UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

November 30, 2000

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RE: Petition For Rulemaking
Dr. Julian M. Whitaker et al.
Project No. P004501

Dear Mr. Emord:

This letter is in response to your Petition for Rulemaking on behalf of Dr. Julian Whitaker, Pure Encapsulations, Inc., Imagenetix, Inc. and XCEL Medical Pharmacy, Ltd. (hereinafter "Petitioners"). The Petition requests that the Commission promulgate either: 1) a rule whereby the agency would issue advisory opinions on the adequacy of substantiation for advertising claims for dietary supplements or, in the alternative; 2) a rule further defining the principles of substantiation for such claims. After careful consideration of the Petition and for the reasons stated below, the Commission has decided to deny the Petition.

Petitioners' proposal that the agency implement a policy of pre-approving, through advisory opinions, advertising claims about the benefits of supplements does not conform to the Commission's Rules of Practice[1] governing the appropriate use of advisory opinions. Moreover, the proposed policy would be unfeasible because of the large number of potential claims and the extensive resources that would be required to conduct a thorough analysis of the scientific literature relevant to each claim. Petitioners request in the alternative that the Commission promulgate a rule that more definitively sets out the specific elements of the "competent and reliable scientific evidence" standard. Such a rule is unnecessary given the guidance that is already available.[2]

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[1] 16 C.F.R.§ 1.1.

[2] For example, specific guidance on how the Commission's standard applies to dietary supplement advertising is set out in *Dietary Supplements: An Advertising Guide for Industry*, FTC, Bureau of Consumer Protection (1998). The Supplement Advertising Guide addresses many of the questions enumerated in the petition.

Although we deny the rulemaking request, the Commission believes it would be helpful to Petitioners, and others, to address some of the questions and criticisms about the FTC's approach to evaluating supplement advertising. In addition, we respond to the contention that this approach violates Petitioners' Constitutional rights and is insufficient under the Administrative Procedure Act.

FTC Approach to Evaluating Dietary Supplement Advertising: Background

The Federal Trade Commission is primarily a law enforcement agency. The FTC's authority over dietary supplement advertising derives from Sections 5 and 12 of the Federal Trade Commission Act.[3] With respect to advertising, these sections impose two basic obligations: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for objective product claims.[4] Under the FTC Act, there is no regulatory scheme for the pre-market review and approval of advertising claims for products or services, including dietary supplements. Instead, advertisers are free to make the advertising claims they deem appropriate, subject to these two basic obligations. When there are concerns about specific claims, the Commission staff conducts non-public investigations and the Commission may institute an enforcement action if it finds reason to believe that the claims are false, misleading, or unsubstantiated and that a law enforcement action would be in the public interest.[5]

In assessing substantiation for claims, staff reviews all of the materials submitted by the advertiser and also reviews the pertinent scientific literature.[6] The assessment of the proffered

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[3] Section 5 of the FTC Act broadly prohibits deceptive and unfair acts or practices in or affecting commerce, including deceptive advertising. 15 U.S.C. § 45. In addition, supplement advertising falls under Sections 12 and 15 of the FTC Act, which prohibit false advertisements, defined as advertisements that are misleading in a material respect. 15 U.S.C. §§ 52, 55.

[4] These principles are articulated in the FTC's Deception Policy Statement, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984); and Substantiation Policy Statement, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984).

[5] Staff's investigations are non-public in large part to protect the reputation of the party under investigation and the confidentiality of the materials they submit. No public announcement is made about a case until the Commission has made a formal allegation of law violation.

[6] In reviewing the science, the Commission has indicated that it gives great deference to FDA determinations of whether there is adequate support for such claims. *See* Supplement Advertising Guide at 1. In that regard, the Commission notes that FDA has recently reviewed the science relating to a variation of one of the claims referenced by Petitioners. As a result of that review, FDA has now authorized, for labeling, a claim relating to omega-3 fatty acids and cardiovascular health. The FDA-authorized claim is carefully qualified, with detailed disclosures about the inconclusive nature of the science. *FDA Letter to Jonathan Emord,* Oct. 31, 2000

substantiation is closely tied to how the claims are presented and the extent to which they are qualified. Typically, the advertiser has an opportunity to discuss the alleged violations with staff and the Commissioners before any formal action is taken.[7] In a case involving unsubstantiated claims, staff routinely explains to the advertiser the factors leading to the conclusion that the claims have not been adequately substantiated and provides the advertiser with an opportunity to respond.

If staff concludes that the substantiation is inadequate or that the claim is not sufficiently qualified to accurately reflect the substantiation that exists, staff will lay out the alleged violations in a draft complaint and will propose an appropriate remedy. This relief typically includes a provision prohibiting the advertiser from making false or unsubstantiated claims.[8] In appropriate cases, staff also seeks additional relief, such as disclosures about the efficacy or safety of the product, redress for consumers, disgorgement of profits, or corrective advertising.

The Commission believes that requiring advertisers to possess adequate substantiation for their claims in the first instance is the best way to protect consumers and is the most efficient use of government resources. It also provides maximum flexibility for advertisers to fashion claims and develop support with minimal government involvement. The Commission believes that its enforcement approach best serves the interests of consumers and businesses.

Rulemaking to Define "Competent and Reliable Scientific Evidence"

"Competent and reliable scientific evidence" is the standard the Commission requires for all claims relating to the safety or health benefits of a dietary supplement.[9] Petitioners have

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(No. 91N-0103).

[7] The opportunity to discuss the matter generally will not be provided in certain circumstances such as where doing so might risk the dissipation of assets or destruction of documents or otherwise frustrate effective final relief.

[8] An order provision prohibiting an unsubstantiated claim does not preclude the advertiser from making the challenged claim in future advertising if the advertiser subsequently develops adequate substantiation or qualifies the claim sufficiently to reflect the current state of the science.

[9] Petitioners refer in their rulemaking request to "structure/function" claims for dietary supplements, referencing the definition of that term established by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. Under DSHEA, "structure/function" claims are permitted in labeling without prior FDA approval, provided they are truthful, not misleading and substantiated, and provided other notification and disclaimer requirements are met. In contrast, "health" claims in labeling must be submitted to FDA for prior approval pursuant to rulemaking. Under FTC law, the Commission does not similarly categorize claims and all advertising claims that pertain to a supplement's health-related benefit must be substantiated by "competent and reliable scientific evidence." The FTC

requested that the Commission promulgate a rule to define this term. The Commission, however, believes that it has already adequately defined its standard and that such a rule is unwarranted.

There is significant guidance for advertisers on how the FTC interprets and applies its substantiation standard. Sources include: 1) the FTC's Substantiation Policy Statement;[10] 2) a body of case law, including cases involving dietary supplements;[11] 3) the FTC's Supplement Advertising Guide, written specifically for the dietary supplement industry, which illustrates the principles of substantiation with numerous examples;[12] and 4) public presentations on this subject made by FTC officials at various industry conferences.[13] In addition to these sources, acknowledged in the Petition, additional sources of guidance include the Commission's Food Policy Statement, which lays out the FTC's approach to substantiation of health claims for food advertising;[14] two staff comments, one submitted to FDA and the other to the Presidential

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does not pre-approve any claims. References to "claims" in this document are to any health-related claim whether relating to structure/function or disease.

[10] Substantiation Policy Statement, 104 F.T.C. 648, 839 (1984).

[11] The substantiation doctrine was first articulated by the Commission in *Pfizer, Inc.*, 81 F.T.C. 23 (1972). That opinion set out the factors that determine what level of substantiation is appropriate in a particular case where no express claim has been made about the level of support. The six "Pfizer factors" are: 1) the type of product; 2) the type of claim; 3) the benefits of a truthful claim; 4) the cost/feasibility of developing substantiation; 5) the consequences of a false claim; and 6) the amount of substantiation that experts in the field believe is reasonable. *Id.* For claims related to health or safety, the Commission has determined that these factors translate to "competent and reliable scientific evidence," which has been defined in numerous consent orders as: "tests, analyses, research, studies, or other evidence based upon 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." *See, e.g., Schering Corp.*, 118 F.T.C. 1030 (1994)(consent order); *The Quigley Corp.*, C-3926 (Feb. 10, 2000)(consent order); *Met-RX USA, Inc. et al.*, Civ. No. SACV99-1407 DOC(ANX) (C.D.Cal. Nov. 24, 1999)(Stipulated Final Order).

[12] *Supplement Advertising Guide* (1998).

[13] Individual Commissioners and FTC staff make presentations on the subject of dietary supplement advertising, including the FTC's approach to substantiation of claims, in a variety of public forums. These workshops and conferences, sponsored by the major dietary supplement trade associations and others, are widely attended by supplement industry members and typically provide an opportunity for parties to pose questions to staff.

[14] *Enforcement Policy Statement on Food Advertising*, 59 Fed. Reg. 28388 (June 1, 1994)("Food Policy Statement"). Although the Commission issued the Food Policy Statement to describe how its approach to food advertising related to FDA's regulation of food labeling under the Nutrition Labeling and Education Act of 1990, the principles of claim substantiation set forth

Commission on Dietary Supplement Labels, concerning the regulation of dietary supplement claims;[15] and business education materials, available both in print and through the Commission's Web site at *www.ftc.gov*.[16]

Petitioners assert that, notwithstanding these sources of guidance, the Commission has failed to provide sufficient certainty about the criteria it uses to evaluate the scientific support for a claim. According to Petitioners, this failure, coupled with the agency's active enforcement program, has deterred Petitioners from making certain claims for their products.[17] The Commission has not established particular requirements for size, duration or protocol of a scientific study, nor has it provided any single fixed formula for the number and type of studies required to substantiate a claim. Instead, the Commission's substantiation doctrine allows for some flexibility in the type and amount of evidence required depending on the nature of the claim and how it is presented and qualified. The Commission has determined that further refinement of the standard through rulemaking might result in a more rigid standard that, in some instances, could be higher than necessary to ensure adequate scientific support for certain specific claims.

The Petition lists a number of specific questions about the Commission's substantiation standard. Most of these questions have already been addressed with as much specificity as possible in the Supplement Advertising Guide. While there may not be a single dispositive answer to every question, the Commission has set out simple and clear principles to determine what type and amount of scientific support will be required in any given case. Examples of questions raised in the petition include:

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in the Policy Statement are no different than for claims about dietary supplements or other health-related products.

[15] FTC Staff Comment on Draft Report of the Commission on Dietary Supplement Labels, Letter to Kenneth D. Fisher, Ph.D., Executive Director (Aug. 14, 1997); In the Matter of Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Proposed Rule: Comments of the Staff of the Bureau of Consumer Protection of the Federal Trade Commission, Docket No. 98N-0044 (Aug. 27, 1998).

[16] *See, e.g., Frequently Asked Advertising Questions: A Guide for Small Business.*

[17] A review of Petitioners' Web sites suggests that they have not been completely deterred from making the claims at issue in the Petition. For example, at the time Petitioners filed the petition, Dr. Whitaker's web site, www.healthydirections.com, was advertising a product "EPA/GLA Essentials: Balanced Omega Oil Complex" to "enhance your cardiovascular health." The same site currently markets "Prostate Health," a supplement containing saw palmetto and pygeum, to "maintain healthy prostate size and normal sexual and urinary function." These are two of the specific claims that Petitioners charge the FTC's policy has chilled.

Type of Studies Required (Human vs. Animal or In Vitro)

Petitioners list a series of questions relating to the nature, quality and quantity of evidence required. The Supplement Advertising Guide outlines the principles for assessing what amount and type of evidence is necessary, as well as the criteria for evaluating the design, implementation and other aspects of the quality of individual studies. In response to Petitioners' question about whether animal studies are sufficient, the Supplement Advertising Guide makes clear that, "as a general rule, well-controlled human clinical studies are the most reliable form of evidence."[18] The Supplement Advertising Guide also indicates, however, that the Commission will consider other forms of evidence, like animal and *in vitro* studies "where they are widely considered to be acceptable substitutes for human research or where human research is infeasible."[19]

Number of Studies Required

Petitioners also ask how many studies are necessary to substantiate a claim. The Supplement Advertising Guide states expressly that "there is no requirement that a dietary supplement claim be supported by any specific number of studies" and also emphasizes that "the quality of studies will be more important than quantity."[20] At the same time, the Supplement Advertising Guide notes that "replication of research results in an independently-conducted study adds to the weight of the evidence."[21] The Commission has determined that there is no set number of studies that would fit every situation. Consideration has to be given to such widely variable factors as the nature of the claim being made, the nature of the product being studied, how dramatic or subtle the studied effect is, and the context of the surrounding scientific literature.[22]

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[18] Supplement Advertising Guide at Section B.2. Petitioners suggest that the cost of controlled blinded clinical trials would be prohibitive, particularly since supplements cannot be patented. The Commission is confident that adequate studies can be conducted for far less than the "several hundred million dollars" cited by Petitioners. In addition, the advertiser may rely on existing research provided it is relevant to the product and claims advertised.

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] The Commission's consent order with Schering Corp. provides one example of a specific determination of the type and number of studies required in a particular case. In that matter, the Commission concluded that "at least two adequate and well-controlled, double-blinded clinical studies" would be necessary to substantiate weight loss and appetite suppressant claims for the supplement, Fibre Trim. *Schering Corp.*, 118 F.T.C. 1030 at 1127 (1994)(consent order).

Study of Individual Ingredients in a Product

Petitioners also ask whether advertisers must test each ingredient in a multi-ingredient product and whether the product itself must be tested. Rather than imposing an absolute rule that all ingredients in a product must be evaluated or that the specific product itself must always be tested, the Supplement Advertising Guide lays out clear principles for making these determinations on a case-by-case basis. In an example designed to specifically illustrate this point, the Supplement Advertising Guide states, "where there is a reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients, studies showing the effect of the individual ingredients may be insufficient...."[23] The Supplement Advertising Guide also makes clear that if an advertiser wishes to rely on research done on other products, it must make sure that its own product is consistent in dosage and formulation with the product that has been studied.[24]

Publication in Peer-Reviewed Journal

Petitioners also ask whether studies in peer-reviewed scientific journals are preferred over unpublished clinical trials. The Supplement Advertising Guide indicates clearly that "the FTC does not require that studies be published and will consider unpublished, proprietary research." However, it also recognizes that "the publication of a peer-reviewed study in a reputable journal indicates that the research has received some measure of scrutiny."[25] More important to the Commission than the question of publication is the actual quality of the study design and implementation and the reliability of the written report on the study results.

Criteria for Evaluating Internal Validity of Study

Petitioners also raise a series of questions about the criteria the FTC uses to evaluate studies. As set forth in the Supplement Advertising Guide, the Commission considers various factors in evaluating research. Among these, the Commission looks at whether the study uses specific methods accepted to enhance validity, such as control, blinding of subjects and researchers, and adequate duration to ensure that the effect will persist. The Supplement Advertising Guide also stresses the importance of results that are both statistically and clinically significant.[26] These are some of the more fundamental aspects of what constitutes competent and reliable scientific research. More specific guidance about how the Commission evaluates scientific evidence is set out in some of the Commission's litigated cases involving dietary

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[23] Supplement Advertising Guide at Section B.5, Example 24.

[24] *Id.* at Section B.5.

[25] *Id.* at Section B.3. At the same time, the fact that a study has been peer-reviewed does not, in and of itself, establish that the study is competent and reliable proof of a supplement's efficacy.

[26] *Id.*

supplements and other health-related products. For example, having determined that the appropriate evidence for the weight loss claims made in the case were clinical trials, the Initial Decision in the *Schering* case provides a detailed discussion of the requirements for a well-designed clinical trial and applies those requirements to the studies relied on by Schering.[27]

Guidance from FTC Consent Orders

Petitioners assert that they cannot adequately discern the criteria staff applies in evaluating substantiation in part because consent agreements do not describe the basis for a determination that the claims have not been adequately substantiated. Materials submitted in the course of an investigation, including materials relating to the scientific support for a claim, are often proprietary or otherwise protected by confidentiality privileges. For that reason, the Commission typically refrains from discussing the details of specific studies submitted by a supplement marketer unless the matter is litigated and a decision is issued. The Commission is aware, however, that its reasoning in certain settled cases can be a useful source of guidance. In recent settlements, the Commission has provided specific information about the shortcomings of the substantiation for a claim, either in the complaint and consent order or in materials accompanying the settlement. This practice will continue.[28]

Rulemaking for Issuance of Advisory Opinions

Petitioners have alternatively requested that the Commission promulgate a rule providing for the issuance of advisory opinions on the adequacy of substantiation for dietary supplement advertising claims. In fact, Section 1.1 of the Commission's rules already provides for the issuance of advisory opinions by the Commission or its staff in appropriate circumstances and "where practicable."[29] Petitioner's request for such advisory opinions on substantiation of supplement claims, however, is not practicable for several reasons.

Section 1.1 provides in relevant part that a "request for advice will ordinarily be considered inappropriate where: * * * (2) an informed opinion cannot be made or could be

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[27] *Schering Corp.*, 118 F.T.C. at 1080-1119.

[28] *See, e.g., Michael D. Miller d/b/a Natural Heritage Enterprises,* C-3941 (Consent Order)(May 16, 2000). The settlement in that matter included a letter to customers describing with specificity the lack of adequate scientific evidence on the relationship between the herbal product, Essiac Tea, and cancer and other diseases. *See also Melinda R. Sneed and John L. Sneed d/b/a Arthritis Pain Care Center*, C-3896 (Consent Order)(Sept. 7, 1999). These cases are typical of many of the Commission's supplement cases in that the claims challenged were extreme and unqualified (cures arthritis, lupus, breast cancer, prostate cancer) and the scientific support either nonexistent or clearly inadequate by any objective standard.

[29] 16 C.F.R. § 1.1.

made only after extensive investigation, clinical study, testing or collateral inquiry."[30] The review of scientific literature that would be necessary in order for the Commission to issue an informed opinion on the adequacy of substantiation for specific claims clearly would require extensive investigation and collateral inquiry. For example, for the limited number of specific claims that are the subject of this petition alone, Petitioners have submitted approximately 2,000 pages of exhibits setting out some of the scientific literature relevant to the claims at issue. Before the Commission or its staff could issue an advisory opinion on the adequacy of substantiation for these claims, the agency would have to hire scientific experts in each of the relevant fields of inquiry, and, with the help of those experts, conduct a comprehensive review of the scientific literature, including both the materials submitted by Petitioners and any other relevant scientific evidence.[31]

The resource commitment necessary to implement a general policy of advisory opinions for supplement advertising substantiation would be considerable. Such a policy would redirect Commission resources away from law enforcement efforts. FDA has estimated that there are more than 29,000 dietary supplement products in the market with about 75,000 distinct labels. Of these, the agency estimates that sixty percent, or 17,400, are marketed with specific claims.[32] The number and variation of claims that are being made in supplement advertising are likely to be far larger and review of even a small percentage of these claims would be too great a strain on Commission resources.[33]

The task of pre-approving specific supplement claims or ads would be further complicated by the many elements of advertising that can effect ad meaning. The question of whether a claim about a particular health benefit of a dietary supplement has been adequately substantiated depends in large part on how the claim is worded, what disclosures and qualifications are included in the ad, as well as other elements of the ad that might affect what the claims actually convey to consumers.[34]

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[30] Id. at § 1.1(b)(2).

[31] In other areas where the Commission or its staff have issued advisory opinions, the type of extensive collateral investigation envisioned by Petitioner's proposal has not been required.

[32] *See* discussion of supplement industry in *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body,* 65 Fed. Reg. 1000, 1046 (Jan. 6, 2000).

[33] It would also be difficult to justify issuing advisory opinions for supplement advertising claims but not for other competing health-related industries.

[34] In many cases, it might also be necessary, in order to determine the precise nature of the claims being communicated by the ad, to conduct consumer research before issuing an advisory opinion. As an example, it is possible under FTC law to make a carefully qualified claim about an area of emerging science in a situation where the science has not yet reached the

Although it is not practicable for the Commission or its staff to issue formal advisory opinions based on comprehensive evaluations of scientific evidence, Commission staff routinely provides informal advice to supplement marketers about how to ensure that they have adequate scientific support for a claim and how to present claims that accurately reflect that support. As part of its regular industry outreach efforts, staff encourages supplement marketers to contact them with any questions they may have about FTC law and how it applies to their advertising. Staff has met in person or by telephone with supplement marketers who are preparing new advertising campaigns in order to provide general guidance on the agency's substantiation policy. While such advice does not give the advertiser a definitive answer on scientific questions, it can assist in identifying potential problems with a claim or the support behind it, as well as identifying measures to address any shortcomings.

Petitioners' APA and Fifth Amendment Challenges

Petitioners have raised a number of objections to the Commission's current approach to substantiation of supplement advertising claims, including that it violates both the Administrative Procedure Act (APA) and the Fifth Amendment because of vagueness. The Commission believes that both challenges are without merit.

Petitioners assert that the FTC has not adequately defined the criteria for determining what constitutes competent and reliable scientific evidence and that this failure to define the standard is arbitrary and capricious in violation of the APA. They similarly assert that the standard is unconstitutionally vague in violation of the Fifth Amendment in that it deprives the Petitioners of their liberty and property rights because the uncertainty of the standard forces them to refrain from making the claims at issue. As discussed above, the Commission has provided guidance defining the criteria it uses in evaluating substantiation, through policy statements, guides and case law, and in the specific context of dietary supplement advertising, through a special guide for this industry.

Petitioners' reliance on the D.C. Circuit Court's opinion in *Pearson v. Shalala,* as authority that the Commission has violated the APA, is misplaced.[35] The court in *Pearson* ruled that FDA had completely failed to give content to its significant scientific agreement standard, either through general guidance or on a case-by-case basis, and that this failure violated the APA.[36] The FTC, in contrast, has developed a large body of guidance both general and case-specific, formal and informal, that gives content to the agency's competent and reliable scientific

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level of certainty necessary for an unqualified claim. Before approving such a qualified claim, however, the Commission would need to assess whether the wording of the claim effectively communicated the limitations of the scientific support.

[35] *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (1999).

[36] *Id.* at 660-661. Having ruled that FDA's failure to define its standard violated the APA, the court did not reach the Fifth Amendment argument.

evidence standard. In fact, this standard has been repeatedly upheld by the courts in response to challenges of "vagueness."[37]

In addition, the FDA regulatory regime at issue in the *Pearson* case is fundamentally different from the FTC's law enforcement approach. The statutory framework for health claims in dietary supplement labeling requires the manufacturer to obtain *prior approval* from FDA.[38] The manufacturer must file a petition with FDA requesting authorization of the specific health claim, must submit scientific evidence to persuade the agency that the health benefit is supported by "significant scientific agreement," and must wait for FDA approval before it can put the claim on labeling. Under FTC law, there is no requirement that a supplement marketer obtain prior agency approval before making health-related advertising claims.[39] Instead, the Commission reviews the substantiation for claims already in the market in response to complaints or when it has concerns that the claims are false or unsubstantiated. Only after investigation and review of the supporting science and a determination that the evidence is lacking will the FTC seek to stop advertising claims through a negotiated consent agreement or litigation. In cases where the FTC decides to challenge advertising claims as unsubstantiated, other than cases of outright fraud, Commission staff will typically meet with the advertiser, explain staff's assessment of the substantiation and provide an opportunity for the advertiser to respond before determining whether formal agency action is necessary. The Commission's approach, therefore, is in no way analogous to the *Pearson* court's characterization of the FDA practice as "simply saying no without explanation."[40]

Petitioners' First Amendment Challenge

Finally, Petitioners have asserted that the FTC's approach to supplement advertising violates the First Amendment. Petitioners' analysis, however, appears to be largely founded on the incorrect premise that the Commission has a policy of opting for outright bans over qualification as a means of remedying potentially misleading advertising claims. In fact, the Commission has a long history of allowing, and even encouraging, the use of disclaimers or qualifiers as a means of curing potential deception. The Commission reiterated this policy in its

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[37] *See, e.g., Bristol-Myers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1145, 1156-57 (9th Cir. 1984); *Thompson Medical Co. v. FTC*, 791 F.2d 189, 194-96 (D.C. Cir. 1986). *See also U.S. v. Alpine Industries, Inc.*, No. 2:97-CV-509 (E.D. Tenn. 1999).

[38] 21 U.S.C. §§ 343(r)(1)(B) and (r)(5)(D).

[39] In contrast to the *Pearson* case, where FDA had prohibited certain labeling claims, Petitioners in this matter have continued to make some of the claims that are the subject of the petition.

[40] *Pearson* at 660. In response to the *Pearson* decision, FDA has issued guidance on its "significant scientific agreement" standard. *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims*, 64 Fed. Reg. 71794 (Dec. 22, 1999).

1994 Food Policy Statement and again in the 1998 Supplement Advertising Guide. Both documents clearly acknowledge that there is room for carefully qualified claims based on emerging science, provided the claims are expressly qualified to convey effectively the extent of the scientific support.[41]

Petitioners also assert that, in failing to provide adequate guidance, the Commission has chilled claims in violation of the First Amendment. They object that the Commission has not only failed to adequately define the type and amount of science required to substantiate a claim, but also has failed to specify the circumstances in which claims can be rendered "unobjectionable" through use of appropriate disclaimers. As already discussed, the Commission has provided substantial guidance on its substantiation standard. It has similarly provided detailed guidance on the use of disclaimers. The Supplement Advertising Guide, for example, includes sections on when to disclose qualifying information and how to ensure that such disclosures are sufficiently clear and prominent.[42] In addition, in 1998 the Commission published the results of a three-part copy test that addresses a number of specific issues relating to the types of disclosures necessary to effectively qualify claims about the benefits of foods and dietary supplements.[43] Advertisers who remain uncertain about whether their claim is adequately qualified can also conduct their own copy testing or other forms of consumer research to ensure that their ad does not convey deceptive or misleading messages. The Commission routinely considers any such extrinsic evidence obtained from the advertiser when evaluating claims.

The Commission believes its approach is fully consistent with the First Amendment and sees no indication of a chilling effect on claims by supplement marketers. In fact, supplement advertising has increased dramatically in recent years.[44] We note again that Petitioners are making numerous claims for their supplement products, including some that are the subject of this petition.[45]

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[41] Food Policy Statement, 59 Fed. Reg. 28388, 28394; Supplement Advertising Guide at Section B.4 and B.5.

[42] Supplement Advertising Guide at Section A. The Commission also recently published a business education piece on the effective use of disclosures in Internet advertising. *Dot Com Disclosures: Information about Online Advertising.*

[43] *Generic Copy Test of Food Health Claims in Advertising*, FTC Bureaus of Economics and Consumer Protection (Nov. 1998). The Food Copy Test examines, among other things, the type of disclosures required to convey limitations on the scientific support for a health related claim.

[44] A 1998 report in Advertising Age, for example, estimated that media spending had increased 40% over one year from 1997 estimated expenditures of $184.5 million. *St. John's Wort Brand is First Backed by National Advertising,* Advertising Age, Sept.7, 1998 at 3, 43.

[45] *See supra* n.17.

Conclusion

The Commission is committed to providing clear and specific guidance on its enforcement policies to dietary supplement marketers and to all other industries it regulates. For this reason, the agency has engaged in extensive efforts to define its substantiation standard and to illustrate, through its Supplement Advertising Guide, how that standard applies to supplement advertisers. The Commission will continue to refine and elaborate on its guidance as new questions arise. At present, however, the Commission believes that it has provided sufficiently specific and concrete guidance about the "competent and reliable scientific evidence" standard. As the courts have noted in reviewing this standard, "...absolute precision is not possible."[46] Any standard that must be applied to such a wide variety of products, claims, and fields of science must include flexibility. Further refinement would result in greater rigidity and overbroad regulation.

Nor is it practical for the Commission to review and pre-approve through advisory opinions each claim submitted by a supplement marketer. Such an effort would require resources far exceeding those available to the Commission and could not fairly be limited to the supplement industry alone.

For all of the foregoing reasons, the Commission denies Petitioners' request for rulemaking.

By direction of the Commission.

Donald S. Clark
Secretary

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[46] *See Bristol-Myers*, 738 F.2d at 560.