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Comments of the Consumer Healthcare Products Association in Response to the  
Proposed Rule - Food Labeling: Revision of the Nutrition and Supplement Facts  
Labels (Docket No. FDA-2012-N-1210)

**I. Introduction**

The Consumer Healthcare Products Association (CHPA) is pleased to submit these comments in response to the FDA proposed rule – Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Docket No. FDA-2012-N-1210).<sup>1</sup>

CHPA, founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter (OTC) or nonprescription medicines and dietary supplements in the United States. Several CHPA members make dietary supplements affected by the proposed rule and, as such, we have an interest in the subject matter.

CHPA applauds FDA's efforts to amend labeling regulations for conventional foods and dietary supplements in order to provide updated nutrition information to consumers. CHPA believes that label amendments, if effected, would help to assist consumers in developing and maintaining healthy dietary practices.

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<sup>1</sup> 79 Fed. Reg. 11880-987 (Mar. 3, 2014)

FDA has proposed a number of significant changes to Nutrition Facts labeling as well as conforming changes to Supplement Facts labeling to maintain consistency of content and format. Aspects of the proposed rule of particular interest to CHPA members marketing dietary supplement products are addressed below. In addition, we have provided additional general comments on the need to ensure that consumers are aware of and understand any enacted changes. These comments include suggestions for cooperative consumer outreach efforts that the agency and industry trade organizations could undertake to ensure that any enacted changes to Nutrition and Supplement Facts labeling are widely understood. Our comments cover the following topics:

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**Comments**

**1. Reformulation of Dietary Supplements Resulting from Proposed Changes to Percent Daily Values**

FDA has requested comment on the reformulation of dietary supplement products resulting from proposed changes to the Daily Values, as well as information on the potential consequences of such reformulations. Some companies may decide only to relabel to the new nutritional guidelines without reformulation, others may totally reformulate to the new guidance

in order to retain the same potency declaration as previously listed on their product for all nutrients, and some may adopt an intermediate approach, changing levels of only some of the nutrients. At this point in time CHPA member companies are still evaluating this question. While we expect to see slight reformulations over time, many CHPA members have been adjusting nutrient levels in their formulations as changes to recommended levels have been published by the U.S Institute of Medicine (IOM) or other authoritative scientific bodies. Due to the extensive changes the final rule will require in labeling, batch records, release specifications, along with web sites and supporting documents, CHPA largely expects to see members respond by relabeling existing formulations during the implementation period.

## **2. Use of Population Coverage RDAs or AIs as the Basis for Establishing RDIs**

FDA has previously established the Reference Daily Intake (RDI)<sup>2</sup> for vitamins and minerals based primarily on Recommended Daily Allowances (RDAs)<sup>3</sup> and tentatively concluded that RDAs (rather than Estimated Average Requirements) continue to provide the most appropriate basis for establishing RDIs. Using corresponding RDAs, FDA has proposed to update the RDIs for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B<sub>6</sub>, B<sub>12</sub>, C, D, and E, and zinc. In the absence of a determined RDA, FDA has tentatively concluded that Adequate Intake (AI)<sup>4</sup> provides an acceptable basis for determining RDIs. FDA is proposing to use AIs to set the RDIs for biotin, chloride, choline, chromium, manganese, pantothenic acid, potassium, and vitamin K. CHPA supports the use of population-coverage RDAs (as opposed to population-weighted RDAs) to calculate DVs as this approach is based on the entire target population, not on weighted averages for various population subgroups, and results in appropriate nutritional requirements for approximately 98% of the population. Using EARs would result in only 50% of the population having their nutritional needs met.

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<sup>2</sup> Reference Daily Intake - intended to provide an overall population reference value for use in calculating the percent DV for the food label that can help consumers understand the nutritional content of foods in the context of the total daily diet.

<sup>3</sup> Recommended Daily Allowance – intake level designed to meet the nutrient needs of nearly all (97- 98 percent) individuals within a life stage and gender group

<sup>4</sup> AI - a value based on observed or experimentally determined approximations of nutrient intake by a group (or groups) of healthy people—used when an RDA cannot be determined.

### 3. Proposed Formatting Changes to the Nutrition Facts/Supplement Facts panels

The agency has proposed a number of changes to the Nutrition Facts panel including shifting the % DV column to the left side of the label in order to make this information more prominent; and removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets. FDA has requested comment on whether it is necessary for Supplement Facts labeling to be consistent with Nutrition Facts labeling for dietary supplement products listing calories or other macronutrients. FDA's tentative view is that there is no need to propose changing the order of how serving size and servings per container are listed on the Supplement Facts label, or to make amendments in the type size or capitalization corresponding to proposed changes for this information on the Nutrition Facts labels. FDA is also not proposing any changes in the position of the % DV listing on the Supplement Facts label relative to the position of the nutrient and dietary ingredient information. FDA has requested comment on whether there is a need to include vertical lines that are similarly placed on Supplement Facts labels for multiple vitamins in packets (§101.36(e)(11)(iii)) and for dietary supplements that list "per serving" and "per day" information. As consumers have become familiar with the layout of Supplement Facts and the nutritional impact of supplements on the overall consumer diet is not significant in terms of *e.g.*, calories and sugar, we agree with FDA that the proposed formatting changes should not apply to dietary supplements. Similarly, CHPA members believe that there is not a need to include vertical lines as this would merely add to the display without improving column formatting.

#### 3.1 Linear Format

The proposed rule includes a sample linear display (box below). However, as changes for the Nutrition Facts are not proposed for supplements, CHPA requests that FDA allow companies to continue to utilize the current linear display format for foods and dietary supplements. And, as such, CHPA requests that FDA include sample Nutrition Facts and Supplement Facts panels applying the linear display format in any final rule on this subject.

<p><b>Nutrition Facts</b> Serv. Size: 1 package. Amount Per Serving. <b>Calories</b> 45. Fat Cal: 10. <b>Total Fat</b> 1g (2% DV). <b>Sat. Fat</b> 0.5g (3% DV). <b>Trans Fat</b> 0.5g. <b>Cholest.</b> 0mg (0% DV). <b>Sodium</b> 50mg (2% DV). <b>Total Carb.</b> 8g (3% DV). <b>Fiber</b> 1g (4% DV). <b>Sugars</b> 4g. <b>Protein</b> 1g. <b>Vitamin A</b> (8% DV). <b>Vitamin C</b> (8% DV). <b>Calcium</b> (10% DV). <b>Iron</b> (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.</p>
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#### 4. Mandatory Ingredients

Current regulations require manufacturers to declare the percent daily values of vitamins A and C, calcium and iron when present in food and dietary supplement products regardless of the intended use. Under the proposed rule, declaration of vitamin A and vitamin C would become voluntary. Nutrients proposed to become mandatory for declaration are vitamin D and potassium.

CHPA is supportive of the agency's proposed changes that would add vitamin D and potassium as mandatory nutrients. However, CHPA members are concerned that exempting vitamins C and A as mandatory nutrients may lead to shortfalls in the American diet.<sup>5</sup> In addition, CHPA member companies are proposing to voluntarily declare phosphorus amounts on their dietary supplement products given the potential for elevated serum phosphorus (hyperphosphatemia) in patients with kidney disease or those undergoing dialysis. Hyperphosphatemia is associated with an increased risk of death in dialysis patients and this voluntary declaration addresses this concern for phosphorus-containing dietary supplements.<sup>6</sup>

##### 4.1 Potassium

In light of the agency's recognition that potassium is a nutrient of public health significance, CHPA members are requesting clarity on the use of potassium in dietary supplement products. Many dietary supplement industry members have been limiting potassium in their formulas to 99 mg per serving (99 mg of potassium is not an appreciable fraction of the current (3,500 mg) or proposed (4,700 mg) reference daily intake for potassium). This limitation is based on FDA's conclusion in 1975 that any capsule or coated tablet of a potassium salt intended for oral ingestion (without prior dilution with an adequate volume of liquid to preclude gastrointestinal injury) should carry a warning statement regarding small-bowel lesions related to the use of oral drug products containing 100 mg or more potassium.<sup>7</sup> However, FDA has not

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<sup>5</sup> Fugloni III *et.al.*, Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?, *J Nutrition*, August 2011.

<sup>6</sup> Kalantar-Zadeh, K Patient education for phosphorus management in chronic kidney disease. *Patient Prefer Adherence*. 2013; 7:379-390; Rodriguez-Benot A, Martin-Malo A, Alvarez-Lara MA, Rodriguez M, Aljama P., Mild hyperphosphatemia and mortality in hemodialysis patients; *Am J Kidney Dis*, 2005 Jul 46(1): 68-77

<sup>7</sup> 21 CFR §201.306

established an upper limit for potassium in dietary supplement formulations. As such, CHPA members request agency guidance on the use of potassium in solid oral dietary supplement forms.<sup>8</sup>

## 5. Folate and Folic Acid

The proposed rule recognizes only “folate” and “folic acid” and FDA is proposing to only allow the use of the term “folic acid” (and not “folate” or “folacin”) for the labeling of dietary supplements while reserving use of the term “folate” for use on conventional food labels. Folate, the naturally-occurring form of vitamin B<sub>9</sub>, is found in many foods and is also sold as a dietary supplement. Folic acid, which is found only rarely in whole foods and is synthetically produced, is also used in dietary supplements and to fortify processed foods. Since most public health messages about folic acid mention 400 mcg folic acid (or folate), we request FDA retain interchangeable use of “folic acid” and “folate” for dietary supplement labeling. In 21 CFR §101.79(a)(2) FDA concludes that studies of multivitamins with folic acid had results consistent with the conclusion that folate at levels attainable in usual diets may reduce risk of neural tube defects; this is further support that the terms folic acid and folate should be interchangeable.

CHPA members also request the agency consider alternative synthetic forms of folate such as 5-methyltetrahydrofolate (5-MTHF; metafolin). Beneficial effects on folate status and reductions in total homocysteine concentrations have been observed with MTHF.<sup>9</sup> FDA previously accepted (2001) without objection a New Dietary Ingredient Notification for metafolin<sup>10</sup> and, in addition, other regulatory bodies have found it to be appropriate for use in dietary supplements and dietetic foods.<sup>11</sup>

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<sup>8</sup> Section 411, Federal Food, Drug and Cosmetic Act – see Proxmire Amendment of 1976

<sup>9</sup> Lamers Y, Prinz-Langenohl R, Brämwig S, Pietrzik K Red blood cell folate concentrations increase more after supplementation with [6S]-5-methyltetrahydrofolate than with folic acid in women of childbearing age, *Am J Clin Nutr* 2006 Jul 84(1): 156-61; Venn BJ, Green TJ, Moser R, Mann JI Comparison of the effect of low-dose supplementation with L-5-methyltetrahydrofolate or folic acid on plasma homocysteine: a randomized placebo-controlled study, *Am J Clin Nutr* 2003 Mar 77(3): 658-62.

<sup>10</sup> <http://www.metafolin.com/about-metafolin/regulatory-status/>

<sup>11</sup> European Food Safety Authority, October 2004; Joint FAO/WHO Expert Committee on Food Additives, July 2005.

FDA is also proposing to use mcg Dietary Folate Equivalents (mcg DFE) to declare the amount of total folate (food folate and synthetic folic acid) on Nutrition and Supplement Facts labeling as the current unit of measure (mcg) does not account for the difference in bioavailability between folate and folic acid. CHPA requests the agency retain the current Daily Value of 400 mcg as folate or folic acid without adopting a dietary folate equivalents approach. Over the past 20 years numerous agencies such as the Institute of Medicine, the Centers for Disease Control and Prevention, the United States Public Health Service and the March of Dimes have educated the public on the importance of women of child-bearing age consuming at least 400 mcg of synthetic folic acid daily to help prevent birth defects. A change in the unit of measure (for this nutrient in particular) may promote suboptimal intake of the nutrient, especially if women do not understand the difference in the bioavailability of naturally occurring folate versus synthetic folic acid. An educational campaign would be necessary, especially for obstetricians and women of child-bearing age, to teach them how to achieve adequate dietary folate levels if FDA chooses to harmonize declaration to units of measure used for this important nutrient in other global markets (mcg DFE).

## **6. Fiber**

FDA has proposed a number of changes in regards to defining and measuring dietary fiber which could impact the status of various ingredients currently marketed as fiber. These include a definition for “dietary fiber” which would include:

1. Non-digestible, soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants
2. Certain isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units).

Of the currently marketed non-digestible carbohydrates, FDA has stated that only  $\beta$ -glucan and barley  $\beta$ -fiber would meet the proposed definition of dietary fiber. Isolated and synthetic carbohydrates would qualify as dietary fiber only pursuant to approval of a citizen petition or a health claim petition providing evidence of a physiological effect beneficial to human health.

FDA did not include criteria in the proposed rule for identifying specific “physiological benefits” that would qualify isolated and synthetic non-digestible carbohydrates as dietary fiber. CHPA recommends FDA adopt the list of beneficial physiological effects developed at the Ninth Vahouny Fiber Symposium in 2010<sup>12</sup> and asks FDA to recognize these benefits when qualifying isolated and synthetic non-digestible carbohydrates as dietary fiber:

- Reduced blood total and/or LDL cholesterol levels
- Attenuation of postprandial glycemia/insulinemia
- Reduced blood pressure
- Increased fecal bulk/laxation
- Decreased transit time
- Increased colonic fermentation/short chain fatty acid production
- Positive modulation of colonic microflora
- Weight loss/reduction in adiposity
- Increased satiety

Should FDA decide to create a list of acceptable fibers in the Final Rule, CHPA asks that FDA utilize existing dietary fiber lists recognized by other authoritative bodies.<sup>13</sup>

Requiring approval of a citizen petition would serve to delay inclusion of isolated fibers that are increasingly recognized for their benefit to human health. Instead, CHPA requests that FDA require manufacturers of such dietary fiber products to keep information supporting one or more of these beneficial physiological effects in house. Manufacturers would notify FDA of the documented physiological effects of the dietary fiber ingredient via a process similar to that utilized for substantiation of structure/function claims. If petitions are required, this would impart a significant burden on manufacturers of innovative fiber products as well as on the agency. Due to the numerous dietary fiber sources available in the US, this would make it

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<sup>12</sup> Howlett JF, Betteridge JA, Champ M, Craig S, Meheust A, and Jones JM The definition of dietary fiber discussions at the Ninth Vahouny Fiber Symposium: building scientific agreement, *Food Nutr Res* 2010, 54: 5750

<sup>13</sup> Health Canada Food Directorate (2013); European Safety Authority (2010); Institute of Medicine Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (2005).



difficult for companies to prepare and submit timely petitions in compliance with the proposed 2-year period. We also ask that FDA clarify how the agency will address fiber products that are already marketed and for which a petition has already been submitted but not yet fully evaluated, and whether approval of an individual petition would apply to all manufacturers.

Fibers already qualified to make authorized health claims should automatically be recognized as dietary fiber and meet the proposed definition, including  $\beta$ -glucan soluble fiber and barley  $\beta$ -fiber<sup>14</sup>, as well as any meeting the definition of dietary fiber in 21 CFR §101.76 and 21 CFR §101.77. Specifically, CHPA proposes that psyllium husk be included in any list of isolated fibers in 21 CFR §101.9(c)(6)(i). Like  $\beta$ -glucan soluble fiber and barley  $\beta$ -fiber, psyllium husk is already the subject of an authorized health claim for reduced risk of heart disease as defined and recognized in 21 CFR §101.81.

CHPA also requests clarification in the final rule of the methodology for calculation of nutrition information. Soluble fibers from viscous sources such as psyllium are not accurately determined by standard AOAC methods.<sup>15</sup> As such, we request that FDA allow continued use of a modified AOAC method, as specified by 21 CFR §101.81, as a suitable test method for psyllium. We also believe that there is an opportunity to incorporate HPLC analysis to quantify the DP 3-9 fraction which previously has not been detected by the CFR mandated method for psyllium. We request that alternative methods be allowed provided they have been sufficiently validated (*e.g.*, if they are noted in USP or CFR citations). In this way, test methods may evolve to incorporate superior measurement technologies and will better keep pace with the science and understanding of dietary fiber.

CHPA agrees that currently available test methods are not capable of distinguishing between the fibers that have accepted physiological benefit, versus other fibers that lack that scientific evidence of benefit. We therefore support the proposal to require recordkeeping for manufacturers using ingredients that do not meet the definition of fiber as modified above and

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<sup>14</sup> mentioned in the Proposed Rule; Fed. Reg. Vol 79, No 41, p. 11910

<sup>15</sup> Lee SC, Rodriguez F, Storey M, Farmakaladis E, Prosky L Determination of soluble and insoluble dietary fiber in psyllium-containing cereal products. *JAOAC Int* Vol. 78(3), 1995

described in the proposed rule. We would appreciate additional guidance from the Agency on appropriate measures or sources for manufacturers to use to establish these records, since analytical methods would not apply to the marketed product.

## 7. Units of Measure

FDA is proposing<sup>16</sup> to replace “IU” for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg  $\alpha$ -tocopherol for vitamin E. FDA is also proposing to quantify and declare folate and folic acid in “mcg DFE” instead of “mcg.”. CHPA is supportive of replacing “IU” with mcg RAE for vitamin A and vitamin D and with replacing “IU” with mg  $\alpha$ -tocopherol for vitamin E. However, we request the agency include an explanation of this change in any educational efforts directed towards consumers. As noted in comments above, CHPA requests the agency retain the current Daily Value of 400 mcg as folate or folic acid without adopting a dietary folate equivalents approach.

For dietary ingredients not having an established RDI or DRV, the current regulation<sup>17</sup> requires amounts of such ingredients be expressed using metric measures. This may not be appropriate for some ingredients such as probiotics and enzymes. CHPA requests FDA consider permitting use of additional units of measure such as “colony forming unit” (CFU) for probiotics and enzyme assay units (*e.g.*, HUT, PC, SU, ALU)<sup>18</sup> for enzymes. These units are generally recognized as the appropriate labeling for probiotics and enzymes.

## 8. Footnote

FDA has requested comment on whether to consider changes to the footnote statement on the Supplement Facts label to be consistent with any changes to the footnote statement in the Nutrition Facts label. FDA has also noted the agency is continuing consumer research to evaluate how variations in label format may affect consumer understanding of Nutrition Facts labeling.

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<sup>16</sup> § 101.9(c)(8)(iv)

<sup>17</sup> 21 CFR §101.36(b)(3)(ii)(A)

<sup>18</sup> HUT – Hemoglobin Units on a Tyrosine basis; PC – Bacterial Protease Unit; SU – Invertase Activity; ALU- Acid Lactase Units

To maintain consistency with changes proposed for Nutrition Facts labeling, FDA has proposed changes in Section § 101.36<sup>19</sup> which would affect the footnotes used in Supplement Facts labeling for products intended for use in infants, children under 4 years of age, and pregnant and lactating women and, adults and children over 4 years of age.

CHPA members are supportive of keeping consistency with footnote statements used between Nutrition Facts and Supplement Facts labels, even if FDA consumer research shows footnotes are not required. However, in the interest of transparency, CHPA requests the agency make the results from these studies publicly available.

#### **9. Vitamin K**

FDA has proposed that the RDI for vitamin K be specific to phylloquinone (vitamin K<sub>1</sub>) only. However, this would limit other forms of vitamin K from being labeled as sources of vitamin K in a dietary supplement, including vitamin K<sub>2</sub> (menaquinone). Vitamin K is a group name for a number of structurally related compounds including phylloquinone (vitamin K<sub>1</sub>) and the menaquinones (vitamin K<sub>2</sub>). Several subtypes of vitamin K<sub>2</sub> exist which are classified according to the length of their aliphatic side chain, designated as MK-n, where n stands for the number of isoprenoid residues in that side chain. In food, the long chain menaquinones MK-7, MK-8 and MK-9 (synthesized by bacteria and present in fermented foods, notably cheese and natto) are readily absorbed and distributed to several tissues, including bone and arteries.

Research over the last few years has been focused particularly on natural vitamin K<sub>2</sub>, and has greatly expanded. Vitamin K<sub>2</sub> has been shown to help activate vitamin K-dependent proteins responsible for healthy tissues and in bone it has been shown to help activate osteocalcin, a matrix protein synthesized by osteoblasts which constitutes of about 20% of the non-collagenous protein found in bone. Based on this emerging research, it would be beneficial to include vitamin K<sub>2</sub> as a suitable form of vitamin K. CHPA members request FDA include both

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<sup>19</sup> § 101.36(b)(2)(iii); § 101.36(b)(2)(iii)(D); § 101.36(b)(2)(iii)(E); § 101.36(b)(2)(iii)(F)

phylloquinone (vitamin K<sub>1</sub>) and menaquinone (vitamin K<sub>2</sub>) as sources of nutritional vitamin K in Supplement Facts labeling, as both are important contributors of vitamin K in the diet.<sup>20</sup>

## 10. Vitamin E

According to the proposed rule, FDA indicates there is a difference in vitamin E activity between all *rac*- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol and that “AOAC methods or other validated analytical methods would be needed for individually measuring naturally occurring vitamin E (RRR- $\alpha$ -tocopherol) and all *rac*- $\alpha$ -tocopherol acetate in food products”. FDA also indicates “it is necessary to know the amount of both RRR- $\alpha$ -tocopherol and all *rac*- $\alpha$ -tocopherol acetate in a food product to calculate vitamin E equivalents for declaration as mg  $\alpha$ -tocopherol”. CHPA requests FDA provide for the development of methods validated for measurement of all *rac*- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol.

CHPA members contend that in addition to  $\alpha$ -tocopherol, other natural forms, in particular  $\gamma$ -tocopherol, contribute to vitamin E activity. Due to widespread use of plant sources rich in  $\gamma$ -tocopherol such as corn and soybean oils,  $\gamma$ -tocopherol represents ~60-70% of the vitamin E consumed in the US diet whereas  $\alpha$ -tocopherol accounts for 20-25%.<sup>21</sup> In addition, recent clinical and mechanistic studies indicate  $\gamma$ -tocopherol may also impart physiological benefits, *e.g.* antioxidant and anti-inflammatory properties. CHPA requests FDA provide guidance on labeling of such other sources of vitamin E activity in foods and dietary supplements- (*e.g.*:  $\beta$ -,  $\gamma$ -,  $\delta$ -tocopherol and  $\alpha$ -,  $\beta$ -,  $\gamma$ -,  $\delta$ -tocotrienols).

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<sup>20</sup> Knapen MH, Drummen NE, Smit E, Vermeer C, Theuvsen E Three-year low-dose menaquinone-7 supplementation helps decrease bone loss in healthy postmenopausal women, *Osteoporos Int.* 2013 24(9):2499-50; Kanellakis S, Moschonis G, Tenta R, Schaafsma A, van den Heuvel EG, Papaioannou N, Lyritis G, Manios Y Changes in parameters of bone metabolism in postmenopausal women following a 12-month intervention period using dairy products enriched with calcium, vitamin D, and phylloquinone (vitamin K(1)) or menaquinone-7 (vitamin K (2)): the Postmenopausal Health Study II, *Calcif Tissue Int.* 2012 90(4):251-62

<sup>21</sup> McLaughlin, PJ; Weihrauch, JL Vitamin E Content of Foods. *J Am Diet. Assoc.* 1979, 75, 647-665; Jiang, Q; Christen, S; Shigenaga, MK; Ames, BN Gamma-Tocopherol, the Major Form of Vitamin E in the US Diet, Deserves More Attention. *Am J Clin Nutr* 2001, 74, 714-722; Jiang, Q Natural Forms of Vitamin E: Metabolism, Antioxidant, and Anti-Inflammatory Activities and Their Role in Disease Prevention and Therapy. *Free Radic. Biol. Med* 2014, 72C, 76-90

## 11. Education – Consumer and Healthcare Provider Comprehension of Changes

Members of the CHPA Dietary Supplement Committee would like to ensure consumers understand changes to the Nutrition and Supplement Facts labeling. In this regard, following publication of the final rule, we recommend the agency undertake a public awareness campaign to ensure consumers comprehend the changes made to Nutrition Facts and Supplement Facts labeling. In particular, changes in percent Daily Values (% DV) and units of measure and how such changes impact labeled amounts. These efforts could include an explanation of the % DV increase (or decrease) for individual nutrients based on reformulation as well as the potential or perceived impact of “over” or “under nutrification” (*i.e.*, amounts above or below 100% DV). In addition, as noted earlier, educational campaigns targeted at obstetricians and women of child-bearing age would help to promote adequate intake of dietary folate levels should FDA decide to declare total folate on Nutrition and Supplement Facts labeling as mcg DFE.

CHPA members believe consumer education is particularly important for conditions where similar products with different labeling may be simultaneously marketed (as would be the case between the effective date and the compliance date for the final rule). For example, a private label product containing the statement “compare to Brand Name” may have an identical amount of nutrients but contain differing % DV amounts in relation to the comparator (or vice versa, if % DV are the same but based on old *vs.* new amounts).

For nutrient content claims such as “high potency” (or other relative claims like “more”),<sup>22</sup> CHPA members are concerned that, during the interim period, such claims could be used inappropriately to make implied superiority claims when, the difference is merely due to use of older or newer RDI amounts as the denominator. CHPA requests FDA consider providing guidance or instruction on how to minimize the likelihood of such misleading nutrient content claims during the period between the effective and compliance dates for the final rule.

To mitigate confusion and enhance consumer understanding, CHPA recommends FDA consider developing consumer-friendly FAQs that could be posted to the FDA website, as well

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<sup>22</sup> 21 CFR §101.54(f)(1)(i)

as individual company websites. This could promote consistency in educating consumers and help maintain an appropriate and balanced competitive environment. CHPA urges the agency to reach out to industry for assistance in the development of such communication in anticipation of and/or following the publication of the final rule.

## **12. Proposed Effective and Compliance Dates**

The proposed compliance date for implementation of all changes in the proposed rule is 2 years after the effective date of the final rule.<sup>23</sup> CHPA requests FDA clarify whether compliance with the final rule refers to the application of labels to products or, to the date of shipment/sale of such relabeled product. CHPA also requests FDA undertake an impact assessment to determine an appropriate time for companies to comply with the proposed rule. The proposed rule includes numerous significant changes that impact all food and dietary supplement products marketed in the United States. Many products will likely need to be reformulated and nearly all must be relabeled. For products being relabeled, this entails not only a change in product labeling but, also updating batch records, release specifications, supporting and intermediate documents, and in some cases methods of analysis, updating internal claim substantiation documentation, updating website and promotional materials and, call-center FAQs. Most of these changes require cross-functional internal review and approval prior to making changes. Due to the substantial undertaking the final rule demands CHPA requests FDA provide additional time, even 3 years or more, for companies to comply. FDA has previously provided compliance dates in excess of 2 years for rulemaking related to medical devices<sup>24</sup> and Drug Facts labeling.<sup>25</sup>

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<sup>23</sup> Section III of proposed rule provides the Proposed Effective and Compliance Dates. Effective date is 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.

<sup>24</sup> [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm\\_source=Members-Only%20Updates](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm_source=Members-Only%20Updates)

<sup>25</sup> 64 Fed. Reg. 13254, 1999

In conclusion, CHPA and the members of its Dietary Supplement Committee applaud FDA for its effort to revise Nutrition and Supplement Facts labeling. CHPA encourages FDA to reach out to our organization to discuss any of these comments in further detail. Should FDA have any questions or seek additional information, please do not hesitate to contact us at 202-429-9260.

Respectfully submitted,

A handwritten signature in blue ink that reads "Jay Sirois". The signature is written in a cursive style with a large initial "J" and "S".

Jay E. Sirois, Ph.D.

Director, Regulatory & Scientific Affairs

Consumer Healthcare Products Association