



May 6, 2013

VIA FEDEX

Timothy G. Hayes
Senior Vice President
Consumer Care Division Bayer HealthCare
36 Columbia Road
Morristown, NJ 09762

Re: Bayer's deceptive trade practices based on unsubstantiated and illegal claims found on multiple varieties of Bayer One A Day multivitamins

Dear Mr. Hayes:

The Center for Science in the Public Interest (CSPI) has identified deceptive practices in the marketing and sale of several lines of Bayer multivitamins.¹ This letter details CSPI's findings and offers to discuss resolution before CSPI takes further legal action. Ultimately, if litigation became necessary, CSPI would seek an injunction prohibiting Bayer from expressly or implicitly (1) representing that any of its dietary supplement products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease; and (2) making unsubstantiated claims for its dietary supplement products. CSPI also may seek corrective advertising, restitution, damages, disgorgement, and attorneys' fees.

Facts Giving Rise to Bayer's Liability

Bayer markets multivitamins with a variety of claims – that they support “breast health,” “heart health,” “healthy blood pressure,” “immunity,” “physical energy,” “bone strength,” “eye health,” “metabolism support,” and “joint health.” These claims imply, or in some cases explicitly state, that Bayer's health benefits have been scientifically established. Therefore, Bayer's claims must

¹ Including Bayer One A Day Women's Formula, One A Day Men's Formula, Women's One A Day 50+ Healthy Advantage, Men's One A Day 50+ Healthy Advantage, Men's One A Day Pro Edge Multivitamin, and Women's One A Day Active Metabolism, Women's One A Day Pro Edge, Women's One A Day Menopause Formula, Women's One A Day Active Mind & Body, Women's One A Day Plus Healthy Skin Support, One A Day Women's Petites, One A Day Teen Advantage for Her, One A Day Teen Advantage for Him, One A Day Essential, One A Day Energy, One A Day Women's Vitacraves Gummies, One A Day Men's Vitacraves Gummies, One A Day Vitacraves Gummies Plus Immunity Support, One A Day Vitacraves Gummies Regular, and One A Day Vitacraves Sour Gummies.

satisfy the Federal Trade Commission's (FTC) requirements for substantiation in order to be lawful.

The FTC has recently required a higher standard of proof for companies making health-related claims:

[A]t the time of making such representation, [the company] possesses and relies upon competent and reliable scientific evidence that is *sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence*, to substantiate that the representation is true . . . [C]ompetent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.²

In addition, the FTC prohibits companies from “misrepresent[ing], in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.”³ Consumers cannot be expected to evaluate whether these claims are true or are supported by clinical studies. Claims that fail to satisfy the FTC's requirements — such as Bayer's, as explained herein — are deceptive and are thus unlawful under state consumer protection laws.

1. “Breast Health”

Bayer markets all of its One A Day Women's multivitamin supplements with the claim that they support “breast health.” This claim implies that by taking a One A Day multivitamin a woman can reduce her risk of breast cancer. This deception is reinforced by language found under the “tips” portion of the One A Day website. For example, the website states:

Every three minutes a woman in the United States is diagnosed with breast cancer and according to the American Cancer Society, the chance of a woman having invasive breast cancer at some point during her life is about 1 in 8. This is why it is incredibly important for women to do what

² *In the matter of Kellogg Company*, Order to Show Cause and Order Modifying Order (Federal Trade Commission May 28, 2010), available at www.ftc.gov/os/caselist/0823145/100602kelloggorder.pdf (emphasis added) (last visited Apr. 25, 2013).

³ *In the matter of Kellogg Company*, Order Containing Consent Agreement at 3 (Federal Trade Commission Apr. 2009), available at www.ftc.gov/os/caselist/0823145/090420kelloggagree.pdf (last visited Apr. 25, 2013).

they can to maintain their breast health.⁴

Directly below this statement, Bayer supplies a list of things that women *should* do to “maintain their breast health” including:

Take One A Day Women’s multivitamins formulated with a high level of vitamin D to support breast health. Emerging research suggests the daily consumption of 1,000 IUs of Vitamin D is associated with support of breast health*. One A Day Women’s and One A Day Women’s 50+ Advantage contain 800 IUs of Vitamin D to help supplement your daily intake of Vitamin D.⁵

The evidence that vitamin D might lower the risk of breast cancer (or otherwise bolster breast health) is inconclusive and does not support this claim.⁶ Further, stating on a website that in order to maintain healthy breasts women *should* take Bayer’s One A Day multivitamin — especially after stating that 1 in 8 women get breast cancer — is blatant product promotion that purposely plays on consumers’ fears. It is deceptive, misleading, insensitive, and appalling to imply that taking a multivitamin will reduce women’s chance of breast cancer.

Bayer’s One A Day “breast health” claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

2. “Heart Health” & “Healthy Blood Pressure”

Bayer claims that many of its One A Day multivitamins “support heart health” and “support healthy blood pressure.” These claims imply to consumers that taking One A Day multivitamins can help prevent cardiovascular disease. The One A Day multivitamin labels that claim “heart health” and “healthy blood pressure” attribute this alleged support to the product’s vitamin B, vitamin C, vitamin E, and folic acid content. Numerous studies have now disproven the

⁴ One A Day website, www.oneaday.com/tas/tips.html (last visited Apr. 30, 2013).

⁵ *Id.*

⁶ *E.g.*, Theresa Shao et al., *Vitamin D and Breast Cancer*, 17(1) ONCOLOGIST 36 (Jan. 2012) (“the relationship between vitamin D and breast cancer remains unclear . . . [w]ell-designed, randomized clinical trials are needed to further address whether or not vitamin D play a role in breast cancer development”). *See also*, JoAnn E. Manson et al., *Vitamin D and Prevention of Cancer – Ready for Prime Time?*, 364(15) NEW ENG. J. MED. 1385 (Apr. 2011) (vitamin D’s relation to cancer “found to be inconsistent and inconclusive as to causality”; “Regarding breast-cancer risk specifically, three observational cohort studies of plasma 25-hydroxyvitamin D levels had inconsistent results”).

notion that taking B vitamins reduces the risk of cardiovascular disease.⁷ Bayer's claims may mislead consumers into believing that these multivitamins are replacements for cholesterol-lowering drugs. "Heart health" and "healthy blood pressure" claims are unlawful because they are claims of disease prevention, lack prior substantiation, and are deceptive.

3. "Immunity"

Bayer claims that many of its One A Day multivitamins help "support immunity." Consumers interpret these "immunity" claims to mean that taking One A Day multivitamins will help them get sick less often. The FTC has found that "reasonable consumers may interpret an advertisement to mean that the product will reduce the likelihood of getting [the disease], even if respondent includes language indicating that the science supporting the effect is limited in some way."⁸

Bayer cannot substantiate that its claims are true "in light of the entire body of relevant and reliable scientific evidence." Randomized controlled trials — the gold standard of clinical research — suggest that, as measured by the number or length of illnesses, taking multivitamins does not affect immunity.⁹ Therefore, this claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

4. "Physical Energy"

Bayer markets many varieties of its One A Day multivitamins (including One A Day Women's and Men's Formulas, Women and Men's 50+ Healthy Advantage formulas, and Men's Pro Edge formula) with the claim that they "support physical energy." Consumers interpret energy claims to mean that they will feel more energetic. Using the word "physical" with the word "energy" further encourages consumers to assume that taking a One A Day multivitamin will give them an actual boost of physical energy.

For example, Bayer's commercials for its One A Day Men's Pro Edge multivitamins reinforce this misrepresentation by depicting athletic men playing basketball, swimming, and biking while a voice-over tells consumers to "give

⁷ Robert Clarke et al., *Homocysteine and Vascular Disease: Review of Published Results of the Homocysteine-Lowering Trials*, 34 J. INHERITED METABOLIC DISEASE 83 (February 2011).

⁸ In re The Dannon Company, Inc., FTC File No. 0823158, Analysis of Proposed Consent Order to Aid Public Comment (Dec. 15, 2010), www.ftc.gov/os/fedreg/2010/december/101221dannonfrn.pdf (last visited Apr. 25, 2013).

⁹ Audrey I. Stephen et al., *A Systematic Review of Multivitamin and Multimineral Supplementation for Infection*, 19(3) J. HUMAN NUTRITION & DIETETICS 179 (June 2006) (a meta-analysis of 17 randomized controlled trials found no evidence for "a reduction in episodes of infection, the number of days of infection, or antibiotic use" in participants supplemented with multivitamins).

yourself an edge” and that Pro Edge multivitamins contain “more B vitamins to help convert food into fuel.” However, studies do not show that increased levels of B vitamins, such as thiamin and riboflavin, produce any significant effects on cardiovascular function, intermediary metabolism, muscle, strength, or performance.¹⁰

Multivitamin supplements are not generally regarded as having an effect on energy.¹¹ While micronutrients “enable the use of macronutrients for all physiologic processes,” it is macronutrients that “provide sources of energy needed to fuel the body.”¹² Restated: it is food that is necessary for the kind of energy and performance depicted in Bayer’s commercials. If individuals are consuming nutritionally adequate diets, performance will not be improved by using most nutritional supplements.¹³ These advertisements are misleading and deceptive because, while B vitamins are elements in various pathways of food conversion, they do not provide the physical boost of energy that Bayer’s advertisements imply.¹⁴

5. “Bone Strength”

Bayer markets many of its One A Day multivitamin supplements for women with the claim that they support “bone strength.” Bayer’s web page for One A Day Women’s multivitamins says, “You can actually start to lose bone mass as early as your 30s. That’s why One A Day Women’s contains a high level of Calcium to support strong bones and more Vitamin D than Centrum Women Under 50 to support strong bones and aid calcium absorption.”¹⁵ When this

¹⁰ E.g., Henry C. Lukaski, *Vitamin and Mineral Status: Effects on Physical Performance*, 20 NUTRITION 632 (2004) (“Controlled human studies have found no significant effects of graded dietary thiamin intakes on physiologic function.”); FOOD & AGRICULTURE ORG. OF THE UNITED NATIONS, HUMAN VITAMIN AND MINERAL REQUIREMENTS, Thiamine, Riboflavin, Niacin, Vitamin B6, Pantothenic Acid, and Biotin (“riboflavin supplementation did not lead to an increase in work performance when such subjects were not clinically deficient.”).

¹¹ *In the matter of Kellogg Company*, Order Containing Consent Agreement at 9, (Federal Trade Commission Apr. 2009), available at www.ftc.gov/os/caselist/0823145/090420kelloggagree.pdf (internal citations omitted) (last visited Apr. 25, 2013).

¹² Henry C. Lukaski, *Vitamin and Mineral Status: Effects on Physical Performance*, 20 NUTRITION 632, 634-635, 641 (2004).

¹³ *Id.* at 641.

¹⁴ Bayer One A Day Women’s Active Mind & Body, One A Day Active Metabolism, and One A Day Energy multivitamin products contain “about as much caffeine as a cup of coffee.” However, this amount of caffeine will not give any more “physical energy” or boost physical performance (as depicted in the commercials) than a simple cup of coffee.

¹⁵ One A Day website, www.oneaday.com/womens.html (last visited May 3, 2013).

statement is viewed in conjunction with the “bone strength” claim, it implies that taking One A Day can prevent osteoporosis, but fails to meet federal requirements for osteoporosis claims set forth in 21 C.F.R. § 101.72. Specifically, permissible claims must (1) “make[] clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in a healthful diet, are essential to reduce osteoporosis risk”; (2) “not imply that adequate calcium intake . . . is the only recognized risk factor for the development of osteoporosis”; and (3) “not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake . . .” Because this language is not part of the “bone strength” claim, that claim is an illegal claim of disease prevention.

Therefore, this claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

6. “Eye Health”

Bayer claims that its One A Day Men and Women’s 50+ Healthy Advantage multivitamins support “eye health.” This claim is marketed to an age group that is at a higher risk for cataracts and macular degeneration. However, there is no evidence that the levels of zinc and vitamins E, A, and C contained in these products will assist in the treatment or prevention of cataracts or macular degeneration.¹⁶ Because the claim of “eye health” is meant to convey that taking One A Day 50+ multivitamins can prevent cataracts, macular degeneration, or other eye disease, it is a claim of disease prevention that Bayer is not authorized to make about supplements.

Therefore, this claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

7. “Supports Metabolism”

Bayer claims that its One A Day Women’s Active Metabolism multivitamins are “specially formulated to help support your metabolism.”¹⁷ This claim implies that taking this multivitamin supplement will aid weight loss.

¹⁶ See Milan C. Mathew et al., *Antioxidant Vitamin Supplementation for Preventing and Slowing the Progression of Age-Related Cataract*, 13(6) COCHRANE DATABASE SYST. REV. CD004567 (June 2012) (“There is no evidence from RCTs that supplementation with antioxidant vitamins (beta-carotene, vitamin C or vitamin E) prevents or slows the progression of age-related cataract.”); see also Nat’l Inst. of Health, Nat’l Eye Inst., *The Age-Related Eye Disease Study (AREDS)*. Although the AREDS suggests that taking high levels of antioxidants and zinc may reduce the risk of developing advanced age-related macular degeneration, that study used levels of the vitamins and zinc many times that contained in Bayer’s 50+ Healthy Advantage multivitamins).

¹⁷ One A Day website, www.oneaday.com/womens_active_metabolism.html (last visited Apr. 19, 2013).

The label purports that the product contains B vitamins to “support metabolism.” Taking B vitamins will not help someone lose weight.¹⁸

The One A Day website also highlights the multivitamin’s chromium and caffeine ingredients as support for its “supports metabolism” claims. However, according to the National Institutes of Health’s Office of Dietary Supplements, studies concerning the role of chromium in lipid metabolism yielded “mixed results” and studies concerning its role in weight loss showed “differences [that] were small and of debatable clinical relevance.”¹⁹

Finally, while caffeine may speed up metabolism for a brief period of time, there is little evidence that it helps people lose weight.²⁰

In a society plagued by obesity with a population eager for any quick fix, implying that a multivitamin will assist someone with their weight loss goals is misleading. Therefore, this claim is unsubstantiated and deceptive.

8. “Joint Health”

Bayer markets One A Day Women’s 50+ Healthy Advantage with the claim “supports joint health.” This claim is targeted at an age group that is at a higher risk for arthritis and could easily be interpreted by consumers to be a disease prevention claim. By itself, the potential for vitamin C to reduce the risk of arthritis is virtually nil.²¹ There has not been an adequate amount of research done on vitamin C’s effect on arthritis to even come close to satisfying the requirement for competent and reliable evidence. Therefore, this claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

¹⁸ Genevieve Major et al., *Multivitamin and Dietary Supplements, Body Weight and Appetite: Results from a Cross-Sectional and a Randomised Double-Blind Placebo-Controlled Study*, 99(5) BRITISH J. NUTRITION 1157 (May 2008).

¹⁹ National Institutes of Health, Office of Dietary Supplements, *Dietary Supplement Fact Sheet: Chromium*, available at <http://ods.od.nih.gov/factsheets/Chromium-HealthProfessional/> (last visited Apr. 24, 2013).

²⁰ David Schardt, *Caffeine!*, NUTRITION ACTION HEALTHLETTER 7 (Dec. 2012), available at www.cspinet.org/nah/articles/caffeine.html (last visited Apr. 24, 2013).

²¹ DukeHealth.org, *Vitamin C Worsens Knee Osteoarthritis in Animal Study*, www.dukehealth.org/health_library/news/7640 (last visited Apr. 1, 2013); N.H. Jensen, *Reduced Pain from Osteoarthritis in Hip Joint or Knee Joint During Treatment with Calcium Ascorbate*, 165(25) UGESKR LAEGER 2563 (June 2003) (study supporting link between vitamin C and joint pain used significantly more vitamin C than found in Bayer Healthy Advantage).

Bayer's Violations of State Consumer Protection Laws

Bayer's claims regarding One A Day multivitamins as documented herein (1) are illegal claims of disease prevention; (2) do not have prior substantiation; and (3) are generally false, misleading, and deceptive. As such, these claims violate state consumer protection laws such as Massachusetts G.L. c. 93A, Texas Business & Professions Code § 17.41 *et seq.*, District of Columbia Code § 28-3905 *et seq.*, New Jersey Statutes Ann. 56:8-1 *et seq.*, California Business & Professions Code Sections 17200 and 17500, and California Civil Code §§ 1770(a)(5) & 1770(a)(14).

Further, Bayer's misrepresentations render One A Day multivitamins misbranded in violation of state food and drug laws, such as California's Sherman Food, Drug, and Cosmetic Law.²²

As the manufacturer and distributor of One A Day multivitamins, Bayer is responsible for the injuries caused by its actions. Consumer injury occurs each time a consumer sees marketing for or purchases one of these products. Each occurrence is a separate injury.²³

Settlement Demand

In light of the foregoing, CSPI invites Bayer to resolve these instances of illegal and deceptive advertising in order to avoid further legal action. CSPI seeks to prevent Bayer from (1) making claims about its products' disease-prevention benefits, (2) misrepresenting the findings of scientific studies, and (3) deceptively advertising unproven health benefits in association with One A Day multivitamins.

Should Bayer choose not to respond to CSPI's findings, CSPI will pursue litigation to seek the following:

- Entry of a permanent injunction that prohibits Bayer from representing (either expressly or implicitly) that any of its dietary supplement products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- Entry of a permanent injunction that prohibits Bayer from making unsubstantiated representations (either expressly or implicitly) about the benefits of One A Day multivitamins.
- Entry of a permanent injunction that mandates a series of corrective advertisements to correct Bayer's prior consumer deception with respect to the benefits of its One A Day multivitamins.

²² California Health and Safety Code § 110660 ("Any food is misbranded if its labeling is false or misleading in any particular.").

²³ *E.g., Aspinall v. Philip Morris Companies, Inc.*, 813 N.E.2d 476 (Mass. 2004).

- Disgorgement of Bayer's profits from the sale of its One A Day multivitamins.

If Bayer is willing to discuss a settlement or requires additional information about the claims documented herein, we welcome contact from counsel.

Yours truly,

A handwritten signature in blue ink, appearing to read "Stephen Gardner". The signature is fluid and cursive, with a large initial "S" and a long, sweeping underline.

Stephen Gardner
Litigation Director

cc: Michael F. Jacobson, Ph.D., Executive Director