount of added sugars to achieve the desired balance between sweet/tart/bitter/pungent flavors or to achieve the desired level of final acidity in a fermented food). The amount of added sugars may change by up to 100% (i.e., there may be some circumstances in which the quantity of sugars added to the food is zero and other circumstances in which it is non-zero).

Therefore, FDA should provide instructions for how the declared quantity of added sugars is to be determined in food products where the amount of added sugars may vary. AHPA strongly opposes any explicit or implicit requirement for manufacturers (a) to adjust their labels from batch to batch of product, from shipment to shipment of agricultural raw materials, or from season to season, or (b) to grossly overstate the level of added sugars. Rather, AHPA suggests that the amount of added sugars should be declared as the mean average of the expected range of variability, or else the range itself should be declared.<sup>31</sup>

Furthermore, AHPA believes the inclusion of added sugars in 21 CFR § 101.9(g)(5), which states that food is misbranded if the nutrient content of a composite sample is greater than 20 percent in excess of the value for that nutrient declared on the label, is not appropriate. The content of added sugars may, consistent with good manufacturing practice, vary by far more than 20%; in fact, it may vary up to 100%, since depending on the sugar content, acidity, or other characteristics of a particular shipment of raw materials it may not be necessary to add any sugar while in other cases it may be necessary to add a significant amount of sugar. Therefore, added sugars should be explicitly exempted from this provision, otherwise manufacturers will be forced either to significantly overstate the content of added sugar, to change their labels frequently (perhaps for every batch), or to sell misbranded food.

#### **4.5 AHPA's recommended changes to 21 CFR §101.9(c)(6)(iii), (g)(5), and (g)(10)**

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<sup>29</sup> For example, in making apple sauce it may be necessary to add sugar, or more sugar, if a shipment of apples is insufficiently sweet or excessively tart.

<sup>30</sup> For example, olives harvested late in the season may contain insufficient quantities of sugars to support fermentation; therefore, addition of sugar may be necessary.

<sup>31</sup> Alternately, the amount might be declared in the form "Added sugars...up to X g" or "Added sugars....Less than X g," but AHPA believes this would be misleading to consumers since it would consistently and sometimes dramatically overstate the level of added sugars.

In view of the above, AHPA recommends the following changes to proposed 21 CFR §101.9(c)(6)(iii):

"Added Sugars": A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If a statement of the added sugars content is not required and, as a result, not declared, the statement "Not a significant source of added sugars" shall [must?]<sup>32</sup> be placed at the bottom of the table of nutrient values in the same type size. Added sugars shall be defined as ~~sugars~~ caloric sweeteners that are either added during the processing of foods, or are packaged for use as such, and include sugars (free, mono- and disaccharides), honey<sup>33</sup>, syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that ~~sugar is~~ sugars<sup>34</sup> are the primary component (e.g., fruit juice concentrates), and other caloric sweeteners. For caloric sweeteners that supply added sugars as well as water or other constituents, the declared quantity of added sugars shall represent only the content of sugars. Where the quantity of added sugars used in the food is variable, the declared quantity of added sugars shall represent the mean average of the expected range of variability. Added sugars content shall be indented under sugars and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and when the amount of added sugars used in a food is variable, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation or chemical reaction, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (g)(11) of this section to verify the declared amount of added sugars in the label and labeling of food.

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<sup>32</sup> AHPA notes that the proposed Nutrition Labeling Rule uses both "shall" and "must" to indicate that a provision is mandatory. AHPA suggests that FDA should standardize use of "shall" vs. "must" throughout the Rule.

<sup>33</sup> AHPA assumes that FDA intends "honey" to be included in "added sweeteners," and suggests that for clarity it should be explicitly listed.

<sup>34</sup> AHPA agrees with other comments that the word "sugar" is ambiguous, insofar as it is commonly used to mean specifically "sucrose" rather than "any free, mono-, or disaccharide." For clarity, AHPA recommends FDA use the plural "sugars" when referring to free, mono-, or disaccharides as a group.

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AHPA also recommends the following changes to proposed 21 CFR §101.9(g)(5):

(5) A food with a label declaration of calories, sugars, ~~added sugars (when the only source of sugars in the food is added sugars)~~, total fat, saturated fat, trans fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label, except that any discrepancy caused solely by declaration of nutrient content in accordance with the rounding or increment requirements of this Rule (such as a requirement to express the content of a nutrient in increments of 1, 5, or 10) shall not constitute misbranding.<sup>35</sup> No regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved. This paragraph does not apply to added sugars.

In addition, AHPA recommends the following changes to proposed 21 CFR §101.9(g)(10):

(iv) When a mixture of naturally occurring and added sugars is present in the food, and when the amount of added sugars is variable, a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) ~~When the amount of added sugars added to yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, or beer that does not meet the definition of a "malt beverage," as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)),~~ food is reduced through the process of fermentation or chemical reaction, manufacturers must: (A) Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates<sup>36</sup> the amount of added sugars in the food after fermentation processing and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of ~~fermented~~ food manufactured; or (B) Make and keep records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or

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<sup>35</sup> See comment # 6.5 regarding the importance of the preceding clause.

<sup>36</sup> "Data and information" are plural so "demonstrate" should not end in "s."



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more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label.

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## 5. Folic acid vs. folate nomenclature

FDA proposes to make changes in the nomenclature associated with declaration of folic acid/folate in foods. The unit of measure is proposed to be changed from "mcg" to "mcg DFE" where DFE stands for "dietary folate equivalents"; the new unit of measure is intended to take into account the difference in bioavailability between folate occurring naturally in food vs. pure or synthetic folic acid. In addition, FDA proposes that (a) use of the synonym "folacin" would no longer be permitted; (b) "folate" would be used exclusively in the labeling of conventional foods; and (c) only "folic acid" would be used in the labeling of dietary supplements.

### 5.1 Comments regarding "folate" vs. "folic acid"

The proposal that the term "folate" shall be used in labeling conventional foods and that "folic acid" shall be used in labeling dietary supplements appears to be predicated on the assumptions that conventional foods contain either naturally-occurring folate only or a mixture of naturally-occurring folate and added folic acid (i.e., no conventional food contains added folic acid only)<sup>37</sup>, and that dietary supplements exclusively contain added folic acid (i.e., no dietary supplement contains naturally-occurring folate).

AHPA disagrees that these assumptions are correct. For example, while it is true that many dietary supplements contain added folic acid, there are others that contain added L-methylfolate,<sup>38</sup> and there are a large number that are "whole food" supplements containing naturally-occurring folate rather than added folic acid (e.g., multivitamin capsules manufactured using powdered cultured yeast). Furthermore, while many conventional foods contain naturally-occurring folate, and folic acid is added to certain folate-containing conventional foods (e.g., enriched whole wheat bread), there may also be conventional foods containing only added folic acid (e.g., meal-replacement foods based on protein concentrates that do not contain significant levels of naturally-occurring folate).<sup>39</sup>

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<sup>37</sup> In the preamble, FDA indicates that conventional foods may contain either "folate only or a mixture of folate and folic acid" and makes no mention of conventional foods containing folic acid only.

<sup>38</sup> Also known as L-5-MTHF, this ingredient is available as (6S)-5-methyltetrahydrofolic acid, calcium salt and (6S)-5-methyltetrahydrofolic acid, glucosamine salt. These have come into the US market since the year 2000.

<sup>39</sup> AHPA believes there also probably are or will be conventional foods in the US marketplace that contain added folate other than folic acid.

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Thus, AHPA believes it inappropriate for FDA to limit use of the term "folate" or "folic acid" to one or the other category of food. Each food should be labeled as appropriate for the particular ingredient(s) it contains, irrespective whether it is a conventional food or a dietary supplement.

AHPA also believes that many consumers are highly interested in as much information as possible about the ingredients in their food. Therefore, AHPA strongly encourages FDA to permit food manufacturers to disclose additional information about the type(s) and relative amounts of folate/folic acid contained in the product, as by declaring the additional information in parentheses following the name of the nutrient.

## **5.2 Comments regarding the unit of measure**

Proposed 21 CFR §101.9(c)(8)(iv) defines "1 DFE = 1 microgram food folate = 0.6 micrograms folic acid from fortified food or as a supplement consumed with food = 0.5 micrograms of a supplement."

AHPA has no strong objection to incorporating estimates of bioavailability into the definition of the folate/folic acid unit of measure (UOM), although AHPA is also not convinced that such complications will have much effect on the health or nutritional status of the American public. However, AHPA has a number of concerns regarding the proposed definition in the Rule.

(a) If such a UOM is adopted, it is necessary to indicate how use of L-methylfolate is to be addressed. AHPA notes that both the calcium and glucosamine salts of L-methylfolate have bioavailability similar to folic acid on an equimolar basis.<sup>40,41</sup>

(b) Since both conventional foods and supplements can contain folate, folic acid and/or L-methylfolate, the definition must not prescribe values based simply on the form of the food (e.g., "0.5 micrograms of a supplement"); rather, the definition needs to account for the form of the vitamin.

(c) AHPA doubts the wisdom of requiring supplement manufacturers to make assumptions about how consumers will ingest their product. Even if a supplement's directions for use specify taking the product with food or alone, many consumers will

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<sup>40</sup> EFSA. "Opinion of the scientific panel on food additives, flavourings, processing aids and materials in contact with food on a request from the Commission related to Calcium L-Methylfolate." *The EFSA Journal* (2004) 135: 1-20.

<sup>41</sup> EFSA. "Scientific opinion on (6S)-5-methyltetrahydrofolic acid, glucosamine salt as a source of folate added for nutritional purposes to food supplements." *EFSA Journal* (2013) 11(10): 3358.

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not comply. Furthermore, AHPA does not believe the differences observed in folate/folic acid bioavailability are linked only to the presence or absence of other food in the stomach at the time of ingestion; rather, bioavailability is affected by a myriad of factors that influence folate/folic acid such as entrapment, stability, and absorption.<sup>42</sup>

(d) FDA's proposed definition establishes a somewhat different value of mcg DFE for folic acid in a supplement taken with food and in conventional foods, compared to folic acid in supplements taken alone. AHPA finds this to be overly complex and difficult to implement. Furthermore, given the many variables affecting the bioavailability of nutrients (e.g., individual physiology and health status; variability in the composition of meals; technical details of food/supplement form and formulation; etc.) AHPA doubts there is a valid basis to make generalizations with the level of accuracy and precision the proposed definition appears to imply.

While there is consensus that pure folic acid is more bioavailable than naturally-occurring folate in food, there is currently no scientific consensus as to the magnitude of this effect. One recent review of the issue states, "The bioavailability of food folate is commonly estimated at 50% of folic acid bioavailability when establishing food recommendations, but this should be considered a rough estimate, as data on the bioavailability of food folate vary between 30% and 98%...."<sup>43</sup>

AHPA notes that FDA's proposed definition is based on IOM recommendations dating to 1998. AHPA believes that this definition, while it may have represented IOM's best thinking at the time, no longer accurately represents current knowledge and current developments in the formulation of foods and supplements.

AHPA therefore recommends that the definition assign a value to naturally-occurring folate at 50% of the value of folic acid (as well as at 50% of the value of L-methylfolate salts on the equimolar basis to folic acid). AHPA does not believe more precise estimates (i.e., based on consumption of the nutrient in fortified food or a supplement taken with food vs. a supplement taken alone) are justified by the data available at this time.

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<sup>42</sup> These effects are summarized in Ohrvik V.E. and Witthoft C.M. "Human Folate Bioavailability" (Nutrients. (2011) 3(4): 475-490), along with references to more extensive discussions.

<sup>43</sup> *ibid.* See also, for example, Sanderson P. et al. "Folate bioavailability: UK Food Standards Agency workshop report." Brit. J. Nutr. (2003) 90: 473-479; and Winkels R.M. et al. "Bioavailability of food folates is 80% of that of folic acid." Am. J. Clin. Nutr. (2007) 85: 465-473.

### 5.3 AHPA's suggestions regarding 21 CFR §101.9(c)(8)(iv), §101.9(c)(8)(vii), and §101.9(g)(10)(vii)

In view of the above, AHPA recommends the following changes to footnote 3 in proposed 21 CFR §101.9(c)(8)(iv), for clarity and to provide appropriate flexibility:

"Folic Acid" must be used for purposes of declaration in the labeling of dietary supplements for foods that contain this nutrient solely in the form of added folic acid. Foods which supply both folate and folic acid must list the predominant form. Folate and folic acid must also both be declared in mcg DFE. Additional information regarding the type(s) or source(s) of the nutrient (e.g., folate, folic acid, or L-methylfolate<sup>44</sup>), and/or relative amount(s) where more than one form is present, may be included in parentheses.

AHPA recommends the following changes to footnote 4 in proposed 21 CFR §101.9(c)(8)(iv):

DFE = Dietary folate equivalents; 1 DFE = 1 microgram ~~food~~ naturally-occurring<sup>45</sup> folate = 0.6 micrograms folic acid from fortified food or as a supplement consumed with food = 0.5 micrograms of a supplement = 0.5 microgram folic acid (anhydrous basis<sup>46</sup>) = 0.56 microgram L-methylfolate calcium salt (anhydrous basis) = 0.93 microgram L-methylfolate glucosamine salt (anhydrous basis).<sup>47</sup>

AHPA recommends the following changes to proposed 21 CFR §101.9(c)(8)(vii), for clarity, accuracy, consistency, and completeness:

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<sup>44</sup> AHPA believes these should remain as examples only, rather than a prescriptive list, as it is possible that additional forms of folate will be commercialized in the future.

<sup>45</sup> AHPA suggests "food folate" (a term which is not defined and which may be unclear or confusing) be replaced with "naturally-occurring" for consistency with the terminology used elsewhere in the Rule, e.g. in 21 CFR §101.9(g)(3)(ii).

<sup>46</sup> Since these numbers will often be calculated rather than determined through testing, it is important to specify how water present in the ingredient is to be accounted for in the calculation.

<sup>47</sup> L-methylfolate calcium salt has a molecular weight of 497.5 amu and L-methylfolate glucosamine salt has a molecular weight of 817.8 amu, whereas the molecular weight of folic acid is 441.4 amu. AHPA's proposed equivalencies are intended to provide equimolar amounts of L-methylfolate compared to folic acid.

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~~When the amount of folate is declared in the labeling of a conventional food, the~~  
The nutrient name "folate" shall be listed for products containing either only or  
predominantly folate alone or a mixture of folate and folic acid. The name of the  
~~synthetic form of the nutrient,~~ The nutrient name "folic acid" shall be used when the  
~~nutrient is declared in the labeling of dietary supplements listed for products containing~~  
only or predominantly folic acid. Additional information regarding the type(s) or  
source(s) of the nutrient (e.g., folate, folic acid, or L-methylfolate<sup>48</sup>), and/or relative  
amount(s) where more than one form is present, may be included in parentheses.

AHPA recommends the following changes to proposed 21 CFR §101.9(g)(10)(vii), for clarity and completeness. These records will be necessary any time folic acid or folate salt is added to food in order to justify the calculation of the declared mcg DFE, even if no naturally-occurring folate is present.

~~When a mixture of folate and folic acid and/or purified folate salt<sup>49</sup> (e.g., L-methylfolate)~~  
is ~~present in~~ added to a food, manufacturers must make and keep written records of the  
amount of folic acid and/or purified folate salt added to the food, as well as the amount  
of naturally-occurring and folate if present in the finished food.

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<sup>48</sup> AHPA believes these should remain as examples only, rather than a prescriptive list, as it is possible that additional forms of folate will be commercialized in the future.

<sup>49</sup> AHPA believes the general term "purified folate salt" should be used rather than a specific form such as "L-methylfolate," as it is possible that additional forms of folate will be commercialized in the future.

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## 6. Other comments

### 6.1 Comments regarding "niacin equivalents"

AHPA notes that footnote 2 in proposed 21 CFR §101.9(c)(8)(iv) states, "NE = Niacin equivalents, 1 milligram niacin = 60 milligrams of tryptophan." This represents a change from current 21 CFR §101.9(c)(8)(iv) which establishes the UOM for niacin to be simply milligrams.

FDA does not discuss in the preamble the basis for this change nor how compliance is to be determined. AHPA assumes FDA intends to determine compliance by testing the product using AOAC methods for both niacin and for tryptophan, then adding 1/60th of the tryptophan content to the niacin content. If this is not correct then AHPA recommends FDA provide clarification.

AHPA doubts this change to the niacin unit of measure will measurably improve the health or nutritional status of the American public, and notes that the change will increase the burdens on manufacturers, especially insofar as it necessitates additional testing.

Should FDA proceed with this change, AHPA suggests that for additional clarity and consistency the definition in footnote 2 should mirror the definitions in footnotes 1 and 3:

NE = Niacin equivalents, 1 NE = 1 milligram niacin = 60 milligrams of tryptophan.

Furthermore, AHPA suggests FDA should explicitly clarify whether a declaration of niacin content will be required for products that contain no actual niacin. If so, the regulation should include a provision specifying that products containing more than 19 mg of tryptophan (corresponding to 0.32 mg of niacin or 2% of the proposed RDI) must declare niacin even if there is no actual niacin present, otherwise manufacturers of such products are likely not to notice the revised requirements for niacin declaration.

### 6.2 Comments regarding choline

AHPA supports FDA's proposal to include choline as an essential nutrient.

FDA proposes that "Choline" should be listed following "Potassium" in the Nutrition/Supplements Facts box.

AHPA believes choline should be listed with the B-vitamin group rather than following the group of minerals. As FDA states in the preamble to the proposed Rule, "Proximity is a graphic design principle that asserts that items closer together are perceived to be more related." Since choline is commonly

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considered a B-vitamin,<sup>50</sup> it is appropriate to list it with the other B-vitamins as this will help to educate consumers that it is a B-vitamin. In contrast, it would not be appropriate to list it following the minerals group, as this would erroneously imply it is a mineral and is therefore likely to confuse consumers as to the nature of this nutrient.

AHPA therefore recommends that the placement of "Choline" in the table in proposed 21 CFR §101.9(c)(8)(iv) be moved to follow "Pantothenic acid."

AHPA also recommends the following changes to proposed 21 CFR §101.36(b)(2)(i)(B):

The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutritional label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B<sub>6</sub>, folate/folic acid,<sup>51</sup> vitamin B<sub>12</sub>, biotin, pantothenic acid, choline, calcium, iron, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium, ~~and choline~~. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)(2) of this section.

### 6.3 Comments regarding placement of other nutrients

Under current nutrition labeling regulations, the 4 nutrients vitamin A, vitamin C, calcium, and iron are deemed of particular importance to the health of the American public. As a result, current 21 CFR § 101.9(c)(8)(ii) requires that these 4 nutrients be listed first in the Nutrition Facts box and 21 CFR § 101.9(c)(8)(iv) lists these 4 nutrients first in the list of nutrients for which RDIs and nomenclature are established.

In the proposed revision to 21 CFR § 101.9(c)(8)(ii), FDA proposes to change the list of 4 nutrients to vitamin D, calcium, iron, and potassium. However, proposed 21 CFR § 101.9(c)(8)(iv) continues to begin the nutrient list with vitamin A, vitamin C, calcium, and iron.

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<sup>50</sup> For example, Wikipedia states "Choline...is usually grouped with the B-complex vitamins." <http://en.wikipedia.org/wiki/Choline>, accessed 05/12/14.

<sup>51</sup> See comment # 5 regarding the potential presence of folate in dietary supplements.



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AHPA suggests that for consistency and to avoid confusion, the table in proposed 21 CFR § 101.9(c)(8)(iv) should be updated so that vitamin D, calcium, iron, and potassium are listed first.

#### **6.4 Comments regarding rounding**

FDA states in the preamble, "We acknowledge that for some vitamins and minerals with RDIs that contain three or four digits (e.g., phosphorous has a proposed RDI of 1,250 mg), a difference of 1 mg per serving may not be meaningful in terms of health impacts. We request comment on whether quantitative amounts for nutrients with RDI values that contain three or four digits should be rounded, what the rounding increments should be, and data to support suggested rounding increments for such vitamins and minerals."

AHPA suggests any nutrient in an amount greater than 10 units (e.g., 10 mg or 10 mcg) should be rounded to the nearest 1 (unless a larger increment is specified in the proposed Rule, such as "Calories from saturated fat" for which 5-Calorie increments are specified for amounts up to and including 50 Calories), those in an amount greater than 100 units should be rounded to the nearest 10 (unless a larger increment is specified in the proposed Rule), and those in amounts greater than 1000 units should be rounded to the nearest 100 (unless a larger increment is specified in the proposed Rule). The rounding should be based on the declared quantity of nutrient rather than the RDI or DRV for the nutrient. For example, 1051 mg calcium would be rounded to 1100 mg; 1042 mg vitamin C would be rounded to 1000 mg; and 106 mg RAE vitamin A would be rounded to 110 mg RAE. (For clarity and simplicity, FDA should specify in the Rule that numbers ending in "5" should be rounded up; alternately, FDA could specify they be rounded to the nearest even number, but AHPA believes this will be confusing and counterintuitive for most members of industry.)

Assuming the nutrient content were measured with perfect accuracy and precision, and were perfectly consistent in every package, the proposed rounding conventions would result in over- or understatement of the nutrient by 5% or less. AHPA does not believe differences smaller than this are useful to consumers in dietary planning,<sup>52</sup> nor do the accuracy and precision of test methods applied to

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<sup>52</sup> Even the recommended daily values that are listed on the labels are only estimates that hide considerable variability, and themselves often represent rounded numbers. For example, FDA's proposal to establish a DRV of 10 g for saturated fat for children 1 through 3 years of age represents a number rounded down from 11 g. The fact that FDA believes it appropriate to round from 11 g to 10 g - a change of 10% in the DRV - reflects the fact that the scientific data simply does not warrant assigning these numbers too much precision. Similarly, FAO (WHO/FAO/UNU. Paragraph 14.1.2 in "Protein and Amino Acid Requirements in Human Nutrition." Report of a joint WHO/FAO/UNU Expert Consultation, WHO Tech. Rep. Ser. no. 935. (2007) Geneva: WHO) rounds the values reported in its summary of protein requirements to two significant figures, because its

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many food matrices warrant a higher number of significant figures, especially when inter-laboratory variation is considered.<sup>53</sup> Furthermore, most foods have an inherent level of variability (e.g., batch to batch or season to season) that makes a higher number of significant digits inappropriate since the content will vary somewhat over time.

### **6.5 Additional comments regarding 21 CFR §101.9(g)(5)**

AHPA strongly recommends that proposed 21 CFR §101.9(g)(5) be changed to stipulate that products labeled in accordance with the rounding or increment requirements of the Rule are not misbranded if use of such rounding or increments causes the content of Calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium to be understated by more than 20%.<sup>54</sup>

AHPA considers this to be an extremely important clarification, because the existing definition of misbranding in 21 CFR §101.9(g)(5) leaves companies unfairly vulnerable to lawsuits under State consumer protection laws. As the nutrition labeling rules are currently established, a company could be challenged or sued for selling a "misbranded" product labeled as containing 5 Calories per serving when the actual caloric content was just over 6 Calories per serving, despite the fact that such labeling faithfully follows the regulatory requirement to express the number of Calories to the nearest 5 Calories. AHPA is aware of one instance where such a lawsuit has, in fact, occurred.

Thus, absent the clarification AHPA proposes, the nutritional labeling regulations unintentionally force companies into a catch-22: if they strictly follow the requirements of 21 CFR §101.9(g)(5) they will often be out of compliance with various provisions specifying a particular increment be used in connection with particular levels of a nutrient, while if they follow the increment requirements they may be selling products which are "misbranded" and may be therefore exposed to the risk of expensive legal action.

AHPA therefore strongly requests FDA to clarify the definition of "misbranding" in 21 CFR §101.9(g)(5) by stipulating that any discrepancy caused solely by declaration of nutrient content in accordance with the rounding or increment requirements of the Rule shall not constitute misbranding.

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calculations in have been "made with a greater degree of precision, or apparent precision, than can ever be useful in practice."

<sup>53</sup> For example, the coefficients of variation for standardized amino acid methods of analysis in food are about 5% for intra-laboratory and about 10% for inter-laboratory data. (FAO. "Dietary protein quality evaluation in human nutrition." Report of an FAO Expert Consultation 31 March - 2 April 2011, Auckland, New Zealand. (2013) Rome: FAO.)

<sup>54</sup> See comment # 4.5 for a detailed markup of proposed 21 CFR §101.9(g)(5).

## 6.6 Comments regarding dietary fiber

FDA proposes to limit "dietary fiber" to "(1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; (2) isolated and synthetic nondigestible carbohydrates (with 3 or more monomeric units) that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 (21 CFR 10.30) demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or (3) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim."

AHPA is concerned that the proposed Rule does not clarify what evidence would be required to demonstrate that "such carbohydrates have a physiological effect(s) that is beneficial to human health," and FDA does not specify the timeframe in which guidance on this subject would be forthcoming. AHPA is also concerned that development of such evidence could be quite expensive (especially if it is required on a manufacturer-by-manufacturer or product-by-product basis), and is concerned that FDA is not likely to have the resources necessary to evaluate in a timely manner any petitions to include additional types of fiber in the definition.

AHPA suggests that the Rule should, at a minimum, stipulate that "dietary fiber" includes isolated or synthetic nondigestible carbohydrates (with 3 or more monomeric units) which have been shown through credible scientific evidence to have any of the beneficial physiologic effects identified at the Ninth Vahouny Fiber Symposium in 2010<sup>55</sup> (i.e., 1. Reduced blood total and/or LDL cholesterol levels; 2. Attenuation of postprandial glycemia/insulinemia; 3. Reduced blood pressure; 4. Increased fecal bulk/laxation; 5. Decreased transit time; 6. Increased colonic fermentation/short chain fatty acid production; 7. Positive modulation of colonic microflora; 8. Weight loss/reduction in adiposity; 9. Increased satiety); that companies may include such carbohydrates in the declared amount of "dietary fiber" in their product(s) provided the company maintains on file documentation that substantiates the beneficial physiologic effect of the fiber; and that such substantiation may be based on publicly available scientific evidence regarding the isolated or synthetic nondigestible carbohydrate (i.e., evidence need not be developed by each manufacturer or for each food product).

## 6.7 Comments regarding testing for vitamin E

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<sup>55</sup> Howlett J.F. et al. "The definition of dietary fiber - discussions at the Ninth Vahouny Fiber Symposium: building scientific agreement." *Food and Nutr. Res.* (2010) 54: 5750.

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FDA proposes to limit the label declaration of vitamin E to certain stereoisomers of the vitamin, and to require manufacturers of foods containing a mixture of all rac- $\alpha$ -tocopheryl acetate and RRR- $\alpha$ -tocopherol to verify through analytical testing the declared amount of both all rac- $\alpha$ -tocopheryl acetate and RRR- $\alpha$ -tocopherol in the finished food product. However, FDA notes that current AOAC methods cannot individually measure these two forms of vitamin E, and solicits comments regarding validated methods suitable for this purpose.

AHPA is concerned that even if such methods can be identified, they may not be valid for a wide variety of food matrices, and furthermore may be prohibitively expensive (e.g. if LC/MS is required).

FDA states that such testing of the finished food product is necessary because "It is not possible to determine the amount of RRR- $\alpha$ -tocopherol in a food product by subtracting the amount of all rac- $\alpha$ -tocopherol [sic] acetate from the total amount of vitamin E declared." However, AHPA notes that such a calculation should be possible for the finished food product if the content of the specified stereoisomers (i.e., RRR, RSR, RRS and RSS) present in the vitamin E ester ingredient (e.g., all rac- $\alpha$ -tocopheryl acetate) is known. AHPA suggests that it will be much more practical for manufacturers of vitamin E esters to ascertain the RRR, RSR, RRS and RSS content in their ingredients and disclose this information to finished food manufacturers for use in calculating the declared amount of vitamin E, than it will be for every finished food manufacturer to be burdened with testing the finished product to verify the amounts of various forms of vitamin E, especially since valid methods for many food matrices may not be available.

Also, AHPA notes that the proposed Rule mentions only  $\alpha$ -tocopherol and "alpha-tocopheryl acetate" (properly named "alpha-tocopheryl acetate"), but in fact alpha-tocopheryl succinate is also used as a food ingredient. Furthermore, AHPA notes that the proposed Rule mentions only "all rac- $\alpha$ -tocopheryl acetate" (i.e., dl-alpha-tocopheryl acetate), when in fact d-alpha-tocopheryl acetate is also used as a food ingredient.<sup>56</sup> AHPA believes the proposed Rule requires modification to account for use of these other ingredients.

## 6.8 Comments regarding the timeframe for maintenance of records

Proposed 21 CFR §101.9(g)(11) would require that "Records necessary to verify certain nutrient declarations that are specified in paragraph (g)(10) of this section must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce."

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<sup>56</sup> See for example [http://www.adm.com/en-US/products/food/vitamin\\_e/Pages/default.aspx](http://www.adm.com/en-US/products/food/vitamin_e/Pages/default.aspx), accessed 07/30/14.

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AHPA finds this to be a confusing and impractical basis for the recordkeeping timeframe, insofar as it requires the manufacturer to keep track of an additional data point (i.e., the date on which the food is actually shipped, as opposed to simply the date on which it is manufactured) and will result in widely divergent record maintenance timeframes for different foods or different batches (since the ship date may in some cases occur immediately after manufacture, while in others it may occur many months after manufacture).

Furthermore, AHPA notes that the requirement is subject to various interpretations, since it is not clear whether "the food" is intended to refer to a particular *lot or batch* of food or to a particular *formulation* of food. AHPA assumes, based on the specified 2-year timeframe, that FDA intends the requirement to refer to records related to particular lots or batches of food, because a much longer timeframe would often be appropriate if the records were based on a particular formulations of food. However, this appears to be inconsistent with statements that "analyses of databases" or "recipes or formulations" (i.e., records that would apply to the formulation of the food rather than to individual lots or batches of food) are among the records that would satisfy the requirement.

Under proposed 21 CFR §117.315, food manufacturers will be required to maintain records "for at least 2 years after the date they were prepared" (e.g., for records pertaining to manufacture of a particular lot or batch) or "at least 2 years after their use is discontinued" (e.g., for the results of process evaluations). AHPA suggests that 21 CFR §101.9(g)(11) should provide similar options for recordkeeping, i.e. at least 2 years past the date of manufacture for records pertaining to a particular lot or batch, or at least 2 years after their use is discontinued for records pertaining to a particular formulation of food.

#### **6.9 Additional comments regarding the nutrition labeling format for dietary supplements**

FDA proposes a number of other changes to the nutrition labeling format without clarifying whether they would apply to dietary supplement labels.

AHPA notes that many companies already struggle to find room for all the required information on supplement labels. AHPA therefore opposes changes to supplement labels that would increase the space required for nutrition labeling, such as a potential requirement to print nutrient names in bold or semi-bold type. For similar reasons, AHPA opposes a mandatory change from "Amount Per Serving" to "Amount Per \_\_\_\_" on supplement labels, but rather believes this option should be made available to supplement companies. If this change is made mandatory, then the regulation should provide an option to use the abbreviation "Amt Per \_\_\_\_" in case the quantity statement requires more space than "Serving" (e.g., "2 capsules").

With respect to providing an increased prominence for "Serving Size," AHPA agrees that this change is not necessary for supplements. With respect to providing an increased prominence for "Calories," AHPA disagrees that supplements should be included in this change if "Calories" is listed on the label (i.e., if the number of Calories is more than 5), because in most cases the number of Calories will still be too small to affect the diet significantly. Any increased prominence for "Calories" on supplement labels should be required only where consumption of the supplement would make a major contribution to daily caloric intake, e.g. 50 or more Calories per serving.

AHPA opposes a potential requirement for supplement labels to right-justify the serving size quantity, because the words "Serving Size" are required to be left-justified and the quantitative amount per serving should appear in relatively close proximity to those words, not on the other side of the panel separated by a large white space. This may be a particular concern for supplements with dual-column labeling (e.g., with columns for "Per Serving" and "Per Day").<sup>57</sup>

#### **6.10 Comments regarding the proposed compliance date**

In the preamble to the proposed Rule, FDA stated, "We intend that any final rule resulting from this rulemaking, as well as any final rule resulting from the proposed rule entitled 'Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments' become effective 60 days after the date of the final rule's publication in the Federal Register with a compliance date 2 years after the effective date. We recognize that it may take industry time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the Nutrition Facts label (which may be coordinated with other planned label changes), review and update their records of product labels, and print new labels. A compliance date that is 2 years after the effective date is intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to have the information in a timely manner. We invite comment on the proposed compliance date."

AHPA believes the meaning of "compliance date" must be more fully explained in the final Rule. Accordingly, AHPA proposes that FDA clearly state in the final Rule that product labeled before the "compliance date" may be lawfully shipped and sold. In the past, e.g., the promulgation of the final regulation regarding Nutrition Labeling of Dietary Supplements, FDA has provided this clarity as

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<sup>57</sup> AHPA notes a similar concern may exist for conventional foods with dual-column labeling.

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follows: “In other words, products bearing labels that are affixed prior to March 23, 1999 do not have to be in compliance with these final rules, and products labeled after March 23, 1999 do.” AHPA believes a statement such as this provides clarity and also avoids the economic waste that would occur if the compliance date were to mean that product lawfully labeled under the prior regulation were not allowed to be introduced into interstate commerce or otherwise distributed or sold after the compliance date.

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## Conclusions

AHPA appreciates the opportunity to provide comments on FDA's proposed Rule on Food Labeling: Revision of the Nutrition and Supplement Facts Labels. As stated in these comments, AHPA generally supports much of what FDA has proposed, though has provided here specific comments and suggestions to address details in the proposed Rule with which AHPA disagrees or believes greater regulatory clarity can and should be achieved.

AHPA staff and counsel will make themselves available at any mutually convenient time to address any of the topics addressed herein. Please feel free to contact us if clarification or further discussion is needed on the issues raised in these comments.

Respectfully submitted,



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