



April 4, 2023

VIA EMAIL

Maximilian Gabath, Co-Founder and Co-CEO
Prime6 Brands/Primal Harvest
max@prime6brands.com
support@primalharvest.com

Re: Primal Harvest's Marketing Practices

Dear Mr. Gabath:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, I write to alert you to a deceptive marketing trend that is currently prevalent in the supplement industry, as well as the hair product industry. That is, companies are marketing supplements and topical products as able to grow hair and reduce or prevent hair loss without the required FDA approval¹ or competent and reliable scientific substantiation required by the FTC.²

In addition, some companies are marketing products through the use of social media influencers without ensuring that the influencers properly disclose their material connection to the company or that the promotional posts are ads, as is required by the FTC.³

Such deceptive marketing practices violate the Federal Trade Commission Act and/or the Federal Food, Drug, and Cosmetic Act.

TINA.org urges Primal Harvest to review its marketing, which includes, among other things, claims that its supplements can grow hair and reduce hair loss,⁴ and take the necessary steps to ensure compliance with FTC and FDA law.

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

Sincerely,

A handwritten signature in blue ink that reads 'L. Smith'.

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

¹ See, e.g., FDA warning letter to Santhigram Kerala Ayurvedic Co. of U.S., Inc., May 19, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/santhigram-kerala-ayurvedic-co-us-inc-625892-05192022> (“Examples of claims observed on your website and social media websites that establish the intended use of your Santhigram ayurvedic products as drugs included, but are not limited to, the following: ... ‘Benefits: Triphala has several health benefits, such as; ... stimulates hair growth...’”); FDA warning letter to Speedwinds Nutrition, Inc., Dec. 22, 2020, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/speedwinds-nutrition-inc-609298-12222020> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include the following: ... ‘With Sephren, you can feel confident that Sephren will: . . . Stop the root causes of hair [sic] female hair loss.’”); FDA warning letter to KetoKerri LLC, Mar. 31, 2020, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ketokerri-llc-598163-03312020> (“Examples of some of the claims observed on your website, www.ketokerri.com, that provide evidence that these products are intended for use as drugs include the following: ... ‘People take MSM by mouth for ... hair loss...’”); FDA warning letter to Soleo, Dec. 13, 2018, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/soleo-567046-12132018> (“**Unapproved New Drugs** ‘GEN+LE THERAPY Shampoo’ Examples of claims ... that establish the intended uses of the product as defined in 21 CFR 201.128 include, but may not be limited to, the following: ... ‘Prevents Hair Loss...Hair Loss Prevention...’ ... Based on the above claims, ‘GEN+LE THERAPY Shampoo’ is a ‘drug’ as defined by section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)) because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act (21 U.S.C. 321(g)(1)(C)) because it is intended to affect the structure or any function of the body. Specifically, this product is intended as a hair growth, hair loss prevention, and anti-dandruff drug product.”); FDA warning letter to Silver Armor, Inc., May 17, 2018, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/silver-armor-inc-543786-05172018> (“Examples of some of the claims on the product labels, accompanying promotional literature, and your website that provide evidence that your products are intended for use as drugs include, but are not limited to the following: ... ‘Stimulated hair growth’”); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017> (“Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... ‘HGH has been found to reverse and/or slow down the aging process by: ... Restoring lost hair growth’ ... ‘Fuller Thicker Hair In As Little As Two Months,’ ‘[A] natural alternative to combat hair loss...,’ ‘Restore thinning hair with visible results,’ ‘[R]estores and maintains healthy hair.,’ ... ‘[T]o restore thickness and prevent more hair from falling out.,’ ‘Nugen HP – The All-Natural Hair Restoration System?,’ ‘[R]evitalizes your hair follicles stimulating fuller, thicker hair.’”).

² FTC, Advertising Substantiation Principles, <https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf>; FTC Health Products Compliance Guidance, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

³ FTC, Disclosures 101 for Social Media Influencers, https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf; FTC, Guides Concerning the Use of Endorsements and Testimonials in Advertising, <https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-publishes-final-guides-governing-endorsements-testimonials/091005revisedendorsementguides.pdf>.

⁴ *See, e.g.*, Primal Harvest, Hair Growth Complex, <https://primalharvest.com/products/hair-growth-complex>.