



April 7, 2011

VIA OVERNIGHT COURIER

Ian Read
President and Chief Executive Officer
Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Re: Pfizer's deceptive trade practices based on unsubstantiated and illegal claims for
Centrum multivitamins

Dear Mr. Read:

The Center for Science in the Public Interest ("CSPI") has identified deceptive practices in the marketing and sale of Pfizer's line of Centrum multivitamins. 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 Pfizer 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 Pfizer's Liability

Pfizer markets Centrum multivitamins with a variety of claims – that they support “energy and immunity,” “heart health,” “eye health,” “breast health,” “bone health,” and “colon health.” These claims imply, or in some cases explicitly state, that Centrum's health benefits have been scientifically established; therefore, Pfizer's claims must satisfy the Federal Trade Commission's (“FTC”) requirements for substantiation in order to be lawful. FTC has recently required a higher standard of proof for companies making deceptive 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.¹

In addition, 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.”² Claims that fail to satisfy the FTC’s requirements – such as Pfizer’s, as explained herein – are considered deceptive and are thus unlawful under state consumer protection laws.

1. “Energy and Immunity”

Pfizer markets all varieties of Centrum multivitamins with the claim that they support energy and immunity. One recent television commercial shows an actor in a lab coat who states:

There’s scientific news about Centrum. In a recently published study, key nutrients reviewed were found to be absorbed by the body. These nutrients help support energy and immunity. Impressive. Science gives you more reason to trust Centrum.

However, Pfizer’s predecessor Wyeth Consumer Healthcare (Wyeth) clarified to CSPI that this commercial refers to a single study that tested a prior formulation of Centrum multivitamins, and had nothing to do with energy or immunity. This one study does not provide the requisite “competent and reliable scientific evidence that is sufficient in . . . quantity . . . to substantiate that the representation is true.” Pfizer’s claim that the results of this study have implications for energy and immunity also impermissibly misrepresents the research, since the study was not related to energy and immunity and reached no conclusions about the effect of vitamins on either.

Moreover, Pfizer cannot substantiate that its claims are true “in light of the entire body of relevant and reliable scientific evidence.” Current scientific trials as to multivitamins’ effect on immunity suggest the opposite of Pfizer’s single study. As measured by the number or length of illnesses, taking multivitamins does not affect immunity.³ Likewise, multivitamin supplements are not generally regarded as having an effect on energy.⁴ Thus, to the extent Pfizer’s one study is incon-

¹ *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).

² *In the matter of Kellogg Company*, Order Containing Consent Agreement (Federal Trade Commission April 2009) (available at www.ftc.gov/os/caselist/0823145/090420kelloggagree.pdf).

³ David Schardt, *Claims Adjustment*, NUTRITION ACTION HEALTHLETTER (Center for Science in the Public Interest), July/Aug. 2010, at 10 (internal citations omitted).

⁴ *Id.* at 9 (internal citations omitted).

sistent with current scientific evidence, it fails to provide a legitimate basis for Pfizer's claims.

Finally, the appearance of an actor in a lab coat touting the results of scientific studies further seeks to establish that Pfizer's claims are backed by sufficient scientific evidence. Deceptive visual representations such as those featured in the Centrum commercial to promote unsubstantiated claims constitute false advertising.⁵

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

2. "Heart Health"

Pfizer markets Centrum Ultra Men's, Centrum Cardio, and Centrum Silver with the claim that they support "heart health." For example, a recent print advertisement says, "Centrum Cardio is the only complete multivitamin with CoroWise™ phytosterols, an ingredient derived from soybeans that may *reduce the risk of heart disease* by lowering LDL (bad) cholesterol. *Centrum Cardio is the multivitamin that's complete and all heart.*" (Emphases added.)

However, existing research on the effectiveness of phytosterols has evaluated them in foods, like margarine or yogurt, which help disperse the phytosterols in the GI tract to do their work. There is little or no evidence that the free phytosterols in hard, dry pills have the same effect. In fact, Pfizer has failed to produce any convincing evidence as to their effects in response to previous requests from CSPI. Therefore, this claim is unlawful because it lacks prior substantiation and is deceptive.

3. "Eye Health"

Pfizer markets Centrum Silver, Centrum Silver Ultra Men's, and Centrum Silver Ultra Women's with the claim that they support "eye health." One commercial for Centrum Silver Ultra Men's, available on centrum.com, simply states that it contains "nutrients" to support eye health. Centrum's website mentions the supplement contains lutein for eye health. One Centrum Silver Ultra Men's tablet has 300 mcg lutein.

To the extent that the claim of "eye health" is meant to convey that taking Centrum multivitamins can prevent cataracts, macular degeneration, or other eye disease, it is more akin to a disease prevention claim that Pfizer is not authorized to make about supplements.

⁵ See *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1152 (9th Cir. 2984) (FTC's conclusions that aspirin company made deceptive establishment claims "were based on visual aspects of the advertisements ... includ[ing] pictures of medical and scientific reports ... convey[ing] a 'serious tone' or a 'scientific aura' that implied scientific approval of the product.").

FDA has reviewed the effect of lutein on eye health, and found the substantiation lacking. For example, in 2009 FDA rejected a qualified health claim for lutein, finding “no credible evidence for a relationship between intake of . . . lutein . . . and reduced risk of AMD [age-related macular degeneration].”⁶

Moreover, Centrum multivitamins fall far short of the necessary amount of lutein to have any potential affect eye health. An April 2004 study on lutein supplements concluded that 10,000 mcg of lutein supplements per day had an impact on participants’ eye health.⁷ However, Centrum multivitamins provide only 300 mcg, only 3% of the amount tested in the study. In fact, the average person naturally consumes 1,000 to 2,000 mcg of lutein daily. Although Pfizer does state that 300 mcg is less than the daily recommended dose, it fails to do so in a manner that actually conveys that information to consumers who notice the prominent “Eye Health” panel on the front of the package.

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

4. “Breast Health”

Pfizer markets Centrum Ultra Women’s and Centrum Silver Ultra Women’s with the claim that they support “breast health.” Centrum’s website and recent commercials for these products, available on centrum.com, also make this representation. However, there is only limited evidence that Vitamin D might lower the risk of breast cancer (or otherwise bolster breast health), so existing knowledge does not support this claim.⁸ Moreover, to the extent that this claim implies that taking Centrum can prevent breast cancer, it is a claim of disease prevention that Pfizer is not legally authorized to make. Therefore, this claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

5. “Bone health”

Pfizer markets Centrum, Centrum Ultra Women’s, Centrum Silver, and Centrum Silver Ultra Women’s with the claim that they support “bone health.” To the extent that this claim implies that taking Centrum can prevent osteoporosis, it fails to meet federal requirements for osteoporosis claims set forth in 21 C.F.R. § 101.72. Specifically, per-

⁶ www.fda.gov/food/labelingnutrition/labelclaims/qualifiedhealthclaims/ucm073291.htm.

⁷ Stuart Richer, O.D., Ph.D., *Lutein Antioxidant Supplementation Trial*, OPTOMETRY – THE JOURNAL OF THE AMERICAN OPTOMETRIC ASSOCIATION, Apr. 2004.

⁸ David Schardt, *supra*, at 3? (internal citations omitted).

See also, JoAnn E. Manson, M.D., Dr.P.H. et al, *Vitamin D and Prevention of Cancer – Ready for Prime Time?* NEW ENGLAND JOURNAL OF MEDICINE, (10.1056/NEJMp1102022), Mar. 23, 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”).

missible 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 the “bone health” claims on Centrum multivitamins are not accompanied by these requisite disclaimers, they are claims of disease prevention that Pfizer is not legally authorized to make.

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

6. “Colon health”

Pfizer markets Centrum Ultra Men’s and Centrum Silver Ultra Men’s with the claim that they support “colon health.” Centrum’s website also makes this representation. However, the relationship between Vitamin D and colon cancer is inconclusive in light of the current body of scientific evidence, so existing knowledge does not support this claim.⁹ To the extent that this claim implies that taking Centrum can prevent colon cancer, it is a claim of disease prevention that Pfizer is not legally authorized to make. Therefore, this claim is unlawful because it is a claim of disease prevention, it lacks prior substantiation, and it is deceptive.

Pfizer’s Violations of State Consumer Protection Laws

Pfizer’s claims regarding Centrum 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, Pfizer’s misrepresentations render Centrum multivitamins misbranded in violation of state food and drug laws, such as California’s Sherman Food, Drug, and Cosmetic Law.¹⁰

⁹ K. Cooper, et al, *Chemoprevention of Colorectal Cancer: Systematic Review and Economic Evaluation*, HEALTH TECHNOL ASSESS, 2010 Jun;14(32):1-206, xiii-xiv. (though of relatively short duration of 4-7 years, two studies “addressed calcium (1000-1500 mg/day) plus vitamin D (400-1100 IU/day) in populations with no increased baseline risk of colorectal cancer,” finding “no significant effect on the relative risk of colorectal cancer.”); JoAnn E. Manson, *supra*, at 7 (Observational studies of serum vitamin D levels and colorectal cancer generally support an inverse association).

¹⁰ California Health and Safety Code § 110660 (“Any food is misbranded if its labeling is false or misleading in any particular.”).

As the manufacturer and distributor of Centrum multivitamins, Pfizer 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.¹¹

Settlement Demand

In light of the foregoing, CSPI invites Pfizer to resolve these instances of illegal and deceptive advertising in order to avoid further legal action. CSPI seeks to prevent Pfizer from making claims about its products' disease-preventative benefits, from misrepresenting the findings of Pfizer's studies, and from deceptively advertising unsubstantiated health benefits in association with Centrum multivitamins.

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

- Entry of a permanent injunction that prohibits Pfizer 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 Pfizer from making unsubstantiated representations (either expressly or implicitly) about the benefits of Centrum multivitamins.
- Entry of a permanent injunction that mandates a series of corrective advertisements to correct Pfizer's prior consumer deception with respect to the benefits of its Centrum multivitamins.
- Disgorgement of Pfizer's profits from the sale of its multivitamins since October 15, 2009, when it completed its acquisition of Wyeth.

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

Yours truly,



Stephen Gardner
Litigation Director

cc: Michael F. Jacobson, Ph.D., Executive Director
Seema Rattan, Staff Attorney

¹¹ *E.g., Aspinall v. Philip Morris Companies, Inc.*, 813 N.E.2d 476 (Mass. 2004).