



United States of America  
FEDERAL TRADE COMMISSION  
Washington, D.C. 20580

Division of Advertising Practices

Mary K. Engle  
Associate Director

March 19, 2015

John E. Villafranco, Esq.  
Kelley Drye & Warren LLP  
Washington Harbour, Suite 400  
3050 K Street, NW  
Washington, DC 20007-5108

Re: CVS Pharmacy, FTC File No. 142-3112

Dear Mr. Villafranco:

As you know, the staff of the Federal Trade Commission's Division of Advertising Practices has conducted an investigation into whether your client, CVS Pharmacy, Inc., violated Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52, in connection with the marketing of CVS Pharmacy's Advanced Eye Health.

Our inquiry focused on the claim found on product packaging that the product is "Comparable to Ongoing Study Formula in AREDS2." AREDS2 refers to a large, multi-center study conducted by the National Institutes of Health ("NIH") on age-related macular degeneration ("AMD").<sup>1</sup> The NIH conducted AREDS2 to see if adding additional ingredients to a formula tested in a previous study, the Age-Related Eye Disease Study ("AREDS"), would further improve the formulation. The results of the first study, AREDS, showed that, for those at high risk for advanced AMD, a formula containing high doses of Vitamin C, Vitamin E, zinc, and beta-carotene reduced the risk of advanced AMD by 25%. *See* For the Public: What the Age-Related Eye Disease Studies Mean for You, <https://nei.nih.gov/areds2/PatientFAQ> (last visited Mar. 2, 2015).

The subjects in AREDS2 received the ingredients from the original AREDS formulation, the standard of care for those at high risk for advanced AMD, plus: 1) 10 mg lutein and 2 mg zeaxanthin; 2) 1000 mg omega-3 fatty acids (350 mg DHA and 650 mg EPA); or 3) 10 mg lutein, 2 mg zeaxanthin, and 1000 mg omega-3 fatty acids (350 mg DHA and 650 mg EPA). A fourth group received only the original AREDS formulation, and thus served as a control for the

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<sup>1</sup> The Age-Related Eye Disease Study 2 (AREDS2) Research Group, Lutein + Zeaxanthin and Omega-3 Fatty Acids for Age-Related Macular Degeneration, *The Age-Related Eye Disease Study 2 (AREDS2) Randomized Clinical Trial*, 309 *J. Am. Med. Ass'n* No. 19 (May 15, 2013).

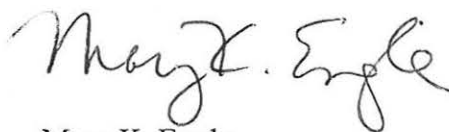
additional tested ingredients.<sup>2</sup> The results of AREDS2 showed that adding lutein, zeaxanthin, and omega-3 fatty acids to the formula had no overall effect above the AREDS ingredients on the risk of progression to advanced AMD. However, for those participants with very low levels of lutein and zeaxanthin in their diets, the addition of these ingredients to the AREDS formulation helped lower their risk of progression to advanced AMD. Further, the combination of lutein and zeaxanthin appeared to be a safe and effective alternative to beta-carotene, an ingredient that may increase the risk of lung cancer among people who smoke.<sup>3</sup>

Section 5 of the FTC Act requires that advertising claims be truthful and non-misleading. We were concerned that reasonable consumers would interpret the claim that CVS Pharmacy's Advanced Eye Health was "Comparable to Ongoing Study Formula in AREDS2" to mean that it contained the full AREDS formula. In fact, the Advanced Eye Health product does not contain Vitamin C, Vitamin E, zinc, or beta-carotene, the key ingredients studied in AREDS and also provided to virtually all AREDS2 study participants. Instead, it contains only lutein, zeaxanthin, and DHA/EPA, ingredients found to have no overall benefit above the AREDS ingredients on the risk of progression to advanced AMD.

Upon careful review of this matter, we have decided not to recommend enforcement action at this time. We considered a number of factors in reaching this decision, including CVS's voluntary agreement to remove the claim from product packaging and the relatively low sales of the product.

Our decision not to pursue enforcement action should not be construed as a determination that a violation did not occur, just as the pendency of an investigation should not be construed as a determination that a violation has occurred. The Commission reserves the right to take further action as the public interest may warrant.

Very truly yours,



Mary K. Engle  
Associate Director for Advertising Practices

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<sup>2</sup> AREDS2 at 2007. Only 19 individuals out of more than 4000 did not take Vitamins C and E, zinc, and copper, ingredients from the original AREDS formulation. Some groups received no beta-carotene and other groups received reduced amounts of zinc. *Id.*

<sup>3</sup> *Id.* at 2010-14; *see also* For the Public: What the Age-Related Eye Disease Studies Mean for You, <https://nei.nih.gov/areds2/PatientFAQ> (last visited Mar. 2, 2015).