

**BEFORE THE
UNITED STATES FOOD AND DRUG ADMINISTRATION**

**In re Food and Drug Administration;
Food Labeling: Revision of the Nutrition
and Supplement Facts Labels**

**FDA Docket No.
FDA-2012-N-1210
RIN 0910-AF22**

**JOINT COMMENT ON FOOD
LABELING: REVISION OF THE
NUTRITION AND SUPPLEMENT
FACTS LABELS PROPOSED RULE**

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JOINT COMMENT ON FOOD LABELING: REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS PROPOSED RULE

The Alliance for Natural Health USA (“ANH”), Robert Verkerk, Ph.D., the Weston A. Price Foundation (“Weston Price”), and the Organic Consumers Association (“OCA”) (hereinafter the “Group”) hereby submit this joint comment in response to the Food and Drug Administration’s (“FDA” or the “Agency”) Proposed Rule in the above-referenced docket. *See Food and Drug Admin.; Food Labeling: Revision of the Nutrition and Supplement Facts Labels*, 79 Fed. Reg. 41, 11880 – 11987 (Mar. 3, 2014) (hereinafter “Proposed Rule”).

ANH is a Virginia nonprofit corporation founded in 1992. ANH, formerly the American Association for Health Freedom and, before that, the American Preventative Medical Association, is a membership-based organization consisting of consumers, healthcare practitioners, food and dietary supplement company members, and over 260,000 advocate members. ANH focuses on the protection and promotion of information in the market concerning the actual and potential benefits of healthy foods and dietary supplements, and access to these healthy products that consumers need to maintain optimal health. By educating the general public and ANH members about the actual and potential benefits of a healthy diet and lifestyle, and ensuring the proper options are available, ANH strives to arm consumers with the tools necessary to make informed market selections and take personal responsibility for their health. The ultimate goal is to promote disease prevention, reduce medical intervention, and reduce of the public cost of healthcare in the United States.

Robert Verkerk, Ph.D., the Scientific Director of ANH, is an internationally acclaimed scientist with over 25 years of experience in the field of agriculture and healthcare sustainability. The Weston A. Price Foundation is a nonprofit nutrition education foundation dedicated to

putting nutrient-dense foods back on American tables. The Organic Consumers Association is an online and grassroots non-profit 501(c)(3) public interest organization advocating for health, justice, and sustainability on behalf of more than one million consumers. The Organic Consumers Fund is a 501(c)(4) allied organization of the Organic Consumers Association, focused on grassroots lobbying and legislative action.

BACKGROUND

At the outset of the Proposed Rule, the FDA sets forth the purpose of this regulatory action as an effort “to assist consumers in maintaining healthy dietary practices.” 79 Fed. Reg. 41 at 11881. Additionally, there is recognition “that it is important for the updated Nutrition Facts Label to be useful and relevant to the American population.” *Id.* at 11887. In developing the Proposed Rule, the FDA claims to have “considered new scientific evidence and dietary recommendations about the relationship between nutrients and health.” *Id.* at 11887-88. The Proposed Rule is set against the backdrop of the general purpose of the FDA labeling law which is to encourage truthful and non-misleading labeling content to permit informed consumer choice. *See, e.g.*, 21 U.S.C. §343(a). The Proposed Rule affects both nutrition labeling of conventional foods and dietary supplements. 79 Fed. Reg. 41 at 11881.

The Group has concerns that the Proposed Rule represents one of the biggest challenges to supplement information and access in decades. While some of the proposed labeling changes are improvements, others could be incredibly damaging to the health of Americans. Much of the nutritional science relied on by the FDA is out of date. The Group challenges and proposes revisions to certain portions of the proposal, as discussed below, to improve labeling to make sure citizens and health professionals are getting all the information they need to make informed decisions about their health.

I. The Proposals Regarding Folate Are Problematic

A. Dietary Supplement Labels Will No Longer Be Permitted To Include The Word “Folate” If The Proposed Amendments to §§101.36(b)(2)(i)(B) And 101.36(b)(2)(i)(B)(2) Become Effective

Under the FDA’s new rules, Supplement Facts labels will not be able to include the word “folate,” but instead would be required to use the term “folic acid” in the declaration of the content of dietary supplements. *See* 79 Fed. Reg. 41 at 11947. This directly conflicts with the FDA regulation that permits the source of the ingredient to be cited, 21 C.F.R. §101.36(d). While it is unclear which approach ultimately will prevail, the new proposal contains the express intent to eliminate the term folate and thus is more likely to prevail. The impact of this amendment would be that supplement companies currently using dietary folate in their products either will be forced to remove dietary folate from their products or misleadingly label the folate ingredient as “folic acid” and thus risk facing enforcement actions for misbranding. Consequently, the proposal violates the First Amendment, the Equal Protection Clause, FDA labeling laws, and creates potential liability under the FTC Act for supplement companies.

Folate is the naturally occurring form of the water-soluble vitamin B9. It is found in food as well as in supplements as naturally derived folate (*e.g.* in extracts derived from cruciferous or green-leaved vegetables, legumes) or natural folate produced by fermentation by lactic acid bacteria.¹ The human body needs folate to synthesize and repair its DNA. Folate is especially important during the kind of rapid cell division and growth seen in infancy and pregnancy. Children and adults require folate to produce healthy red blood cells and prevent anemia, among other things. Folate also is thought to play a role in heart health and preventing cell changes that

¹ *E.g.*, LeBlanc JG, et al., *B-group Vitamin Production by Lactic Acid Bacteria – Current Knowledge and Potential Applications*, *J. Applied Microbiology*, 111(6): 1297-309 (2011).

may lead to cancer.² Folate deficiency is a very serious and dangerous medical condition that can lead to Alzheimer's and other brain diseases. In pregnant women, folate deficiency can lead to spina bifida and other neural tube birth defects, such as anencephaly, in their children.³ The elderly population likely benefits from increased folate intake as it is associated with reduced homocysteine, which in turn has been linked with fewer heart disease and stroke events, major causes of morbidity [disease] and mortality.⁴

The use of the term “folate” on dietary supplement labels currently refers to “dietary folates,” which are members of the folate group that can be found in food, including folinic acid (5-formyltetrahydrofolate), calcium methylfolate, and various other tetrahydrofolates. In comparison, folic acid is synthetically produced and refers to only one member of the folate group: pteroylmonoglutamic acid. It would be scientifically and chemically incorrect and misleading to consumers to refer to the reduced folate forms in supplements as folic acid, given that folic acid represents only the monoglutamic form. The appropriate use of the term folate and the differences between folate and folic acid are well described by the FAO/WHO expert consultation in the paper titled “Human vitamin and mineral requirements” in Chapter 4 pertaining to folate and folic acid.⁵ The FAO report emphasizes the monoglutamic nature of folic acid, as distinct from the polyglutamic structure of the reduced folates.

Many people are able to convert folic acid to the folate needed by the body; however, many cannot. While there is not agreement regarding the number of people whose bodies have difficulty doing the conversion, there is agreement that it is a matter of serious concern for many

² See *Folic Acid Fact Sheet* (July 16, 2012) (available at <http://womenshealth.gov/publications/our-publications/fact-sheet/folic-acid.html>).

³ See *id.*

⁴ *Folic Acid; Preventing Birth Defects, and More*, Life Extension Magazine, (Jan. 1998) (available at <http://www.lef.org/magazine/mag98/jan-research98.html?source=search&key=folate%20diet>).

⁵ Available at <http://www.fao.org/docrep/004/y2809e/y2809e0a.htm> (last visited May 29, 2014).

individuals.⁶ There is a lot of knowledge available now regarding defects in two DNA sequences responsible for producing enzymes needed for the final stage of conversion of folic acid into the active form needed by the human body. These defects relate to an enzyme called MTHFR⁷ and are very common, although the defects vary enormously between ethnic groups and regions. The defects can be found in as many as 44% of North American Caucasians and over 50% of Italians.⁸ They are also more common among those predisposed to diseases such as cancer, heart disease, and autism, where the mutation frequency can exceed 90% of these populations. These estimates do not account for mutations in other genes involved in folate metabolism such as DHFR, data for which has only been emerging recently.⁹

For individuals who have mutations impacting MTHFR or other genes relating to folate metabolism, there is a distinct possibility of building up too much unmetabolized folic acid thereby potentially increasing the risk of cancer, heart disease and stroke.¹⁰ Consequently, a substantial segment of the population needs to consume folate rather than folic acid and would not be able to process dietary supplements containing folic acid. Moreover, individuals seeking to get their folate, and other vitamins, from food alone, will have a difficult time getting enough. First, due to industrial farming practices, food has only a fraction of the nutrients once present.¹¹

⁶ See, e.g., <http://journeyofhealth.org/hello-world/> (estimating 30% to 40% of the population cannot efficiently make the conversion); Jean Guy LeBlanc, et al., *Folate Prod. by Lactic Acid Bacteria and Other Food-Grade Microorganisms*, *Communicating Current Research and Educ. Topics and Trends in Applied Microbiology*, 329 – 339 (2007).

⁷ See *Methylenetetrahydrofolate Reductase (MTHFR) 2 Mutations*, ARUP Laboratories (Jan. 2009).

⁸ See Marvin Boris, M.D., et al., *Ass'n of MTHFR Gene Variants with Autism*, *J. of Am. Physicians and Surgeons*, 9(4): 106-108 (2004).

⁹ See Bahram S. Askari, et al., *Dihydrofolate Reductase Gene Variations in Susceptibility to Disease and Treatment Outcomes*, *Current Genomics*, 11(8): 578-583 (2010).

¹⁰ See M.P. Hermans, et al., *The MTHFR C 677 T Polymorphism Confers a High Risk for Stroke in Both Homozygous and Heterozygous T allele carriers with Type 2 Diabetes*, *Diabetic Med.*, 23(5): 529-536 (2006).

¹¹ See, e.g., Cheryl Long, *Industrially Farmed Foods Have Lower Nutritional Content*, *Mother Earth News* (June/July 2009), <http://www.motheearthnews.com/nature-and-environment/nutritional-content-zmaz09jjzraw.aspx>; *Dirt Poor: Have Fruits and Vegetables Become Less Nutritious?* *Scientific American* (2011), <http://www.scientificamerican.com/article/soil-depletion-and-nutrition-loss/>.

Second, getting folate from food depends on what leafy greens, beans, oranges and other folate-rich sources you eat, as well as how the food is prepared. Dietary folates are sensitive to heat, so a lot can be destroyed in cooking.¹² Without taking into consideration the effects of cooking, one would have to eat 1.5 pounds of broccoli, or 1.75 pounds of spinach, daily to meet the recommended amount of 800 mcg without taking a supplement.¹³

The Group disagrees with the faulty logic relied upon by the FDA that supplements cannot use the word “folate” on their labels because folate does not exist outside of conventional food. The FDA provides no justification for making this distinction. The requirement to use a different name for a nutrient in conventional food than in dietary supplements has not been imposed on any other nutrient. The FDA’s flawed logic fails to recognize the facts and will have the effect of harming consumers’ ability to maintain healthy dietary practices. As of March 11, 2014, ANH was able to confirm that at least the following companies have dietary folate, not folic acid, in their nutritional supplement products: BioGenesis, Complementary Prescriptions, Daily Essentials, Designs for Health, Doctor’s Best, Douglas Labs, Europharma, Innate Response, Jarrow Formulas, Kirkman Labs, Life Extension Foundation, MegaFood, Mercola, Metabolic Maintenance, Metagenics, Physician’s Preference, Priority One Vitamins, ProThera, Pure Encapsulations, Solgar, Thorne, Vitacost, and Xymogen.

i. The Proposed Amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) Violate the First Amendment

The requirement that labels for dietary supplements only use the term “folic acid” violates the First Amendment because the restriction does not advance the FDA’s interest and is

¹² McKillop DJ, et al., *The Effect of Different Cooking Methods on Folate Retention in Various Foods that Are Amongst the Major Contributors to Folate Intake in the UK Diet*, Br J. Nutrition, 88(6): 661-8 (2002).

¹³ *Folic Acid; Preventing Birth Defects, and More*, supra note 4.

not narrowly tailored. First of all, the information at issue constitutes speech within the meaning of the First Amendment. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667 (2011) (“the creation and dissemination of information are speech within the meaning of the First Amendment.”); *see, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (“information on beer labels” is commercial speech). Facts, such as the content of dietary supplements, “are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs.” *Sorrell*, 131 S. Ct. at 2667.

A government regulation affecting commercial speech is subjected to a four-part test to determine First Amendment protection. *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012). First, the commercial speech “at least must concern lawful activity and not be misleading.” *Rubin*, 514 U.S. at 482 (quoting *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980)). “Second, to justify regulations restricting speech, the asserted government interest must be substantial.” *Caronia*, 703 F.3d at 164. The next two factors for consideration are “whether the regulation [at issue] directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.” *Rubin*, 514 U.S. at 482 (quoting *Central Hudson*, 447 U.S. at 566). In other words, this involves “consideration of the fit between the legislature’s ends and the means chosen to accomplish those ends.” *Id.* at 486 (quoting *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 341 (U.S. 1986)) (internal quotation marks omitted); *see also FTC v. Wellness Support Network, Inc.*, 2014 U.S. Dist. LEXIS 21449, at *33 (N.D. Cal. Feb. 19, 2014) (explaining application of *Central Hudson* test regarding FDA regulations requiring preapproval of claims made on product labels in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). “A restriction that provides only ineffective or remote support for the government’s purposes is not

sufficient, and the government cannot satisfy its burden by mere speculation or conjecture.” *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1218-1219 (D.C. Cir. 2012) (quoting *Rubin*, 514 U.S. at 770, 487) (internal quotation marks omitted). Additionally, the requirement of directly advancing the government’s purpose “is critical because without it, the government could interfere with commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.” *Id.* (internal quotation marks and annotations omitted).

Here, the Group seeks to enable the disclosure of truthful, verifiable, and non-misleading factual information about folate on the labels of dietary supplements. When a supplement includes reduced folate forms such as those that are naturally derived (*e.g.* in extracts derived from cruciferous or green-leaved vegetables, legumes) or produced by fermentation by lactic acid bacteria, it would be misleading to describe it as “folic acid.” There are also two new dietary ingredient approved forms of the reduced, bioactive form of folate, 5’-methyltetrahydrofolate (5-MTHF), namely its calcium salt (Metafolin[®]) and its glucosamine salt (Quatrefolic[®]), that are Generally Recognized as Safe (“GRAS”) by the FDA, as well as another GRAS form, folinic acid (5’-formyltetrahydrofolate), widely used in dietary supplements. Labeling these dietary folates as “folic acid” would be misleading and scientifically incorrect.

Having passed the first requirement that the speech at issue concern lawful activity and not being misleading, the next requirement is whether the FDA’s interest is substantial. There are three potential FDA interests at play in the Proposed Rule. First is the explicitly asserted interest in assisting consumers with maintaining healthy dietary practices (79 Fed. Reg. 41 at 11881). Second is the Agency’s interest in encouraging truthful and non-misleading labeling. *See, e.g.*, 21 U.S.C. §343(a). And third is the FDA’s interest in removing information and access

to dietary folate, which is completely unsubstantiated. The FDA has provided no evidence regarding public health concerns, negative studies or potential harm caused by consuming folate. Consequently, the conclusion cannot be drawn that this interest is substantial. If the Agency relies on its general interest in protecting health or in encouraging truthful and non-misleading labeling, it necessarily fails at the next prongs of the *Central Hudson* test.

The remaining *Central Hudson* factors are whether the FDA proposal advances the FDA's interest and is more extensive than necessary to serve that interest. The Agency's proposal to remove folate from supplement labels fails both of these elements of the test. In actuality, the FDA's interest in helping consumers maintain healthy dietary practices is impaired by this proposal. The Agency offers no explanation for this proposal, because there is none. *Cf. Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J.) ("The First Amendment directs us to be especially skeptical of regulations [of truthful, nonmisleading information] that seek to keep people in the dark for what the government perceives to be their own good."). It follows that the FDA cannot meet its burden of showing by more than "mere speculation or conjecture" that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Rubin*, 514 U.S. at 487 (internal citations omitted). There is no chance this proposal will advance the Agency's goal, thus requiring its rejection. *See Educ. Media Co. at Va. Tech, Inc. v. Insley*, 731 F.3d 291, 299 (4th Cir. 2013) (internal citation omitted).

As discussed in detail above, removing folate from supplements will harm rather than help the FDA's interest in helping consumers maintain healthy dietary practices. Many consumers require access to dietary folate in supplements. By mandating that only the term "folic acid" be used on supplement labels, the FDA is either forcing the removal of dietary folate

from being used in supplements, or requiring that manufacturers withhold full disclosure of the contents on their supplements. Removing folate from supplements will make it very difficult for a substantial portion of the population, specifically those whose bodies cannot convert folic acid to folate, to maintain healthy dietary practices that include getting enough folate. Moreover, inaccurately labeling the contents of a supplement as it pertains to folic acid and/or folate is directly contrary to the FDA's purpose of encouraging truthful and non-misleading labeling. *See, e.g.*, 21 U.S.C. §§321(n), 343(a). The total absence of support regarding the basis for the removal of folate forces the conclusion that this proposal is contrary to serving the interest of encouraging healthy dietary practices. Given that there is no support for the FDA's actions, they are certainly far more extensive than necessary to serve the interest of encouraging healthy dietary practices.

ii. The Proposed Amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) Violate the Equal Protection Clause of the United States Constitution

The Fifth Amendment's Equal Protection Clause generally requires that government agencies treat similarly situated individuals in a similar manner. *See Cornerstone Christian Sch. v. Univ. Interscholastic League*, 563 F.3d 127, 139 (5th Cir. 2009). "The Equal Protection Clause commands that no State shall deny to any person within its jurisdiction the equal protection of the laws, which is essentially a direction that all persons similarly situated should be treated alike." *Id.* (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985)) (internal quotations omitted).

The Equal Protection clause limits legislative discretion in delineating classifications, particularly when those classifications are predicated on arbitrary or irrational grounds. *See, e.g.*, *Buxton v. Lovell*, 559 F. Supp. 979, 997 (S.D. Ind. 1983) (citing *Williamson v. Lee Optical of Okla.*,

Inc., 348 U.S. 483, 489 (1955)). “The central mandate of the equal protection guarantee is that the sovereign may not draw distinctions between individuals based solely on differences that are irrelevant to a legitimate governmental objective.” *Glenn v. Brumby*, 632 F. Supp. 2d 1308, 1312 (N.D. Ga. 2009) (citing *Lofton v. Sec’y of Dept. of Children and Family Svcs.*, 377 F.3d 1275, 1277 (11th Cir. 2004) (internal quotations omitted)). Specifically, a plaintiff alleging violation of the Equal Protection clause must show that he or she “was a member of an identifiable group and that there was differential treatment based on their membership of that very group.” *Glenn*, 632 F. Supp. 2d at 1314 (internal quotations omitted). Thus, when members of a group with a medical condition are “similarly situated” to other persons who are treated differently, the government must have, at the very least, a rational basis to discriminate. *See Roubideaux v. N.D. Dep’t of Corr. & Rehab.*, 523 F. Supp. 2d 952, 966 (D.N.D. 2007).

In *Glenn*, the United States District Court for the Northern District of Georgia considered allegations that an individual diagnosed with Gender Identity Disorder (“GID”) had been denied equal protection of the law by her government employer’s discrimination based on her medical condition. *Glenn*, 632 F. Supp. 2d at 1314. In holding that the plaintiff had alleged a plausible claim, the court stated, “it is well-established that the Equal Protection clause protects individuals with disability and illness (physical and mental) from discrimination by the states and that laws classifying individuals on such a basis must meet rational basis scrutiny.” *Id.*

Here, the group of people whose bodies are unable to efficiently convert folic acid to folate are a group of people with a medical condition, and they are similarly situated to the group of people who are able to make the conversion, in that everyone needs folate, whether in supplements or converted internally from folic acid, to maintain healthy dietary practices. However, the FDA is treating the two groups differently through the proposed amendments to

§§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) by potentially causing the removal of folate from dietary supplements. As explained in detail above, individuals who are unable to metabolize folic acid could suffer serious medical side effects, such as increased risk of cancer, stroke and heart disease, from the unhealthy buildup of unmetabolized folic acid caused by taking folic acid supplements. Additionally, being unable to get enough folate, these people could suffer from anemia, poor heart health, be at a higher risk of cancer, and for the elderly, have no reduction in homocysteine. In comparison, those who are able to convert synthetically produced folic acid to folate do not run the same risk of medical consequences from the buildup of unmetabolized folic acid. Such individuals have a lower risk of Alzheimer's, and for women in childbearing years, a lower risk of spina bifida and other neural tube birth defects.

Moreover, the effective banning folate from supplements has no rational relationship to the FDA's interest in helping consumers maintain healthy dietary practices. The FDA provides no basis for removing dietary folate from supplements, other than asserting, incorrectly, that folate is not available in supplements. Significantly absent from the Agency's proposal is any evidence of a risk of harm from continuing to permit supplements to provide dietary folate. Also missing is an analysis of the risk to individuals who cannot convert synthetic folic acid to folate. In light of the total lack of a scientifically-based reason, it is not rational to put the health of a substantial number of people at risk in the name of protecting the health of Americans. Without an articulable "rational basis," the FDA's proposed amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) violate the Equal Protection Clause of the United States Constitution.

iii. The Proposed Amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) Contravene Congressional Intent

The Dietary Supplement Health and Education Act of 1994 (“DSHEA”) was enacted by Congress following a lengthy dispute with the FDA regarding the regulation of dietary supplements. *NVE Inc. v. HHS*, 436 F.3d 182, 186 (3d Cir. 2006). It was believed that the FDA was regulating dietary supplements too strictly. *Id.* (citing 140 Cong. Rec. S14780-01 (1994) (statement of Sen. Harkin) (criticizing the FDA for restricting access to information about dietary supplements)). The goal of DSHEA was “to improve public access to dietary supplements based on the belief that there may be a positive relationship between dietary supplement use, reduced health-care expenses, and disease prevention.” *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1038-1039 (10th Cir. 2006); *see Pharmanex v. Shalala*, 221 F.3d 1151, 1158-59 (10th Cir. 2000) (“DSHEA was enacted to alleviate the regulatory burdens on the dietary supplement industry, allowing consumers greater access to safe dietary supplements in order to promote greater wellness among the American population.”). The FDA bears the burden of keeping misleading or misbranded supplements off the market. *See Nutraceutical*, 459 F.3d at 1038; 21 U.S.C. §§321(n), 343(s).

Here, the proposal poses the possibility of bringing to the market misleadingly labeled dietary supplements, which is directly contrary to the FDA’s purpose. Moreover, the FDA is effectively preventing supplement companies from selling a perfectly legal product – dietary folate. Supplement companies have relied on the fact that dietary folate is legal and may have spent money developing supplements containing dietary folate. Now, the FDA is using a backdoor method to remove dietary folate from the market. The effect of this will be to harm consumers rather than provide them access to safe dietary supplements in furtherance of healthy dietary practices. Consequently, the Group respectfully opposes the proposal to remove “folate”

and “folacin” from the list of synonyms that may be used to declare folic acid on the Supplement Facts label.

iv. The Proposed Amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) Violate FDA Labeling Laws

The general mission of the FDA is to “promote the public health” and do so with regards to food by ensuring they are “safe, wholesome, sanitary, and properly labeled.” 21 U.S.C. §393(b)(2)(A). Misbranding of food is expressly prohibited in interstate commerce and conditions are set forth under which food and supplements qualify as “misbranded.” See 21 U.S.C. §§ 331(a)-(c), (k), 343(a), (s); see e.g. *Bruton v. Gerber Prods. Co.*, 961 F. Supp. 2d 1062, 1079 (N.D. Cal. 2013). This express mandate to encourage truthful and non-misleading labeling is not being met by the proposed amendments requiring only the use of the term “folic acid” on Supplement Facts labels. To the contrary, the FDA is violating its own requirements by proposing untruthful and misleading labeling pertaining to folate. This forecloses informed consumer choice.

v. The Proposed Amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) Could Create Liability for Supplement Companies under the FTC Act

Section five of the Federal Trade Commission Act (the “FTC Act”) prohibits unfair or deceptive acts or practices in or affecting commerce, and Section 12 prohibits false advertisements for food, drugs, devices, services or cosmetics in or affecting commerce. *FTC v. Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1188 (N.D. Ga. 2008) (citing 15 U.S.C §§45(a), 52(b), 55). For the FTC to establish corporate liability under Sections 5(a) and 12, it must meet a three pronged test: “(1) that there was a representation; (2) that the representation was likely to mislead customers acting reasonably under the circumstances; and (3) that the representation was

material.” *Id.* at 1188-89 (internal citations omitted). *see also* *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957 (N.D. Ill. 2006) (citing *FTC v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 635 (7th Cir. 2005)). Intent is not necessary, and “the omission of a material fact, without an affirmative misrepresentation, may give rise to an FTC Act violation.” *Bay Area Bus. Council*, 423 F.3d at 635.

To determine if a representation is likely to mislead consumers, “a court may consider the overall net impression conveyed by the activity in question.” *FTC v. John Beck Amazing Profits, LLC*, 2009 U.S. Dist. LEXIS 130923, at *14 (C.D. Cal. Nov. 17, 2009) (citing *FTC v. Cyberspace.Com LLC*, 453 F.3d 1196, 1200 (9th Cir. 2006)). A representation or omission is material if it “is the kind usually relied on by a reasonably prudent person” or “involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.” *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1190 (internal citations omitted).

Here, the proposed amendments to §§101.36(b)(2)(i)(B) and 101.36(b)(2)(i)(B)(2) have the potential of creating liability for supplement companies if they chose to continue to include dietary folate in their products and comply with the label restrictions and reflect this information in advertisements for their products. As discussed above, the net impression created by the proposed amendments will be that supplements do not contain dietary folate. For people who need their supplements to include dietary folate rather than folic acid, the Supplement Facts label, and information reflected in advertisements regarding folic acid, presents critical information and will have a direct impact on their choice of supplements. *See Korber Hats, Inc. v. FTC*, 311 F.2d 358, 361 (1962) (1st Cir. 1962) (noting good reason to insist on higher degree of truth in labeling than in advertising, although often considered together, because consumers may accept labeling statements literally while viewing advertising with more skeptical eye). Consequently, the representation of only folic acid, and omission of dietary folate, in compliance with the proposal, is, without doubt, material. As a result, if a supplement company seeks to comply with the proposed amendments and

also continues to provide a much-needed product in the form of dietary folate, without any intent to make a misrepresentation or omission, it will open itself to being sued by the FTC for violating the FTC Act.

B. Use Of mcg DFE As The Unit To Express Folic Acid Content On Dietary Supplements Is Scientifically Irrational

The FDA proposes to amend §101.36(b)(2)(ii)(B) such that folic acid on dietary supplement labels is measured in “mcg DFE” units. *See* 79 Fed. Reg. 41 at 11932. The Group strongly disagrees with this proposal, although the Group does agree with the general proposal to change the unit of measurement for folate from the existing measure of IU. Even though the proposed amendments discuss differences in the bioavailability between folic acid and dietary folates (*id.* at 11931-32), the actual methodology for assessing bioavailability is not mentioned. This is a glaring omission as there are considerable differences in the methodology relating to bioavailability assessments of folic acid and dietary folates, which makes it scientifically irrational to apply the 1.7-fold DFE conversion factor to the folic acid labeling amount. The generalization necessary to apply the 1.7-fold DFE conversion factor ignores biology and genetics.

It appears the 1.7-fold difference referenced by the FDA was based largely on only a single study of non-pregnant women.¹⁴ In comparison, common methodologies have included determination of erythrocyte folate, plasma folate concentration, and determination of a marker of folate, namely plasma homocysteine.¹⁵ There are numerous confounding factors such as the time period (end-point) over which assessments are determined, and whether the assessments

¹⁴ *See* Howerde E. Sauberlich, et al., *Folate Requirement and Metabolism in Nonpregnant Women*, Am. J. Clinical Nutrition, 46: 1016–28 (1987).

¹⁵ Mary P Hannon-Fletcher, et al., *Determining Bioavailability of Food Foliates in a Controlled Intervention Study*, Am. J. Clinical Nutrition, 80(4): 911-8 (2004).

included mixed diets or individual foods.¹⁶ Accordingly, assessments of folate bioavailability from dietary sources have shown great variability, whereas the bioavailability of folic acid, the monoglutamic synthetic form, is much more predictable.

II. Other Proposals Are Problematic

As discussed herein, in addition to the removal of folate from supplements, the Group has significant concerns regarding some of the proposed amendments, or the FDA's decision not to amend, as in the case of *trans* fat and polyunsaturated fat. Rather than providing better access to nutrients, including all appropriate forms of nutrients, the FDA is making it more difficult for people to obtain the nutrients they need. If adopted, these specific amendments generally would make it more difficult for consumers, including sensitive populations, to distinguish the ingredients in both supplements and food, thus placing consumers at a greater risk of making a mistaken purchase, injury due to heightened sensitivities, or failing to obtain the amounts that are needed for good health. Obviously, this runs contrary to goals of the FDA as a government agency. In addition to failing to protect citizens' health and the American economy, the FDA failed to provide an adequate explanation for its proposals or did not consider all relevant factors, making the proposals with which the Group takes issue arbitrary and capricious in violation of the Administrative Procedures Act.

As a general matter, the current method of labeling Supplement Facts on dietary supplements causes confusion regarding which micronutrients (notably vitamins and minerals) are added to a product, as opposed to those that are naturally-occurring within the product. This issue could be resolved by using terminology such as "natural occurring" when nutrients are naturally present in given ingredients or products, and using terms such as "added" to distinguish

¹⁶ *Id.*

ingredients that have been added. Another source of confusion is whether the Supplement Facts represent only the added nutrients or the total amount based on typical finished product analysis in products in which micronutrients have been added to food or botanical ingredients that are themselves natural sources of particular micronutrients. This issue could be resolved by ensuring that where micronutrients are listed on the Supplement and/or Nutrition Facts panel, the information reflects those micronutrients that are typically present at the end of the shelf-life period in the finished product, taking into account industry-accepted overages/tolerances.

A. The FDA’s Proposals Do Not Support The Health Of Americans

In amending its labeling regulations, which will impact every single consumer, the FDA should consider the substantial nutritional deficiencies in Americans, combined with obesity levels, and the impact on the economy from people’s poor health and poor health choices. A goal of the Group in general and in this joint comment is to protect access to information regarding actual and potential benefits of healthy foods and dietary supplements. By educating consumers about the actual and potential benefits of a healthy diet and lifestyle, and ensuring proper options are available, the Group strives to arm consumers with the tools necessary to make informed market selections and to take personal responsibility for their health. ANH, as a nonprofit organization with its membership made up of consumers, healthcare practitioners, food and dietary supplement company members, and over 260,000 advocate members, as well as OCA and Weston Price, seek to redirect the FDA’s proposals as discussed at length throughout this comment. People need clear and easy to understand information on fact panels, reflecting the high level of nutrients needed. As consumers lose access to essential information, their ability to make decisions in furtherance of a healthy diet and lifestyle is reduced. The result of

this is an increase in the cost of healthcare and an increase in the cost of keeping people healthy in the United States.

i. Americans Are Nutrient Deficient and Obese

Individuals in the United States commonly suffer from nutrient deficiency. Magnesium, calcium and vitamins A, C, D, and E are nutrients of which a large percentage of the population have well below the minimum intake.¹⁷ An estimated one billion people in the world suffer from vitamin D deficiency, which can lead to a wide variety of chronic problems, for example, osteoporosis, heart disease, some cancers, and multiple sclerosis, as well as infectious diseases, such as tuberculosis and even the seasonal flu.¹⁸ More specifically, the elderly and the obese tend to have lower levels of vitamin D.¹⁹ The status of the American food supply is such that food, even if eaten properly, cannot supply all of the nutrients needed for health living.²⁰ Caused by mineral depletion in the soil, among other reasons, nutritional values in food have declined significantly over the past 70 years.²¹ Additionally, the tendency to eat processed foods reduces the level of nutrients Americans are obtaining through food. Nutrients and fiber often are removed from original food sources and replaced with additives and preservatives. This makes processed food, a staple of many Americans' diets, lacking the beneficial nutrients needed to nourish the body.²² Consequently, supplements play a vital role in the health of Americans.

¹⁷ Dave Gabriele, *Average American Diet Deficient in Key Nutrients* (Sept. 29, 2011) (available at http://www.naturalnews.com/033719_American_diet_nutritional_deficiencies.html).

¹⁸ *Vitamin D and Health*, Harvard School of Public Health Nutrition Source (available at <http://www.hsph.harvard.edu/nutritionsource/vitamin-d/#vitamin-d-deficiency-a-global-concern>) (last visited May 29, 2014).

¹⁹ *Id.*

²⁰ John B. Marler and Jeanne R. Walin, *Human Health, the Nutritional Quality of Harvested Food and Sustainable Farming Systems*, Nutrition Security Institute (2006) (available at http://www.nutritionsecurity.org/PDF/NSI_White%20Paper_Web.pdf).

²¹ *Id.*

²² Caitlin Rose, *Obesity in America*, Earth News (Sept. 2011) (available at http://www.nutritionsecurity.org/PDF/NSI_White%20Paper_Web.pdf).

Second only to Mexico, the United States is fattest and most malnourished of industrialized countries.²³ As recognized by the FDA, the public health profile of Americans has changed, for the worse, since its last updates to the Nutrition Facts label and Daily Values (“DVs”). See 79 Fed. Reg. 41 at 11884, 85 (noting dramatic increase in obesity over the past three decades). According to the Centers for Disease Control and Prevention (“CDC”), more than one-third of adults and one-sixth of children in America are obese.²⁴ Obese individuals are more likely to have micronutrient deficiencies compared to normal-weight people due in part to unhealthy eating habits as well as increased demands, which are underestimated by dietary reference intake (“DRI”) numbers meant for the general population.²⁵

Obesity-related conditions include heart disease, stroke, type two diabetes and certain types of cancer, some of the leading causes of preventable death.²⁶ Obesity also may cause health problems such as high blood pressure, high triglycerides and low high-density lipoprotein (HDL) cholesterol, stroke, breathing disorders, gallbladder disease, osteoarthritis, and skin conditions, including poor wound health, among others.²⁷ Many of these more prevalent life threatening chronic diseases today are linked to nutritional deficiencies, and research shows simple nutrition may eradicate many of these common conditions.²⁸ Consequently, the FDA should prioritize protecting access to nutrients to improve the public health rather than removing tools to supplement and improve health.

²³ Tracy Miller, *Mexico Surpasses U.S. as World’s Fattest Nation: Report*, N.Y. Daily News (July 9, 2013) (available at <http://www.nydailynews.com/life-style/health/mexico-surpasses-u-s-world-fattest-nation-report-article-1.1393801>).

²⁴ *Adult Obesity Facts*, Centers for Disease Control and Prevention (March 28, 2014) (available at <http://www.cdc.gov/obesity/data/adult.html>).

²⁵ Antje Damms-Machado, et al., *Micronutrient Deficiency in Obese Subjects Undergoing Low Calorie Diet*, *Nutrition Journal*, 11:34 (2012) (available at <http://www.biomedcentral.com/content/pdf/1475-2891-11-34.pdf>)

²⁶ *Adult Obesity Facts*, *supra* note 24.

²⁷ *Obesity: Complications*, Mayo Clinic (available at <http://www.mayoclinic.org/diseases-conditions/obesity/basics/complications/con-20014834>) (last visited May 29, 2013).

²⁸ Marler and Walin, *supra* note 20.

ii. The Poor Health of Americans Is Bankrupting the Country from Disease that Could Be Prevented by Better Nutrition

The poor nutrition of Americans is having a costly effect on the economy that cannot be ignored. The estimated annual cost of obesity in the United States was \$147 billion in 2008,²⁹ and has risen to \$190 billion since then.³⁰ Diabetes, which can be caused by obesity, racked up a total cost in 2012 of \$245 billion.³¹ This is an increase from \$174 billion in 2007.³² A striking one out of every 400 children and adolescents has diabetes,³³ and the cost of this childhood obesity is estimated at \$14 billion in direct medical costs.³⁴ After adjusting for population age and sex differences, the average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes.³⁵ The majority of the cost of diabetes care in the United States is paid for by government insurance (including Medicare, Medicaid, and the military).³⁶ The enormity of this economic burden and the huge toll excess weight takes on health and well-being should cause alarm to the FDA and motivate it to take all action possible to stem the tide of the increasingly worse health of Americans. One way to do this is *not* to remove access to tools necessary to make informed market selections and take personal responsibility for one's health.

²⁹ Eric A. Finkelstein, et al., *Annual Medical Spending Attributable to Obesity: Payer-And Service-Specific Estimates*, Health Affairs, 28(5): w822-w831 (2009) (available at <http://content.healthaffairs.org/content/28/5/w822.full.pdf+html>).

³⁰ Sharon Begley, *The Costs of Obesity*, Huffington Post (April 30, 2012) (available at http://www.huffingtonpost.com/2012/04/30/obesity-costs-dollars-cents_n_1463763.html).

³¹ *Statistics About Diabetes*, Am. Diabetes Ass'n (available at <http://www.diabetes.org/diabetes-basics/statistics/>) (last visited May 29, 2014).

³² *Economic Costs of Diabetes in the U.S. in 2012*, Am. Diabetes Ass'n (March 6, 2013) (available at http://professional.diabetes.org/News_Display.aspx?TYP=9&CID=91943&loc=ContentPage-statistics).

³³ *Statistics About Diabetes*, *supra* note 31.

³⁴ Agric. Sec'y Vilsack, *Pediatrician and School Nutrition Director to Host Media Call on Need to Protect Child Nutrition Standards*, U.S. Dept. of Agriculture (May 28, 2014).

³⁵ *Statistics About Diabetes*, *supra* note 31.

³⁶ *Economic Costs of Diabetes in the U.S. in 2012*, *supra* note 32.

B. The FDA's Action Is Arbitrary And Capricious

In making the proposals discussed herein, the FDA failed to consider all relevant factors and articulate an adequate explanation for the proposals. Agency action, such as that taken by the FDA, is arbitrary and capricious under the Administrative Procedures Act if the agency abused its discretion, failed to articulate an adequate explanation for new policy, or failed to consider the relevant factors. *See, e.g., James v. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 284 (D.C. Cir. 2000). The agency must “examine all of the relevant data and ... articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.” *See Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). “How much deference an agency decision is due depends in part on such factors as how much deliberation went into reaching it and whether the decision fits with a policy the agency has consistently followed.” *See A&W Smelter & Refiners, Inc. v. Clinton*, 146 F.3d 1107, 1112 (9th Cir. 1998). Here, the FDA either has failed to articulate an adequate explanation for many of its actions or has failed to consider all relevant material facts.

First, the FDA provides no explanation at all for its decision to propose that Supplement Facts labels can no longer use the terms “folate” or “folacin.” For instance, as discussed above, there is no mention of the methodology used for assessing the bioavailability of folic acid and dietary folates. Additionally, mandating only the use of “folic acid” in supplements fails to recognize the multiple ways of obtaining dietary folate that can be included in supplements. Naming such dietary folates as “folic acid” would be scientifically incorrect.

Second, in the proposed changes to Reference Daily Intakes, as discussed in more detail below, the Agency fails to take into consideration many factors, such as the significant scientific problems around the establishment of tolerable Upper Levels (“ULs”). The FDA also does not

explain adequately why it seeks to lower the recommended amounts of vitamins B12 and B6 despite the fact that B12 deficiencies in the American diet are common, and the toxicity potential for B12 is extremely low. For vitamin E, the FDA’s proposal seems to be based on an outdated view rather than more current information. For example, no information is provided that the Agency considered all the benefits from seven out of eight forms of vitamin E. Similarly, for vitamin A, the Agency seems to ignore the roles of other provitamin A and non-provitamin carotenoids. As for *trans* fat, the FDA failed to consider the very relevant factor that there is a way to measure accurately less than 0.5 grams of *trans* fat as shown by its declaration that “[v]alidated analytical methodologies that provide sensitive and reliable estimates of *trans* fatty acids in all foods at levels below 0.5 g per serving are currently not available.” 79 Fed. Reg. 41 at 11896. As discussed in more detail below, this is not true. Additionally, there is no indication that the Agency looked at the studies showing the relationship to be weak between consumption of cholesterol and its effect on blood cholesterol levels. In conclusion, many of the proposals made by the FDA are arbitrary and capricious under the Administrative Procedures Act.

C. The FDA Has Missed The Mark In Its Proposals Pertaining To Reference Daily Intakes For Vitamins And Minerals

i. The FDA’s Approaches to Revising RDIs Is Misguided

The FDA proposes to revise existing Reference Daily Intakes (“RDIs”) for vitamins and minerals based on the DRIs set by the Institute of Medicine (“IOM”). 79 Fed. Reg. 41 at 11926. The Group recognizes the attempt the Agency has made to establish DVs that are both scientifically valid and meaningful to consumers so informed dietary choices can better be made. The FDA has taken advice from the IOM Labeling Committee, which has proposed setting the DV at the Estimated Average Requirement (“EAR”) because this “is most likely to help individuals understand nutrition information about vitamins and minerals on the Nutrition Facts

label in the context of their total daily diet.” *Id.* The FDA also states that there is “no established benefit for consuming amounts of nutrients above the RDA [Recommended Dietary Allowance] or AI [Adequate Intake].” *Id.* at 11928. However, this is not the case considering that doses that induce risks and benefits frequently overlap.³⁷

The Group therefore wishes to express its profound concern with the approaches under consideration, especially because the EAR fails to consider levels of nutrients that elicit optimal responses over and above those that are deemed as adequate to prevent recognized diseases associated with nutritional deficiency. Additionally, there are grave scientific problems around the establishment of tolerable ULs, as considered in detail in the paper, Verkerk, RH and Hickey, S., *A Critique of Prevailing Approaches to Nutrient Risk Analysis Pertaining to Food Supplements with Specific Reference to the European Union*, *Toxicology*, 278(1): 17-26 (2010). As a result of the existing status of nutritional knowledge over dosage levels of vitamins and minerals in relation to different population groups, there will be very few practicing clinical nutritionists who would agree that the proposed RDIs set out in Table 2 (79 Fed. Reg. 41 at 11931) reflect optimal daily intakes for most individuals. Instead of reflecting *optimal* intakes, the proposed RDIs generally reflect only *minimum*, or insufficient, intakes.

These proposed RDIs will penalize high quality, higher dosage supplements, as well as nutritionally deficient individuals, by misleading consumers into thinking that supplements containing nutrients above the DVs are unnecessary or even dangerous. Nutrient deficiency is a common problem in the United States. A large percentage of the population has well below the

³⁷ See Verkerk, RH, *The Paradox of Overlapping Micronutrient Risks and Benefits Obligates Risk/Benefit Analysis*, *Toxicology*, 278(1): 27-38 (2010).

minimum intake of magnesium, calcium and vitamins A, C, D, and E.³⁸ Vitamin D deficiency, which an estimated one billion people in the world suffer from, can lead to a wide variety of chronic problems, for example, osteoporosis, heart disease, some cancers, and multiple sclerosis, as well as infectious diseases, such as tuberculosis and even the seasonal flu.³⁹ Consequently, it is essential that the American people be encouraged to supplement their diets to obtain the necessary and healthy level of nutrients.

ii. Specific Proposed RDIs Are Too Low

Regarding the specific changes to RDIs with which the Group disagrees, the FDA recommended lowering the recommendations for vitamins B12 and B6 even though the toxicity potential for B12 is so low that not even the IOM could set an Upper Limit for it. The need for B12 in the American diet is acute. Evidence shows B12 deficiencies are common, affecting up to 15% of the population,⁴⁰ and often are exacerbated by drug intake (*e.g.* over-the-counter antacids like Prilosec and Zantac). Mild B12 deficiencies can result in weakness, tiredness, pale skin, easy bruising or bleeding, and stomach problems. Severe B12 deficiencies can have alarming side effects, including cognitive difficulties, paranoia, and hallucinations, and can contribute to depression, nerve damage, and dementia.⁴¹ Additionally, B6 deficiencies, which often appear in conjunction with B12 deficiencies, are associated with microcytic anemia, scaling on the lips, cracks at the corners of the mouth, depression, confusion, and weakened immune function.⁴² As a result of the new 2.4 mcg recommended amount of B12, a 5,000 mcg

³⁸ Dave Gabriele, *supra* note 17.

³⁹ *Vitamin D and Health*, *supra* note 18.

⁴⁰ See *Vitamin B12*, Fact Sheet for Consumers, Nat'l Institutes of Health, (*available at* <http://ods.od.nih.gov/factsheets/VitaminB12-QuickFacts/#h5>) (last visited May 29, 2014).

⁴¹ See Patrick J. Skerrett, *Vitamin B12 Deficiency Can Be Sneaky, Harmful*, Harvard Health (Jan. 10, 2013) (*available at* <http://www.health.harvard.edu/blog/vitamin-b12-deficiency-can-be-sneaky-harmful-201301105780>).

⁴² See *Vitamin B6*, Dietary Supplement Fact Sheet, Nat'l Institutes of Health (*available at* <http://ods.od.nih.gov/factsheets/VitaminB6-HealthProfessional/#h5>) (last visited May 29, 2014).

per day vitamin B12 product would have to be labeled as 208,333% of the DV. This large number might cause some to think the level is too high or dangerous, despite a total absence of evidence of potential harm to the vast majority of people.

The Group also disagrees with the FDA's proposal to lower the recommendations for other nutrients as follows:

- Riboflavin because the vitamin is crucial to absorbing other nutrients and has a very low chance of overdose;
- Biotin and chromium, which are critical for blood sugar control, in the midst of an epidemic of metabolic syndrome and Type II diabetes;
- Selenium, copper and zinc, which are mineral powerhouses that fuel key antioxidant enzymes in the body, and without which the body's free-radical defense system can be compromised significantly; and
- Pantothenic acid (often known as B5), which can help the body better manage adrenal stress and regulate blood lipids, and which has no toxicity in any known dose.

D. The Proposed Replacement Measuring Unit For Vitamin E Should Consider All Eight Forms Rather Than Solely Alpha-Tocopherol

In the Proposed Rule, the FDA proposes changing the unit of measurement for Vitamin E from "IU" to "mg," representing mg of alpha-tocopherol. 79 Fed. Reg. 41 at 11933. This proposal is in keeping with the Agency's pattern of recognizing only one form of vitamin E, alpha-tocopherol, as biologically active. However, there are eight different compounds that make up vitamin E—four tocopherols (alpha, beta, delta, and gamma) and four tocotrienols

(alpha, beta, delta, and gamma). The two most important forms of active vitamin E are gamma- and delta-tocopherol, not alpha-tocopherol. According to the FDA's logic, any amount of seven of the eight forms of vitamin E, including the two most important, will be reflected as zero on Nutrition and Fact Labels.

In its proposed changes to the labeling rules, the FDA fails to update its unscientific, outdated view based on the antiquated idea that vitamin E is only good for preventing infertility in rats. However, complete vitamin E is now known to play a vital health role, for example as an antioxidant, immune system booster, blood clot preventer, and vessel dilator, among other things.⁴³ There is evidence that mixed vitamin E can reverse arteriosclerosis.⁴⁴ Additionally, the four isomers of tocotrienols, not recognized as biologically active by the FDA, have been shown to reduce neuro-degeneration⁴⁵ and can provide anti-aging benefits and reduce the risk of stroke.⁴⁶ Also, a 2009 study demonstrated that gamma and delta-tocopherols slowed the growth of breast cancer by up to 80%.⁴⁷ Vitamin E is a complex nutrient: its effects on one's body and gene expression depend on whether the vitamin is natural or synthetic, the form and mixture consumed, and one's original level of vitamin E.

The Group agrees with the proposal to transition from IU to milligrams (mg) and supports the accounting for the fact that natural vitamin E is much more bioavailable than synthetic vitamin E. However, the proposed amendment still considers alpha-tocopherol to be

⁴³ See *Vitamin E*, Fact Sheet for Consumers, Nat'l Institutes of Health (available at <http://ods.od.nih.gov/factsheets/VitaminE-QuickFacts/>) (last visited May 29, 2014).

⁴⁴ Richard A. Passwater, Ph.D., *Reversing Arteriosclerosis with Tocotrienols: and Interview with Marvin Bierenbaum, MD. And Tom Watkins, Ph.D.*, Whole Foods Magazine (available at http://www.drpasswater.com/nutrition_library/bierenbaum.html) (last visited May 29, 2014).

⁴⁵ Sen CK, et al., *Palm Oil-derived Natural Vitamin E Alpha-tocotrienol in Brain Health and Disease*, J. Am. College Nutrition, 29 (3 Suppl): 314S-323S (2010).

⁴⁶ Karin Granstrom Jordan, M.D., *What's Wrong with Vitamin E?*, Life Extension Magazine (May 2002) (available at https://www.lef.org/magazine/mag2002/may2002_report_wrong_01.htm).

⁴⁷ Hong Jin Lee, et al., *Mixed Tocopherols Prevent Mammary Tumorigenesis by Inhibiting Estrogen Action and Activating PPAR-γ*, Clinical Cancer Research, 15(12): 4242-4249 (2009).

the only active form of vitamin E. More specifically, it is unclear whether the inclusion amount and proposed DRI refer only to the alpha-tocopherol forms, their equivalents (as tocopherol equivalents [TE]) or total vitamin E, irrespective of the isomeric forms included. Given the eight isomeric forms of vitamin E, the logical labeling unit would consider all eight forms of vitamin E, with specific conversion factors for each.⁴⁸ The Group suggest that the unit for total vitamin E be measured in milligrams, with the different forms and their relative amounts expressed to give consumers clear information. By not clarifying what forms of vitamin E are referenced, the existing proposal is potentially misleading to consumers, especially those who are new to supplementation and may be confused in thinking they should just supplement with alpha-tocopherol, because it suggests it's the "only" important or active form of vitamin E. Additionally, this proposal creates legal uncertainty for the dietary supplement industry caused by the issue of whether labels can reflect any forms of vitamin E, other than alpha-tocopherol, that may be included in supplements.

E. The Proposed Replacement Measuring Unit for Vitamin A Blurs The Important Distinction Between Synthetic Beta-Carotene And Naturally Derived Vitamin A

The proposed amendment to the unit of measurement for vitamin A is to switch from "IU" to "mcg," with "mcg" representing mcg RAE. 79 Fed. Reg. 41 at 11932. This proposal would have the effect of eliminating the distinction between synthetic beta-carotene and naturally derived vitamin A. The FDA reasons that there are no known benefits of the carotenoid pigments in fruit and vegetables other than their role in being converted to vitamin A. Additionally, the Agency claims there is no evidence that Americans suffer from vitamin A

⁴⁸ There is no established RDI for tocotrienols, which can be used in dietary supplements and have considerable health benefits going well beyond polyunsaturated fat protection offered by alpha-tocopherol. Chandan K. Sen, *Tocotrienols: Vitamin E Beyond Tocopherols*, Life Sci., 78(18): 2088-98 (2006). Nevertheless, where are present, tocotrienols should be declared voluntarily as a subclass of vitamin E, albeit with no established DV.

deficiency, and the source of vitamin A, as either preformed or indirectly from beta-carotene, is inconsequential.

To the contrary, some individuals are not good at converting beta-carotene into the vitamin A needed by the body. As a result, there are huge differences in the conversion rate depending on the individual and whether the beta-carotene is synthetic or delivered naturally (via foods or supplements). Indeed, one study suggests that as much as 45% of the population cannot convert beta-carotene into the vitamin A (retinol) our body needs.⁴⁹ Moreover, in focusing on the role of beta-carotene in its conversion to vitamin A, the FDA seems to have ignored the key roles of other provitamin A and non-provitamin carotenoids. As a result of the proposed changes to the measurement of vitamin A, the amount of vitamin A actually derived from a supplement may be drastically different than what is on the label. Additionally, vitamin A deficiency can result from taking vitamin D, which can suppress the uptake of vitamin A.

While the FDA states that “RAEs consider 6 mcg of dietary beta-carotene to be equivalent to 1 mcg of purified beta-carotene in supplements (i.e., a carotene:retinol equivalency ratio of 6:1)” (79 Fed. Reg. 41 at 11932), it is unclear whether this 6:1 ratio should be used for dietary supplement based on plants or microorganisms that are rich in naturally-occurring carotenes (*e.g.* carrots, capsicum, Spirulina). The FDA has provided only RAE conversions for retinol, beta-carotene, alpha-carotene and beta-cryptoxanthin. It would be incorrect to apply the same conversion factor to naturally-occurring, as compared to synthetically derived, beta-carotene.

⁴⁹ See Lietz G, et al., *Single Nucleotide Polymorphisms Upstream from the Beta-Carotene, 15,15'-monooxygenase Gene Influence Provitamin A Conversion Efficiency in Female Volunteers*, J. Nutr., 142(1): 161S-5S (2012).

F. The *Trans* Fat Declaration Equating 0.5 g To Zero Is Misleading

The Group disagrees with the proposal not to amend the requirement for the declaration of zero when trans fat content is less than 0.5 g per serving. *See* 79 Fed. Reg. 41 at 11896. Instead, the Group agrees with the previous petition that a declaration of 0.5 g as zero is potentially misleading. For individuals who are reliant on processed foods for their nutrition, consuming multiple servings daily of products labeled with zero *trans* fat could still amount to significant *trans* fat consumption. The FDA claims “[v]alidated analytical methodologies that provide sensitive and reliable estimates of *trans* fatty acids in all foods at levels below 0.5 g per serving are currently not available.” *Id.* However, this reasoning is flimsy given the fact that a saturated fat analysis could be undertaken with more than one portion. Assuming the analysis of *trans* fat is accurate to only 0.5 g, measurement of six portions would give sensitivity to less than 0.1 g of *trans* fat. Therefore, a detectable amount (*e.g.*, 0.5 g) for six portions would be labeled as <0.1 g, and only a zero value for six portions should then be labeled as zero grams.

G. The Reasoning Behind the Continued Mandatory Declaration Of Cholesterol Is Faulty And Its Impact May Have A Negative Effect On Dietary Practices

The Group strongly disagrees with the FDA’s contention the cholesterol content of food is strongly linked to its effect on blood cholesterol levels (*id.* at 11899), given the contradictory evidence regarding the relationship that has been revealed following the original work on the subject by Ancell Keys in the 1950s. Even using Ancell Keys’ own formula,⁵⁰ dropping dietary cholesterol from 300 mg per 1000 calories to 150 mg would cause only a 3.75 mg drop in serum cholesterol. A detailed meta-analysis in 1992 found that even at moderate dietary cholesterol intakes, little change to serum cholesterol would be expected. Paul N Hopkins, *Effects of*

⁵⁰ Change in serum cholesterol between two diets = $1.5 \cdot (Z_2 - Z_1)$, where Z is the square root of the cholesterol content of each diet in mg/1000 kcal.

Dietary Cholesterol on Serum Cholesterol: a meta-analysis and review, Am. J. Clinical Nutrition, 55(6): 1060-1070 (1992). A subsequent meta-analysis in 1997 found only a very modest relationship, approximating to 2.2 mg/dl decrease in serum cholesterol for every 100 mg per day decrease in dietary cholesterol. W H Howell, et al., *Plasma Lipid and Lipoprotein Responses to Dietary Fat and Cholesterol: a meta-analysis*, Am. J. Clinical Nutrition, 65(6): 1747-1764 (1997).

Consequently, not only is the relationship between consumption of cholesterol and blood cholesterol levels weak, the mandatory declaration could have a negative effect on protein intake. Because most meat and other protein-rich foods also contain cholesterol, cholesterol declarations likely will dissuade consumers from eating protein-rich foods. The result will be an increase in consumption of carbohydrate-rich foods, causing delayed satiety and contributing to increased caloric consumption. Excess carbohydrate intake, not cholesterol consumption, is the basis of the current obesity epidemic.

H. The Declarations of Vitamins A And C Should Remain Mandatory

The FDA proposes eliminating the mandatory declaration of vitamins A and C. 79 Fed. Reg. 41 at 11918. The Group strongly disagrees with this proposal and regards it as a retrograde step. The FDA's logic that vitamins A and C are "no longer a nutrient of public health significance for the general U.S. population" is unfounded.⁵¹ *See id.* at 11920, 21. It could equally be upheld that the declaration of calcium on its own is less informative than the declaration of calcium in addition to magnesium. This is a similar scenario to the issue of the

⁵¹ Approximately 34% and 25% of the population do not get enough vitamin A and C, respectively. Gabriele, *supra* note 17.

sodium/potassium ratio, which is more informative than a declaration of the sodium level in isolation, as discussed in more detail below.

It is misleading and incorrect scientifically to consider any essential nutrient as being “no longer of public health significance.” In fact, a persuasive body of new research now has demonstrated that vitamin D and potassium are also vital. Rather than having to remove two nutrients from the mandatory declaration list to make way for two new ones, the Group argues that it is important for consumers to know as much as possible about the micro-nutritional content of the foods they choose to purchase and consume.

Given increased awareness and knowledge about the importance of nutrient interactions (e.g., between Ca and Mg, Na and K, Fe and Cu, vitamins D and K, vitamins A and D), the best approach to providing informed choice to consumers is to require a declaration of *all* essential vitamins and minerals when present in a serving over a predetermined significant amount, for instance between 10% and 20% of the DV.⁵²

III. The Group Agrees With Specific Proposed Amendments And Suggests Improvements

A. The FDA’s Proposals Regarding Calories Do Not Raise Significant Concern

The Group agrees with the FDA’s suggestion to remove the existing mandatory declaration of calories from fat. *See* 79 Fed. Reg. 41 at 11891. The declaration of calories from fat is a scientifically out-dated notion derived from a period in which it was thought, erroneously, that excessive fat consumption was one of the main contributors to obesity. It has since been well demonstrated that such is not the case, specifically bearing in mind that all fats are not

⁵² As a point of reference, 15% is the level considered significant in the EU and is the threshold for mandatory declaration of essential micronutrients, which appears justifiable scientifically.

created equally, with different fats having very different impacts physiologically on health and on individuals depending on highly variable factors such as age, gender, other dietary intakes, physical activity, health status and genetic polymorphisms. Additional scientific data shows that even some types of saturated fat (*e.g.* MCTs) are beneficial rather than harmful.⁵³

Along those lines, the Group supports the proposal to maintain the voluntary nature of the disclosure of calories from saturated fat. *See id.* at 11892. Changing this declaration to be mandatory would give consumers the inaccurate view that increasing saturated fat intake always is likely to increase risk of cardiovascular disease. This view is no longer supported scientifically, *e.g.* effects of medium chain triglycerides (MCTs) or palmitoleic acid.⁵⁴

The Group also agrees with the proposal to maintain the current use of the 2,000 calorie reference level. *See* 79 Fed. Reg. 41 at 11892. However, the Group proposes a revision be made to the mandatory explanation, which currently reads: “Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.” *Id.* An individual’s caloric intake may be higher or lower depending not on caloric needs but on the person’s nutritional needs. Consequently, the explanation should be revised as follows: “Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your **nutritional** needs.” (Emphasis added).

⁵³ The Group suggests that based on available scientific information, it would be more scientifically rational to provide mandatory declaration of calories from sugars. This information would be of significantly greater value to consumers wishing to avoid products that are more likely to cause them to gain weight.

⁵⁴ *See, e.g.,* Haiming Cao, et al., *Identification of a Lipokine, a Lipid Hormone Linking Adipose Tissue to Systemic Metabolism*, *Cell*, 134(6): 933-44 (2008); Norbert Stefan, MD, et al., *Circulating Palmitoleate Strongly and Independently Predicts Insulin Sensitivity in Humans*, *Diabetes Care*, 33(2): 405-7 (2010); Dariush Mozaffarian MD DrPH, et al., *Trans-Palmitoleic Acid, Metabolic Risk Factors, and New-Onset Diabetes in US Adults*, *Annals of Internal Med.*, 153(12): 790-9 (2010).

And lastly with regards to calories, the Group does not agree that a percent DV declaration for calories not be permitted. *See* 79 Fed. Reg. 41 at 11892 – 93. Rather, this should be optional, as it would enable consumers to make more informed decisions regarding selection of processed foods.⁵⁵ Additionally, consideration should be given to the levels agreed upon in Europe (Regulation (EU) No. 1169/2011), which also use a 2,000 kcal reference calorie intake level, namely:

Total fat 70 g
Saturates 20 g
Carbohydrate 260 g
Sugars 90 g
Protein 50 g
Salt 6 g

B. Consumer Perception Should Be Considered Regarding Sodium

The FDA has invited comments on various options for proposed changes regarding sodium content on Nutrition Facts labels. *Id.* at 11917. In response to this request, the Group would like to raise the issue of consumer perceptions. While the various approaches to the calculations are valid scientifically, the declaration of “sodium” itself is misleading because the key link to increased hypertension and associated cardiovascular disease is not total sodium but rather the presence of sodium chloride (“salt”), and in particular an excess of sodium in relation to potassium, as recognised by the National Institutes of Health (“NIH”) and the US Department of Agriculture (“USDA”) (*Chapter 8 Sodium and Potassium*, Dietary Guidelines for Americans 2005, USDA, <http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter8.htm>).

⁵⁵ Note: the current 30% DV level for total fat is based on 67 g (not 65 g) total fat intake assuming a 2,000 kcal daily intake (assuming 9 kcal/g of fat).

The importance of the sodium/potassium ratio, and the benefits of consuming less sodium alongside more potassium, was demonstrated clearly in the Trials of Hypertension Prevention follow-up study. Nancy R. Cook ScD, et al., *Joint Effects of Sodium and Potassium Intake on Subsequent Cardiovascular Disease: the Trials of Hypertension Prevention (TOHP) Follow-up Study*, JAMA Internal Med., 169(1): 32-40 (2009). Accordingly, the Group supports the voluntary inclusion of potassium on the Nutrition Facts panel, immediately below the sodium level, along with the 4,700 mg per day DV, to enable consumers to manage more easily their intake of these two minerals. In addition, the sodium/potassium ratio should also be permitted as a voluntary declaration on the label. The Group also supports the 1500 mg DRI value for sodium, given the resultant DV better reflects a level of adequacy, rather than the 2300 mg, which is a daily reference value (“DRV”) based on the upper level of intake.

C. Some Of The FDA’s Proposals Regarding Carbohydrates, Specifically, Sugar And Added Sugar, Are Beneficial

The Group supports the proposal not to change the mandatory declaration of sugars representing total mono and disaccharide sugars, including those added. *See id.* at 11902. Nonetheless, consumers would benefit from an optional declaration of polyols (sugar alcohols) if they are present. The term “polyols” is likely to cause less confusion than sugar alcohols, given that many consumers will recognize both “sugar” and “alcohol” as being detrimental to health when consumed in excess. At the very least, the FDA should conduct consumer testing of the term “polyols” and “sugar alcohols.” It is noteworthy that the EU has introduced optional declaration for “polyols,” under Regulation (EU) No. 1169/2011.

As for Added Sugars, the Group agrees with the FDA’s position that it should be a mandatory declaration where sugars are added. *See id.* at 11904. In addition, consumers would

benefit from a voluntary declaration of “Contains naturally occurring sugars” in cases where sugars are naturally present in the food and the manufacture has not added additional sugars. For many consumers, this is an important distinction.

The Group presents the following comments pertaining to additional proposal regarding carbohydrates:

- The FDA proposes to continue use of the term “sugar alcohols.” *Id.* at 11908. While “sugar alcohols” are kinds of alcohol prepared from sugars, use of the term may mislead or confuse consumers regarding the health effects, given the negative health connotations of the words “sugar” and “alcohol” separately. Furthermore, the term “sugar,” as used in the “Sugars” declaration on labels is based only on mono and disaccharide sugars. By contrast, most so-called “sugar alcohols” are based on pentoses or hexoses (erythritol being an exception). Furthermore, the molecular structure of sugars are rings, whereas ‘sugar alcohols’ form chains. Based on these differences in origin and structure, as well as differences in caloric content and effects on insulin response, the Group proposes that the term “polyols” is more appropriate in reference to carbohydrate-based polyalcohols and is less likely to mislead or confuse consumers. The Group agrees with the FDA that there is no scientific basis on which to establish a DRV for “sugar alcohols” and agrees with the caloric values for the listed sugar alcohols, although the list is incomplete (e.g. erythritol should be 0 kcal/g). *See id.* at 11908-909.

- The Group agrees with the FDA’s proposal to maintain the method of calculating total carbohydrate by difference and include dietary fiber, given that it is a form of carbohydrate. 79 Fed. Reg. 41 at 11899-900.

- The Group agrees that dietary fiber continue to be listed separately on Nutrition Facts labels.
- The 300 g DRV for Total Carbohydrate is excessive. *See id.* at 11901. While the FDA asserts that the “DRV should not be viewed as an intake requirement, but as a reference amount” (*id.*), consumers often perceive it as the former rather than the later. Bearing in mind the RDA for carbohydrate for adults 19 years of age and older is 130 g per day, and that excessive carbohydrate intake is a central cause of the American obesity epidemic, reducing the DRV to 275 g, as per the population-weighted mid-point of the AMDR for adults and children would provide a useful signal encouraging lower carbohydrate consumption.

D. A Fluoride Declaration Should Be Made Mandatory When The Amount Exceeds 0.5 mg Per Serving

The FDA proposes to amend the declaration of fluoride in Nutrition Facts labels to make it voluntary rather than prohibited and proposes that no DRV be set. *Id.* at 11917-18. The Group agrees that no DRV should be set for fluoride and agree with the proposed stipulated amounts and increments. However, the Group suggests that the declaration be made mandatory when the presence of fluoride, a dangerous neurotoxin, exceeds 0.5 mg per serving. This amount is significant physiologically, representing over 15% of 3.5 mg per day, the mid-point for the three and four mg per day AI for adult females and males, respectively, set by the IOM, based on an uncertainty factor of one. As it is, this uncertainty factor is incongruent with the lack of certainty in the available data and the overlap between risk and benefit.⁵⁶ The National Research Council has determined, following an extensive review of data, that consumption of over two mg per day of fluoride in drinking water would cause widespread, significant dental fluorosis. Nat'l

⁵⁶ See Verkerk, RH, *The Paradox of Overlapping Micronutrient Risks and Benefits Obligates Risk/Benefit Analysis*, *Toxicology*, 278(1): 27-38 (2010).

Research Council, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*, The Nat'l Academies Press (2006). This amount could be consumed easily by athletes or others who chose to drink twice the average intake of water.

The Group also considers it necessary, where fluoride is declared over 0.5 g per serving, that the manufacturer declare the form of fluoride present. This information is highly relevant given the well-known differences between the bioavailability and pharmacokinetic profiles of artificial fluorides (e.g. hydrosilicic acid, sodium monofluorophosphate) as compared with naturally-occurring ones (principally calcium fluoride).

E. The FDA's Proposals Not To Set DRVs For Trans Fat And Polyunsaturated Fat Are Well-Founded

The Group supports the conclusion that there is no basis to set a DRV for *trans* fat (*see* 79 Fed. Reg. 41 at 11896), as this category of fact is neither nutritionally essential nor beneficial. As for polyunsaturated fat, the Group also agrees with the FDA's decision not to propose a DRV (*id.* at 11898), in light of the fact there is no agreed upon scientific basis for establishing such DRV due to the diverse nature of this category of facts and variations in individual responses. Additionally, the Group agrees with the proposal to continue to allow the voluntary declaration of polyunsaturated fat. *See id.* at 11897.

F. The FDA Must Ensure Companies Have Adequate Time To Make The Necessary Conversions

The Proposed Rule sets forth significant changes to Nutrition Facts and Supplement Facts labels and currently proposes an effective date of 60 days after the date the final rule is published in the Federal Register and a compliance date of two years after the effective date. *Id.* at 11959. Once this rulemaking procedure results in a final rule, companies will need to undertake a course of action to implement the mandated changes. This process may include such things as alterations in software and other machinery, along with analyzing products for which there may

be new mandatory nutrient declarations, as recognized by the FDA (*see id.*). Moreover, in the process of changing labels to comply with the final rule, additional changes or unexpected difficulties may arise which delay the conversion. Given the extensive scope of the changes which may become final, companies will need substantial time to make the necessary conversions. The Group respectfully requests that the FDA ensure that adequate time is provided for compliance.

CONCLUSION

For the foregoing reasons, the Group respectfully opposes certain provisions in the Proposed Rule and suggests alternatives. The Group's proposals are supported by scientific evidence and are based on the goal of helping consumers make informed decisions in furtherance of healthy dietary practices.

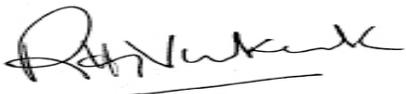
Dated: July 29, 2014

Respectfully submitted,

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