On December 20, 2019, the Direct Selling Self-Regulatory Council (DSSRC) published a report regarding the inquiry of product performance claims disseminated by New U Life, a multi-level marketing company located in Lehi, UT that offers a variety of health, wellness and weight-loss products including Somaderm which the company describes as “a powerful and innovative transdermal solution for homeopathic growth hormone.”

Advertising and marketing materials for New U Life first came to the attention of BBB National Programs in 2018 when the Electronic Retailing Self-Regulation Program (ERSP) reviewed product performance claims that were disseminated for Somaderm. The claims at issue included a) general performance claims (e.g., “There are no side effects, and unlike the injections of the human growth hormone that is the traditional treatment, there are side effects [like] when people are shooting themselves up with that. It’s a very powerful hormone.”); b) establishment claims (e.g., “In clinical human studies, continued use of HGH has been shown to offer incredible results. Many have noticed subtle to significant results in as little as a 6 month period. Here is what you may experience from SOMADERM Gel: MONTH 1 Improved stamina* Increased energy* Improved sleep* . . . MONTH 5 Significant weight loss* Greater improvements in skin texture & appearance* Skin has greater elasticity* Reduction of the appearance of wrinkles* Hair becomes even healthier & thicker* . . . MONTH 6 Benefits from previous months are heightened even more* Cellulite greatly diminishes* Improved immune system* Pain & general soreness diminishes* Wounds heal quicker* Greater metabolic output* Grayed hair begins to return to natural color* Reduction in LDL cholesterol* Blood pressure normalizes*”; c) FDA registered claims (e.g., “SOMADERM™ Gel is the only FDA registered transdermal human growth hormone product available without prescription.”); d) consumer testimonial claims (e.g., “I am shrinking and feeling great contrary to other products I have tried”, and; d) expert endorsement claims (e.g., The “Scientific Advisory Board” section of the New U Life website contains the profile of Dr. Lyn Hanshew. Dr. Hanshew also appears in the YouTube video for Somaderm Gel.

In a decision published in January 2019, ERSP noted that the marketer did not submit any substantiation to support the performance and establishment claims and recommended that product performance claims be discontinued.

With respect to the claim that “SOMADERMGel is the only FDA registered transdermal human growth hormone product available without prescription,” ERSP determined that New U Life could make the limited, truthful and accurate claim that its manufacturing facility is FDA registered and that Somaderm Gel has only been assigned an national drug code (NDC). The decision emphasized the importance of any future “FDA registered” claim including language that specifically limited the claim to the manufacturing facilities and a national NDC, so that consumers would not interpret the claim as meaning that Somaderm is an “FDA approved” drug.
In regards to claims that Somaderm Gel is homeopathic or contains homeopathic HGH, ERSP noted that the marketer did not submit any evidence, such as an HPUC “proving” to support claims that the product is, in fact, homeopathic or contains homeopathic HGH. ERSP recommended that the marketer discontinue any claims that Somaderm Gel is the only transdermal product containing homeopathic HGH, and any substantially similar claims.

In August 2019, the newly created DSSRC commenced a monitoring inquiry to review product performance claims being disseminated by New U Life for its Somaderm product that were communicated on Facebook, Instagram and Youtube posts of New U Life distributors as well as on the Company website including several representations that were similar, if not identical to those claims previously reviewed by ERSP including:

a) unsupported claims about the generally expected benefits of Somaderm (e.g., “Reduced Bodyfat; Deep Sleep; Improved Mood and Energy; Stronger Bones; Heightened Sex Drive; Reduced Appearance of Wrinkles; Increased (L)ean Muscle Mass; Faster Healing; More Endurance & Stamina”);

b) unqualified “FDA Registered” claims - (e.g., FDA registered.... no prescription needed.... No injections!!”);

c) unsupported Homeopathic claims (e.g., “Somaderm…Transdermal; FDA Registered; No Needles

d) establishment claims  - (e.g., “Clinical Applications -Anti-Aging*; May Experience Significant Fat Loss*; May Enhance Muscle Mass*; May Improve Sleep*);

e) consumer testimonials - (e.g., “I can not tell you how amazed I am with this product! What are you waiting for??? I feel like I am 25 again!!! ENERGY! Sleeping Great!! AWESOME LIBIDO! NOT DEPRESSED! NO DIET! NO WORKING OUT! Inches just melting away!!! #getonthegel”); and

f) expert testimonials – (e.g., “I love the gel for my patients because I get the same clinical results as if I was using 30 different products. Better results, better compliance, less money.”).

In addition, the DSSRC inquiry also a number of additional health-related claims (e.g., “Regrowth of heart, liver, spleen, kidney and other organs that shrink with age”; “14.4% loss of fat on average after six months without dieting”; “Superior immune function”; “Greater cardiac output”; “Superior immune function,” etc.) and a number of before-and-after depictions purportedly demonstrating the results received from using the product.

In its decision, DSSRC reached the same conclusions as ERSP did in the previous case, noting that “…there has been no substantive evidence provided by the Company to support product performance claims for Somaderm™” including the Company’s slightly revised claims that Somaderm “May support better mood; May support healthier hair, skin & nails; May promote hair growth. May increase joint mobility; May enhance libido; May increase fat loss (especially around the mid-section) May support greater muscle tone; May increase strength May improve memory.”

Notwithstanding DSSRC’s recommendations, these same claims continue to be disseminated by New U Life on the current labeling of the product, by its salesforce and on the Company website.
During the DSSRC inquiry, although New U Life represented that it was taking several steps to increase oversight of its salesforce and become compliant with regulatory guidance, it became apparent to DSSRC that were systemic issues at the Company that could not be addressed in the context of industry self-regulation. For this reason, DSSRC noted in the December 2019 decision that “Should DSSRC further determine that unsupported product performance and earnings claims appear on the Company website and/or continue to be disseminated in distributor posts that are accessible by consumers and potential recruits, DSSRC will have no recourse but to summarily refer this matter to the appropriate governmental agencies.”

Accordingly, since the time that DSSRC published its decision in December 2019, DSSRC has become aware of the ongoing dissemination of many of these same product performance, establishment and testimonial claims for Somaderm, despite the omission of any testing that would support such efficacy. Despite DSSRC’s conclusions and recommendations that the claims be discontinued, the Company continues to disseminate many of the same performance claims that DSSRC determined were not supported by competent and reliable evidence and continues to disseminate claims stating that it is Somaderm is the “only transdermal, FDA-registered product containing homeopathic human growth hormone.” More troubling is that shortly after the decision was published DSSRC became aware of a lab report prepared by the FDA indicating that the Somaderm contained little to no hGH.

More troubling, in the past several weeks DSSRC identified a number of posts made by the New U Life salesforce indicating that Somaderm is effective at treating and healing the COVID-19 virus despite the existence of any evidence indicating that the product can do so.¹

In sum, DSSRC has determined that New U Life has repeatedly failed to adhere to its recommendations and continues to disseminate unsupported performance and health-related including claims that Somaderm is effective to treat the coronavirus. Accordingly, DSSRC sees no recourse but to refer this matter to the appropriate government agencies including the FDA and the FTC.

(Case No. 16-2020PCM, closed on 3/27/2020)
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¹ According to the World Health Organization, there are no current cures or direct treatments for the novel coronavirus, and the Centers for Disease Control and Prevention and the Food Drug Administration have both stated that there are no approved vaccines, drugs or investigational products currently available to treat or prevent COVID-19.