



September 5, 2019

VIA EMAIL AND OVERNIGHT MAIL

Andrew Smith, Director
Lois Greisman, Associate Director
Mary Engle, Associate Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Ave. N.W.
Washington, D.C. 20580

Jason Humbert, Captain
Health Fraud Branch Chief
Division of Enforcement
Office of Regulatory Affairs
U.S. Food and Drug Administration
12420 Parklawn Drive, ELEM-4041
Rockville, MD 20857

Re: New U Life, Inc.'s Deceptive Marketing of Somaderm Gel

Dear Mr. Smith, Ms. Greisman, Ms. Engle, and Capt. Humbert:

We write to inform you of the findings of a recent Truth in Advertising, Inc. (TINA.org) investigation¹ of New U Life, Inc. (NUL), a Utah-based multilevel marketing company started in November 2017 by Alexy Goldstein that sells and markets, among other things, Somaderm Gel, which the company describes as “the only FDA registered, transdermal product containing homeopathic HGH that’s available without a prescription.” TINA.org’s investigation revealed a host of issues, including an emphasis on recruitment over product sales, the marketing of the business opportunity using inappropriate income claims, and illegal disease-treatment claims being made by the company, its founder and distributors. In this letter, we highlight the inappropriate and deceptive marketing of Somaderm Gel.



Initially, it is worth noting that NUL and its CEO Goldstein are no strangers to the FTC or the FDA.² On August 5, 2019 the FTC sent a closing letter to Natural Life Foods Corp. d/b/a Strike First Nutrition, which is owned by Goldstein,³ concerning Testall Gel.⁴ According to the letter, “Testall Gel was marketed to strengthen bone density, prevent or reduce the risk of osteoporosis, balance blood sugar levels, reduce blood pressure, and prevent depression. It was also promoted as the only FDA-registered transdermal testosterone product available without a prescription.”⁵ The FTC decided not to recommend enforcement action, in part, because of the amount of sales and the fact that Testall Gel was removed from the market.⁶

And earlier this year, after testing Somaderm Gel, the FDA determined that, contrary to the assertions of NUL and its distributors, Somaderm Gel does not actually contain human growth hormone (“hGH”). Specifically, the agency’s case/sample summary report⁷ stated:

There was no evidence for the presence of hGH at a level greater than approximately 7 micrograms per gram in the contents of the bottle based on comparison to a corresponding standard using LC-MS . . . There was no evidence for the presence of any drugs or poisons in the bottle contents using GC-MS.⁸

Based on the FDA’s testing, Somaderm appears to be nothing more than oil and water, which is sold for \$170 per bottle.⁹ Yet NUL and its distributors continually use the phrase “FDA registered” in their marketing of Somaderm Gel with the apparent goal of conveying the message that the FDA favors and endorses this “hGH” product.¹⁰ As one distributor put it:

To have this product [Somaderm] and have it FDA registered is super huge. That never happens. . . There has never been, to my knowledge, a homeopathic that’s ever been registered with the FDA – that’s huge. . . So, looking for some kind of safety factor – there it is.¹¹

It is a necessary marketing ploy given that “[d]istributing human growth hormone to customers in the United States without the order of a physician is in direct violation of Section 303(e) of the FD&C Act and may be punishable by up to 10 years in prison and applicable fines.”¹²

Moreover, not only are NUL’s 94,000 distributors¹³ marketing a product that they assert has “homeopathic HGH” in it (even though it contains no hGH) but they are using inappropriate health claims to do so. A marketing tactic that appears to be working as the company claims to have sold more than half a million bottles of Somaderm Gel in its first year of business.¹⁴

TINA.org has found that the company and its distributors are using a multitude of unsubstantiated health and treatment claims to sell Somaderm and the NUL business opportunity, such as the gel’s ability to regrow hair, relieve the symptoms of fibromyalgia, stop migraines, increase bone density, treat arthritis, improve memory and

eyesight, heal organs faster, disappear anxiety, take the place of hormone replacement therapy, and treat and/or cure a host of other diseases. For example, in one video, NUL CEO Goldstein tells consumers:

If a woman is taking estrogen or progesterone due to menopause, will Somaderm effect anything? This is a great question. . . . One of the main ingredients in Somaderm is the mother of all hormones and this is the hormone that breaks down to progesterone and estrogen. . . . As you're using Somaderm month after month you'll feel you're a little less dependent on other hormones like progesterone or estrogen. Again that depends on the person – everybody's a little bit different . . . so I have had women that use the product for six months and then they quit using progesterone and even with estrogen. So but again make sure you talk to your doctor before you change anything important that your doctor has put you on. But this is how it works with . . . progesterone and estrogen. . . . As your organs start improving in functionality as well, you will notice that you are less dependent on outside hormones, especially high doses.¹⁵

TINA.org has compiled more than 100 examples, all of which are available at <https://www.truthinadvertising.org/new-u-life-health-claims-database/>, in which NUL and its distributors have either made or referenced claims that Somaderm can treat, cure, alleviate the symptoms of, prevent, or reduce the risk of developing diseases and disorders.¹⁶

TINA.org urges the FTC and the FDA to immediately commence an investigation of the claims being made by NUL and its distributors and take prompt and appropriate enforcement action against those found to be violating the law.

If you have any questions, please do not hesitate to contact us.

Sincerely,



Laura Smith, Esq.
Legal Director
Truth in Advertising, Inc.



Bonnie Patten, Esq.
Executive Director
Truth in Advertising, Inc.

Cc via email: Alexy Goldstein, CEO, New U Life

¹ See What You Should Know About New U Life, Aug. 27, 2019, <https://www.truthinadvertising.org/what-you-should-know-about-new-u-life/>.

² NUL and the marketing of its Somaderm Gel was also the subject of an Electronic Retailing Self-Regulation Program (ERSP) investigation. ERSP's January 2019 investigation determined the "the marketer did not adequately support claims that Somaderm Gel will confer health benefits. Specifically, the marketer failed to submit any competent and reliable evidence to demonstrate that the Somaderm Gel formula and/or transdermal administration would provide the purported health benefits of HGH. Based upon the information provided, ERSP recommended that the marketer discontinue all performance and establishment claims. . . . As to claims that Somaderm Gel is FDA registered, ERSP determined that the marketer could make limited claims that were truthful and accurate. Specifically, the marketer could state that the marketer's facilities are FDA registered and that Somaderm Gel has been assigned a National Drug Code (NDC) number." Hormone Gel Cannot Make Health Benefit Claims; Somaderm Agrees to Modify, Discontinue Certain Claims After ERSP Review of Its Advertising, Jan. 23, 2019, <https://asrcreviews.org/hormone-gel-cannot-make-health-benefit-claims-somaderm-agrees-to-modify-discontinue-certain-claims-after-ersp-review-of-its-advertising/> (Note: ERSP did not address the issue of NUL and its distributors marketing Somaderm as an hGH product.) It appears that NUL and its distributors have basically ignored the recommendations of the ERSP.

³ See Alexy Goldstein's LinkedIn profile, <https://www.linkedin.com/in/alex-y-goldstein-2564bb14/>.

⁴ See Letter from FTC re Natural Life Foods Corp. d/b/a Strike First Nutrition, FTC File No. 192-3065, dated Aug. 5, 2019, https://www.ftc.gov/system/files/documents/closing_letters/nid/2019-08-05_engle_closing_letter_to_goldstein_re_natural_life_foods_corp.pdf.

⁵ *Id.*

⁶ As of July 2019, the FTC had also received more than 100 consumer complaints concerning New U Life. <https://www.truthinadvertising.org/wp-content/uploads/2019/08/New-U-Life-FTC-Complaints.pdf>. About 71 percent of the complaints seek a refund from the company and include complaints of not being able to reach anyone at the company, being put on hold for hours, and being told that their checks were in the mail when they weren't. Relatedly 30 percent of consumers complained about unauthorized charges or not being able to cancel their auto-shipments. Twenty-seven percent of consumers warn that New U Life is a scam, fraud or pyramid scheme, and 24 percent complain about health issues surrounding Somaderm.

⁷ FDA Summary Report, Sample Number 1026141, <https://www.truthinadvertising.org/wp-content/uploads/2019/08/NUL-FDA-Summary-Report.pdf>.

⁸ As of August 2019, the FDA had received numerous health complaints from consumers using Somaderm Gel. *See, e.g.*, FDA Consumer Complaint/Injury Report Complaint #155581, <https://www.truthinadvertising.org/wp-content/uploads/2019/08/New-U-Life-FDA-complaints.pdf>.

⁹ <https://www.newulife.com/products/>.

¹⁰ See TINA.org's New U Life "FDA Registered/Approved" Claims database, available at <https://www.truthinadvertising.org/new-u-life-fda-registered-claims-database/>.

¹¹ Incredible HGH Gel Opportunity Call w/Doctor's Comments, available at <https://www.truthinadvertising.org/wp-content/uploads/2019/08/Incredible-HGH-Gel-Opportunity-Call-with-Doctors-Comments-comp-wm.mp4>.

¹² See FDA Warning Letter to Steroid Bazaar, dated June 2, 2016, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/steroid-bazaar-kabs-software-urettin-yagmur-bokurt-495561-06022016>; 21 USC § 333(e).

¹³ New U Life Relocates to Tech, Wellness and Direct Selling Mecca of Silicon Slopes, dated July 23, 2019, https://www.prweb.com/releases/new_u_life_relocates_to_tech_wellness_and_direct_selling_mecca_of_silicon_slopes/prweb16457464.htm.

¹⁴ New U Life Sells Over 500,000 Bottles of HGH Gel in their First Year, Mar. 5, 2019, <https://www.prnewswire.com/news-releases/new-u-life-sells-over-500-000-bottles-of-hgh-gel-in-their-first-year-300807168.html> (Note: dividing the number of Somaderm bottles sold (500,000) by the number of distributors (94,000) equals 5.5 bottles per distributor, which is less than a year's supply for each distributor.)

¹⁵ See New U Life video, available at https://www.truthinadvertising.org/wp-content/uploads/2019/09/Alexy-Goldstein-New-U-Life-QnA-12_2_2018-wm.mp4.

¹⁶ Note: this database does not include the "secret" Men's and Women's private testimonial Facebook groups. See https://www.truthinadvertising.org/wp-content/uploads/2019/08/Team-NewULife-Monthly-Newsletter-for-Distributors_wm.pdf.