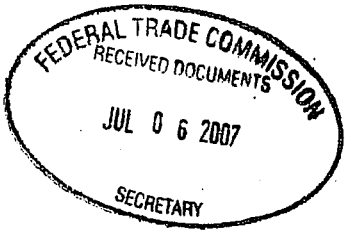
Natural Products ASSOCIATION™
Promoting Natural Products for Healthy Lifestyles
Formerly NNFA

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



Hon. Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room H-135 (Annex S)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

June 18, 2007

RE: Endorsement Guides Review, Project No. P034520

Dear Mr. Clark;

The Natural Products Association, formerly the National Nutritional Foods Association NNFA), is submitting the following comments in response to a request from FTC for input on the *FTC's Guides Concerning the Use of Endorsements and Testimonials in Advertising*.

The Natural Products Association would like to participate in any upcoming FTC workshops or meetings at which this subject would be discussed. The Natural Products Association was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. The Natural Products Association is a non-profit 501 (c) (6) association whose mission is to unite a diverse membership, from the smallest health food store to the largest natural products supplier. We champion consumers' freedom of choice in our marketplace. We strengthen and safeguard retailers and suppliers. We build strong markets to fuel industry growth. We act together with uncompromising integrity, and we encourage all to reach ever higher standards of quality.

The Natural Products Association wishes to comment on the following questions per the Commission's solicitation:

"(1) What are the implications and limitations of the Endorsement Booklet Study with respect to the question of whether consumer testimonials about a product's efficacy or performance convey that the product is effective for the purpose(s) discussed in the testimonials? What are the implications and limitations of the study with respect to the question of whether consumer testimonials convey that the endorser's experience is representative of what consumers will generally achieve with the advertised product? Is there any other research or evidence that would be relevant in answering these questions?"

"(2) What are the implications and limitations of the Endorsement Booklet Study with respect to the effectiveness of disclaimers in limiting any communication of product efficacy from consumer testimonials? What are the implications and limitations of the study with respect to the effectiveness of disclaimers in limiting any communication of typicality from consumer testimonials? Is there any other research or evidence that would be relevant in answering these questions?"

In addition to the limitations the study authors reference, sample size, age of participants, etc., a number of limitations exist with respect to the booklet study. FTC has previously advised consumers to be suspicious of: claims that a product is an effective cure for a wide range of ailments; claims that a product is a "scientific breakthrough," "miraculous cure," "secret ingredient," or "ancient remedy"; and testimonials from people who claim amazing results. Testimonials often are undocumented and are not a substitute for scientific proof. However, the majority of the sample claims/testimonials used in the booklet study fall into this area of suspicion. Thus, there is no baseline to distinguish how consumers respond to claims and testimonials supported by scientific agreement, as well as disclaimers accompanying that level of science. For example a testimonial of this nature, "My wife Mrs. X just turned 80 and by taking 1200 mg of Calcium daily with vitamin D her doctor says she has stronger bones than she did at 70," is much more representative of the majority of products that are sold and distributed by the responsible industry and much more in-line with what consumers will generally achieve and expect with an advertised dietary supplement product versus a product making questionable claims/testimonials that falls within FTC's opinion of a suspicious product.

One other point that needs to be addressed is that with an older population, as was used in this study, there is a high level of unfamiliarity and a lack of knowledge regarding the abundant resources available on the internet regarding claims and testimonials. Resources like FTC's Operation Cure-All-Consumer Information Page (http://www.ftc.gov/healthclaims/) and FDA's Buying Medicines and Medical Products Online (http://www.fda.gov/oc/buyonline/) have been very helpful to consumers in choosing healthcare products. With over 69% of the population of the United States with internet access (http://www.internetworldstats.com/america.htm#us) and that number growing, any future study population should address the effects these resources have on consumers. Lastly, users of Complementary and Alternative Medicine (CAM), which includes supplements tend to be well educated and female (JAMA. 1998 Nov 11;280(18):1569-75) obviously these trends would need to be represented appropriately.

"(3) What are the implications and limitations of the Second Endorsement Study with respect to the question of whether consumer testimonials about a product's efficacy or performance convey that the product is effective for the purpose(s) discussed in the testimonials? What are the implications and limitations of the Second Endorsement Study with respect to the question of whether consumer testimonials convey that the endorser's experience is

representative of what consumers will generally achieve with the advertised product? Is there any other research or evidence that would be relevant in answering these questions?

(4) What are the implications and limitations of the Second Endorsement Study with respect to the effectiveness of disclaimers in limiting any communication of product efficacy from consumer testimonials? What are the implications and limitations of the Second Endorsement Study with respect to the effectiveness of disclaimers in limiting any communication of typicality from consumer testimonials? Is there any other research or evidence that would be relevant in answering these questions?"

As described above, many of the limitations are carried over to this study as well. Again the examples used in this study err on the side of suspicion. Thus, the findings that the disclosures "failed" is less likely to be based on the sample presented and more likely to be influenced by what consumers will generally achieve and expect with most dietary supplement products versus a product making questionable claims/testimonials that falls within FTC's opinion of a suspicious product. Additionally the bottled product does not represent a properly formatted label per the Dietary Supplements Health and Education Act (DSHEA) thus introducing bias into the study. As FTC is aware all statements of nutritional support for dietary supplements must be accompanied by a two-part disclaimer on the product label: that the statement has not been evaluated by FDA and that the product is not intended to "diagnose, treat, cure or prevent any disease." Although DSHEA does not directly apply to advertising, there are situations where such a disclosure is desirable in advertising as well as in labeling to prevent consumers from being misled about the nature of the product and the extent to which its efficacy and safety have been reviewed by regulatory authorities. FTC currently has An Advertising Guide for Industry. As stated per the Guide "*Consumer testimonials raise additional concerns about which advertisers need to be aware. Ads that include consumer testimonials about the efficacy or safety of a supplement product should be backed by adequate substantiation that the testimonial experience is representative of what consumers will generally achieve when using the product. As discussed earlier, anecdotal evidence of a product's effect, based solely on the experiences of individual consumers, is generally insufficient to substantiate a claim. Further, if the advertiser's substantiation does not demonstrate that the results are representative, then a clear and conspicuous disclaimer is necessary. The advertiser should either state what the generally expected results would be or indicate that the consumer should not expect to experience the attested results. Vague disclaimers like "results may vary" are likely to be insufficient.*" To effectively measure the impact of claims, testimonials and disclaimers, the better approach would be to use materials properly formatted to both FTC's and FDA's guidelines, not those that are suspect, which have already been established to be confusing.

"(9) The current Guides allow advertisers to use testimonials that are not generally representative of what consumers can expect from the advertised product so long as the advertisers clearly and conspicuously disclose either (1) what the generally expected performance would be in the depicted circumstances, or (2) the limited applicability of the depicted results to what consumers can generally expect to receive, i.e., that the depicted results are not representative.

(a)What would be the effects on advertisers and consumers of requiring clear and conspicuous disclosure of the generally expected performance whenever the testimonial is not generally representative of what consumers can expect from the advertised product?

(b) What information, other than what is required to substantiate an efficacy or performance claim, would be required for an advertiser to determine generally expected results? How difficult would it be for the advertiser to make this determination? Do the answers to these questions vary by product type and, if so, how?"

The current FTC guidelines, coupled with the provisions in DSHEA have allowed FTC to file over 100 cases, since 1990, that have challenged false and misleading weight-loss claims involving over-the-counter drugs, dietary supplements, commercial weight-loss centers, weight-loss devices and exercise equipment. The most recent ruling in this area was a settlement for $25 million from supplement makers making weight loss and weight control claims not supported by scientific evidence. As part of the settlement, the FTC indicated the marketers promised to limit future advertising claims. Thus the current guides in tandem with the laws allow for enforcement against labeling and advertising that is not truthful and misleading.

Perhaps if it could, FTC could attribute the problems with testimonials and celebrity endorsements accordingly, namely those that appear in endorsements of prescription pharmaceutical products. For example, Ms. Sally Field, is the celebrity spokesperson for Roche Therapeutics™' "Rally With Sally For Bone Health" promotion for the drug Boniva™. Nowhere on the Boniva™ web materials, or in the print and TV ads featuring Ms. Field is there any disclosure that indicates Ms. Field is paid for her endorsement. Although FTC apparently does not make that kind of assumption with regard to non-pharmaceutical endorsements, FDA assumes this is understood by consumers, thus FTC will not go after Pharmaceutical manufacturers making suspicious testimonials. The FDA and FTC have agreed that pharmaceutical products are the FDA's purview, which makes it much easier for "legitimate" pharmaceutical companies to sponsor outrageous "miracle" claims by paying celebrities to say whatever they like. The Natural Products Community obviously does not enjoy the same "protection", nor do we believe we should be allowed to blur the lines of truthful and not misleading advertising, marketing and labeling of our products. We believe that this disparity in regulation has only created greater confusion in the marketplace for consumers, retailers and suppliers, alike, of all consumer healthcare products, often found side-by-side on store shelves. As we know dietary supplements are regulated as foods by the FDA. On

the safety continuum, foods are generally recognized as safe, in contrast to pharmaceuticals which have to prove their benefit in comparison to their risk. Thus, we ask that the concern be attributed appropriately where the greatest risk to consumers resides. We believe the current guides and guidelines have been sufficient for regulation of dietary supplement products.

Going forward, the Natural Products Association reiterates its interest in partnering with FTC and the US government to improve the quality of the products and marketing practices impacting the health of our Nation.

Very truly yours,

Daniel Fabricant, Ph.D.
Vice President, Scientific and Regulatory Affairs
dfabricant@naturalproductsassoc.org