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1773 T Street, N.W., Washington, DC 20009
(202) 223-0101, Fax (202) 223-0250
www.NaturalProductsAssoc.org

February 4, 2014

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

RE: Proposed Consent Agreements *In the Matter of GeneLink, Inc.*, and *In the Matter of foru™ International Corporation*, File No. 112-3095

Dear Commissioners:

The Natural Products Association (NPA) is submitting this letter as a general comment to File No. 112-3095, Proposed Consent Agreements *In the Matter of GeneLink, Inc.*, and *In the Matter of foru™ International Corporation*, published January 15, 2014. NPA, founded in 1936, is the nation's largest and oldest non-profit organization dedicated to the rights of consumers to access natural products that will maintain and improve their health, and the rights of retailers and suppliers to sell these products. NPA represents more than 10,000 retailers, manufacturers, wholesalers, and distributors of natural products, including natural and organic foods, dietary supplements, and more. NPA appreciates the opportunity to comment on this matter.

These comments address two critical issues. First, a requirement that claims be substantiated by two randomized controlled trials (RCTs) is unduly demanding for claims about safe foods and dietary supplements, particularly structure/function claims. This onerous standard is contrary to FDA's well-established position and FTC's published guidance, which has been in effect since 2001. The standard is also demonstrably at odds with the Dietary Supplement Health and Education Act (DSHEA), 21 U.S.C. § 321 *et seq.*, and chills constitutionally protected speech, raising serious First Amendment concerns.

Second, FTC should publicly reaffirm that it intends to adhere to the flexible "competent and reliable scientific evidence" standard in its published guidance. Through its recent consent decrees and enforcement actions, the agency (or at least

half of the Commissioners) appears to be headed towards a *de facto* requirement of two RCTs for all disease- and health-related claims. In addition, our members are well aware of Staff efforts behind the scenes to impose this same requirement on ordinary structure/function claims. This backdoor approach to heightening the substantiation standard is procedurally improper and adverse to consumers and the industry. If the agency intends to abandon its long-standing guidance and to impose a two RCT standard on the food and dietary supplement industries, then new formal guidance is necessary, and proponents of the change must justify their position.

1. FTC should not require two RCTs by independent researchers on an "essentially equivalent product" to substantiate health- and disease-related claims, particularly structure/function claims, about safe foods and dietary supplements: NPA agrees with Commissioner Ohlhausen that a two-RCT standard is "unduly high" for health- and disease-related claims about safe foods and dietary supplements. *Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part and Concurring in Part* (*Ohlausen Statement*), at 1. It is particularly inappropriate for ordinary structure/function claims.

Indeed, imposing a two-RCT requirement for such claims would put FTC demonstrably out of line with FDA. FDA requires only "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 has 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." FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act* (December 2008). FDA has expressly stated that "competent and reliable scientific evidence" does *not* require RCTs for all health- and disease-related claims, let alone standard structure/function claims. *Id.* In fact, "trials of this type may not always be possible, practical, or ethical." *Id.*

Until recently, FTC embraced this same definition of "competent and reliable scientific evidence." *See* Dietary Supplements: An Advertising Guide for Industry, *available at* http://www.business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry (*FTC Guidance*), at 3, 9; *see* Enforcement Policy Statement on Food Advertising, *available at* http://www.ftc.gov/enforcement-policy-statement-on-food-advertising (setting forth the same standard for health claims about food). And, in its guidance, FTC acknowledged that "competent and reliable scientific evidence" is a "*flexible* standard," *id.* at 8 (emphasis added), for which "there is no fixed formula," *id.* at 9, and does *not* require RCTs for all claims, such as structure/function claims. *Id.*; *see also* Enforcement Policy Statement on Food Advertising (FTC will "look to well-designed studies, including clinical research *and other forms of reliable and probative scientific evidence*, in evaluating health claims for foods") (emphasis added).

FTC's traditional substantiation factors, applied in the agency's case law, have led to the same conclusion. For decades, FTC directed that the level of substantiation depends on (1) the nature of the claim made; (2) the type of product it covers; (3) the

possible consequences of a false claim; (4) the benefits of a truthful claim, (5) the cost of developing the required substantiation for the claim, and (6) the amount of substantiation experts in the field believe is reasonable for such a claim. *In the Matter of Pfizer, Inc.*, 81 F.T.C. 23 (1972); *FTC Policy Statement Regarding Advertising Substantiation*, 104 FTC 839 (1984) (appended to *In the Matter of Thompson Medical Co.*, 104 FTC 648). Under these factors, a variety of sources other than two RCTs could substantiate claims about safe products.

This flexible standard, which has been in effect for over 40 years, has made great practical sense. Given the extreme costs of conducting two RCTs and the benefits of allowing a free flow of information to consumers, a two-RCT standard would be overly stringent and stifling. Unlike prescription drugs, foods and dietary supplements generally cannot be patented, and companies therefore cannot recoup the extremely high costs of conducting RCTs. Indeed, RCTs may be even *more* difficult and costly to conduct for structure/function claims than for disease claims. For instance, RCTs to substantiate a claim that a food or dietary supplement improves long-term health could take years or even decades to complete. Under these circumstances, requiring multiple RCTs to substantiate a claim would effectively ban the claim altogether, depriving consumers of valuable information about safe and effective products that promote human health.

Moreover, as Commissioner Wright noted, there is a "tradeoff between deterring deceptive advertising and preserving the benefits to competition and consumers from truthful claims." *Statement of Commissioner Joshua D. Wright* (*Wright Statement*), at 1. Requiring two RCTs for claims about safe foods and dietary supplements would not strike the right balance between these interests. Instead, "[a]dopting a one-size-fits-all approach to substantiation by imposing such rigorous and possibly costly requirements for such a broad category of health- and disease-related claims may, in many instances, prevent useful information from reaching consumers in the marketplace and ultimately make consumers worse off." *Ohlausen Statement* at 1. The Commission has previously recognized the importance of "ensur[ing] that consumers have access to truthful, well-qualified information about emerging areas of science, while at the same time ensuring that consumers can have confidence in the accuracy of claims." FTC Staff Comments, *In re Request for Comment on First Amendment Issues* at 18 (2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf. The Commission's prior "flexible approach to commercial speech" was specifically designed to encourage "greater dissemination of valuable information with benefits for both consumers and competition." *Id.* at 22. Further, the Commission recognized that "[t]he benefits of a flexible approach are especially significant when the information relates to consumer health." *Id.* These vital benefits include "empower[ing consumers] to manage better their own health" and "provid[ing] a strong incentive to competitors to develop new products and to improve existing products, giving consumers more and better choices." *Id.* The Commission should not depart from this flexible approach and impose an arbitrary, rigid, and costly two-RCT standard.

Accordingly, NPA respectfully disagrees with Chairwoman Ramirez's and Commissioner Brill's statement that the "fact that the ingredients in . . . products are

safe" should "not alter [the agency's] conclusion" as to the level of substantiation required. *Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill* (*Ramirez and Brill Statement*), at 4. When a product is safe, the "consequences of a false claim" are far lower than when the product poses risks to consumers, and therefore a lower degree of substantiation should be required. *FTC Policy Statement Regarding Advertising Substantiation*, 104 FTC 839 (1984); *see also Pfizer*, 81 F.T.C. at 91. Furthermore, Congress expressly found in enacting DSHEA that "although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." DSHEA, at § 2(13). The rigid and burdensome two-RCT standard is a regulatory barrier that is inappropriate for safe foods and dietary supplements. A variety of other sources, such as human clinical trials that are not placebo controlled, observational studies, epidemiological evidence, and relevant animal and *in vitro* studies, should be allowed to substantiate claims.

NPA also disagrees with the general requirement that all products be tested by different researchers working independently. As Commissioner Olhausen explained, this requirement is unduly stringent absent "an indication that the defendant fabricated or otherwise interfered with a study or its results." *Olhausen Statement* at 2-3. FDA imposes no such general requirement even on the clinical trials conducted to obtain approval for new drugs; there is thus certainly no basis for FTC to impose a more stringent standard upon dietary supplements and foods. *See FDA Guidance for Industry Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring* (Aug. 2013), *available at* http://www.fda.gov/downloads/Drugs/.../Guidances/ UCM269919.pdf; 21 C.F.R. § 314.126 (listing requirements for "adequate and well-controlled studies"). Similarly, NPA agrees that the requirement that tests be conducted upon an "essentially equivalent product" is unduly stringent because it "appears to be more rigorous than FDA requirements for food and supplement products, [and] can significantly and unnecessarily increase the costs of substantiation, again potentially depriving consumers of useful information." *Olhausen Statement* at 3.

Finally, a two-RCT requirement would raise serious First Amendment concerns. Government restrictions on commercial speech are subject to heightened scrutiny unless the speech is actually false or inherently misleading. Claims are not false or misleading simply because they have not been tested by two RCTs. As the courts of appeals have explained, they can be supported by other evidence. *See, e.g.*, *Pearson v Shalala*, 164 F.3d 650, 655-60 (D.C. Cir. 1999) (claims lacking "significant scientific agreement" were not false or "inherently misleading," and it violated the First Amendment for the government to prohibit them); *Beneficial Corp. v. FTC*, 542 F.2d 611, 620 (3d Cir. 1976) ("[A] remedy, even for deceptive advertising, can go no further than is necessary for the elimination of the deception"). Because the First Amendment applies to speech about dietary supplements and foods just like it does to any other commercial product, FTC cannot adopt an overbroad standard that prevents manufacturers from sharing truthful information with consumers.

2. If FTC intends to depart from its traditional "competent and reliable scientific evidence" standard, then new formal guidance is necessary: Due to FTC's recent actions, which depart from decades of precedent and reflect a deep divide within the Commission itself, the widespread perception in the food and dietary supplement industries is that the agency—or at least two Commissioners and their Staff—intend to impose this heightened standard upon all disease- and health-related claims, even structure/function claims.

Industry is not alone in that assessment. As Commissioner Olhausen explained, recent actions "might be read to imply that two RCTs are required to substantiate *any* health- or disease-related claims, even for relatively safe products." *Olhausen Statement* at 2 (emphasis added). In addition to the proposed GeneLink and foru International settlements, FTC entered into several consent agreements prohibiting companies from making disease- and health-related claims about a number of other safe products, including yogurt, *Dannon Co., Inc.*, 151 FTC 62 (2011), acai berry drinks, *FTC v. Labra*, No. 11 C 2485 (N.D. I.. Jan. 11, 2012), probiotic drinks, *Nestlé HealthCare Nutrition, Inc.*, FTC File No. 092-3087, Agreement Containing Consent Order (July 14, 2010), and dietary supplements, *FTC v. Iovate Health Sciences USA, Inc.*, Case. No. 10-CV-587, slip op. at 7 (W.D.N.Y. July 29, 2010) (Stipulated Final Judgment), unless the companies had at least two RCTs on the products. Furthermore, the Commission recently held that advertisements for pomegranate juice were unlawful because they were not substantiated by RCTs, *In re POM Wonderful*, No. 9344, 2013 FTC LEXIS 6, at *7-*9 (Jan. 10, 2013), overturning the ruling of an administrative law judge that when a product is safe and not being offered as a substitute for medical treatment, "double blind, randomized, placebo-controlled clinical trials . . . are not required," *In re POM Wonderful LLC*, 2012 FTC LEXIS 106, at *328 (May 17, 2012). And, in non-public investigations, FTC Staff has asserted that NPA's members must acquiesce in the same two-RCT standard or face potential enforcement actions.

If the agency does not actually intend to impose "a *de facto* two-RCT standard on health- and disease-related claims for food or other relatively-safe products," *Ramirez and Brill Statement* at 2, the agency should clearly and publicly reaffirm that it will continue to follow the flexible "competent and reliable scientific evidence standard" set forth in its guidance. If, on the other hand, the agency *does* intend to change its substantiation standard, then it should promptly issue rules or guidance clearly setting forth the circumstances under which two RCTs will and will not be required, after providing all stakeholders a full opportunity to comment and placing the burden of persuasion on any parties seeking to change the agency's long-standing position. Consistent with sound government and the rule of law, the agency should *not* continue down its current path of coercing companies into accepting the heightened standard by threatening them with enforcement actions and the prospect of multi-million dollar fines.

Clarity is needed, and the time is now. As Chairwoman Ramirez and Commissioner Brill have recognized, "clear rules" bring critical benefits, including "facilitating the setting of future research and marketing agendas, and preserv[ing] law enforcement resources by minimizing future argument over the quantity and quality of substantiation needed." *Ramirez and Brill Statement* at 2. As discussed above, to

"strike[] the right balance between deterring deceptive advertising and preserving for consumers the benefits of truthful claims," *Wright Statement* at 1, the agency must make clear that RCTs are *not* required to substantiate all health-related claims, particularly structure/function claims, about safe foods and dietary supplements.

Sincerely,

John Shaw
Chief Executive Officer