



## Council for Responsible Nutrition

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February 3, 2014

### VIA ELECTRONIC SUBMISSION

Federal Trade Commission  
Office of the Secretary Room H-113 (Annex D)  
600 Pennsylvania Avenue, N.W.  
Washington, DC 20580

**Re: GeneLink, Inc. and foru™ International Corporation - Consent Agreement;  
File No. 112–3095**

Dear Commissioners:

The Council for Responsible Nutrition (CRN) appreciates the opportunity to submit these comments to the Federal Trade Commission (FTC) in response to FTC's Proposed Consent Agreement with GeneLink, Inc. and foru™ International Corporation, as published in the January 15, 2014 issue of the Federal Register, 79 Fed. Reg. 2662. CRN is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements.<sup>1</sup>

CRN supports FTC's ongoing enforcement efforts against dietary supplement marketers that engage in false and deceptive advertising practices. Since 2007, CRN has supported these efforts through our initiative with the National Advertising Division of the Council of Better Business Bureaus, which targets dietary supplement advertising that may not have adequate substantiation.<sup>2</sup> Continuous monitoring of the industry, whether by FTC or through self-regulation, is essential to increase consumer confidence in the truth and accuracy of advertising

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<sup>1</sup> CRN, founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at [www.crnusa.org](http://www.crnusa.org).

<sup>2</sup> In cases where the advertiser declines to participate or declines to abide by the terms of an NAD decision, the advertising at issue is referred to FTC.

claims for dietary supplement products and encourage fair competition within the industry. However, CRN believes that the proposed consent agreement referenced above raises important issues regarding the appropriate level of substantiation for health-related claims for dietary supplements and other foods, which were also noted by two FTC Commissioners in their accompanying statements.

### ***Concerns Regarding the Two-RCT Standard***

We echo the concerns of Commissioner Maureen Ohlhausen in her dissenting statement in the matter of GeneLink, Inc. and foru™ International Corporation, specifically with regard to the proposed consent agreement's requirement of two randomized controlled trials (RCTs) to substantiate all disease-related claims. We agree that the two-RCT standard imposed by FTC in this case, as well as in prior consent agreements involving dietary supplements and food products<sup>3</sup>, creates an "unduly high standard" which departs from FTC's traditional analysis based on the *Pfizer*<sup>4</sup> factors, and may leave consumers without useful information to help them make informed purchasing decisions. Further, the requirement that studies must always be conducted by independent researchers and must be on the product itself or an essentially equivalent product creates even greater burdens, which we believe are not justified under the circumstances.<sup>5</sup>

While CRN does not dispute the facts of the present matter or previous enforcement actions, CRN shares Commissioner Ohlhausen's concern that FTC is creating a "one-size-fits-all approach" and in essence, a "de facto two-RCT standard on health- and disease-related claims for food and other relatively safe products." This approach fails to take into consideration the particular circumstances and challenges that are unique to substantiating the benefits of dietary supplements, and will suppress useful consumer information. Commissioner Wright expressed similar views in his statement, encouraging FTC "to explore more fully whether the articulation and scope of injunctive relief in these and similar settlements strikes the right balance between deterring deceptive advertising and preserving for consumers the benefits of truthful claims", further noting that the "optimal amount and type of evidence to substantiate a future claim will vary from case to case."

In addition, as noted by Commissioner Ohlhausen, the burden of substantiating the benefits of a drug or biologic should be greater because of the higher risks posed by these products. Dietary supplements and other food products with well-established safety profiles should not be subject to the same stringent standards as drugs, especially given the inherent

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<sup>3</sup> See *FTC v. Iovate Health Sciences USA, Inc.*, Case No. 10-CV-587 (W.D.N.Y. July 29, 2010); *Nestlé HealthCare Nutrition, Inc.*, 151 F.T.C. 1 (2011); *Dannon Co., Inc.*, 151 F.T.C. 62 (2011); *POM Wonderful LLC*, Docket No. 9344 (F.T.C. Jan. 10, 2013).

<sup>4</sup> *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

<sup>5</sup> As noted by Commissioner Ohlhausen in her statement, unless there is evidence that the defendant fabricated results, the requirement of independent testing on the actual product or its equivalent is overly restrictive and unnecessary.

difficulties when attempting to adapt the evidence-based medicine model to the evidence-based nutrition model, discussed in further detail below. Using the traditional *Pfizer* analysis takes into account the key differences between these types of products, which would result in a more balanced, fact-based determination as to the appropriate level of substantiation, rather than an across-the-board, “de facto standard” that ultimately will not benefit consumers.

### ***Limits of RCTs in Evidence-Based Nutrition***

Although RCTs are often referred to as the “gold standard” for substantiation because they can provide a high level of accuracy and reliability, such testing has notable limitations when utilized outside the evidence-based medicine paradigm. In the case of drugs, RCTs are necessary to ensure efficacy and safety due to the high risk these products carry. However, in the field of nutrition science, this methodology may not be appropriate or even feasible. For example, researchers may be unable to contrast a nutrient intervention group with a placebo group when studying the effect of a given nutrient in the human body, because achieving a “zero exposure” (i.e., placebo) group is extremely difficult if not possible, and in many cases unethical. Further, drugs generally have a single targeted effect and work within a shorter period of time, making it easier to contrast with a true placebo group. Unlike pharmaceutical ingredients, nutrients work together in complex ways, and their effects on health develop over a longer period of time. CRN encourages FTC to examine the body of peer-reviewed scientific literature that discusses the limitations of RCTs in more detail. We have provided several citations below following our comments.

When establishing the relationship between nutrients and human health effects, experts in nutrition science agree that assessing the totality of the available evidence – which may or may not include RCTs – is a more useful approach in evidence-based nutrition. This approach also aligns with FTC’s current guidelines for the dietary supplement industry, whereby “competent and reliable scientific evidence” is defined as tests, studies, and other evidence “using procedures that are *generally accepted in the profession* to yield accurate and reliable results” (emphasis added).<sup>6</sup> We therefore suggest that FTC carefully consider the methodology that is “generally accepted” by experts in the field, and also the inherent limits of RCT-based evidence, when evaluating the substantiation requirements for dietary supplements and other food products.

### ***Conclusion***

In conclusion, we encourage the Commission to consider Commissioner Ohlhausen’s and Commissioner Wright’s statements regarding the current substantiation requirements included in the proposed Genelink and foru™ consent agreement and for future consent agreements, as well

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<sup>6</sup> Federal Trade Commission, Bureau of Consumer Protection, *Dietary Supplements: An Advertising Guide for Industry* (2001), at 9, available at <http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf>.

as CRN's comments regarding the limits of RCTs to substantiate health- and disease-related dietary supplement and other food claims.

CRN appreciates the opportunity to comment on this important matter. Please contact me if you would like additional information on the issues discussed above.

Respectfully Submitted,

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Regulatory Counsel  
Council for Responsible Nutrition

**Recommended Scientific Literature – Limitations of RCTs:**

Biesalski HK, et al., 26th Hohenheim Consensus Conference, September 11, 2010 Scientific substantiation of health claims: Evidence-based nutrition. *Nutrition*: Oct. 2011, Vol. 27 (10) Supplement, S1-S20, available at <http://www.nutritionjrn.com/article/S0899-9007%2811%2900143-2/fulltext>.

Blumberg J, Heaney RP, Huncharek M, Scholl T, Stampfer M, Vieth R, Weaver CM, & Zeisel SH. Evidence-based criteria in the nutritional context. *Nutrition Reviews*: Aug. 2010, Vol. 68 (8), 478-84, available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1753-4887.2010.00307.x/full>.

Heaney RP. Nutrients, Endpoints, and the Problem of Proof. *The Journal of Nutrition*: Sept. 2008, Vol. 138 (9), 1591-1595, available at <http://jn.nutrition.org/content/138/9/1591.full>.

Heaney RP. Nutrition, chronic disease, and the problem of proof. *The American Journal of Clinical Nutrition*: Sept. 2006, Vol. 84 (3), 471-472, available at <http://ajcn.nutrition.org/content/84/3/471.long>.

Heber D, Shao A. Bioactive Food Components: Changing the Scientific Basis for Intake Recommendations (Oct. 2011). *International Alliance of Dietary/Food Supplement Associations, Scientific Publications*, available at [http://www.iadsa.org/publications/1320152635\\_Bioactive\\_Food\\_Components\\_Ch.pdf](http://www.iadsa.org/publications/1320152635_Bioactive_Food_Components_Ch.pdf).

Perez-Escamilla R, King J. Evidence-Based Public Nutrition: An Evolving Concept. *The Journal of Nutrition*: Feb. 2007, Vol. 137 (2), 478-479, available at <http://nutrition.highwire.org/content/137/2/478.full>.

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Shao A, Mackay D. A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition. *Natural Medicine Journal*: Dec. 2010 Issue, available at [http://www.naturalmedicinejournal.com/article\\_content.asp?article=117](http://www.naturalmedicinejournal.com/article_content.asp?article=117).

Victora CG, Habicht J, and Bryce J. Evidence-Based Public Health: Moving Beyond Randomized Trials. *American Journal of Public Health*: Mar. 2004, Vol. 94 (3), 400-405, available at <http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.3.400>.