- Vendor Privacy Program
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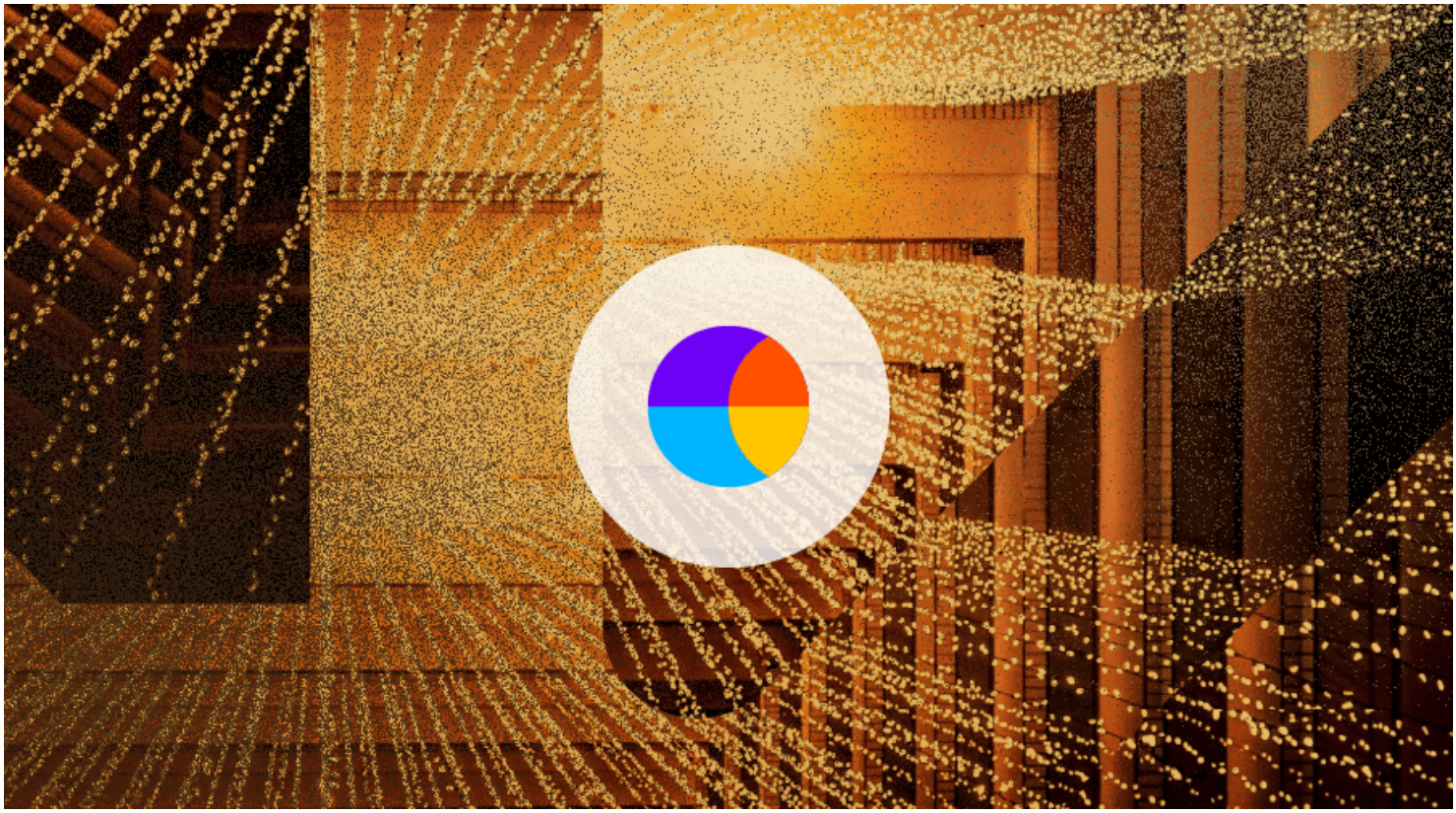

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Case #144-2023: NGO Inquiry – Modere USA, Inc.

BBB NATIONAL PROGRAMS

Direct Selling Self-Regulatory Council
Case #144-2023: NGO Inquiry – Modere USA, Inc.

Company Description

Modere USA, Inc. (“Modere” or the “Company”) is a direct selling company founded in 2012 and based in Newport Beach, California that markets health, beauty, and wellness products.

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 earning 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 instance, a non-governmental advocacy group ("NGO") identified to DSSRC certain earnings claims that the NGO believes overstated the amount of income that can be generally expected by salesforce members participating in the Company's business opportunity. The NGO also challenged product performance claims disseminated by salesforce members of the Company, and, in some instances by the Company itself, that the NGO believes embellished the efficacy of two lines of supplements named Modere Ova and Modere Ova-m (formally known collectively as Project 23).

Earnings Claims

According to the NGO, Modere and its salesforce members have communicated deceptive and unsubstantiated earnings claims to promote the business opportunity in conjunction with Project 23. DSSRC identified the following representative earnings claims in its Notice of Inquiry to the Company while also asking Modere to address additional earnings claims that were communicated in social media posts that the NGO had archived in its online database[1]:

- "…People's lives are being changed, their finances, their health, and their families…This market will be $48 Billion by 2027 (and up to $58.2B by 2030)!!…#project23".
- "…I'm also going to help a whole lot of people kick their financial struggles to the curb."
- "How I went from waiting tables all weekend to working online on my own time from magical Bali. … A friend approached me about working online and creating a freedom lifestyle for ourselves and I thought could this really be true? Do people really get to make an income online and get their time freedom back?? And it turns out it was true. … Gone are the days where I would work double shifts and burn myself out. 6 years later I am working from Bali with my partner and I no longer have to work for my vacations because I have created a passive income online and that has given me my time freedom and choice back. … If you're looking to create an income online send me a message…#multiplestreamsofincome."
- "This business has afforded me the opportunity to travel and to live my life, and to design a life that I've always wanted … If we learned anything during the lockdown, it's that working from home and actually being able to generate an income that is versatile, that is residual, that is long lasting, is important, and being able to be with your family is important, but also being able to make money and pay your bills is important too."

Product Performance Claims

The NGO maintained that since December 2022, Modere and its salesforce members were engaged in a pre-launch marketing campaign that included a number of unsubstantiated health and disease-treatment claims. DSSRC identified the following representative product performance claims in its Notice of Inquiry while also asking Modere to address what the NGO alleged were disease treatment claims that were communicated in social media posts that the NGO had archived in its online database[2]:

- "Cultural and societal views about women have made it difficult to discuss what's happening with our bodies let alone find solutions. …Whether you're dealing with unpredictable menstrual cycles, normal symptoms of PMS, occasional hot flashes, night sweats, or a low libido, you know, we often chalk our experiences up to simply being women, you know, but not anymore. Together, we're going to empower women to reinvent their hormone stories…".
- "…There is nothing else on the market that does all this without medication or hormone therapies: • painful cramping • uncomfortable bloating • embarrassing periods • tender breasts • uncontrollable mood swings • cyclical acne • hot flashes • night sweats • low or no libido • hormone-related dryness or itchiness • mental clarity • menstrual-related UTIs • iron metabolism • stress and energy • sleep health • cardiovascular health TONIGHT I'm changing my hormone story. YOU can change yours…".
- "…Project 23 takes a unique approach to hormonal health unlike anything else… If you suffer from PMS, cramps, bloating, low energy, low iron levels, UTI's, low libido, mental clarity, thyroid levels, inflammation, skin issues, hot flashes, night sweats, vaginal dryness, mood... basically all the terrible things our hormones and cycles can do to us women...THIS IS FOR YOU! …".
- "Now there's a natural way to treat the cause of all of your PMS symptoms[.] It will help to relieve/ease: -Cramps -Bloating -Support energy levels – Healthy blood flow".
- "…How does… • No more cramps • More energy • No Bloat • Better Mood • Sleeping sound • No more hot flashes • No more Night sweats • Healthy Libido • Flow not heavy • Stress & Anxiety levels down, Sound to you?? …".
- "…I've been using the menopausal formula and Alyson Layser the period formula for almost 3 weeks. I've noticed ✓ deeper sleep (& I don't have problems sleeping anyway but this is DEEP sleep) ✓ improved word retrieval less brain fog ✓ weight loss Alyson has noticed ✓ improved skin/less acne ✓ less bloating ✓ lighter period ✓ less cramping …".
- "Whether you're dealing with unpredictable menstrual cycles, terrible PMS, cramping, low libido, hormonal skin issues, occasional hot flashes or night sweats, we often just accept it as simply part of being a woman. NOT ANYMORE.…There are 2 formulas - one for menstruating women and one for post-menopausal women. This is a product category that does not exist in the marketplace yet. It is going to change lives (and marriages). … It is about damn time we supported and empowered women to reinvent their hormone stories, optimize how they experience their cycles, and their transition into menopause…".
- "…Regulate those hormones without hormone therapy??? Count me in!"
- "…What if there was a NATURAL way to treat: ✓ Heavy flow ✓ Menstrual cramps ✓ Irregular cycles ✓ Skin congestion ✓ Hot Flashes ✓ Hormones ✓ Moodiness ✓ Brain Fog ✓ Energy…#EveryWoman #ReinventYourHormoneStory #Project23…".

- "I feel I lost my Mom to menopause She started in her 40's and took hormones to help her with symptoms. She was looking for some help for a racing heart, lack of sleep and anxiety. At age 56 she developed a hormone fed breast cancer … She passed away 10 years late[r]. Now I'm in menopause and my doctor recommended hormone therapy. I'm not against the concept but, for me, it's to [sic] large of a risk … I am really excited about a new product line Project 23! A unique to hormone health unlike anything else!...".According to the NGO, claims that a product can balance and regulate hormones, as well as treat PMS, menopause, hot flashes, acne, anxiety, urinary tract infections, inflammation, and brain fog, among other things, require substantiation in the form of competent and reliable scientific evidence as well as prior approval from the U.S. Food and Drug Administration (FDA). The NGO further asserted that Modere does not possess the prerequisite substantiation in violation of Federal Trade Commission (FTC) and FDA law.

As support for this contention, the NGO called DSSRC's attention to a "Q&A" posted online, in which Modere stated the following in response to the question: "What clinical and/or testing has been done on our P23 formulas?: Project 23 delivers intuitive nutrition based on the latest available research surrounding women's health. Its comprehensive formulas feature potent, hormone-free and soy isoflavone-free ingredients extensively studied and backed by science. Several key ingredients have undergone clinical trials, however, the final Project 23 formula trials are still pending." The NGO argued that this material information was not disclosed in any of the marketing claims that the NGO identified. The NGO similarly argued that Modere and its salesforce members did not disclose in their marketing the material fact that Project 23 is not recommended for women who are on birth control, are pregnant, or are breastfeeding despite marketing claims that it is for "every women."

Company's Position

Modere informed DSSRC that Ova and Ova-m officially launched on March 10, 2023.

At the outset of the inquiry, the Company explained that its highest priority is the health and safety of its customers, and ensuring they only receive truthful and non-misleading information. Modere stated that it provides guidance and training regarding appropriate product representations and adhering to company approved statements regarding any potential product benefits as well as the Company's earnings opportunity. The Company noted that it also employs ongoing and active monitoring of claims made by its salesforce members to ensure compliance.

Modere disputed the NGO's assertion that FDA approval was required for the claims at issue and asserted that all of the social media posts communicated substantiated structure/function claims consistent with FDA's guidance and Modere's policies.

According to Modere, the FDA does not require prior approval of structure/function claims for dietary supplements. Section 201(g) of the Food, Drug and Cosmetic Act (the "FDCA"), defines "drug," in relevant part, as: "an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[3] The Company explained that dietary supplements are regulated as a subset of "foods" and maintained that Section 403(r) of the FDCA further provides that dietary supplements can make a claim that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans."[4] Modere explained that, as such, dietary supplements that claim to diagnose, cure, mitigate, treat, or prevent a "disease" would be drugs requiring FDA approval and, conversely, dietary supplements that claim to affect the structure or function of the body do not require such approval.

The Company stated that, in an effort to guide the industry, the FDA issued a regulation defining "disease" as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." 21 C.F.R. § 101.93(g)(1). The Company contended that PMS, menopause, and hormone balance do not fit that definition of "disease."[5]

Earnings Claims

Modere informed DSSRC that the Company provides clear guidance and training to its salesforce members on appropriate earnings-related claims and freely shares accurate information regarding potential earnings so that salesforce members can truthfully communicate business opportunities. All salesforce members are expressly told by the Company that they cannot make false, misleading, or unsubstantiated representations regarding potential income. The Company's policies and procedures explicitly prohibit salesforce members from making income projections, income claims, representations, or disclosing their Modere income or the income of any other Modere salesforce member. The Company also provides materials to all salesforce members explaining in clear terms the compensation plans and types of compensation available.

Furthermore, Modere stated that it releases additional training documents as well as average earning statements to provide accurate and full disclosure of the potential opportunity. According to the Company, compliance with Modere's policies and procedures, including earnings claims, are a common component of the Company's monthly calls and larger semi-annual events. In addition to training, Modere stated that it has implemented a program designed to identify noncompliant posts so that they are removed from the marketplace as quickly as possible. The Company maintained that these efforts are augmented by a third-party administered monitoring tool that scans the internet for non-compliant communications.

At Modere's request, the salesforce members responsible for the earnings claims at issue have either modified or removed all social media posts with the alleged unsupported earnings claims.

Product Performance Claims

Moderee Ova-m

The Company stated that Modere Ova-m is formulated for women in perimenopause, menopause, or post-menopause with ingredients to help relieve symptoms of menopause, including hot flashes, night sweats, vaginal dryness, and to support libido, sleep health, cognitive health, cardiovascular health, and energy levels.[6]

It was the Company's position that, consistent with the FTC's 2022 Health Product Compliance Guidance, the benefits of the ingredients in the Modere Ova-m supplement are backed by voluminous scientific research.

Estro-G

According to the Company, Ova-m is formulated with Estro-G, which is the key ingredient in the product. Estro-G is used to manage symptoms of menopause, such as hot flashes and night sweats, mood swings, occasional sleeplessness, and vaginal dryness. The company stated that Estro-G has been shown to relieve these normal menopausal symptoms in at least two double-blind, placebo-controlled clinical trials.

The first study was a 12-week clinical trial on women experiencing menopausal symptoms. The subjects were randomized to take either one Estro-G tablet twice daily or a placebo. The Kupperman Menopausal Index ("KMI") questionnaire was administered at the outset of the study, as well as at week six and week 12, and measured menopausal symptom severity, with a higher score indicative of higher severity. According to the Company, the study found that the mean KMI score in the treatment group was significantly reduced compared to the placebo group, indicating a significant improvement between groups for "insomnia" (sleeplessness), hot flashes and night sweats, melancholia (mood), and vaginal dryness.[7]

Modere also submitted a second study on the efficacy of Estro-G, which it maintained found improvement in KMI scores with Estro-G supplementation and showed improvement in menopausal hot flashes and vaginal dryness. The study was a 12-week clinical trial, in which women who were experiencing menopausal symptoms were randomized to take either an Estro-G tablet twice daily or a placebo. The KMI score was measured at baseline, week four, and week 12. According to Modere, after 12 weeks of supplementation, the mean KMI score was significantly reduced in the Estro-G group as compared to the placebo group. The Company stated that both hot flashes and vaginal dryness significantly decreased in the Estro-G group as compared to the placebo group.

Sage

According to Modere, sage (i.e., *Salvia officinalis*) has been shown to regulate neurotransmitters implicated in hot flashes as well as mood and cognition. The Company provided DSSRC with clinical data as support for statements pertaining to normal menopausal symptoms.

Modere maintained that in its study on the ingredient, menopausal women between the ages of 48 and 65 who ranked high on the Menopause Rating Scale ("MRS") (a tool to assess menopausal symptoms, including hot flashes, heart discomfort, sleep problems, and joint/muscular discomfort) were randomized to receive either the same dosage of the ingredient as contained in Ova-m or a placebo. At baseline and on day 28, participants completed the MRS, the psychological subscale with the four symptoms: depressive mood, irritability, anxiety, and physical and mental exhaustion, and the genitourinary subscale with the three symptoms: sexual problems (change in sexual desire, change in sexual activity and satisfaction), bladder problems, and vaginal dryness. In addition, participants reported scores pursuant to the Hamilton Anxiety Rating Scale, Profile of Mood State, a sleep quality questionnaire, and a Quantitative electroencephalography.

The Company stated that the study found a significant and clinically relevant hot flash reduction in the treatment group as compared to the placebo. There was also a significant difference in reduction of physical and mental exhaustion and reduction of sexual problems, including lack of sexual desire and activity (libido). Additionally, electrical brain activity in all brain areas showed statistically significant spectral power differences in the sage group compared to the placebo group for concentration, memory test, concentration performance test, reaction time test, number identification test, number connection test, and "eyes open."

Olive Fruit Extract

The Company stated that olive fruit extract (Olea europaea) is widely known for its role in supporting cardiovascular health and contains high oleic acid content, as well as polyphenols, which leads to its antioxidant properties. The Company maintained that olive fruit extract supports cardiovascular health and has antioxidant properties.

As support for the efficacy of the ingredient, Modere submitted a cross-over, placebo-controlled study testing blood samples in healthy volunteers between the ages of 20 and 45 years old which found hydroxytyrosol, the major component of olive fruit extract present in Ova-m, to benefit cardiovascular health using various blood test measures. In the study, participants consumed a hydroxytyrosol treatment or a placebo for three weeks, followed by a two-week washout interval, and then a second supplementation period. During the study, four blood samples were obtained: one at the beginning and one at the end of each supplementation period.

The Company contended that this study shows the importance of hydroxytyrosol in cardiovascular health and protecting from oxidative stress. More specifically, Modere stated that the study indicated that oxidized low-density lipoprotein ("LDL" or "bad cholesterol") values, as well as oxidized LDL to total LDL-cholesterol ratio was significantly improved in those who consumed hydroxytyrosol as compared to the placebo. Moreover, the Company noted that aryl esterase activity, which defends against cardiovascular disease and protects lipoproteins from oxidation, was significantly greater during hydroxytyrosol supplementation than placebo supplementation. Finally, soluble vascular cell adhesion molecule 1 ("sVCAM-1") levels were significantly lower during treatment supplementation than placebo supplementation. Modere further explained that sVCAM-1 is a biomarker that is involved in inflammation and cardiac remodeling, so a lower value means less inflammation.

Modere Ova

The Company informed DSSRC that Modere Ova is formulated for women over 18 who menstruate regularly with ingredients that help relieve symptoms typically associated with the menstrual cycle. Modere Ova contains three "phases" – RELEASE, RENEW, and BALANCE – packaged in a single blister pack that informs women when to take each phase to align with a woman's individual menstrual cycle, up to 32 days.[8] Modere explained that Ova contains several vitamins and minerals that are essential to everyday health and wellness, including niacinamide, copper, iron, and iodine. According to the Company, when these ingredients are taken together they act to support hormone health, energy levels, and overall wellbeing. The Company stated that the individual roles of each ingredient are backed by science and well understood by consumers.

Modere provided DSSRC with several clinical studies that it maintained demonstrated that the ingredients in Ova provide several health-related benefits.

RELEASE

Clove Flower Bud Extract

Modere explained that Clove flower bud extract is present in the Release phase of Ova to promote antioxidant activity, detoxification and to support liver health. The Company provided one study to DSSRC which found that the chemical hexanal was completely oxidized to hexanoic acid after 30 days in a control group; but when clove buds at various concentrations were present, the hexanal oxidation was inhibited by almost 100% for 30 days. As such, it was Modere's position that the study indicated that clove buds demonstrate antioxidant activity by inhibiting oxidation in chemical compounds.

Moreover, Modere asserted that not only do clove buds support antioxidant activity, but they also have been found to promote detoxification and liver health and that clove buds may work by modulating acetaldehyde levels, which is a metabolite of alcohol. As proof of this contention, the Company submitted a randomized double-blinded placebo-controlled crossover study in which healthy adults with a history of hangovers between the ages of 25 and 55 years old were randomized to receive alcohol along with either clove bud extract or a placebo.

As per the study protocol, after the baseline visit, participants visited at two-week intervals, and at each visit were given each treatment in a crossover fashion. Subjects then consumed alcohol for four hours and were allowed to sleep for seven hours. A hangover severity assessment tool was used 14 hours after alcohol consumption, blood samples were obtained after 0.5, 2, 4, and 12-hours post alcohol consumption, and blood sugar, blood pressure, and heartbeat measurements were obtained at 0 and 12-hours post alcohol consumption. According to the study administrators, the decrease in blood acetaldehyde concentrations with clove bud treatment was significantly faster compared to the placebo. Thus, Modere contended, clove bud administration reduced the extent of lipid peroxidation by 25% and helped it remain in a normal range following alcohol ingestion and maintained baseline 8-isoprostane levels, an oxidative stress marker formed by lipid peroxidation.

Further, according to Modere, the study also determined that clove bud treatment significantly inhibited depletion of SOD and GSH, two critical antioxidant enzymes, and inhibited the elevation of inflammatory markers, which resulted in the mean overall hangover severity score being significantly lower in the clove bud group than in the placebo group.

Based on the foregoing, the Company contended that this study also showed that clove bud is an effective antioxidant and can also help support liver health and detoxification.

Niacinamide

Modere informed DSSRC that niacinamide is present in the Release phase of Ova. Modere stated that all tissues in the body convert absorbed niacin ("niacinamide" – also known as vitamin B3) into its metabolically active form (i.e., the coenzyme nicotinamide adenine dinucleotide), which is required to catalyze over 400 enzymes in the body.[9] The Company maintained that this coenzyme is predominantly involved in reactions that transfer the energy in carbohydrates, fats, and proteins to adenosine triphosphate ("ATP"), which is the cell's primary energy currency. According to the Company this means that niacinamide helps with cellular energy and energy metabolism. In addition to its role in energy production, the Company argued that niacinamide also improves circulation and supports healthy blood flow[10] which are both important to menstruating women.

Copper

According to Modere, copper is an essential mineral that is a cofactor for several enzymes ("cuproenzymes") involved in energy production, iron metabolism, neuropeptide activation, and more. One cuproenzyme is ceruloplasmin, which plays a role in iron metabolism and carries more than 95% of the total copper in healthy human plasma. Thus, Modere asserted, copper supports energy levels as well as iron metabolism which is particularly important for menstruating women.[11]

RENEW

Theacrine

The Company informed DSSRC that theacrine is a naturally occurring alkaloid that supports energy levels and is present in the Renew phase of Ova.

Modere provided DSSRC with one study in which participants were randomized to take either the same dosage of theacrine that is present in Ova or a placebo in a crossover fashion, with one week separating the two test groups. Subjects completed a Visual Analogue Scale ("VAS") before taking theacrine, and again after ingestion of theacrine at the 1, 2, and 3-hour marks. Resting heart rate and blood pressure was also assessed prior to ingestion, and again every 30 minutes after ingestion for 180 minutes. Results showed that there were significant benefits for energy and fatigue in the treatment group as compared to the placebo group. Additionally, according to Modere, the study concluded that participants who ingested theacrine reported an increased libido. Accordingly, the Company maintained that the study provides the basis for its position that theacrine supports energy levels and a healthy libido.

Iodine

According to the Company, iodine is present in the Renew phase of Ova and is a trace element that is an essential component of the thyroid hormones thyroxine ("T4") and triiodothyronine ("T3"). Modere stated that thyroid function is primarily regulated by the thyroid-stimulating hormone ("TSH"), and TSH secretion increases uptake of iodine and accelerates the synthesis and release of T3 and T4. Thus, the Company explained, in the absence of sufficient iodine, TSH levels may remain elevated, which may lead to an enlargement of the thyroid gland as the body is trying to trap more iodine and produce thyroid hormones. The Company maintained that not only is iodine crucial for thyroid health but, because the thyroid plays an important role in metabolism, iodine also regulates the conversion of energy obtained from food into cellular energy.[12]

Iron

Modere explained that iron is present in the Renew phase of Ova and is an essential component of hemoglobin, which are red blood cells that transfer oxygen from the lungs to the tissues.[13] The Company stated that iron is also a component of another protein (myoglobin) that provides oxygen to the body, which is important for energy, and supports muscle metabolism and healthy connective tissue and is necessary for cellular functioning and synthesis of some hormones. The Company also noted that women with heavy menstrual bleeding are at an increased risk of an iron deficiency. According to Modere, the presence of iron in Ova is important for supporting energy levels and overall cellular functioning and wellness.

BALANCE

Chaste Tree Berry Extract

Modere stated that chaste tree berry extract (i.e., Vitex agnus-castus) contains flavonoids and similar compounds to help alleviate symptoms that may occur during the menstrual cycle such as abdominal cramps, bloating, breast tenderness, and mood swings. The Company submitted two studies to DSSRC which it maintained demonstrated that chaste tree berry extract reduces PMS symptoms.

The first study was a double-blind, placebo-controlled crossover study, in which women of child-bearing age (mean age 30) with normal menstrual cycles were randomized to receive either a daily dosage of chaste tree berry extract, similar to what is found in Ova, or a placebo. All patients answered a self-assessment questionnaire about six symptoms during the premenstrual period before the study: headache, nervousness, restlessness, depression, breast swelling and pain, bloating, and tympani -- using a VAS ranging from 0 (no symptoms) to 10 (unbearable). They were then instructed to supplement with either the treatment or placebo from the sixth day prior to menstruation until menstruation for six consecutive cycles, mirroring the ingestion of the ingredient in Ova during the Ova Balance phase. After six menstrual cycles patients filled out the second questionnaire and self-assessment. The study found greater reductions in headaches, nervousness, restlessness, depression, breast swelling and pain, bloating, and tympani compared to the control.

The second study was another double-blind placebo-controlled study on women with PMS. According to the Company, this study also found that the consumption of a dosage of chaste tree berry extract similar to the contained in Ova, significantly improved PMS symptoms compared to the placebo based on the VAS ratings scale including the symptoms of breast fullness, mood alteration, and irritability.

Extramel (Melon Fruit Juice Concentrate)

Based upon information provided by the Company, Extramel is a proprietary freeze-dried melon juice concentrate containing high levels of Superoxide dismutase ("SOD" - an antioxidant enzyme) as well as other antioxidants and is used in the Balance phase of Ova to reduce occasional stress.

As support for the ingredient's efficacy, Modere submitted a double-blind, placebo-controlled study which assessed the effectiveness of Extramel for stress in healthy participants. 70 volunteers between the ages of 30 and 55 years old were randomized to receive either Extramel or a placebo for 28 days. Four validated scales were used to measure stress and its impact on quality of life and sleep. The study found that participants in the Extramel group had a lower perceived stress and a higher cognitive concentration and quality of life at the end of the study than the participants in the placebo group. Modere noted that those in the Extramel group were also less irritable than those in the placebo group. According to Modere, this study demonstrated the efficacy of Extramel in improving perceived stress levels and mental clarity.

Zinc

Modere stated that healthy levels of zinc are present in the Balance phase of Ova and is important for maintaining healthy skin. The Company provided DSSRC with one study that measured the effect of zinc on acne. As per the study protocol, patients with inflammatory acne were randomized to receive either elemental zinc or a placebo. Patients were examined for inflammatory score prior to supplementation, and again after one and two months of treatment. Inflammatory score was measured using the number and severity of lesions counted on the face, back, and chest. After two months of supplementation, inflammatory scores were significantly lower in the treatment group compared to the placebo. The Company confirmed that the amount of zinc administered in the study was consistent with the amount of zinc present in Ova.

A second study was provided to DSSRC and aimed to explore the effect zinc had on a strain of acne. In this study, thirty patients with inflammatory face acne received the same amount of zinc administered in the first zinc study for two months. Inflammatory lesions on the face were numbered at baseline, day 30, and day 60. The Company stated that the study data showed that there was a significant reduction in inflammatory lesions at day 30 and even more reduction in inflammatory lesions at day 60.

Modere provided DSSRC with a third study indicating that the absorption of zinc from zinc oxide was 49.9%, and the absorption from zinc gluconate was 60.9%. The Company maintained that the findings in this study demonstrate that the elemental zinc absorbed by subjects in the two zinc studies is equivalent to the elemental zinc absorbed by consumers taking Ova.

Levagen

Modere stated that Palmitoylethanolamide ("PEA"), the main component of Levagen, is an endocannabinoid-like bioactive lipid mediator[14] and that Levagen is present in the Balance phase of Ova. The Company noted that PEA is found in all tissues including the brain and is multi-faceted due to its unique mechanisms of action that affect multiple pathways, primarily targeting the nuclear receptor peroxisome proliferator-activated alpha, as well as some G-protein coupled receptors (cannabinoid receptors).

The Company provided DSSRC with a study of 125 participants over the age of 18 with a disturbed sleeping pattern that were randomly allocated to take either placebo or PEA in the amount present in Ova. A sleep diary and sleep monitor were worn at baseline, day 5, and weeks 2, 4, and 8. Various sleep questionnaires were also completed on day 5 and weeks 2, 4, and 8. Modere explained that the study analysis found that there was a significant reduction in sleep onset latency time in the PEA group as compared to the placebo group.

It was Modere's position that this study demonstrated that Levagen can help promote better sleep through interaction with the endocannabinoid system.

Black Pepper Fruit Extract (Piperine)

According to Modere, black pepper extract ("piperine") enhances the absorption of key vitamins and minerals necessary during the menstrual cycle. The Company informed DSSRC that black pepper extract is present in the Balance phase and is used to enhance the absorption of key nutrients during the menstrual cycle.

As support, the Company provided DSSRC with a study showing that the amount of piperine in Ova significantly enhances the bioavailability of coenzyme Q10 as compared to placebo.

Modere also maintained that black pepper extract improves the absorption of other vitamins and minerals and submitted a study as support for its position that black pepper extract has a thermogenic action in the epithelial cells of the small intestine, which acts as a thermonutrient that allows for increased absorption and bioavailability of nutrients.

Analysis

DSSRC appreciated the good faith efforts of Modere to immediately remove and/or modify the social media posts brought to its attention during the inquiry. The social media posts at issue were part of a pre-launch for a line of supplements called Ova and Ova-m formally known, collectively, as "Project 23." In total, the Company removed or modified well over 200 of the social media posts brought to its attention.

Earnings Claims

Shortly after it received DSSRC's Notice of Inquiry, the Company contacted the individuals responsible for the social media posts and facilitated the removal of all of the earnings claims at issue in this inquiry, completing a process that it maintained was implemented before it became aware of the DSSRC inquiry. DSSRC expressed its appreciation to Modere and determined the Company's actions to be necessary and appropriate.

As a general principle, DSSRC cautions direct selling companies and their independent salesforce members against the use of any words or images communicating that a direct selling business opportunity will result in earnings beyond what can be generally expected by the typical salesforce member in the depicted circumstances (e.g., modest or supplemental income).[15]

While DSSRC will evaluate any claim based upon the context in which the claim appears and the potential net impression of such claim to the audience, some words and phrases are prohibited when made to a general audience of prospective or current salesforce members. Such words and phrases include statements such as "quit your job," "be set for life," "make more money than you ever have imagined or thought possible," "unlimited income," "full-time income," "replacement income," "career-level income," or any substantially similar statements or representations. Other terms, such as "passive income" and "residual income," are prohibited when they convey that income can be continuously earned by salesforce members with little or no ongoing effort. Some words or phrases carry a particularly high risk of being misleading to consumers when communicated in a general context. Such words and phrases include but are not limited to "financial freedom," and "time freedom."[16]

Product Performance Claims

Although Modere was successful in removing or modifying a significant number of social media posts and claims that were the subject of this inquiry in the spirit of voluntary self-regulation, the Company reserved its right to disseminate what it considered to be permissible structure-function and general efficacy claims for Ova and Ova-m based upon its testing data. Conversely, the NGO alleged that Modere and its salesforce members were communicating inappropriate and unsupported health claims that required FDA approval and that the representations would not be considered permissible structure function claims in the context in which they were communicated.

DSSRC notes that the National Advertising Division ("NAD"), a sister self-regulation program also administered by BBB National Programs, generally does not make FDA regulatory distinctions between structure/function and disease claims, and instead examines the messages reasonably conveyed by the advertising as a whole and determines whether the submitted evidence supports those messages.[17] Accordingly, DSSRC aims to align its oversight of health claims in the direct selling industry with that of NAD to ensure a consistent and uniform self-regulatory environment for the advertising industry.

The Company did not provide testing on the Ova or Ova-m products themselves and instead relied on testing conducted on the products' ingredients at the same or a similar dosage level to the amount of those ingredients as contained in the two products. As has been noted in previous self-regulatory inquiries, the omission of testing on the product itself is not a fatal flaw in the marketer's evidentiary support for its advertising claims. As NAD has concluded in past cases involving individual ingredient testing, so long as the marketer can

demonstrate that the ingredient testing was reliably conducted using a dosage of the ingredient that is the same or substantially similar to the dosage of that ingredient as is contained in the advertised product, testing of individual product ingredients may be sufficient to support claims of general product efficacy.[18]

As noted above, although the Company did remove and/or modify the social media posts highlighted by DSSRC during this inquiry, it continued to assert that it possessed a reasonable basis for several substantive claims regarding the efficacy of the ingredients contained in Ova and Ova-m. Accordingly, because the Company did not commit to permanently discontinuing specific representations regarding the product's efficacy in future advertising, DSSRC continued its assessment of the appropriateness of such representations based upon the evidence provided by the Company in this inquiry.[19]

Modere Ova-m

Reduction of Hot Flashes and Night Sweats

Hot flashes are temporally sensations of heat mainly experienced by postmenopausal women and involve sweating, the sensation of heat, palpitations, anxiety, and irritability. This phenomenon results from dilating skin vessels and a consequent decrease in core body temperature.[20]

Modere provided two studies to support the claim that Ova-m is effective in reducing hot flashes and night sweats. Both of the studies were randomized, double-blind, placebo-controlled studies that examined the effectiveness and safety of Estro-G on pre, peri, and post-menopausal women.

The results of the first 12-week study provided by Modere indicated that hot flash scores in the treatment group were significantly reduced and that the difference in scores between the placebo and treatment groups were statistically significant. The results of this study were corroborated by a second study (also a 12-week study) that showed a statistically significant improvement in hot flashes as compared with the placebo group.

In both studies the results were aggregated using the KPI index, a widely accepted instrument used to evaluate menopause symptoms and DSSRC confirmed that the studies evaluated Estro-G at a dosage level which is identical to the amount of Estro-G that is present in Modere Ova-m.

Based upon the results of the two studies, DSSRC determined that Modere provided a reasonable basis for the general claim that the ingredients contained in Ova-m are effective in reducing hot flashes and reducing night sweats.

Reduction of Vaginal Dryness

DSSRC also concluded that the results of the two Estro-G studies provided adequate support for the Company's position that Ova-m reduces vaginal dryness. The two studies (i.e., evaluating Estro-G at a dosage level identical to the amount present in Modere Ova-m) measured vaginal dryness using the KMI Index. Vaginal dryness was added to the primary outcome measures as it is a common symptom experienced by postmenopausal women.[21]

In the first study, the mean score for vaginal dryness significantly decreased in the treatment group at week six and at week 12 ($p < 0.01$) compared with that of the placebo group. The study administrators confirmed that the change was statistically significant between the treatment and placebo groups.

Similarly, in the second study, significant improvement was found in the mean vaginal dryness score. The improvement in vaginal dryness scores between the baseline and week 12 scores for the treatment group was significantly greater than the baseline comparison with the 12-week score in the control group and the improvement between the two groups was statistically significant.

DSSRC determined that the two studies submitted by Modere provided a reasonable basis for its claim that Ova-m can reduce vaginal dryness.

Improved Sleep Health

Both of the abovementioned studies also assessed how administration of Estro-G changes the sleeping behavior of pre-, peri-, and post-menopausal women. The first study concluded that "a 12-week treatment with EstroG-100 showed a statistically significant improvement in the various menopausal symptoms such as… insomnia."

The second study also measured insomnia in both the treatment and control groups and found that the mean insomnia (i.e., trouble sleeping) score was significantly reduced in the Estro-G group from baseline at both the week 4 and week 12 measurement intervals.

DSSRC determined that the two studies provided adequate support for claims that Ova-m will result in improved sleep health.

Mood Support and *Energy support*

The same two studies on Estro-G referenced in the above sections of this analysis further demonstrated that the ingredient has a significant impact on energy, mood, and temperament.

In the first study, melancholia and fatigue were two of the primary endpoint symptoms assessed as part of the subjects' KMI index scores. The study results indicated that the mean scores for melancholia and fatigue (also described as "tired feelings") were significantly lower in the Estro-G group at weeks six and 12 compared with baseline and that the improvement of the individual symptoms were significant between the groups at weeks six and week 12 of the study.

In addition, with respect to melancholia, in the second study the KMI score was significantly reduced in the Estro-G group at baseline to week four and at week 12. The improvement at week 12 in the Estro-G group was significant between the Estro-G group and placebo group. Similarly, significant improvement was found in the mean fatigue scores in the second study and the improvement between the two groups was statistically significant.

As noted earlier, both studies tested the Estro-G ingredient at the identical level at which it is present in Ova-M.

As such, DSSRC concluded that Modere provided a reasonable basis to support its position that the ingredients in Ova-m provide mood and energy support.

Libido Support

The Company relied on testing conducted on the sage extract ingredient to support a representation that Ova-m supports libido. More specifically, the double-blind, randomized placebo-controlled study assessed the effectiveness of Salvia officinalis (commonly referred to as sage) in the same amount that is present in Ova-m.

Over the treatment period, the treatment groups' scores indicated a significant difference ($p < 0.05$) in the reduction of the symptoms of hot flashes, physical and mental exhaustion, and sexual problems (changes in sexual desire, in sexual activity and satisfaction).

These results were consistent with a recently published double-blind randomized controlled clinical trial of 66 postmenopausal women complaining of menopausal symptoms who were divided into two groups of intervention and control, respectively. The intervention group received a dosage of salvia officinalis that is almost identical to the amount of sage extract present in Ova-M, while the control group received placebo tablets. According to the paired *t*-test, the mean score of sexual desire and satisfaction significantly improved in the intervention group ($P < 0.05$) following the conclusion of the three-month intervention period.

Accordingly, DSSRC agreed with Modere that the Company possessed a reasonable basis for its assertion that ingredients in Ova-m have a positive impact on libido.

Cognitive Health Support

Cognitive health is an important component of brain health and refers to the ability to clearly think, learn, and remember, and encompasses processes associated with attention, memory, judgment and evaluation, reasoning, problem solving, and decision making.

DSSRC agreed with Modere that its study (referred to in the previous section of this analysis) provided a reasonable basis for its assertion that sage extract supports cognitive health. More specifically, the study results indicated that electrical brain activity in all brain areas showed statistically significant spectral power differences in the sage extract group compared to the placebo group for concentration, memory test, concentration performance test, reaction time test, number identification test, number connection test, and "eyes open."[22]

The results of the study appear to be consistent with previous in-vivo and in-vitro research assessing the cognitive benefits of sage extract. For example, in a 2005 randomized, double-blind, placebo-controlled, crossover clinical trial, 30 young healthy volunteers received a single dose of one of two dosages of sage extract or placebo, each dosage provided on three different days and separated by 7-day intervals. Participants took part in the experimental test consisting of a set of four cognitive and psychomotor tasks. On the basis of these results, test administrators concluded that single doses of sage extract can improve cognitive performance and mood in healthy young volunteers.

DSSRC concluded that Modere demonstrated a clear link between the dosage of sage extract in Ova-m and cognitive well-being.

Protect cells from oxidative stress and supports cardiovascular health

While sage extract is also known to contain compounds with potential antioxidant properties that can help neutralize free radicals in the body and reduce oxidative stress[23], the Company pointed to its research on olive fruit extract as providing the most compelling basis for its position that ingredients in Ova-m provide an antioxidant benefit and contribute to cardiovascular health.

Generally, olive fruit extract is known for its potential to protect cells from oxidative stress due to its high content of bioactive compounds such as polyphenols. These polyphenols (particularly hydroxytrosol and oleuropein) can help neutralize free radicals in the body. Modere provided evidence showing that hydroxytrosol, a major phenolic compound in olive oil, is prominent in Ova-m and that its role within the body is well established and supported by scientific and clinical research. As noted by the Company, the FDA has acknowledged the significance of oleic acid in cardiovascular health and has issued a qualified health claim addressing oleic acid's potential role in reducing the risk of coronary artery disease.

DSSRC concluded that the Company's testing supported the ingredient's antioxidant capabilities. The cross-over study conducted on healthy individuals aged 20-45 wherein blood samples were analyzed under placebo-controlled conditions found that hydroxytrosol conferred cardiovascular benefits through various blood test metrics and demonstrated significant improvements in individuals who consumed hydroxytrosol over a three-week period, followed by a two-week interval, and a subsequent intervention period.[24] Notably, the study indicated a significant increase in arylesterase activity during the hydroxytrosol supplementation period, a factor that plays a defensive role in cardiovascular health by protecting lipoproteins from oxidation.

Lastly, one biomarker associated with inflammation in cardiac remodeling (i.e., sVCAM-1) was significantly lower during the hydroxytrosol supplementation phase suggesting a reduction in inflammation. In sum, DSSRC determined that the study underscored the significance of hydroxytrosol, a key component of olive fruit extract contained in Ova-m in promoting cardiovascular health and shielding against oxidative stress.

Modere Ova

Ova is marketed as a natural supplement that features three unique formulas to target a woman's period, pre-ovulation, and post ovulation phases in one package. The Company indicated to DSSRC that it possessed the appropriate evidence to support the following general representations:

Reduce the Discomfort associated with PMS: Mood swings, abdominal cramps, bloating, breast tenderness

As support for statements regarding mood swings, abdominal cramps, bloating and breast tenderness, the Company principally relied on two studies on the chaste tree berry extract ingredient (i.e., vitex agnus-castus) in Ova to support its position that the product helps alleviate symptoms that may occur during the menstrual cycle such as abdominal cramps, bloating, breast tenderness, and mood swings.

The first study investigated the therapeutic effect of vitex agnus castus on women who had PMS, in comparison with placebo. In this randomized, placebo-controlled, double-blind study, 128 women suffering from PMS were evaluated regarding the severity of headaches, anger, irritability, depression, breast fullness, and bloating and tympani during the premenstrual period before the study. Following six menstrual cycles, participants completed a second questionnaire and self-assessment. The research revealed significant differences in the occurrence and severity of headaches, anxiety, unease, mood changes, breast discomfort, and abdominal bloating compared to the control group.

In the second study, the main efficacy variable prospectively sought in the protocol was the change from baseline to end point in the combined scores of the six self-assessment items (irritability, mood alteration, anger, headache, bloating, and breast fullness). According to the results, patients who received vitex agnus castus had a significant improvement in the combined symptoms compared with those taking a placebo. The self-assessment scores were corroborated by the physicians' own evaluation of the clinical global impression scale used to evaluate the effectiveness of the treatment.

Although DSSRC determined that the two studies provided a reasonable basis for claims regarding the reduction of mood swings and breast tenderness, it concluded that the evidence did not provide reliable data to support claims of a reduction in abdominal cramps and bloating.

As noted in the second study, five of the six self-assessment items indicated significant superiority for vitex agnus castus regarding irritability, mood alteration, anger, headache, and breast fullness, however, other symptoms including bloating were unaffected by the treatment. As such, the results of the second study appeared to contradict the conclusion reached in the first study, which found a significant difference in abdominal bloating compared to the control group in that study.

As noted in the FTC's Health Products Compliance Guidance, when evaluating claim substantiation, the surrounding body of evidence will have a significant impact on the type, amount, and quality of evidence required to substantiate a claim, particularly when there is some relevant research that fails to support the claimed benefit.[25] The totality of the evidence also will affect how a claim is presented – that is, how carefully the claim is qualified to reflect accurately the strength of the evidence. If a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive.[26]

Based upon the results of the submitted testing, DSSRC determined that the statement that Ova can reduce bloating was not adequately supported.

With respect to claims of reducing abdominal cramps, neither study indicated that abdominal cramps were specifically examined. In the first study, all patients answered to a self-assessment questionnaire specifically about their headache, anger, irritability, depression, breast fullness, and bloating and tympani during the premenstrual period before the study. As noted above, abdominal cramping was not one of the six conditions assessed in the second study.

In the absence of reliable evidence showing that the ingredients contained in Ova are effective in reducing abdominal cramps, DSSRC concluded that this specific aspect of the claim was not adequately supported.

Reduces occasional stress and supports mental clarity

Modere relied on testing of the Extramel ingredient in Ova as support for statements that the product reduces occasional stress and supports mental clarity.

The double-blind, placebo-controlled study provided by the Company demonstrated that supplementation with Extramel significantly improved signs and symptoms of stress and fatigue linked to performance, physical, cognitive, and behavioral symptoms following supplementation of the proprietary ingredient. According to the test administrators, after the 7^{th} day of treatment with an identical amount of the ingredient as contained in Ova, perceived stress decreased with a statistically significant improvement of 12% ($p = 0.01$) in the treatment group compared to the placebo group and indicated a global decrease of 30%. Accordingly, it was concluded that an oral supplementation with Extramel, which is known to have an antioxidant activity on the cellular level and fighting against oxidative stress, had a positive effect on several signs and symptoms of perceived stress and fatigue and particularly perceived stress, quality of life (physical and mental health condition), and some aspects of neurobehaviour.

The results of the above study are consistent with conclusions reached in a more recent randomized, double-blind, placebo-controlled trial involving Extramel that was performed on 61 people, divided into an active supplement group and placebo for 12 weeks. Four psychometric scales were used to assess stress and fatigue and the study's findings revealed that incorporating Extramel resulted in a notable reduction in perceived stress compared to the placebo. Additionally, it was concluded that Extramel supplementation resulted in an enhancement of the quality of life and a reduction in both physical and mental fatigue. The data between groups was statistically significant on Day 28 of the test for both stress reduction and mental fatigue. DSSRC also noted that the supplementation of Extramel in this study was identical to the amount of the proprietary ingredient as present in Ova.

Based upon the results of the two studies, DSSRC determined that Modere provided a reasonable basis for a statement that the Extramel ingredient in Ova reduces stress and supports mental clarity.

Supports healthy blood flow

The Company relied on the presence of niacinamide in Ova as support for its claim that Ova is formulated with ingredients support healthy blood flow. Niacinamide is a derivative of niacin and a form of vitamin B3 which is an essential nutrient for the body. It is water-soluble, has anti-inflammatory properties and plays a crucial role in several biological processes including the metabolism of fats, proteins, and carbohydrates.

DSSRC confirmed that the amount of niacinamide in Ova provides more than the recommended daily value of the ingredient according to the FDA and improves circulation (i.e., "blood flow").[27] Further, the European Food Safety Authority ("EFSA") has stated that maintenance of normal blood flow is a beneficial physiological effect of niacin and for products with at least 100% of the recommended daily allowance of niacin a claim that the ingredient is "important for vascular blood flow" is appropriate.

Based upon the information provided by the Company DSSRC determined that Modere provided a reasonable basis for the claim that ingredients in Ova support healthy blood flow.

Supports iron metabolism

Modere's support for this claim was based upon the presence of copper in the Ova formula and predicated its support on the FDA's recommended daily value of the ingredient. However, unlike the presence of niacin in Ova, the copper in Ova is well below the recommended daily value for the ingredient (i.e., 900 mcg). Although it may be true that, broadly speaking, copper is essential to effectuate and maintain many important bodily functions including the nervous and immune systems, the pertinent question for DSSRC is whether the amount of copper in Ova has any demonstrable impact on the absorption, transport, or utilization of iron in humans.

In the absence of any testing conducted to assess the copper content in Ova and in the omission of information regarding the potential impact of the presence of this ingredient in Ova on iron metabolism, particularly in a quantity of the ingredient similar to that contained in

the subject product, DSSRC concluded that there was insufficient evidence provided to support a claim that ingredients in Ova support iron metabolism.

"Supports hormones" and "Supports thyroid health"

Modere's claim is based upon the presence of iodine in Ova. DSSRC confirmed that the amount of iodine present in the product provides almost 100% of the daily value recommended by the FDA. According to the National Institutes of Health, iodine is an essential component of the thyroid hormones thyroxine (T4) and triiodothyronine (T3) that regulate many important biochemical reactions, including protein synthesis and enzymatic activity, and are critical determinants of metabolic activity and helps protect the body from hyperthyroidism (i.e., an overactive thyroid) and hypothyroidism (i.e., an underactive thyroid).

Although DSSRC agreed that Modere provided sufficient information to appropriately communicate a claim regarding the relationship between the iodine present in Ova and thyroid health, DSSRC recommended that the Company limit any assertions regarding iodine and hormone support solely to thyroid hormones as the human body contains numerous hormones other than thyroid hormones and the Company did not establish the association of iodine with any other hormones other than those related to the thyroid.

Improve feelings of well being

DSSRC was not troubled by the Company's representation that the ingredients in Ova can improve feelings of well-being. Section 403(r)(6) of the FD&C Act requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. DSSRC recognizes that the improvement of an individual's well-being is a subjective and broad term that generally refers to an individual's perception or experience of an enhanced state of overall health, happiness, and contentment – i.e., it is a qualitative measure rather than a specific quantifiable metric pertaining to aspects such as a person's emotional state and physical and mental health.

As noted in this decision, the Company submitted several studies on the ingredients in Ova which examined the efficacy of the ingredients at the same or at a similar dosage level at which they are present in the product. Specifically, the studies provided on the Extramel ingredient in Ova demonstrated that the ingredient significantly improved signs and symptoms of stress and fatigue linked to performance, physical, cognitive, and behavioral symptoms following supplementation. DSSRC concluded that Modere's double-blind, placebo-controlled studies on Extramel as well as several additional studies conducted on other ingredients in the product provided a reasonable basis for a general statement that the ingredients in Ova can improve feelings of well-being.

Promotes clear-looking and healthy skin

Zinc is an essential mineral that plays a role in various bodily functions, including immune system regulation and skin health. A number of studies have demonstrated that zinc has anti-inflammatory and antimicrobial properties that help reduce acne.

The Company provided DSSRC with three different studies on the impact of zinc on acne, all of which examined a substantially similar dosage of zinc that is present in Ova.

The first study (i.e., randomized, double-blind, placebo-controlled) indicated that oral zinc at a low dose provided significantly superior results than placebo including a significant reduction in inflammatory lesions 60 days after treatment. The study administrators noted that the effectiveness of zinc on inflammatory lesions can be attributed to its action on inflammatory cells.

The objective of the second study was to assess how zinc affects the resistance of Propionibacterium acnes to erythromycin in individuals with inflammatory acne, both in an in-vitro and in vivo setting. More specifically, the in-vitro experiments indicated that the combination of zinc gluconate and erythromycin had a greater inhibitory effect on the growth of Propionibacterium acne 60 days after treatment as compared to erythromycin alone, suggesting that the zinc gluconate enhances the antibacterial activity of erythromycin against acne-causing bacteria.

The in-vivo arm of the study involved individuals with inflammatory acne and indicated that those individuals who received a combination treatment of zinc gluconate and erythromycin showed a more significant reduction in acne lesions than erythromycin alone.

Finally, a third study aimed to compare the absorption of zinc from three common zinc supplements: zinc concentrate, zinc gluconate and zinc oxide and demonstrated that the absorption levels of zinc observed in the first two studies closely matched the elemental zinc absorption seen in the first two studies.

In sum, DSSRC concluded that the Company provided a reasonable basis for the statement that ingredients in Modere Ova promote clear-looking and healthy skin.

Supports the absorption of key nutrients

DSSRC did not object to the Company's general statement that Modere Ova supports the absorption of key nutrients based upon the studies Modere submitted on black pepper fruit extract.[28]

One study provided by Modere determined that pipermine (which is derived from black pepper), significantly increases the plasma level of coenzyme Q10 as compared to the placebo-controlled group. The Company confirmed that the black pepper extract observed in the study was the same amount that is present in Modere Ova.

Moreover, the second study submitted by Modere examined the properties of black pepper extract and its potential applications in improving absorption of iron. More specifically, the study investigated how black pepper extract, when used as a bioavailability enhancer, enhances the uptake of iron and the benefits the extract provides to individuals engaged in physical exercise.

Based upon the research cited by Modere, DSSRC determined that the Company provided adequate support for a statement that ingredients in Ova support the absorption of key nutrients.

Supports the endocannabinoid system

The endocannabinoid system comprises a vast network of chemical signals and cellular receptors that are densely packed throughout our brains and bodies. The "cannabinoid" receptors in the brain — the CB1 receptors — outnumber many of the other receptor types in the brain. A second type of cannabinoid receptor, the CB2 receptor, exists mostly in immune tissues and is critical to helping control our immune functioning, and it plays a role in modulating intestinal inflammation, contraction, and pain in inflammatory bowel conditions.[29]

Modere pointed to research on Palmitoylethanolamide, the main component in Ova's Levagen ingredient, as evidence of the endocannabinoid's role as a bioactive lipid mediator. Modere also submitted a study as support for the efficacy of the Levegen ingredient in Ova. The study showed that after eight weeks, PEA supplementation (i.e., in the same amount that the ingredient is present in Ova) reduced sleep onset latency, time to feel completely awake and improved cognition on waking.

While DSSRC does not dispute that the research provided by Modere demonstrated that Palmitoylethanolamide has positive effects on sleep latency, time to feeling completely awake, and cognitive improvement upon waking, DSSRC was not persuaded that the study provided sufficient support for a general "supports the endocannabinoid system" claim. DSSRC noted that there was no significant differences in sleep quality or quantity between the treatment and placebo groups after eight weeks of administration, although a "subgroup analysis" showed a significant difference in sleep onset latency at week four and week eight between the treatment and placebo groups.[30]

Moreover, while the study on the effect of Levegan as a potential sleeping aid did demonstrate a positive interaction of the ingredient with one component of the endocannabinoid system, DSSRC notes that the endocannabinoid system is involved in regulating a wide range of physiological processes[31], only one aspect of which pertains to the sleep-wake cycle.

Accordingly, DSSRC determined that the evidence submitted by Modere was not of sufficient reliability to support a broad representation that Ova supports the endocannabinoid system.

Supports liver health and detoxification

Liver health and detoxification are complex processes influenced by multiple factors. While clove bud extract is sometimes associated with liver health benefits due to its antioxidant and anti-inflammatory properties, the well-being of the liver is influenced by a multitude of factors including, but not limited to diet, exposure to toxins and chemicals, genetics, and other metabolic conditions such as diabetes and high blood pressure.

The randomized, double-blind placebo controlled cross over study provided by Modere did provide compelling data showing that a standardized polyphenolic extract of clove buds was effective in ameliorating the oxidative stress and inflammation caused by the accumulation of acetaldehyde after binge drinking. However, DSSRC was concerned about the extrapolation of testing results on a small sample size (i.e., 16 subjects) of adult men consuming copious amounts of alcohol to the advertising's target audience of healthy females.

As stated by the FTC in its Health Products Compliance Guidance, "Even when an advertiser doesn't make a specific claim about the level of support, claims about the health benefits of a product must still meet the basic substantiation standard of 'competent and reliable scientific evidence' … Although there is no requirement for a specific number of RCTs, the replication of research in an independently-conducted study adds to the weight of the evidence. Replication in a second study by independent researchers reduces the chance that the results of a single RCT may be influenced by unanticipated, undetected, systematic biases that may occur despite the best intentions of sponsors and investigators. An additional, independently conducted study to corroborate findings provides much greater confidence in the validity of the initial results."[32]

DSSRC concluded that the Company's study did not provide an adequate basis for its claim that ingredients in Ova support liver health and detoxification.

Supports libido

Modere relied on testing on the theacrine ingredient in Ova to support the general claim that the product is formulated with ingredients that "support libido". The study provided by the Company directly assessed the ingredient's effects on sexual desire at the same dosage level at which it is present in Ova.

The study employed a two-part approach to evaluate the effectiveness of theacrine in a small human population. Test participants recorded their subjective changes using the VAS scale[33]. In Part 1, a randomized, open label dose-response investigation was conducted on nine participants (six males and three females). Three participants received a high theacrine dosage, while six participants received a dosage equivalent to that contained in Ova. Part 2 of the study involved a randomized, double-blind controlled, cross-over investigation with 15 healthy subjects (eight males and seven females), where all participants received the same theacrine dosage as found in Ova.

DSSRC found that although the study showed promising results regarding the effectiveness of theacrine across various measurable parameters, the overall data lacked the necessary reliability to support a conclusive assertion that the theacrine dosage in Ova unequivocally "supports libido."

In assessing the reliability of testing to support a product or ingredient's health-related benefits, the FTC will consider several parameters such as sample size, duration and outcome measurements.[34] Accordingly, DSSRC was concerned with the very small sample size of females used in the study as well as the conflation of results among male and females test subjects.[35] For example, in Part 1 of the study, only 2 females received the dosage of theacrine that is present in Ova. DSSRC also observed that Part 1 of the study lacked a double-blind methodology and instead employed an open-label dose-response.

Moreover, with respect to Part 2 of the study, there was no indication that there was a statistically significant difference in the improvement of libido between the treatment and the placebo groups. More specifically, the test administrators noted only that statistically significant effects were found for psychometric measures of energy and fatigue. In addition, a trend for improved concentration was observed. According to the test administrators, no significant group interactions were detected for oxygen consumption, carbon dioxide production, or respiratory quotient or for any systemic hemodynamic variables over the 180-minute period post administration.

For these reasons, DSSRC determined the Company's study did not provide an adequate basis for a general representation that the ingredients in Ova support libido.

Conclusion

DSSRC recognized the good faith efforts of Modere in this inquiry to remove and/or modify over 200 social media posts, an action that DSSRC determined was necessary and appropriate. While the Company did remove and/or modify the social media posts highlighted by DSSRC during this inquiry, it also maintained that it possessed a reasonable basis for several substantive claims regarding the efficacy of Modere Ova and Ova-m that it anticipates preserving in future advertising. Accordingly, because the Company did not commit to permanently discontinuing specific representations regarding the product's efficacy in future advertising, DSSRC continued its assessment of the appropriateness of such general representations.

DSSRC determined that Modere provided a reasonable basis for general representations that the ingredients in Ova-m: reduce hot flashes, night sweats and vaginal dryness; improve sleep health; provide mood, libido, cognitive health, cardiovascular and energy support; and help protect cells from oxidative stress.

With respect to the Ova supplement, DSSRC concluded that Modere provided adequate support for the general statement that the supplement helps protect cells from oxidative stress and supports cardiovascular health; reduces the comfort associated with mood swings, bloating, and breast tenderness; supports the absorption of key nutrients; supports healthy blood flow; provides mood and energy support; promotes clear looking and healthy skin; and reduces stress, supports mental clarity, and improves feelings of well-being.

Conversely, DSSRC determined that the evidence in the case record did not provide a reasonable basis for claims that Ova reduces bloating and abdominal cramps; supports libido; supports liver health and detoxification; and the broad representation that Ova supports the endocannabinoid system.

Company Statement

"Modere takes great pride in being a leader in the direct selling industry and is committed to fostering a transparent and ethical business environment. As such, Modere is a strong supporter of the DSSRC and the self-regulatory process. Modere appreciates DSSRC's review of the substantiation and will take DSSRC's findings into consideration in its future advertising."

(Case #144-2023, Closed on 12/18/23)

[1] In the Notice of Inquiry sent to the Company, DSSRC noted that the product and income claims identified in this notice and those listed in the NGO's database, were not intended to be exhaustive but rather were illustrative of the types of core messages that were being disseminated in the marketplace by the Company and its salesforce members. More specifically, The NGO identified more than 200 social media posts and videos in its database that it alleged communicated unsubstantiated product and/or earnings claims.

[2] See www.truthinadvertising.org/evidence/moderes-project-23-health-claims-database.

[3] 21 U.S.C. § 321(g).

[4] 21 U.S.C. § 343(r)(6).

[5] Modere additionally referred to updated language in 65 Fed. Reg 1000, stating that "FDA has revised the criterion that applies to conditions associated with such natural states or processes as menopause, aging, adolescence, and pregnancy. The proposed rule stated that menopause, aging, and pregnancy are not themselves diseases but that certain conditions associated with them are diseases if they are recognizable to consumers or health professionals as abnormal. Many comments objected to classifying as diseases such common conditions as hot flashes, premenstrual syndrome (PMS), and decreased sexual function associated with aging. In response to these comments, FDA has revised proposed § 101.93(g)(2)(iii). Common conditions associated with natural states or processes that do not cause significant or permanent harm will not be treated as diseases under the final rule. For example, hot flashes, common symptoms associated with the menstrual cycle, ordinary morning sickness associated with pregnancy, mild memory problems associated with aging, hair loss associated with aging, and non-cystic acne will not be treated as diseases under this provision. Uncommon or serious conditions like senile dementia, toxemia of pregnancy, severe depression associated with the menstrual cycle, and cystic acne will continue to be treated as diseases under the final rule."

[6] The Company provided DSSRC with the composition of its proprietary blend for both Ova and Ova-m on a confidential basis in accordance with Section IX(D) of DSSRC's Policies and Procedures.

[7] Modere noted that the Council of Better Business Bureaus' (BBB National Programs' predecessor organization) Electronic Retailing Self-Regulation Program ("ERSP") previously reviewed the same study as support for menopause relief claims in a previous self-regulatory inquiry and found it to be reliable, determining that the study "provided reliable evidence that showed a statistically significant improvement in hot flushes/sweating and that subjects had less problems sleeping through the night."

[8] More specifically, from days 1-4 of the menstrual cycle, women take the "RELEASE" phase to help relieve common symptoms associated with menstruation, with ingredients that support healthy blood flow, support iron metabolism, and support energy levels. They then move to the "RENEW" phase from days 5 -16 with ingredients designed to improve feelings of wellbeing, healthy libido, iron absorption, thyroid support, and antioxidant capacity. Finally, from day 17 to the start of the next period, women take the "BALANCE" phase with ingredients to reduce symptoms associated with PMS such as mood swings, abdominal cramps, bloating, and breast tenderness.

[9] National Institutes of Health, Niacin Fact Sheet for Health Professionals. (available at: https://ods.od.nih.gov/factsheets/Niacin-HealthProfessional/).

[10] Mount Sinai, Vitamin B3 (Niacin). (available at: https://www.mountsinai.org/health-library/supplement/vitamin-b3-niacin) (Exhibit 15); See also European Food Safety Authority. Scientific Opinion on the substantiation of health claims related to niacin and reduction of tiredness and fatigue (ID 47), contribution to normal energy-yielding metabolism (ID 51), contribution to normal psychological functions (ID 55), maintenance of normal blood flow (ID 211), and maintenance of normal skin and mucous membranes (ID 4700) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. 2010 (available at https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1757) (recognizing the role that niacin has in enhancing blood flow due to its vascular dilatation effect).

[11] National Institutes of Health, Copper Fact Sheet for Health Professionals. (available at: https://ods.od.nih.gov/factsheets/Copper-HealthProfessional//).

[12] Harvard – The Nutrition Source. Iodine. (available at: https://www.hsph.harvard.edu/nutritionsource/iodine/).

See also European Food Safety Authority Scientific Opinion on the substantiation of health claims related to iodine and contribution to normal cognitive and neurological function (ID 273), contribution to normal energy-yielding metabolism (ID 402), and contribution to normal thyroid function and production of thyroid hormones (ID 1237) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA, Parma, Italy 2010 (available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1800). (Recognizing the role iodine plays in normal thyroid function and thyroid hormones, as well as energy-yielding metabolism).

[13] National Institutes of Health, Iron Fact Sheet for Health Professionals. (available at: https://ods.od.nih.gov/factsheets/Iron-HealthProfessional/).

[14] Clayton, Paul, et al., Palmitoylethanolamide: A Natural Compound for Health Management, Int J Mol Sci. 22(10): 5305 (2021).

[15] *See* DSSRC Guidance on Earnings Claims for the Direct Selling Industry at https://tinyurl.com/DSSRCEarnings.

[16] *Id* at section 6.

[17] National Media Group (Neurocet), Report #6066, *NAD/CARU Case Reports* (March 2017).

[18] *See* Prestige Brands Holdings, Inc. (Honey-Containing Little Remedies Products), Report #5815, *NAD/CARU Case Reports* (March 2015); Biologic Solutions, Inc. (Stem Cell Therapy Cream/NARB #177), Report #5368, *NAD/CARU Case Reports* (August 2011);; Biologic Solutions, Inc. (Stem Cell Therapy Cream/NARB #177), Report #5368, *NAD/CARU Case Reports* (August 2011)

[19] DSSRC notes that, here, its evaluation of the appropriateness of any representations regarding Ova and Ova-m was limited to general statements of product efficacy and, accordingly, any determinations made by DSSRC herein may vary depending on the context in which such claims are presented in future advertising. It is a fundamental tenet of advertising law that in reviewing advertising claims, the context in which claims appear must be considered when evaluating all messages reasonably conveyed by the advertising.

[20] Fredi Kronenberg, Hot flashes: "Phenomenology, quality of life, and search for treatment options," Experimental Gerontology, Volume 29, Issues 3–4, 1994.

[21] The administrators of the second study also stated that "It is notable that vaginal dryness was also one of the symptoms significantly improved, along with most of the individual symptoms in the KMI questionnaire."

[22] The administrators of the study also noted that that "memory improvement has been shown for Salvia off. preclinically and supports the clinical findings of enhanced cognition as seen in the present study."

[23] Brindisi M, Bouzidi C, Frattaruolo L, Loizzo MR, Cappello MS, Dugay A, Deguin B, Lauria G, Cappello AR, Tundis R. New Insights into the Antioxidant and Anti-Inflammatory Effects of Italian *Salvia officinalis* Leaf and Flower Extracts in Lipopolysaccharide and Tumor-Mediated Inflammation Models. Antioxidants (Basel). 2021 Feb 19;10(2):311. doi: 10.3390/antiox10020311. PMID: 33669555; PMCID: PMC7922507.

[24] Specifically, the study revealed notable enhancements in oxidized low-density lipoprotein (LDL) (often referred to as "bad cholesterol" as well as the oxidized LDL; total LDL-cholesterol ratio among those who ingested hydroxytrosol compared to those on placebo).

[25] FTC Health Products Compliance Guidance, section (B)(4) page 21

[26] *Id*.

[27] Daily values are the recommended amounts of nutrients that an individual should consume each day. The %DV is how much a nutrient in a single serving of an individual packaged food or dietary supplement contributed to an individuals' daily diet. See https://www.fda.gov/food/nutrition-facts-label/daily-value-nutrition-and-supplement-facts-labels.

[28] Black pepper extract is a broad term that refers to any substance derived from black pepper. It can include various components of black pepper including the bioactive compound piperine, *See* "Piperine: A comprehensive review of methods of isolation, purification, and biological properties", Anshuly Tiwari, Kakasaheb R. Mahadik, Satish Y. Gabhe, Medicine in Drug Discovery, Volume 7, 2020.

[29] *See* "The endocannabinoid system: Essential and mysterious", Peter Grinspoon, MD, Harvard Health Publishing at https://www.health.harvard.edu/blog/the-endocannabinoid-system-essential-and-mysterious-202108112569.

[30] It was also noted by the test administrators that "A major limitation of this study was that it was disrupted by the COVID-19 pandemic, limiting the number of participants able to provide blood samples. Therefore, we were only able to measure pathology markers on a limited number of participants greatly reducing the power of the analysis making it difficult to make inferences on the outcomes."

[31] The endocannabinoid system is involved in various processes, including brain plasticity, learning and memory, neuronal development, nociception, inflammation, appetite regulation, digestion, metabolism, energy balance, motility, and regulation of stress and emotions. *See* Matei D, Trofin D, Iordan DA, Onu I, Condurache I, Ionite C, Buculei I. The Endocannabinoid System and Physical Exercise. Int J Mol Sci. 2023 Jan 19;24(3):1989. doi: 10.3390/ijms24031989. PMID: 36768332; PMCID: PMC9916354.

[32] *Supra* at 26. Page 13.

[33] In Part 1 of the study, test participants recorded their subjective changes throughout seven consecutive days, in cognitive, psychometric and exercised attributes using a visual analog scale before ingestion at 1, 4 and 6 hours after ingestion. In Part 2 of the study the VAS questionnaires were used to detect subjective changes in various aspects of physical and mental energy along with changes in gas exchange and hemodynamic parameters before 1,2 and 3 hours after acute ingestion.

[34] *Supra* at 26. Page 12

[35] In addition, here, DSSRC is asked to assume that men and women have identical libido. However, sexual desire is typically higher in men than in women, with testosterone thought to account for this difference as well as within-sex variation in desire in both women and men. However, few studies have incorporated both hormonal and social or psychological factors in studies of sexual desire. *See* an Anders SM. Testosterone and sexual desire in healthy women and men. Arch Sex Behav. 2012 Dec;41(6):1471-84. doi: 10.1007/s10508-012-9946-2. Epub 2012 May 3. PMID: 22552705.

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