

BBB NATIONAL PROGRAMS

THE DIRECT SELLING SELF-REGULATORY COUNCIL

Elomir, Inc.

Case No. 139-2023

Filed: 11/29/2023

NGO Inquiry

I. Company Description

Elomir, Inc. (“Elomir” or the “Company”) is a Texas-based multi-level marketing company that sells nutritional supplements including its flagship product, Axis Klarity. The Company’s website describes Axis Klarity as an oral mouth strip made with the Company’s proprietary blend of N-acetylcysteine (“NAC”) conjugate, Thiamine Conjugate, and Curcumin Conjugate paired with diffusion technology and Cyclodextrin for optimal delivery.

II. Basis of Inquiry

The Direct Selling Self-Regulatory Council (“DSSRC”) is a national advertising self-regulation program administered by BBB National Programs. Pursuant to section V(A) of DSSRC’s Policies & Procedures, any person or legal entity may provide to DSSRC a written submission regarding any earnings claims or product claims disseminated by or on behalf of a direct selling company which such person or legal entity believes should be modified or discontinued.

In this inquiry, a non-governmental advocacy group (“NGO”) identified to DSSRC certain core product performance claims disseminated by both the Company and its salesforce members that the NGO alleged conveyed unsubstantiated health benefits. More specifically, the NGO contended that the Company and its salesforce members have been disseminating unsubstantiated health and disease-treatment claims to market Axis Klarity, including the product’s ability to bring mental clarity and focus to users as well as to treat, cure, or alleviate the symptoms of several other medical conditions, including, for example, anxiety, depression, inflammation, and diabetes.

The NGO also identified to DSSRC certain earnings claims made by both the Company and its salesforce members that the NGO contended conveyed unsubstantiated claims that overstate the amount of income that can be generally expected by salesforce members participating in the Company’s business opportunity.

A selection of representative claims identified by the NGO was set forth in DSSRC's Notice of Inquiry to the Company. Specifically, in its Notice of Inquiry, DSSRC identified the following claims to the Company as representative of the types of claims that are being disseminated by the Company and its salesforce members in connection with the marketing of Axis Klarity.

A. Product Performance Claims

- “Axis Klarity helps to promote healthy joints, a mellow mood, focus and mental clarity and gut health”
- “...many have had the chance to take their daily Axis Klarity strip for over a month. How has this product helped you and your friends and family? #mental clarity #guthealth #healthyjoints.”
- “Foremost I want to thank Elomir for not only helping me feel much better but for my son, Tey. He is my spectrum boy who has also benefited tremendously...he has been able to talk in sentence form...Today he started his school year and it was so nice not having him have a meltdown due to the change in his normal schedule.”
- “I know some that are reluctant about giving their kids a prescription. 😞 ... Its all about lack of focus, trouble in school, concentration and more”; and “... blood sugar support, cognitive support, immune support; mood support; focus and clarity; stimulant free energy; stress relief; gut health”
- “Emotional? Overwhelmed? Anxious? Foggy head? Feeling heavy?” / Image of testimonial with copy stating “the first time I took the strip was on a very emotionally charged day and honestly within 5 minutes the feeling of heaviness and overwhelm drifted away! I feel so inspired, have amazing clarity, feeling happy and my focus is zen like yet so sharp every time!”
- “When you have stomach issues from years of stress, ulcers, and GERD, you look for ways to get your supplements into your system by bypassing your tummy. I just tried @Elomir Corporate #axisklarity and I am in love! Not sure what #NAC #curcumin or #bvitaminsforenergy do for your body? You'll want to search it up! My chiropractor has had me taking these supplements for months to combat #inflammation & to help my fight off viruses. This strip is phenomenal! ❤️🌻🌟 #gastricbypasscommunity #gastricbypassjourney #weightlossjouney #bariatriclife #bariatricbabe #bariatriccommunity #healthsupplements #bounty”
- “Guess who beat DIABETES 🙌 Unexpected news from my doctor this week! He asked what did I do differently. He was amazed by what I showed him 🟡 #diabetes #beatdiabetes.”

- “What I have noticed that improved since being on Axis Klarity: better mood; better focus; better skin, no breakouts because my gut health is better; better sleep.”

B. Earnings Claims

- “Whether you want the chance to earn a little extra income to help pay your bills or build a long-term home-based business, the possibilities await you at ELOMIR.”
- “#buildingmyretirement”

DSSRC also referred the Company to additional claims archived on the NGO’s website, including claims that the Company would be paying out “multiple 7 figures [in commissions]” by the end of the month, and claims such as “[p]ay off 3 of our credit cards,” and “paid our house note.”¹

In the Notice of Inquiry, DSSRC noted that the claims identified above, and those listed on the NGO’s database, were not intended to be exhaustive but rather were illustrative of the types of core messages that are being disseminated in the marketplace by the Company and its salesforce members.

III. Company’s Position

A. Product Performance Claims

The Company took action to facilitate the removal² of the vast majority of the health-related claims identified by the NGO. The Company was successful in having at least 60 such claims removed. Also, in at least three instances where a salesforce member was unresponsive to the Company’s removal request, the Company commented directly on the social media post in question to state that such post contains unsubstantiated medical claims.

While the Company agreed to remove the vast majority of the product claims at issue in this inquiry, which it agreed conveyed improper health-related or disease treatment claims, the Company nonetheless provided DSSRC with information that the Company contended substantiated certain other health-related product claims.

¹ DSSRC referred the Company to additional product and earnings claims identified on an online database maintained by the NGO that aggregated more than 75 examples of allegedly unsubstantiated health and disease-treatment claims made about the product and more than 35 examples of allegedly improper earnings claims.

² The Company also edited several additional social media posts.

1. The Company's Substantiation

Axis Klarity is a dietary supplement comprised of a 45mg proprietary ingredient blend containing cyclodextrin, thiamine conjugate, NAC conjugate, and curcumin conjugate.³ In support of its product performance claims, the Company submitted over 30 studies, papers, and other research pertaining to each of the ingredients contained in the Company's Axis Klarity product, in addition to an ingredient study and several statements attributed to medical doctors ("M.D.s"). An overview of the substantiation provided by the Company to DSSRC is described below.

a. Cyclodextrin

With respect to product claims relating to the "belly," "better gut health," and "less bloating," the Company provided published articles from the National Library of Medicine's PubMed,⁴ Critical Review in Food Science and Nutrition,⁵ the Probiotics and Antimicrobial Proteins Journal,⁶ the European Medicines Agency,⁷ and the Institute of Human Nutrition and Food Science⁸ pertaining to the product ingredient cyclodextrin. Broadly, the cyclodextrin ingredient studies assert that cyclodextrins are prebiotic dietary fibers capable of improving the intestinal microflora, preventing gastrointestinal irritation, and increasing the bioavailability of the product ingredient curcumin.

With respect to claims regarding "cyclodextrin technology" and the statement "our conjugate formulas are water soluble and deliver optimal absorption through passive diffusion," the Company submitted published articles from Pharmacie Globale (International Journal of Comprehensive Pharmacy),⁹ Research Gate,¹⁰ the Journal of Pharmaceutical Sciences,¹¹ the Institute of Human Nutrition and Food Science,¹² and the Journal of Inclusion Phenomena and Macrocyclic Chemistry¹³ pertaining specifically to cyclodextrin technology. Elomir contended that the cyclodextrin technology studies demonstrate that cyclodextrins are routinely used as host

³ The Company provided DSSRC with the composition of its proprietary blend on a confidential basis in accordance with Section IX(D) of DSSRC's Policies and Procedures.

⁴ <https://pubmed.ncbi.nlm.nih.gov/29733482/>

⁵ <https://pubmed.ncbi.nlm.nih.gov/25764389/>

⁶ <https://link.springer.com/article/10.1007/s12602-019-09621-x>

⁷ https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-cyclodextrins-used-excipients-medicinal-products-human-use_en.pdf

⁸ <https://www.mdpi.com/2218-273X/11/3/401/htm>

⁹ https://www.researchgate.net/profile/Kumud-Padhee/publication/228712442_REVIEW_ON_SOLUBILITY_ENHANCEMENT_TECHNIQUES_FOR_HYDROPHOBIC_DRUGS/links/0fcfd51305cced347f000000/REVIEW-ON-SOLUBILITY-ENHANCEMENT-TECHNIQUES-FOR-HYDROPHOBIC-DRUGS.pdf

¹⁰ https://www.researchgate.net/publication/267381800_Cyclodextrins_-_A_Review_on_Pharmaceutical_Application_for_Drug_Deliver

¹¹ <https://onlinelibrary.wiley.com/doi/epdf/10.1021/js960213f>

¹² <https://www.mdpi.com/2218-273X/11/3/401/htm>

¹³ <https://link.springer.com/article/10.1007/s10847-017-0752-2>

complexation agents to enhance the water solubility and bioavailability of drug molecules.

b. Thiamine

With respect to claims regarding “focus and mental clarity,” “improves brain fog,” “improves memory and concentration,” and “clean energy,” the Company provided compound summaries from the National Library of Medicine’s PubChem¹⁴ and Mount Sinai,¹⁵ as well as published articles from the International Journal of Molecular Sciences,¹⁶ the Annals of the New York Academy of Sciences,¹⁷ and the Journal of Evidence-Based Integrative Medicine¹⁸ pertaining to the product ingredient thiamine. In broad terms, the thiamine summaries and ingredient studies indicate that thiamine is a B-vitamin that contributes as an enzyme cofactor to energy metabolism and brain function. The literature further asserts that thiamine deficiency has historically been associated with neurological deficits, including memory impairment demonstrated in animal studies and preclinical models.

c. N-Acetyl-L-Cysteine¹⁹

With respect to claims regarding “better gut health,” “less bloating,” and “fights free radicals and oxidative stress,” the Company submitted published articles from Alternative Medicine Review: A Journal of Clinical Therapeutic,²⁰ the Cellular and Molecular Life Sciences journal,²¹ Oxidative Medicine and Cellular Longevity,²² and Pharmacology & Therapeutics²³ pertaining to product ingredient n-acetyl-l-cysteine

¹⁴ <https://pubchem.ncbi.nlm.nih.gov/compound/Thiamine#section=Information-Sources>

¹⁵ <https://www.mountsinai.org/health-library/supplement/vitamin-b1-thiamine>

¹⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8196556/>

¹⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4846521/>

¹⁸ <https://journals.sagepub.com/doi/abs/10.1177/1533210110392941>

¹⁹ The FDA has stated that NAC is excluded from the definition of “dietary supplement” under section 201(ff)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In August 2022, the FDA issued a guidance document entitled “Policy Regarding N-acetyl-L-cysteine: Guidance for Industry,” which advised of its “intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain N-acetyl-L-cysteine (NAC) and are labeled as dietary supplements.” The enforcement discretion policy applies to products that would otherwise be lawfully classified as dietary supplements were NAC not excluded from the definition of “dietary supplement,” and does not apply to NAC containing products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or products misbranded under the FD&C Act. The Company acknowledged this guidance by submission of a document which broadly asserts that the FDA did not ban NAC as a dietary supplement and that NAC may continue to be sold and marketed in the USA as a dietary supplement. The full FDA guidance document is available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-final-guidance-enforcement-discretion-certain-nac-products>.

²⁰ <https://europepmc.org/article/med/9577247/reload=0>

²¹ <https://link.springer.com/article/10.1007/s000180300001>

²² <https://www.hindawi.com/journals/omcl/2018/2835787/#copyright>

²³ <https://www.sciencedirect.com/science/article/abs/pii/S0163725813001952>

(“NAC”). According to Elomir, the NAC ingredient studies indicate that NAC, a derivative of amino acid L-cysteine and precursor of antioxidant glutathione, has been used to modulate oxidative stress and inflammation-related conditions. To further substantiate the antioxidant abilities of glutathione, the Company provided published articles from the Central Drugs Academy²⁴ and Proceedings of the National Academy of Sciences of the United States of America.²⁵

d. Curcumin

With respect to claims regarding “improved joint mobility,” “fights free radicals and oxidative stress,” “improved immune system,” and “better mood,” the Company submitted several published sources pertaining to curcumin, in addition to a National Library of Medicine clinical trial pending result.²⁶ The sources submitted include an Academic Press textbook,²⁷ published articles from the European Journal of Nutrition,²⁸ the Centre for Human Psychopharmacology,²⁹ Frontiers in Pharmacology,³⁰ the Journal of Medicinal Food,³¹ the International Journal of Pharmaceutics,³² Critical Reviews in Food Science and Nutrition,³³ Foods,³⁴ and the Journal of Traditional and Complementary Medicine³⁵ pertaining to curcumin.

The Company maintained the research indicates that curcumin, a flavonoid derived from turmeric, promotes antioxidant, antimicrobial, and neuroprotective activities and has historically been used to relieve inflammation and treat pathological conditions. According to the Company, the submitted literature provides evidence illustrating that the efficacy of curcumin is dependent in part upon consumption in large quantities, with one promising study citing a necessary dosage range of 90-5000 mg/day to increase antioxidant capacity.³⁶

e. Supplemental Study and Statements by M.D.s

The Company submitted ingredient substantiation for the claim “promotes gut health to support your second brain.” Specifically, Elomir provided DSSRC with a

²⁴ [https://www.welltopiarx.com/download/1173/auro-glutathione/26211/the-use-of-glutathione-for-liver -pancreas -and-gut-health-cda.pdf](https://www.welltopiarx.com/download/1173/auro-glutathione/26211/the-use-of-glutathione-for-liver-pancreas-and-gut-health-cda.pdf)

²⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC53553/?page=1>

²⁶ <https://classic.clinicaltrials.gov/ct2/show/NCT04506411>

²⁷ https://www.researchgate.net/profile/Fernanda-Neutzling-Kaufmann/publication/332443578_Curcumin_in_Depressive_Disorders/links/5cd33af7458515712e9b54bb/Curcumin-in-Depressive-Disorders.pdf

²⁸ <https://pubmed.ncbi.nlm.nih.gov/35831667/>

²⁹ <https://www.mdpi.com/2072-6643/12/6/1678>

³⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7522354/#>

³¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5003001/>

³² <https://www.sciencedirect.com/science/article/abs/pii/S037851739290230Y?via%3Dihub>

³³ <https://pubmed.ncbi.nlm.nih.gov/32319320/>

³⁴ <https://pubmed.ncbi.nlm.nih.gov/29065496/>

³⁵ <https://www.sciencedirect.com/science/article/pii/S2225411016302528>

³⁶ See *supra* note 25.

published Nutrition Reviews article³⁷ and statement attributed to Rebecca A. Natrajan, M.D., asserting that the gut microbiome affects brain function.

In addition, the Company submitted ingredient substantiation to support diffusion technology and phytochemical conjugation. A statement attributed to Dr. Panian explains that the diffusion technology was developed as a solution to poor bioavailability to facilitate absorption of ingredients. With respect to phytochemical conjugation, the Company provided a statement from Edwin Hu, M.D./Ph. D., contending that water-soluble conjugating technology was developed to increase the uptake of phytochemicals into the body. The statement further maintains that ingesting a conjugate formula as opposed to a conventional form, such as “lip” or “nano,” requires less of the same ingredient due in part to absorption performance.

B. Earning Claims

The Company did not attempt to substantiate the earnings claims identified by the NGO but instead elected to edit or have removed almost all of the earnings claims identified by the NGO. In at least two instances where a salesforce member was nonresponsive to the Company’s takedown request, the Company commented on the post directly to indicate that the earning claim was unsubstantiated.

IV. Analysis

A. Product Performance Claims

Though the Federal Trade Commission (FTC) expects that advertisers have a reasonable basis for all product claims, the standard of substantiation for health-related product claims is particularly rigorous. The FTC has defined the health claim substantiation standard as requiring “competent and reliable scientific evidence” in the form of “tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; and (2) are generally accepted in the profession to yield accurate and reliable results.”³⁸ Health claim substantiation evidence must generally take the form of randomized, controlled human clinical trials (“RCT”), with animal and *in vitro* studies generally being insufficient without RCT confirmation, and anecdotal evidence being insufficient. Moreover, the evidence relied upon must be relevant to the advertised product with respect to, among other things, dosage, formulation, and method of administration. In addition, the FTC has advised in its recent Health Product Compliance Guidance that the quality of substantiation evidence far outweighs the quantity. Specifically, that, “numerous flawed and inadequate studies are unlikely to add up to competent and reliable scientific evidence sufficient to substantiate a claim.”³⁹

³⁷ <https://pubmed.ncbi.nlm.nih.gov/29701810/>

³⁸ See FTC Health Product Compliance Guidance at 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

³⁹ *Id.* at 13.

Here, DSSRC thoroughly reviewed the substantiation provided by the Company and acknowledged that the Company possessed and provided DSSRC with significant research indicating the promise or positive benefits of the individual ingredients contained in Axis Klarity. Nonetheless, DSSRC determined that the substantiation evidence submitted by the Company is insufficient to support the health-related product claims that are at issue in this inquiry.

Specifically, the research provided to DSSRC included studies on non-human subjects, including mice,⁴⁰ “various laboratory model organisms,”⁴¹ *in vitro* models,⁴² and preclinical models.⁴³ In addition, DSSRC was not persuaded that the submitted information and research, though relevant to each ingredient individually, were a good fit to support the health-related product claims made as to Axis Klarity’s 45mg proprietary ingredient blend. As noted in the FTC’s Health Product Compliance Guidance, “A common problem in the substantiation of advertising claims is that an advertiser has valid studies, but the studies don’t support the claim made in its ad. Advertisers should make sure that the research on which they rely isn’t just internally valid, but also relevant to their specific product and to the specific advertised benefit.”⁴⁴ Here, DSSRC concluded that while the Company does not publicly disclose the concentration of each individual ingredient in its proprietary blend, the curcumin studies provided to DSSRC suggest that 90-5000 mg/day, a far higher dosage than the collective 45mg in the Company’s proprietary blend, is necessary to achieve the purported benefit. Thus, the research provided of studies on non-human subjects and on curcumin individually at such high dosages is insufficient to support the health-related product claims for Axis Klarity.

Accordingly, and as noted above, DSSRC determined the Company’s efforts to remove the health-related product claims in this inquiry to be necessary and appropriate and recommended that the Company discontinue any similar claims.⁴⁵

⁴⁰ *Supra* notes 1, 22, 24.

⁴¹ *Supra* note 5.

⁴² *Supra* note 34.

⁴³ *Supra* note 14.

⁴⁴ The Health Product Compliance Guidance goes on to say “Therefore, advertisers should ask questions such as: How do the dosage and formulation of the advertised product compare to the product used in the study? Is the ingredient or combination of ingredients in the advertised product the same as what was used in the study? Is the advertised product administered in the same manner as the product in the study? How well do the outcomes tested in the study relate to the specific benefits advertised? Does the study population reflect the characteristics of the population targeted by the ad? If there are significant discrepancies between research conditions and the real-life use being promoted, advertisers must evaluate whether it is appropriate to extrapolate from the research to the claimed effect.”

⁴⁵ The Company asserted that more general claims such as “promotes gut health to support your second brain,” “improved joint mobility,” “better mood,” “focus and mental clarity,” and “improved brain fog” were supported by the substantiation submitted by the Company. For the reasons articulated above, however, DSSRC concluded that such claims should be

B. Earnings Claims

DSSRC recognized and appreciated the Company's efforts to address DSSRC's concerns by removing or significantly modifying almost all of the earnings claims brought to its attention in this inquiry. DSSRC also acknowledged that the Company removed a video from its YouTube page that DSSRC was concerned communicated that a secondary income stream could be easily generated by the typical Elomir salesforce member. DSSRC acknowledged the Company's efforts to address virtually all the earnings claims identified in this inquiry and determined them to be necessary and appropriate.

With respect to a claim that remains available on the Company's website "Earn a little extra income to help pay your bills and build a home-based business. We allow you to be your own boss and provide you with the compensation plan to help you meet your goals," DSSRC remained concerned that such claim in the context presented on the Company website reasonably conveys that the typical salesforce member of the Company may earn significant income through the Company's business opportunity and recommended that such claim be discontinued.

As DSSRC notes in its Guidance on Earnings Claims for the Direct Selling Industry, if a direct selling company does not have substantiation that an earnings claim is representative of what the audience can generally expect to achieve, the claim or post should include a clear and conspicuous disclosure communicating the generally expected results in the depicted circumstance.⁴⁶

Generally, in this scenario, discontinuance or modification of earnings claims to include a disclosure that references the amount of income that can be generally expected by the typical salesforce member would be recommended. Here, however, Elomir is a new company launched in July 2022. Due to its limited operational history, the Company has stated that it "lacks enough statistical data to prepare reliable income disclosures."⁴⁷ In the absence of such data, it is DSSRC's recommendation that the Company disable any existing, unqualified earnings claims and refrain from the dissemination of future earnings claims until it is able to qualify such claims with reliable statistical data demonstrating the amount of income that can be generally expected by the typical salesforce member.

discontinued. With respect to claims regarding "cyclodextrin technology" and the statement "our conjugate formulas are water soluble and deliver optimal absorption through passive diffusion," DSSRC concluded that the Company provided information that cyclodextrin may improve water solubility and/or bioavailability but recommended that the Company discontinue the claim that its technology provides absorption that is "optimal."

⁴⁶ DSSRC's Guidance on Earnings Claims for the Direct Selling Industry also notes, however, that "Depending on the level of success, some income claims and lifestyle claims may be so extraordinary that they cannot be effectively qualified by a disclosure of generally expected results."

⁴⁷ *Income Disclosure Statement*, Elomir,

https://cdn.raveretailer.com/34C7E8DEEF/2022/03/GSR_6228b75aab7b54776141646839146.pdf.

V. Conclusion

DSSRC determined the Company's efforts to remove the health-related product claims in this inquiry to be necessary and appropriate and recommended that the Company discontinue any similar claims.

DSSRC recognized and appreciated the Company's efforts to address DSSRC's concerns by removing or significantly modifying almost all the earnings claims brought to its attention in this inquiry. DSSRC also acknowledged that the Company removed a video from its YouTube page that DSSRC was concerned communicated that a secondary income stream could be easily generated by the typical Elomir salesforce member. DSSRC acknowledged the Company's efforts to address virtually all the earnings claims identified in this inquiry and determined them to be necessary and appropriate.

With respect to a claim that remains available on the Company's website "Earn a little extra income to help pay your bills and build a home-based business. We allow you to be your own boss and provide you with the compensation plan to help you meet your goals," DSSRC remained concerned that such claim reasonably conveys that the typical salesforce member of the Company may earn significant income through the Company's business opportunity and recommended that such claim be discontinued in the context in which the claim is presented on the website.

VI. Company Statement

Elomir, Inc. (the "Company") appreciates the DSSRC's cooperation in this process and will follow the DSSRC's recommendations. We are grateful the DSSRC recognizes the Company's ongoing good faith efforts to ensure the Company and its independent sales force maintain compliance with the Company's Policies & Procedures and regulatory standards. We understand maintaining compliant content is an ongoing process for direct sales companies and will continue to monitor our field for any non-compliant material. We appreciate the DSSRC's work and continue to welcome its guidance for self-regulation in the direct selling industry.

(Case #139-2023, Closed on 11/29/23)

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