ATTACHMENTS TO COMPLAINT COUNSEL'S MOTION TO STRIKE RESPONDENTS' "ADDITIONAL DEFENSES"

(1) *In re Volkswagen, Inc.*, No. 9154, slip op. (July 8, 1981).[17]

(2) Corporate Resp'ts' Resp. to First Set of Interrogs. (Aug. 16, 2004).

(3) Letter from FTC to Jonathan W. Emord, Esq. (Nov. 30, 2000).

(4) Federal Trade Commission, Press Release (June 16, 2004).

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[17] The *Volkswagen* order bears handwritten marks not made by Complaint Counsel. These marks were on the archived copy obtained by Complaint Counsel.

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ATTACHMENT A

FEDERAL TRADE C...
RECEIVE...
JUL ...
...ISION OF
Energy & ...

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of VOLKSWAGEN OF AMERICA, INC., ET AL., a corporation,	)	DOCKET NO. 9154

ORDER WITH RESPECT TO COMPLAINT COUNSEL'S MOTION TO STRIKE PORTIONS OF ANSWER OF VOLKSWAGEN OF AMERICA, INC.

Respondent, Volkswagen of America, Inc. (VWoA), filed its Answer to the complaint herein on May 13, 1981. Complaint counsel, by their motion filed June 11, 1981, seek to have stricken the introductory paragraph to such Answer and all thirteen of the numbered affirmative defenses claimed therein. Respondent has opposed such motion by its memorandum in opposition filed June 30, 1981. Having reviewed the pleadings of the parties and the applicable law and Rules of Practice of the Federal Trade Commission, I grant in part and deny in part complaint counsel's motion, for the reasons cited below.

A. Legal Discussion

Although the Commission's Rules of Practice do not specifically provide for motions to strike, the Commission has held that under appropriate circumstances such motions may be granted. Warner Lambert Co., 82 F.T.C. 749 (1973). It would appear that a motion to strike might be appropriately granted where a respondent's Answer injects irrelevant or immaterial issues into the case, or makes assertions which are frivolous or clearly invalid as a matter of law. This is especially so where the injection of such issues into the case appears to threaten an expansion of discovery needs and the undue prolongation of the proceeding. Warner Lambert Co., at 750-753. The authority of the administrative law judge to strike portions of a respondent's Answer is a necessary derivative of his general powers to simplify issues and regulate the course and conduct of the proceedings, as set out in Sections 3.42 and 3.21 of the Commission's Rules of Practice.

In determining whether such authority should be exercised, it is useful to consider the case law under Rule 12(f) of the Federal Rules of Civil Procedure. While the Federal Rules are not controlling in Commission proceedings they may be instructive of the principles to be applied. Rule 12(f)

provides that "any insufficient defense, or any redundant, immaterial, impertinent, or scandalous matter" may be stricken. This accords with Commission practice as found in Warner Lambert and other cases.[1] The one important element that the case law under Rule 12(f) adds to Commission precedent is the understanding that motions to strike are generally disfavored and rarely granted. OKC Corp. v. Williams, 461 F. Supp. 540, 550 (N.D. Tex., 1978), 5 Wright & Miller, Federal Practice and Procedure, § 1380 (1969). Thus, it is clear that the presiding authority should take a strict view of such a motion and grant it only to the extent that the Answer clearly contains irrelevant, immaterial or otherwise offensive or extraneous material.

B. The Motion To Strike

1. First Affirmative Defense. Respondent VWoA, in its first affirmative defense asserts that the Commission lacks jurisdiction over the subject matter of the complaint. Complaint counsel move to strike under Rule 3.12(b)(1)(i) on the ground that respondent has failed to provide a "concise statement of the facts constituting" the ground of this defense. In its memorandum in opposition respondent argues that it is apparent from the over-all tenor of its Answer that this defense is grounded in the facts alleged in Paragraph 6 of its answer, as well as those alleged in the fourth, fifth, sixth, seventh and twelfth of its affirmative defenses.

Jurisdiction is a matter which is properly before the Administrative Law Judge for consideration. Crush International Limited, 80 F.T.C. 1023 (1972), Phillip Morris, Inc., 79 F.T.C. 1023 (1971), Suburban Propane Gas Corp., 71 F.T.C. 1965 (1967). If respondent's basis for this defense was not adequately pleaded in its Answer, any deficiency has been remedied by its opposition memorandum. Therefore, I will not strike this defense.

Second and Third Affirmative Defenses. In these defenses respondent VWoA denies that the Commission had "reason to believe" that this proceeding would be in the public interest or that VWoA has violated or is violating the Federal Trade Commission Act. Complaint counsel move to strike such defenses

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[1] See for example, Order Denying Complaint Counsel's Motion to Strike Affirmative Defenses of Hughes Tool Company, In Re Hughes Tool Company et al., Docket No. 9138, August 29, 1980, and Order Granting In Part Complaint Counsel's Motion to Strike Certain Affirmative Defenses, In Re The Kroger Company, October 18, 1977.

on the ground that these Commission determinations "are beyond the scope of this adjudicative proceeding and are purely within the province of the Commission to decide." (Motion to Strike, p. 3.) Complaint counsel cite to a number of cases supporting their position and discuss an earlier ruling of mine in the matter of International Harvester Company, Docket 9147, in which I held that "the 'reason to believe' issue cannot be raised in the present forum," but then went on to refuse to strike such defenses so that they would be preserved for "subsequent judicial review." (Order With Respect to Complaint Counsel's Motion to Strike, pp. 7-8, Docket 9147, January 15, 1981.) Complaint counsel argue that this was insufficient reason to deny a motion to strike, since under the "exhaustion of administrative remedies" doctrine respondent's right to argue its position in this regard in connection with subsequent judicial review is preserved by an order striking those defenses as being insufficient as a matter of law. They further argue that to deny the motion to strike in this instance would "inevitably lead to unnecessary and burdensome discovery requests into the clearly privileged mental processes of the Commissioners." (Motion to Strike, pp. 5-6.)

Respondent in its opposition to the motion to strike urge that "like respondent in International Harvester . . . VWoA seeks simply to preserve these issues for possible later judicial review. . . ." (Memorandum in Opposition, p.7.)

I am persuaded by complaint counsel that there was some inconsistency in my prior ruling on this point in the International Harvester case. On the one hand, I ruled therein that such issues were not properly before me and that I would allow no discovery thereon, and on the other hand I refused to strike the contested defenses, simply to preserve them for later judicial review. Complaint counsel correctly point out that this purpose would have been served equally as well by striking the defenses. The basic logic of my ruling in International Harvester was that preservation of the defenses solely for the purpose of later appellate review would work no harm in the administrative proceeding. However, respondent VWoA's reply in opposition reinforces complaint counsel's argument concerning the danger of expansion of discovery by a refusal to strike. VWoA in its opposition memorandum argues that the opinion in the SOCAL case "specifically contemplates that a reviewing court considering the unlawfulness of the issuance of complaint shall have a proper evidentiary record upon which to decide the issue." (Memorandum in Opposition, p. 7.) Thus, it appears that respondent may intend to seek discovery in this administrative proceeding into the mental processes of the Commissioners.

It is clear that the SOCAL case does not anticipate such a broadening of proceedings at the administrative level at the present time. As noted in my order in International Harvester

the SOCAL decision specifically recognized that it is the official position of the Commission that its finding of reason to believe in connection with the issuance of a complaint is unreviewable because it is an agency action "committed to agency discretion by law." FTC v. Standard Oil of California, 101 S. Ct. 488, 49 U.S.L.W. 4054, 4055, n.7 (December 16, 1980). The Court did not find the Commission's position in this regard to be erroneous, but only held that the reviewability of such finding was still an open question. 49 U.S.L.W. at 4057. This was the basis for my ruling that this issue cannot be raised in the administrative proceeding and that no discovery would be allowed thereon.

Respondent's apparent position that the SOCAL decision contemplates an evidentiary record on the "reason to believe" issue at this stage of the proceeding flies in the face of the clear language of the Supreme Court's opinion in that case. The Court rejected Standard Oil of California's argument that review of the "reason to believe" issue should not be deferred until appellate review of a cease and desist order. It was Standard Oil's contention that such deferral would "insulate" the question of unlawfulness in the issuance of the complaint because the reviewing court would lack an adequate record. The Court in rejecting this argument stated that "The Act expressly authorizes a court of appeals to order that the Commission take additional evidence." 49 U.S.L.W. at 4057. It is clear, therefore, that the Supreme Court did not contemplate an evidentiary hearing on such issues at the administrative level in anticipation of some future adverse appellate ruling.

The fact that VWoA might still raise this argument, however, illustrates the potential difficulties inherent in my prior ruling. If the Commission's "reason to believe" is not properly an issue before me and if discovery thereon should not be allowed, then VWoA's second and third affirmative defenses should be stricken, for it is clear that they inject invalid issues into the case which unduly complicate the proceeding and threaten an unwarranted expansion of discovery needs. I, therefore, grant complaint counsel's motion to strike the second and third affirmative defenses of respondent VWoA.[2]

Fourth Affirmative Defense. Respondent VWoA's arguments in opposition to the motion to strike its fourth affirmative defense are not persuasive. I agree with complaint counsel that

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[2] This ruling is really not at variance with my ruling in International Harvester, since in that case the effect of my order was to strike similar affirmative defenses insofar as the administrative proceeding was concerned.

Section 18(a)(1)(A) of the Federal Trade Commission Act merely gives the Commission the authority to prescribe rules and general statements of policy, but does not mandate any situation where the Commission must proceed by rulemaking. I further agree with complaint counsel's position that Section 18(b)(2)(c) of the Act does not apply until the Commission has exercised its discretion to proceed by way of rulemaking. I also find persuasive complaint counsel's review of the case law concerning the exercise of the Commission's discretion to proceed on a case-by-case basis, rather than by way of rulemaking. Further, it is clear that this affirmative defense threatens to inject extraneous issues into this case which would unduly broaden discovery and undoubtedly greatly prolong this proceeding.[3] Under these circumstances, I am compelled to grant complaint counsel's motion to strike VWoA's fourth affirmative defense.

Fifth Affirmative Defense. It is clear from the pleadings that this affirmative defense raises substantial questions of fact and law which are relevant to the charges of the complaint. Thus, I will not strike this affirmative defense.

Sixth and Seventh Affirmative Defenses. Respondent's sixth and seventh affirmative defenses raise questions of law which cannot be deemed wholly frivolous, nor irrelevant or immaterial. Further, they do not appear to threaten a substantial expansion of discovery, nor undue prolongation of this proceeding. Consequently, they will not be stricken.

Eighth Affirmative Defense. VWoA's eighth affirmative defense appears to raise issues of fact and law which are relevant to this proceeding. I am somewhat concerned with the possible scope of discovery which might be sought under this affirmative defense, but that is a matter which can best be dealt with when it arises. I will not strike this defense.

Ninth Affirmative Defense. Respondent urges that this affirmative defense is identical to one raised by International Harvester Company in Docket 9147, which defense was upheld by me in my order ruling on a motion to strike in that case. I fail to see the similarity between VWoA's ninth affirmative defense and that raised by International Harvester (IH). In the

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[3] Respondent's references in its opposition memorandum to various public statements by officials of the Bureau of Consumer Protection indicate that it might well seek broad discovery into the programs and policies of that Bureau and into investigational files involving other automobile manufacturers, based on this affirmative defense.

latter case, IH alleged that the proceeding violated the due process clause because the complaint itself allegedly was vague, indefinite and failed to apprise IH of the conduct deemed unlawful. VWoA's ninth affirmative defense alleges that this proceeding violates the due process clause because it "has never been provided with reasonable notice that its conduct . . . constituted . . . a violation of Section 5 of the Federal Trade Commission Act." This allegation goes far beyond an attack on the sufficiency of the wording of the complaint. In fact, VWoA at pages 23 and 24 of its Memorandum in Opposition indicates that this defense urges that the complaint can not "satisfy ex post facto the due process requirement that a person have adequate notice of the requirements of law at the time of the acts complained of."

Complaint counsel have made a strong argument to the effect that such affirmative defense is frivolous in view of a well-established case law dealing with a "failure to disclose material facts" by sellers. On the other hand this defense appears to principally involve a question of law which would not seem to threaten an undue broadening of the issues herein, nor prolong the proceeding to any material extent. Consequently, I am not inclined to strike it at this point in time.

Tenth and Eleventh Affirmative Defenses. Respondent's tenth and eleventh affirmative defenses take issue with the relief being sought by complaint counsel in this proceeding. As such, these defenses raise genuine issues which are relevant and material to this proceeding. I am concerned that these defenses might be interpreted by respondent as providing a vehicle for a very broad discovery into the business and practices of competing automobile manufacturers. Such discovery might unduly broaden the issues herein and greatly prolong this proceeding. However, I think such problem, if it exists, can best be handled by me during the discovery stage. I will allow complaint counsel to be heard before any discovery of competing manufacturers is allowed.[4] I can then take appropriate steps to keep discovery within reasonable limits. With this in mind, I decline to strike VWoA's tenth and eleventh affirmative defenses.

Twelfth Affirmative Defense. Respondent's twelfth affirmative defense alleges that any Congressional delegation to the Commission of authority to extend Section 5 of the Federal

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[4] Since all parties have an interest in the timely disposition of this proceeding I will require each party to keep the others informed of all discovery requests, even where such requests are made on an ex parte basis.

Trade Commission Act to encompass VWoA's acts or practices complained of herein is excessive and therefore void. Complaint counsel urge that such defense is "insufficient as a matter of law" and should be stricken.

Again respondent refers to my order in the International Harvester case as being analogous and supportive of its affirmative defense. The situation here is not quite like that in International Harvester, however. At issue there was the question as to whether the authority was or could be delegated to the Commission to proceed against practices which allegedly involved tractors which were over 10 years old, were no longer being manufactured, and were not likely to be manufactured again. IH contended in its affirmative defense that any delegation which encompassed "a continuing obligation to disclose product information for an unlimited period of time" was excessive and void. IH's affirmative defense, as further refined by the pleadings in connection with the motion to strike, went far beyond that now pleaded by respondent VWoA.[5]

The constitutionality of the Congressional delegation of authority to the Commission in cases such as the present one has long been settled. See, e.g., United States v. Vitasafe Corporation, 212 F. Supp. 397, 399 (S.D.N.Y. 1962). Therefore, this affirmative defense is insufficient as a matter of law and should be stricken.

Thirteenth Affirmative Defense. This affirmative defense appears to raise the same "reason to believe" and "public interest" questions as were raised by VWoA's second and third affirmative defenses. In keeping with my ruling above in connection with those affirmative defenses, and for the same reasons, I will strike respondent's thirteenth affirmative defense.

VWoA's Denial of the Preamble to the Complaint. In keeping with the logic of my rulings concerning respondent's second, third and thirteenth affirmative defenses, I will also strike the first sentence of VWoA's Answer, which denies that the Commission has "reason to believe" or that this proceeding is in the public interest.

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[5] In fact, as is indicated by my ruling, the pleadings of the parties in the International Harvester case revealed that the underlying issues of the defense therein extended beyond the question of "excessive delegation" into areas which were more clearly before me in the administrative proceeding.

ACCORDINGLY, IT IS ORDERED that:

1. The opening sentence of respondent VWoA's Answer and its second, third, fourth, twelfth and thirteenth affirmative defenses are stricken.

2. Complaint counsel's motion to strike portions of VWoA's Answer is denied in all other respects.

John J. Mathias
Administrative Law Judge

July 8, 1981

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of

BASIC RESEARCH, LLC,
a limited liability company;

A.G. WATERHOUSE, LLC,
a limited liability corporation;

KLEIN-BECKER USA, LLC,
a limited liability company;

NUTRASPORT, LLC,
a limited liability company;

SÖVAGE DERMALOGIC LABORATORIES, LLC,
a limited liability company;

BAN, LLC,
a limited liability corporation, also doing business as BASIC RESEARCH, L.L.C., OLD BASIC RESEARCH, L.L.C., BASIC RESEARCH, A.G. WATERHOUSE, KLEIN-BECKER USA, NUTRA SPORT, and SOVAGE DERMALOGIC LABORATORIES,

DENNIS GAY,
individually and as an officer of the limited liability corporations,

DANIEL B. MOWREY, Ph.D.,
Also doing business as AMERICAN PHYTOTHERAPY RESEARCH LABORATORY, and

MITCHELL K. FRIEDLANDER,

Respondents.

Docket No. 9318

PUBLIC DOCUMENT

RESPONSE TO COMPLAINT COUNSEL'S FIRST SET OF INTERROGATORIES

Pursuant to Rule 3.35 of the Federal Trade Commission's Rules of Practice, Respondents Basic Research, LLC, A.G. Waterhouse, LLC, Klein Becker usa, LLC, Nutrasport, LLC, Sovage

Dermalogic Laboratories, LLC, Ban, LLC (collectively, "Respondents") object and respond to Complaint Counsel's First Set of Interrogatories ("Request") as follows:

General Objections

A. Respondents object to the Interrogatories as overbroad and unduly burdensome on the grounds and to the extent that they call for responses that are neither relevant to the subject matter of the pending action nor reasonably calculated to lead to the discovery of admissible evidence.

B. Respondents object to the Interrogatories on the grounds and to the extent that they seek responses that are subject to (i) the attorney-client privilege; (ii) the attorney and/or party work product immunity, and (iii) any other privilege or immunity, including common law and constitutional right of privacy and/or trade secret protection. Respondents hereby claim such privileges and immunities. Any disclosure of any such privileged or immunized information is inadvertent and is not, and is not intended, as a waiver of those privileges and immunities.

C. Respondents object to the Interrogatories and to the Definitions and Instructions on the grounds and to the extent that they are overbroad, unduly burdensome and oppressive, and purport to impose obligations on Respondents that are beyond the scope of the Rules of Practice or other applicable law.

D. Respondents object to the Interrogatories on the grounds and to the extent that they are vague, ambiguous and unintelligible, particularly in light of the inherent vagueness and ambiguity in the standards employed by the Commission as well as in the charges that have been levied in this matter, which is the subject of Respondents' pending motion for an interlocutory appear and more definite statement by the Commission.

E. Respondents incorporate by this reference Respondents' Motion to Quash in Part and to Limit Subpoenas on Non-Parties and each response, objection and basis therefore in the motion, and further objects to each Interrogatory on those grounds.

F. Respondents' objections and responses to the Interrogatories are not intended to waive or prejudice any objections that Respondents may assert now or in the future, including,

without limitation, objections as to the relevance of the subject matter of any interrogatory, or of the admissibility of any response or document or category of responses or documents, at hearing, trial or any other time. Respondents expressly reserve any and all rights and privileges under the Rules of Practice, applicable evidentiary rules, and any other law or rule, and the failure to assert such rights and privileges or the inadvertent disclosure by Respondents of information protected by such rights or privileges shall not constitute a waiver thereof, either with respect to these responses or with respect to any future discovery responses or objections.

Specific Objections and Responses

Based on, subject to, and without waiving its General Objections, Respondents specifically and additionally respond to each of the Specifications contained in Complaint Counsel's Interrogatories as follows:

Interrogatory No. 1:

Identify and **describe** in detail the current and former duties, responsibilities, or work performed by each **person relating to** the **promotional materials** for each of the **challenged products**. (This request **includes**, but is not limited to, the creation, development, evaluation, approval, modification, and dissemination of **promotional materials**.)

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence; and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy. Based on, subject to, and without waiving the foregoing responses and objections, Respondents responds as follows:

Respondents interpret this interrogatory as requesting the identity of persons and descriptions of duties, responsibilities and work performed. In providing the following response,

Respondents do not discuss or imply, or intend to discuss or imply, any relationship between any of the parties and/or any of the persons identified below:

1. Dan Mowrey, Ph.D, researched and developed product ideas, concepts and ingredients; performed ad substantiation research, and reviewed ads for substantiation;
2. Mitch Friedlander, determined commercial viability of products, wrote copy, directed ad layout, and assisted with marketing;
3. Gina Gay, placed advertisements with media;
4. Jeff Davis, proof read advertisements;
5. Brett Madsen, assisted with copy layout;
6. Ned Simpson, assisted with copy layout;
7. John Swallow, reviewed ad copy;
8. Nathalie Chevreau, Ph.D., PediaLean project director; assisted with website development for PediaLean; performed PediaLean safety tests;
9. Carla Fobbs, facilitated and obtained substantiation review from outside counsel;
10. Dennis Gay, final approval of products and advertisements; and
11. Stephen Nagin, Esq., performed substantiation review.

Interrogatory No. 2:

Identify and **describe** in detail the current and former duties, responsibilities, or work performed by each **person** consulted by you, or upon who advise, opinion, or expertise you relied in the production of each of the **challenged products**. (This request **includes**, but it not limited to, the creation, development, evaluation, approval, and manufacture of the **challenged products**.)

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and

ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence; and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy. Based on, subject to, and without waiving the foregoing responses and objections, Respondents respond by referring to their Response to Interrogatory No. 1, which includes the persons consulted.

Interrogatory No. 3:

Describe in detail the composition of each of the **challenged products**. (This request **includes**, but is not limited to, the identity of each ingredient and the amount of each ingredient contained in a single capsule, application, and serving. If any **challenged product** has been reformulated, provide a separate answer for each version of the product that has been marketed and sold, **identifying** the time period(s) in which each version was marketed and sold.

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Based on, subject to, and without waiving the foregoing objections, Respondents refer to Attachment "A," which has been designated pursuant to the Protective Order as "Restricted Confidential, Attorney Eyes Only—FTC Docket No. 9318."

Interrogatory No. 4:

Disclose the total amount of sales, in terms of units and dollars that each Respondent has achieved for each of the **challenged products** for each year from 2001 to the present.

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence (the

requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Interrogatory No. 5:

To the extent a **challenged product** is a **substantially similar product** to others products, identify each other product.

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence (the requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Interrogatory No. 6:

Disclose all payments that each **Respondent** has received, directly or indirectly, in connection with the advertising, marketing, promotion, and sale of ach of the **challenged products** for each year from 2001 to the present. (This request **includes** the total dollar amount and source of all payments. For consumer sales, it is not necessary to disclose names, addresses, or telephone numbers.)

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and

information not reasonably calculated to lead to the discovery of admissible evidence (the requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Interrogatory No. 7:

Disclose the total amount of dollars that each **Respondent** has spent to advertise, market or otherwise promote each of the **challenged products** for each year from 2001 to the present, broken down by each medium used (*i.e.*, television, print, internet, radio, or other means). (This request **includes**, but is not limited to, all expenditures attributable to the creation, development, evaluation, approval, modification, and dissemination of **promotional materials**).

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence (the requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Interrogatory No. 8:

Provide a **dissemination schedule** that **describes** in detail how each item **of promotional materials** submitted in response to the **Requests for Production** was disseminated or otherwise exposed to consumers.

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and

ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence (the requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Interrogatory No. 9:

Describe in detail the actions each **Respondent** has taken to comply with the U.S. Food and Drug Administration's prohibition on the sale of dietary supplements containing ephedrine alkaloids, effective April 12, 2004. (This request **includes**, but is not limited to, **identification** of any product formulations that have been created, modified, or removed from distribution, **identification** of any **promotional materials** that have been created, revised, or removed from dissemination, and the date(s) on which all of the actions described in your answer took place; and how orders for Leptoprin or Anorex or in response to existing **promotional materials** Leptoprin or Anorex have been fulfilled.)

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence (the requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Based on, subject to, and without waiving the foregoing responses and objections, Respondents state that during the first part of April 2004 Basic Research started the process of identifying all products that considered to be "adulterated" according to 21 CFR Part 119, which

states, "*all dietary supplements containing ephedrine alkaloids are adulterated under the Federal Food, Drug, and Cosmetic Act.*"

April 1st through April 6th of 2004 all products and raw materials containing a source of ephedrine alkaloids, such as ephedra, Ma huang and pinellia were gathered together and quarantined along with all boxes, labels, advertising brochures and other artwork containing information relative to ephedrine containing products.

On April 7th, 2004 Basic Research prepared Material Destruction Forms, which contained all necessary information for tracking the materials through all steps of the destruction process. The Material Destruction Forms included approval signatures, raw material lot numbers, finished good lot numbers, label revision numbers, persons responsible for destruction and all other pertinent information required to conform to the regulation.

On April 8th, 2004 Basic Research conducted one last search throughout the facility to ensure that every product considered adulterated by the FDA, had been properly identified and quarantined. All adulterated materials discovered during this comprehensive search were quarantined and Material Destruction Forms filled out.

On Friday the 9th of April 2004, all adulterated materials were destroyed prior to the April 12, 2004 deadline. During the destruction process, each item was verified by two separate individuals who immediately thereupon affixed their signatures to the Material Destruction Forms.

In accordance with 21 CFR part 119, Basic Research immediately destroyed every product containing a source of ephedrine alkaloid (such as ephedra, Ma huang and pinellia) returned to our facility by customers of Basic Research subsequent to the April 12, 2004 deadline.

Interrogatory No. 10:

Disclose the total amount of refunds to consumers, in terms of units and dollars, that each Respondent has made for each of the **challenged products** for each year from 2001 to the present.

Response:

Respondents incorporate by reference each General Objection as set forth here in full. Respondents further objects to this interrogatory on the following grounds: (a) it is vague and ambiguous; (b) it is overly broad and unduly burdensome; (c) it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence (the requested information has no relationship to the alleged false or misleading advertising claims that Complaint Counsel pursues in this matter); and (d) it seeks information protected from disclosure by the attorney-client privilege, work product doctrine, and/or right of privacy, including financial privacy.

Respectfully submitted this 16th day of August, 2004

JEFFREY D. FELDMAN

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was provided to the following parties this 16 day of August, 2004 as follows:

(1) One (1) copy via e-mail attachment in Word document format to Commission Complaint Counsel, Laureen Kapin, Joshua S. Millard, and Laura Schneider, all care of **lkapin@ftc.gov**, **jmillard@ftc.gov**; **rrichardson@ftc.gov**; **lschneider@ftc.gov** with one (1) paper courtesy copy via U. S. Mail, First Class Postage Prepaid to Laureen Kapin, Bureau of Consumer Protection, Federal Trade Commission, Suite NJ-2122, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(2) One (1) copy via U. S. Mail, First Class Postage Prepaid to Stephen Nagin, Esq., Nagin Gallop & Figueredo, 3225 Aviation Avenue, Suite 301, Miami, Florida 33131.

(3) One (1) copy via U. S. Mail, First Class Postage Prepaid to Richard Burbidge, Esq., Jefferson W. Gross, Esq. and Andrew J. Dymek, Esq., Burbidge & Mitchell, 215 South State Street, Suite 920, Salt Lake City, Utah 84111, Counsel for Dennis Gay.

(4) One (1) copy via U. S. Mail, First Class Postage Prepaid to Ronald F. Price, Esq., Peters Scofield Price, A Professional Corporation, 340 Broadway Centre, 111 East Broadway, Salt Lake City, Utah 84111, Counsel for Daniel B. Mowrey.

(5) One (1) copy via U. S. Mail, First Class Postage Prepaid to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84116, Pro Se.

Jeffrey D. Feldman

Office of the Secretary

November 30, 2000

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
1050 Seventeenth Street, N.W.
Suite 600
Washington, D.C. 20036

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)

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 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 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 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:

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)

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 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 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)

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 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 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)

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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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.

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

(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 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 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.

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).

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.*

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.

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 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.

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). S*ee 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).

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.

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

For Release: June 16 , 2004

Ads for Various Diet Supplements and Topical Gels Don't Cut the Fat, Says the FTC

Companies Do Not Have Adequate Substantiation to Support the Claims

The Federal Trade Commission has charged a Utah-based company, five related corporations, and three individuals operating as a common enterprise with making numerous false and unsubstantiated claims for weight-loss and fat-loss gels and supplements. The complaint focuses on six of the respondents' heavily promoted products: Dermalin, Cutting Gel, and Tummy Flattening Gel (topical fat-loss gels with the same active ingredient); Leptoprin and Anorex (identical weight-loss supplements for "significantly overweight" people which contained ECA [ephedrine, caffeine and aspirin], an additional patented ingredient and calcium); and PediaLean (a glucomannan weight-loss supplement for children). In an administrative complaint announced today, the FTC alleges that the respondents violated the FTC Act by making unsubstantiated fat and weight loss claims, false claims that clinical testing proves certain efficacy claims, and false claims that Daniel B. Mowrey, Ph.D, is a medical doctor.

"Dramatic, unsubstantiated weight and fat loss claims continue to tempt the overweight with new hope for a quick fix. It's particularly disturbing, however, when marketers peddle such pills and potions for children without adequate substantiation," according to Howard Beales, Director of the FTC's Bureau of Consumer Protection.

The Commission's administrative complaint names: Basic Research, L.L.C.; A.G. Waterhouse, L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C.; Dennis Gay; Daniel B. Mowrey, Ph.D., also doing business as American Phytotheraphy Research Laboratory; and Mitchell K. Friedlander, all operating from the same Salt Lake City facility. The corporate respondents operate as a common enterprise to sell a broad line of dietary supplements and topical products.

According to the FTC's complaint, the respondents market numerous dietary supplements and topical gels through a variety of media, including the Internet. In particular, Leptoprin has been heavily advertised through short-form infomercials; the topical gels have been promoted through newspapers and national magazines, such as Cosmopolitan, and Muscle and Fitness; and PediaLean has been advertised in magazines such as Redbook.

Dermalin, Cutting Gel, and Tummy Flattening Gel all contain the active ingredient aminophylline in a lecithin base. Dermalin and Tummy Flattening Gel are sold under the Klein-Becker usa and Sovage trade names, and are advertised primarily to women interested in thinning their figures. Cutting Gel, sold under the Nutrasport trade name, is primarily advertised to male bodybuilders who want to eliminate areas of fat that obscure their muscle definition.

The FTC's complaint challenges as unsubstantiated claims that Dermalin, Cutting Gel, and Tummy Flattening Gel cause rapid and visibly obvious fat loss in areas of the body to which they are applied. The complaint challenges as false the claim that published, clinical testing proves that Cutting Gel and Tummy Flattening Gel cause rapid and visibly obvious fat loss in areas of the body to which they are applied.

The complaint further challenges as unsubstantiated claims that Leptoprin and Anorex cause weight loss of more than 20 pounds in significantly overweight users and that those products cause loss of substantial, excess fat in significantly overweight users. In addition, the complaint challenges as false claims that clinical testing proves that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and that clinical testing proves that Leptoprin causes loss of substantial, excess fat in significantly overweight users.

Related Documents:

Docket No. 9318
In the Matter of Basic F

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- **Promotions for Kic Supplements Leav Taste**
- **Amazing Claims**
- **'Miracle' Health Cla a Dose of Skeptici**

In addition, the complaint challenges claims that PediaLean causes substantial weight loss in overweight or obese children, and that clinical testing proves such claims. The complaint further challenges the respondents' claim that respondent Mowrey is a medical doctor. The FTC alleges that he is not.

The notice order issued with the complaint prohibits the respondents from making unsubstantiated claims about the health or weight-loss benefits, performance, safety, or efficacy of any service, program, dietary supplement, food, drug, or device. The notice order also prohibits the respondents from making misrepresentations about tests or the profession, expertise, training, education, experience or qualifications of Mowrey or any other endorser.

The Commission vote to file the administrative complaint was 4-0, with Chairman Timothy J. Muris not participating.

NOTE: The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The issuance of a complaint is not a finding or ruling that the respondents have actually violated the law. The complaint marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

Copies of the complaint and notice order are available from the FTC's Web site at http://www.ftc.gov and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint in English or Spanish (bilingual counselors are available to take complaints), or to get free information on any of 150 consumer topics, call toll-free, 1-877-FTC-HELP (1-877-382-4357), or use the complaint form at http://www.ftc.gov. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

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(http://www.ftc.gov/opa/2004/05/dietsupp.htm)

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