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May 13, 2016

Mr. Darian Braun  
Beverly Hills Formulators, LLC  
[address]

Re: XCellerate 34

Dear Darian:

As a former Federal Trade Commission ("FTC") advertising enforcement official, FTC advertising practitioner, and FTC compliance counsel to Beverly Hills Formulators, LLC, I have been asked to review and offer my opinion on the adequacy of scientific support for hair care claims for XCellerate 34 under FTC substantiation guidelines. My review and opinion are based on my experience as an FTC advertising practitioner and my familiarity with the FTC's advertising substantiation guidelines.

The FTC requires health claims, including hair care claims, to be supported by "competent and reliable scientific evidence, defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." As a matter of FTC policy but not necessarily established law, the FTC requires that health claims, including hair care claims, be supported by human clinical studies, with a strong bias in favor of randomized controlled trials ("RCTs").

I understand that you do not intend to make hair "growth" claims for XCellerate 34 but do wish to make increased thickness, volume, density and fullness claims for men, and an increased length claim for women. I further understand that you intend to base the claims on three clinical studies, each titled, "Controlled Usage Study to Evaluate the Efficacy of a Hair Care Product Intended to Accelerate Hair Release and Recovery," conducted at your request and expense in July 2015 by AMA Laboratories. ("Substantiation"). I am informed that the tested hair care product was XCellerate 34 and that it was used in conformance with the usage instructions that will appear on the XCellerate 34 label, with the exception that study subjects were instructed to apply the product to only one side of the head in order to establish a control. Two studies were all-male and one was all-female. Each study had relatively small sample sizes (21 in the male studies and 9 in the female) and used two modes of measurement, one a scientific method of photographic analysis and the other a self-assessment questionnaire completed by the study subjects. The sample sizes that were subjected to photographic analysis were even smaller (10 in the male studies and 5 in the female). Results were measured and reported at Days 7, 14, 28, and/or 45.

The Substantiation, which I have reviewed, does consist of RCTs, the type of scientific evidence strongly preferred and increasingly required by the FTC for health claims. Based on that review, and within the above-mentioned constraints of relatively small study sample sizes and the subjective character of self-assessments, the Substantiation appears to support these claims:

Day 14 - thicker, denser, fuller, more volume hair for men, and longer hair for women

Day 28 - more volume hair for men, and longer hair for women

Day 45 - longer hair for women

At Day 14 in particular, both the objective (photographic) and subjective (questionnaire) evidence appears to support modest to modestly strong statements in the target claim areas for both men and women. Based on the evidence, I would steer clear of dramatic improvement claims but, within the above-mentioned constraints, XCellerate 34 does appear to be effective in making hair thicker, denser, fuller and more voluminous for men at 14 days, and longer for women at 14, 28 and 45 days—as well as softer, shinier and healthier. Greater density appears to be the most robustly supported claim, since it is backed by both the photographic and self-assessment evidence.

In reviewing the Substantiation for XCellerate 34, it is important to emphasize that I am an attorney only and do not possess, and expressly disclaim, scientific and clinical research expertise. Nevertheless, in my capacity as an experienced FTC advertising practitioner, and based on my review of the Substantiation under a fair and reasonable application of FTC claim substantiation guidelines, it is my opinion that you do possess a "reasonable basis" ("competent and reliable scientific evidence") for the above-identified efficacy claims.

In rendering this opinion, I cannot, and do not, represent, warrant or guarantee that the FTC or other advertising regulators will be in agreement, or that the marketing and sale of XCellerate 34 carries no legal risk. Based on the foregoing, however, I believe the proposed advertising claims for XCellerate 34 are legally defensible.

Sincerely,

A handwritten signature in cursive script that reads "William I. Rothbard".

William I. Rothbard  
Counsel for Beverly Hills Formulators, LLC