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July 27, 2010

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

Re: *In the Matter of* Nestlé HealthCare Nutrition, Inc., a corporation
FTC File No. 092 3087
Request for Public Comments, 75 Fed. Reg. 42752 (July 22, 2010)

Dear Secretary Clark,

The following comments are submitted in regard to the agency's request for public comments on the proposed Consent Decree, noted above. Confidential treatment is not requested for any part of this paper or any of the comments.

A way to layout the circumstances surrounding the proposed Consent Decree is:

On one side are consumers interested in having information, as current as the state of the research, about the benefits of available products.

On another other side are knowledgeable, responsible companies that have products and information that are of interest to consumers.

Between them is, an agency acting to curtail information, grounded in research from peer-reviewed journals, which consumers are able to interpret and use to make personal decisions about health and nutrition.

The proposed decree chills independent resellers of probiotics from informing consumers about competent medical research and the indicated benefits of these products.

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Background to the Decreed Restraints.

"Part I of the {proposed} consent order is designed to address …unsubstantiated representations that {the Nestlé} products prevent upper respiratory tract infections (URTIs)." The order will restrict representations that probiotics "prevent or reduce the risk" of URTIs. While it restrains only a respondent, the proposed decree acts essentially to restrict all resellers of probiotics from making representations based on medical studies that conclude whether certain probiotics are associated with reducing the risk of URTIs.

Review of the ad copy in the FTC file present the fundamental question – was it represented that probiotics "prevent upper respiratory tract infections"? The visual ad, and its textual description, contain a scene where one kid sneezes, and the other kid takes a sip of the Nestlé product through the straw containing the probiotic. Whether a sneeze causes "upper respiratory tract infections," or whether the visual represents that sipping through that straw will "prevent upper respiratory tract infections," are equally in doubt.

For a practice to be deceptive, there first must be a "representation."[1] The ad copy, set forth in Exhibits A-C available for public comment, lacks representations that probiotics "prevent or reduce the risk" of URTIs. The 'sneeze scene' is inadequate to support a broad restraint on commercial free speech, by every reseller, about medical research, and studies, which advocate the potential health benefits of probiotics.[2]

Part I of the proposed consent decree impacts independent resellers of probiotics, and it acts as a prior restraint on resellers' commercial free speech about probiotics and medical opinions on the health benefits of those products.[3] While the commercial free speech guarantees do not protect ads that misrepresent or mislead, the remedies must not be so stringent as to prohibit fair comment and ads that reasonably can be substantiated.[4]

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[1] "[F]irst, there is a representation, omission, or practice that, second, is likely to mislead consumers acting reasonably under the circumstances, and third, the representation, omission, or practice is material." *F.T.C. v. Pantron I Corp*., 33 F.3d 1088, 1095 (9th Cir. 1994).

[2] The "focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made. See *fn.* 3 FTC POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION, (Jan 16, 2009), attached hereto.

[3] G.J. Leyer, S .Li, M.E. Mubasher, C. Reifer, A.C. Ouwehand, *"Probiotic Effects on Cold and Influenza-Like Symptom Incidence and Duration in Children"*, Journal *Pediatrics,* Volume 124: e172-e179 (2009), noted that "Daily probiotic dietary supplementation during the winter months was a safe effective way to reduce episodes of fever, rhinorrhea, and cough, the cumulative duration of those symptoms, the incidence of antibiotic prescriptions, and the number of missed school days attributable to illness."

[4] A remedy "in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation." *In re R.M.J.,* 455 U.S. 191, 203 (1982).

The request for comments perceives a 'net' boundary between ads that *might* be permitted, and those sure to be prohibited. "[I]f the net impression is that a [probiotic] product prevents or reduces the risk of URTIs, and not merely that there is limited scientific evidence supporting the claim," then that commercial message is restrained. Further remarks indicate the 'net' will catch most every ad. The agency's "experience and research show that it is very difficult to" fit the commercial message in between the 'net impression' restraint and the permission to republish 'limited scientific evidence'.[5]

Thus, independent resellers of probiotics must avoid ads about the potential health benefits, as set out in peer-reviewed medical journals. Consequently, consumers lose access to information upon which they can decide whether the products offer nutritional or other benefits. White-boxed products or brown bottles may negate any claims of an 'implied' representation, but totally fail to inform consumers about published research.

This agency has expressed its policy that among the "factors relevant to the benefits and costs of substantiating" advertised claims are: the "consequences of a false claim," and "the benefits of a truthful claim." Here, based on the 'sneeze scene,' the agency will restrain most all ads about research, which may convince consumers, that some probiotics potentially reduce the risk of colds and URTIs. What "consequences" are feared if that potential, risk reduction is not met? Kids get colds. On the other side of the docket, some "benefits" from *re*-reporting current medical studies are that consumers are better informed. Restraining that commercial information makes them less informed.

Part III of the proposed Consent Decree increases the "substantiation" burden for probiotics, and possibly, for most nutriceuticals. This agency's past orders, dealing with other comestibles, have required that express claims in advertising be substantiated with 'state of the art' testing data.[6] Being decreed in this probiotics case are ramped-up, proof standards – "at least two adequate and well-controlled human clinical studies … conducted by different researchers," etc. Requiring substantiation equivalent to proof is unreasonable, and too stringent for probiotics. Independent resellers, to avoid the risks of agency scrutiny, are forced to opt for leaving consumers in the dark about probiotics, and about the benefits reported in published studies that have been shown in testing 'based on the expertise of professionals in the' field. Would the data (Exhibit C) the supports the FAQs with the challenged ads inform, or confuse, a greater number of consumers?

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[5] It can be questioned whether "limited" admits of a singular definition in respect to "scientific evidence." Part III of the proposed Consent Decree does fashion a "*Daubert*" styled standard for "scientific evidence," but it is doubtful that this aids in measurably defining what "limited" evidence is, or what evidence would exceed the undefined 'limits.' See too, Part IV.

[6] In prior matters, "Competent and reliable scientific evidence" meant that the advertiser had "tests, {etc.} based on the expertise of professionals in the relevant area, {etc.}" as orders from *In the Matter of Native Essence Herb Co.*, FTC File No.: 082 3115 (May 12, 2009), and *In the Matter of Kellogg Co.*, FTC File No. 082 3145 (revised Order June 3, 2010).

The Increased Substantiation Requirements Disserve the Goal of Informed Consumers.

The 2009 "Policy Statement" indicates that it has been allowable to advertise that "studies show," if the advertiser has the "amount and type of substantiation the ad actually communicates to consumers," viz., studies that 'show.' Here, the challenged ad visual and ad copy make no express claim about URTIs (Exhibit A to FTC's Complaint).

The proposed Consent Decree indicates that the claims in question are implied claims, for which, this agency typically has not expected the advertiser to have the same substantiation as it expected for express claims in ads. It seems odd then, that here, for implied claims about probiotics, that the substantiation requirements are greater than for *express* claims, and plainly greater than possessing and relying upon "tests, {etc.}based on the expertise of professionals in the relevant area, {etc.}" as mandated in earlier orders (see, fn. 5, *supra*).[7] To depart from a history of decrees that set reasonable substantiation requirements for various comestibles and claims of health benefits, and to move the mark to where implied claims must be proven by multiple, independently-conducted, human clinic studies is unwarranted, particularly in regard to probiotics.[8]

Based on the foregoing, it is respectfully requested that the substantiation requirements for probiotics be reconsidered, and cut back to the former standard of "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." To restrain advertising that informs consumers about state of the art conclusions in peer-reviewed medical journals as to the health benefits of probiotics is unreasonably stringent, and not in the public interest.[9]

Respectfully submitted,

Lee Thomason

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[7] See also, *Federal Trade Com'n. v. Enforma Natural Products, Inc*., 362 F.3d 1204, fn. 2 (9th Cir. 2004) (related to Steve Garvey endorser case) referring to FTC order that defined "competent and reliable scientific evidence that substantiates," as being "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."

[8] Restrictions on commercial free speech must be "no more extensive than necessary to serve" the "government's asserted interest." *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 340 (1986).

[9] Commercial free speech needs to be accorded a "degree of protection ... necessary to insure that the flow of truthful and legitimate commercial information is unimpaired." *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,* 425 U.S. 748, 772 n. 24 (1976).

FTC POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION

Introduction

On March 11, 1983, the Commission published a notice requesting comments on its advertising substantiation program.[1] To facilitate analysis of the program, the notice posed a number of questions concerning the program's procedures, standards, benefits, and costs, and solicited suggestions for making the program more effective. Based on the public comments and the staff's review, the Commission has drawn certain conclusions about how the program is being implemented and how it might be refined to serve better the objective of maintaining a marketplace free of unfair and deceptive acts or practices. This statement articulates the Commission's policy with respect to advertising substantiation.

The Reasonable Basis Requirement

First, we reaffirm our commitment to the underlying legal requirement of advertising substantiation-that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.

The Commission intends to continue vigorous enforcement of this existing legal requirement that advertisers substantiate express and implied claims, however conveyed, that make objective assertions about the item or service advertised. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true.[2] Therefore, a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.

Standards for Prior Substantiation

Many ads contain express or implied statements regarding the amount of support the advertiser has for the product claim. When the substantiation claim is express (e.g.., "tests prove", "doctors recommend", and "studies show"), the Commission expects the firm to have at least the advertised level of substantiation. Of course, an ad may imply more substantiation than it expressly claims or may imply to consumers that the firm has a certain type of support; in such cases, the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers.

Absent an express or implied reference to a certain level of support, and absent other evidence indicating what consumer expectations would be, the Commission assumes that

consumers expect a "reasonable basis" for claims. The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses.

One issue the Commission examined was substantiation for implied claims. Although firms are unlikely to possess substantiation for implied claims they do not believe the ad makes, they should generally be aware of reasonable interpretations and will be expected to have prior substantiation for such claims. The Commission will take care to assure that it only challenges reasonable interpretations of advertising claims.[3]

Procedures for Obtaining Substantiation

In the past, the Commission has sought substantiation from firms in two different ways: through industry-wide "rounds" that involved publicized inquiries with identical or substantially similar demands to a number of firms within a targeted industry or to firms in different industries making the same type of claim; and on a case-by-case basis, by sending specific requests to individual companies under investigation. The Commission's review indicates that "rounds" have been costly to both the recipient and to the agency and have produced little or no law enforcement benefit over a case-by-case approach.

The Commission's traditional investigatory procedures allow the staff to investigate a number of firms within an industry at the same time, to develop necessary expertise within the area of investigation, and to announce our activities publicly in circumstances where public notice or comment is desirable. The Commission intends to continue undertaking such law enforcement efforts when appropriate. However, since substantiation is principally a law enforcement tool and the Commission's concern in such investigations is with the substantiation in the *advertiser's* possession, there is little, if any, information that the public could contribute in such investigations. Therefore, the Commission anticipates that substantiation investigations will rarely be made public before they are completed.

Accordingly, the Commission has determined that in the future it will rely on nonpublic requests for substantiation directed to individual companies via an informal access letter or, if necessary, a formal civil investigative demand. The Commission believes that tailored, firm-specific requests, whether directed to one firm or to several firms within the same industry, are a more efficient law enforcement technique. The Commission cannot presently foresee circumstances under which the past approach of industry-wide rounds would be

appropriate in the ad substantiation area.

Relevance of Post-Claim Evidence in Substantiation Cases

The reasonable basis doctrine requires that firms have substantiation before disseminating a claim. The Commission has on occasion exercised its discretion, however, to consider supporting materials developed after disseminations The Commission has not previously identified in one document the circumstances in which it may, in its discretion, consider post-claim evidence in substantiation cases.[5] Such guidance can serve to clarify the program's actual operation as well as focus consideration of postclaim evidence on cases in which it is appropriate.

The Commission emphasizes that as a matter of law, firms lacking a reasonable basis before an ad is disseminated violate Section 5 of the FTC Act and are subject to prosecution. The goal of the advertising substantiation requirement is to assure that advertising is truthful, however, and the truth or falsity of a claim is always relevant to the Commission's deliberations. Therefore, it is important that the agency retain the discretion and flexibility to consider additional substantiating evidence, not as a substitute for an advertiser's prior substantiation, but rather in the following circumstances:

- When deciding, before issuance of a complaint, whether there is a public interest in proceeding against a firm;
- When assessing the adequacy of the substantiation an advertiser possessed before a claim was made; and
- When deciding the need for or appropriate scope of an order to enter against a firm that lacked a reasonable basis prior to disseminating an advertisement.

First, using post-claim evidence to evaluate the truth of a claim, or otherwise using such evidence in deciding whether there is a public interest in continuing an investigation or issuing a complaint, is appropriate policy. This does not mean that the Commission will postpone action while firms create post-claim substantiation to prove the truthfulness of claims, nor does it mean that subsequent evidence of truthfulness absolves a firm of liability for failing to possess prior substantiation for a claim. The Commission focuses instead on whether existing evidence that claims are true should lead us in the exercise of our prosecutorial discretion to decline to initiate a law enforcement proceeding. If available post-claim evidence proves that the claim is true, issuing a complaint against a firm that may have violated the prior substantiation requirement is often inappropriate, particularly in light of competing demands on the Commission's resources.

Second, post-claim evidence may indicate that apparent deficiencies in the pre-claim substantiation materials have no practical significance. In evaluating the adequacy of prior substantiation, the Commission will consider only post-claim substantiation that sheds light

on pre-existing substantiation. Thus, advertisers will not be allowed to create entirely new substantiation simply because their prior substantiation was inadequate.

Finally, the Commission may use post-claim evidence in determining the need for or appropriate scope of an order to be entered against a firm that lacked a reasonable basis. Thus, when additional evidence offered for the first time at trial suggests that the claim is true, the Commission may frame a narrower order than if there had been no post-claim evidence.

The Commission remains committed to the prior substantiation requirement and further believes that these discretionary factors will provide necessary flexibility. The Commission will consider post-claim evidence only in the circumstances listed above. But, whether it will do so in any particular case remains within its discretion.

Self Regulation Groups and Government Agencies

The Commission traditionally has enjoyed a close working relationship with self regulation groups and government agencies whose regulatory policies have some bearing on our law enforcement initiatives. The Commission will not necessarily defer, however, to a finding by a self-regulation group. An imprimatur from a self-regulation group will not automatically shield a firm from Commission prosecution, and an unfavorable determination will not mean the Commission will automatically take issue, or find liability if it does. Rather the Commission will make its judgment independently, evaluating each case on its merits. We intend to continue our useful relationships with self-regulation groups and to rely on the expertise and findings of other government agencies in our proceedings to the greatest extent possible.

By direction of the Commission.

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' The distinction between pre-claim and post-claim evidence is only relevant when the charge is lack of substantiation. For other chases, such as falsity, when evidence was developed is irrelevant to its admissibility at trial.

[1] 48 FR 10471, March 11, 1983.

[2] Nor presumably would an advertiser have made such claims unless the advertiser thought they would be material to consumers.

[3] Individual Commissioners have expressed differing views as to how claims should be interpreted so that advertisers are not held to outlandish or tenuous interpretations. Notwithstanding these

variations in approach, the focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made.

[4] The Commission's evidentiary rule, 16 C.F.R. 3.40, has sometimes been interpreted as precluding introduction of post-claim substantiation. In fact, it does not. Section 3.40 only provides a sanction against the introduction of evidence that should have been produced in response to a subpoena, but was not.