

Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill
In the Matter of GeneLink, Inc. and foru International Corporation
January 7, 2014

We write to explain our support for the remedy imposed against respondents GeneLink, Inc. and foru International Corporation, which we believe to be amply supported by the relevant facts. In this, as in all of the Commission's advertising actions alleging deceptive health claims, the Commission has called for, as proposed relief, a level of substantiation that is grounded in concrete scientific evidence and reasonably tailored to ensure that the conduct giving rise to the violation ceases and does not recur, among other important remedial goals. In our view, the remedy adopted here accomplishes just that, without imposing undue costs on marketers or consumers more generally.

Respondents market and sell genetically customized nutritional supplements and topical skin products. As described in the complaint, this enforcement action stems from claims made by respondents in promotional materials and through testimonials that their products compensate for consumers' "genetic disadvantages" and cure or treat serious conditions such as diabetes, heart disease, and arthritis. In a newsletter, for example, respondents represented their products had cured "a serious diabetic and cardiac patient," and an affiliate's website stated that the products produced "improvements in everything from blood pressure to eczema to hormonal issues to arthritis."¹ The Commission alleges that respondents lacked adequate substantiation for these claims and that they falsely represented that the products' benefits were scientifically proven.

Disease treatment claims such as these require a rigorous level of substantiation. Based on evidence from genetics and nutritional genomics experts, the Commission has reason to believe that well-controlled human clinical trials (referred to here as "randomized controlled trials" or "RCTs") are needed to substantiate respondents' claims and that the studies relied on by respondents to back up their claims fall far short of this evidence. Because respondents lacked even one valid RCT for their products, it was unnecessary for the Commission to decide, for purposes of assessing liability, the precise number of RCTs needed to substantiate their claims.

In fashioning an appropriate remedy, however, we are requiring that respondents have at least two RCTs before making disease prevention, treatment, and diagnosis claims. We have the discretion to issue orders containing "fencing-in" provisions – "provisions . . . that are broader than the conduct that is declared unlawful." *Telebrands Corp. v. FTC*

determination that “[r]eplication is necessary because there is a potential for systematic bias and

two RCTs,⁶ one RCT,⁷

