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Via Electronic Mail

June 17, 2016

Jessica Rich, Director, Bureau of Consumer Protection
James A. Kohm, Associate Director, Division of Enforcement
Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC 20580



Re: Letter dated June 3, 2016 from Truth in Advertising, Inc. Regarding Decision and Order *In the Matter of I-Health, Inc. and Martek Biosciences Corp.*, Docket No. C-4486

Dear Ms. Rich and Mr. Kohm:

As promised, we are writing on behalf of our client DSM Nutritional Products ("DSM") to respond to the letter sent by Truth in Advertising, Inc. ("TINA") on June 3, 2016. The letter alleges that DSM is in violation of its 2014 consent order with the Federal Trade Commission (FTC) based on: (1) claims made by CVS Pharmacy ("CVS") in the labeling for its Algal-900 DHA supplement; (2) claims made by DSM in the marketing for its reformulated BrainStrong Memory Support supplement; and (3) the fact that Wal-Mart continues to list the discontinued BrainStrong Adult product on its website. These assertions are baseless.

As explained in more detail below, DSM is in compliance with the 2014 consent order. As required by the consent order, DSM revised the labels and ceased making the claims "improves memory in adults" and "prevents cognitive decline in adults" for its BrainStrong Adult product. DSM made these label changes in a timely manner and replaced the claims with appropriate and properly substantiated structure/function claims. While CVS was not a party to the consent decree, CVS revised the label and claims for its Algal-900 DHA dietary supplement and ceased making similar claims to those outlined in the DSM consent decree thereafter. Further, DSM made the decision to discontinue BrainStrong Adult DHA dietary supplement and replaced it with BrainStrong Memory Support, a Gingko biloba and choline-containing dietary supplement. BrainStrong Memory does not bear any explicit or implied claims that it "improves memory" or "prevents cognitive decline." The product does bear appropriately tailored structure/function claims that are substantiated by competent and reliable scientific evidence in accordance with the consent decree.

We suspect TINA is trying to engage the FTC in this matter as a result of the inability of another consumer advocacy group, the Center for Science in the Public Interest (CSPI), to reach acceptable terms in one of the three class action lawsuits that DSM and CVS are defending. One lawsuit was filed before the FTC initiated its investigation while the other two law suits were filed after the FTC announced the consent decree. CSPI filed one of the latter lawsuits on behalf of its client. While the

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parties have reached preliminary terms for settlement in two of the lawsuits, neither involving CSPI, CSPI has raised objections to the proposed settlement terms, particularly the type of structure/function claims that could appear on the product. TINA has joined CSPI in opposition to the preliminary approval of settlement in one of those cases.

We are providing the information in this letter so the FTC can have confidence that DSM is in full compliance with the consent decree. We urge the FTC to recognize it is unnecessary for it to get involved in the underlying dispute between the parties on acceptable terms for settlement of the class action lawsuits. We trust the FTC will recognize the courts are fully able to determine the appropriate terms for settlement.

Background

In August 2014, i-Health, Inc. (“i-Health”) and its then-affiliate Martek Biosciences Corp. (“Martek”) entered an administrative settlement with the FTC to conclude the FTC’s investigation of memory and cognitive-function related claims made in advertisements for the BrainStrong Adult dietary supplement.¹ The consent order covers “any dietary supplement, food, or drug promoted to prevent cognitive decline or improve memory, or containing [DHA],” excluding infant formula (the “Covered Products”). It bars claims that Covered Products prevent cognitive decline or improve memory in adults unless the claim is non-misleading and supported by human clinical testing. The consent order also prohibits claims about the health benefits, performance, safety, or effectiveness of Covered Products unless the claims are supported by competent and reliable scientific evidence. Finally, the consent order prohibits any representations that misrepresent the level of scientific support for benefits of the Covered Products.

CVS and Wal-Mart are Not Subject to DSM’s Consent Decree

The consent decree applies to “Respondents,” which is defined as including “i-Health, Inc. and Martek, and their successors and assigns.” The consent decree specifically states that DSM is a successor of Martek. In contrast, CVS and Wal-Mart are neither successors nor assigns to i-Health, Martek, or DSM.

The consent order restricts certain representations made by “Respondents and their officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, trade name, or other device.” Any representations made by CVS or Wal-Mart are not covered by this language. CVS and Wal-Mart are neither officers, agents, representatives, nor employees of DSM. The claims that appear in CVS marketing materials and product listings on Wal-Mart’s website are not representations made by DSM, either “directly” or “through” CVS and Wal-Mart. DSM has no control over the marketing or website claims made by third parties. While DSM is the supplier of the DHA ingredient contained within the CVS DHA dietary supplement, CVS and Wal-Mart are not in partnership with DSM, nor are they subsidiaries/divisions of DSM.

Further, the consent decree covers specified representations made “in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product.” DSM itself is not making any representations with respect to CVS’s Algal-900 DHA. CVS

¹ FTC Decision and Order *In the Matter of I-Health, Inc. and Martek Biosciences Corp.*, Docket No. C-4486, available at <https://www.ftc.gov/system/files/documents/cases/140821ihealthmartekdo.pdf>.

is responsible for the content of its marketing for that product. And DSM no longer manufactures, advertises, sells, distributes, or conducts any other covered activity in relation to the discontinued BrainStrong Adult product appearing on Wal-Mart's website, so it cannot be making a representation in connection with such activities. Any representations by CVS or Wal-Mart are outside the scope of the DSM consent decree. DSM cannot be held liable under the consent order for representations that it is not directly or indirectly making.

BrainStrong Memory Support Bears Appropriate Structure/Function Claims Supported by Competent and Reliable Scientific Evidence

In its letter, TINA objects to the claims made by DSM in the marketing of its BrainStrong Memory Support supplement, alleging that the claims violate the 2014 order by implying the product can "improve memory and/or prevent cognitive decline." By way of background, we note that BrainStrong Memory Support is a relatively new product. Prior to entering into the consent order with the FTC in 2014, DSM began marketing a different product, BrainStrong Memory Support, which contains Ginkgo biloba and choline, and does not contain DHA. We recognize the consent decree covers any dietary supplement promoted to prevent cognitive decline or improve memory. TINA, however, is misleadingly asserting the BrainStrong Memory Support is making the very same prohibited claims the FTC originally investigated.

Instead, DSM is making structure-function claims for BrainStrong Memory Support that are appropriate and lawful for dietary supplements and that are supported by competent and reliable scientific evidence, as defined in the consent order. Claims for BrainStrong Memory Support cited in TINA's letter include "Supporting brain health," "nourishes the brain," "designed to address the three key areas of brain health—memory, focus and mental sharpness," "gives support to your brain's communication network," "benefit from healthy blood flow and circulation to help maintain overall brain health," and "That means you can help support a higher level of productivity and focus." Each of these claims is a structure/function claim that can lawfully be made for a dietary supplement, in that it describes the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the body.²

The claims identified by TINA are substantiated. When developing the product formulation and marketing and advertising claims for BrainStrong Memory Support, DSM carefully reviewed the scientific literature on Ginkgo biloba and choline as related to memory support and focus and concluded that the claims are supported by competent and reliable scientific evidence as defined in the order.³ DSM specifically avoided claims that the product would "improve memory" and "prevent cognitive decline." TINA has offered no basis upon which to conclude the claims are not supported by the underlying scientific evidence or that the claims imply the product will "improve memory" or "prevent cognitive decline."

² 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(f).

³ See, e.g., Santos, R.F. et al., *Pharmacopsychiatry*, 2003;36:127-33; Mashayekh, A., et al., *Neuroradiology*, 2011;43:185-91; Yang G. et al., *Curr Top Med Chem*. 2016;116(5):520-8; Tan M.S. et al., *J. Alzheimers Dis*. 2015;43(2):589-603; Napryeyenko O. et al., *Arzneimittelforschung*. 2007;57(1);4-11; Poly C. et. al., *Am J Clin Nutr*. 2011 Dec; 94(6):1584-91; Knott V. et al., *Pharmacol Biochem Behav*. 2015 Apr;131:119-29; Caamaño J., et al., *Methods Find Exp Clin Pharmacol*. 1994 Apr.;16(3):211-8; Fiorvanti M. et al., *Cochrane Database Syst Rev*. 2005 Apr.;18(2):CD000269.

The Courts are Assessing a Settlement in Three Class Action Lawsuits

Prior to the initiation of the FTC nonpublic investigation, DSM was defending a lawsuit challenging the claims for BrainStrong Adult. Since 2012, a class action styled as *Jovel v. i-Health, Inc.*, has been pending in the United States District Court for the Eastern District of New York.⁴ In *Jovel*, the plaintiffs claimed that BrainStrong-brand dietary supplements, marketed by i-Health, made false and misleading memory-improvement claims. The U.S. District Court for the Eastern District of New York preliminarily approved a settlement agreement in *Jovel* on March 4, 2016.⁵ On February 1, 2016 – the very next business day after the *Jovel* settlement became public – CSPI on behalf of its client filed the *Worth* action.⁶ The *Worth* plaintiffs made essentially the same claims against CVS for the Algal-900 DHA Product as the *Jovel* plaintiffs had made regarding i-Health's BrainStrong Adult Product. On February 11, 2016, Mario Aliano filed a similar class action concerning the CVS Algal-900 DHA Product in the Circuit Court of Cook County, Illinois.⁷

Because the CVS product involved the same active ingredient and made similar claims, CVS proposed to settle *Aliano* and *Worth* on similar terms as the *Jovel* settlement the Court had preliminarily approved. *Aliano* was officially transferred in to the U.S. District Court for the Eastern District of New York on May 24, 2016, and is currently pending before Judge Frederic Block and Magistrate Judge Marilyn D. Go.⁸ CSPI and TINA have filed objections to the proposed settlement, objecting, in part, to the type of terms that the court in its preliminary order approving the *Jovel* settlement considered acceptable.

* * *

For the reasons above, we believe DSM is in full compliance with the consent order. We trust the FTC will view the TINA submission as an attempt by the *Worth* plaintiffs to do an end-run around a class action settlement CSPI declined to accept. We also trust the FTC will recognize the Eastern District of New York if fully capable of determining the appropriate terms for settlement for the three pending class action lawsuits.

Please do not hesitate to contact us with any questions.

Sincerely,



Martin J. Hahn
Partner

⁴ Case No. 1:12-cv-05614-MDG (hereafter, "Jovel Dkt.").

⁵ Jovel Dkt. 113.

⁶ See *Worth, et al. v. CVS Pharmacy, Inc.*, Case No. 2:16-cv-00498-FB-MDG (E.D.N.Y.).

⁷ *Mario Aliano, individually, and on behalf of all others similarly situated v. CVS Pharmacy, Inc.*, Case No. 2016 CH 2021.

⁸ See *Aliano*, Case No. 1:16-cv-02624-FB-MDG (E.D.N.Y.), ECF No. 32.

CC: Laura Smith, Esq., Legal Director, Truth in Advertising, Inc.
Bonnie Patten, Esq., Executive Director, Truth in Advertising, Inc.
Thomas M. Moriarty, General Counsel, CVS Health
Leon Bechet, Associate General Counsel, Wal-Mart Stores, Inc.