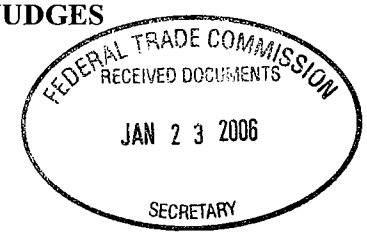
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES



In the Matter of	)	
	)	
BASIC RESEARCH, L.L.C.,	)	
A.G. WATERHOUSE, L.L.C.,	)	
KLEIN-BECKER USA, L.L.C.,	)	
NUTRASPORT, L.L.C.,	)	
SOVAGE DERMALOGIC	)	**FTC Docket No. 9318**
LABORATORIES, L.L.C.,	)	
BAN, L.L.C.,	)	**PUBLIC VERSION**
DENNIS GAY,	)	
DANIEL B. MOWREY, and	)	
MITCHELL K. FRIEDLANDER,	)	
	)	
Respondents.	)	

RESPONDENTS' APPLICATION FOR REVIEW OF THE JANUARY 10, 2006 ORDER THAT EXCLUDES RELEVANT EVIDENCE CONCERNING THE FTC'S PRE-COMPLAINT INVESTIGATION AND ABRIDGES RESPONDENTS' CONSTITUTIONAL RIGHTS

Respondents request review of the portion of your Honor's January 10, 2006 Order ("Order") that excludes evidence concerning Respondents' efforts, during the pre-Complaint investigation by the Commission, to obtain guidance from the Commission concerning the Commission's substantiation standards.[1] [Order at 8-9]. Respondents request that your Honor certify the portions of the Order for interlocutory review under Rule 3.23(b) or, in the alternative, to reconsider and to reverse that Order.

I. INTRODUCTION

The Order states that "pre-Complaint investigations are clearly irrelevant to the present matters . . ." [Order at 8] and cites to *In re Exxon Corporation* for the proposition that "Once the

[1] A copy of the portion of the Order from which appeal is being taken is included at Attachment A.

Commission has . . . issued a complaint, the issue to be litigated is not the adequacy of the Commission's pre-complaint information or the diligence of its study of the material in question but whether the alleged violation has in fact occurred." *In re Exxon Corp.*, 83 F.T.C. 1759, 1760 (1974). However, Respondents do not seek evidence of pre-Complaint information to question "the adequacy" of the information. Respondents do not seek evidence of "the diligence" the Commission applied to a "study of the material in question." *Exxon* is not on point.

Respondents must be permitted to support their affirmative defenses in this case with evidence of the Commission's refusal to explain to them that level, degree, quality, or quantity of scientific evidence necessary to satisfy the "competent and reliable scientific evidence" standard and refusal to identify reasonable disclaimers or qualifications for their claims. Those refusals violate Respondents' rights under the Fifth and First Amendments to the United States Constitution. That evidence is wholly relevant. It arises in the pre-Complaint phase of this case and continues to this day. By eliminating all pre-Complaint evidence, your Honor encumbers Respondents' right to defend themselves and to preserve for appellate review a full record. Respondents are clearly prejudiced by the Order. The evidence goes to a standard that your Honor will apply later in the case. The events in the pre-Complaint phase thus follow through to the present and constitute one continuous violation of the Respondents' constitutional and procedural rights to know with reasonable certainty the standard against which they will be tried. They are also entitled to know of obvious, less speech restrictive alternatives to a charge of unlawful speech (here, deceptive advertising), i.e., to know what this agency will accept in the form of disclaimers or qualifications to render the challenged advertising acceptable to the Commission. Those rights violations commence in the pre-Complaint phase and continue to the present.

The Constitution guarantees defendants "a meaningful opportunity to present a complete defense." *Crane v. Kentucky*, 476 U.S. 683, 690 (1986) (citing *California v. Trombetta*, 467 U.S. 479, 485 (1984); *Strickland v. Washington*, 466 U.S. 668, 684-685 (1984)). A basic requirement of due process is a fair trial in a fair tribunal. *Withrow v. Larkin*, 421 U.S. 35, 46-47 (1975) (citing *In re Murchison*, 349 U.S. 133, 136 (1955); *Gibson v. Berryhill*, 411 U.S. 564, 579 (1973)). That requirement applies to administrative agencies as well as to courts. *Id.* Your Honor's Oath of Office requires faithful allegiance to the Constitution. 5 U.S.C. § 3331. Respondents must be heard to present evidence of actions by this agency that undermine their Constitutional rights and deny them procedural fairness.

An essential component of procedural fairness is an opportunity to be heard. *Id.* (citing *In re Oliver*, 333 U.S. 257, 273 (1948); *Grannis v. Ordean*, 234 U.S. 385, 394 (1914)). That opportunity is denied if the FTC is permitted to exclude material evidence when such evidence is central to Respondents' affirmative defenses. "[E]xclusion of this kind of exculpatory evidence deprives a defendant of the basic right to have the . . . case encounter and 'survive the crucible of meaningful adversarial testing.'" *Id.* (citing *United States v. Cronic*, 466 U.S. 648, 656 (1984); *Washington v. Texas*, 388 U.S. 14, 22-23 (1967)).

An administrative law judge's exclusion of relevant evidence constitutes an abuse of discretion and is grounds for remand. *See Blinder, Robinson & Co. v. SEC*, 837 F.2d 1099, 1112 (D.C. Cir. 1988); *NLRB v. Process & Pollution Control Co.*, 588 F.2d 786, 790-91 (10th Cir. 1978) (reversible error to reject relevant evidence offered in an administrative hearing); *Northcutt v. Califano*, 581 F.2d 164, 167 (8th Cir. 1978) (holding that plaintiff did not receive a fair hearing because the administrative law judge failed to consider all relevant evidence). "In short, the [agency] cannot turn a deaf ear to evidence that should, in reason, bear upon the

judgment that the Commission is called upon to render." *Blinder*, 837 F.2d at 1111.

Further, your Honor issued the Order that excludes Pre-Complaint evidence in response to a motion *in limine* by Complaint Counsel. [Order at 1]. On page 2 of the Order, your Honor stated that "Evidence should be excluded on a motion *in limine* only when the evidence is clearly inadmissible on all potential grounds," citing *Hawthorne Partners v. AT&T Technologies, Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993) and *SEC v. U.S. Environmental, Inc.*, 2002 WL 31323832 at *2 (S.D.N.Y. 2002). Thus, exclusion of the evidence in support of Respondents' defenses would be an error of law, contrary to even the case law cited by your Honor.

Moreover, "[m]otions *in limine* are generally not proper vehicles for determining the validity of affirmative defenses, as such questions require the resolution of factual issues." *Int'l Paper Co. v. Androscoggin Energy LLC*, 2004 U.S. Dist. LEXIS 6914 at *7 (N.D. Ill. Apr. 23, 2004) (citing *Miles v. Barrington Motors Sales, Inc.*, 2003 U.S. Dist. LEXIS 22006 at *2 (N.D. Ill. Dec. 5, 2003); *United States v. Tokash*, 282 F.3d 962, 967 (7th Cir. 2003)). By excluding all pre-Complaint evidence, your Honor effectively has ruled that Respondents' affirmative defenses—including reliance on Constitutional rights—are invalid. Such a determination can only be made, if at all, after a hearing at which evidence is submitted to substantiate the defenses, not in a pre-hearing motion *in limine*. Excluding the evidence prior to resolving factual issues at hearing is contrary to even your Honor's statement in your November 4, 2004 Order Denying Complaint Counsel's Motion to Strike Respondents' Additional Defenses. In that Order, your Honor ruled that "Determination of the merits of Respondents' Fifth Amendment due process defense [and the first amendment defense] must be deferred until a factual record has been developed." Order at 3. Thus, the Order excluding pre-Complaint evidence is contrary to your Honor's prior ruling (November 4, 2004) in which you stated that Respondents were entitled to

develop a factual record on these issues. The determination of prejudged invalidity of Respondents' affirmative defenses by granting Complaint Counsel's motion *in limine* summarily precludes creation of a complete record for appeal. It is antithetical to procedural fairness. It is constitutionally infirm and needs to be corrected before the hearing in March, either by your Honor or by the Commission following an interlocutory appeal.

The pre-Complaint evidence that Respondents seek to adduce is wholly and materially relevant to Respondents' affirmative defenses. Permitting introduction of the excluded evidence will guard against a miscarriage of justice by permitting Respondents to defend themselves fully. By eliminating all pre-Complaint evidence, the Order creates a constitutionally-defective and asymmetrical predicate for, and assures, an unfair proceeding.

II. FACTS

Prior to filing of the Complaint on June 16, 2004, Respondents repeatedly asked the Commission staff on numerous occasions what scientific evidence would satisfy the Commission and what advertising disclaimers or qualifications the Commission would find acceptable. *See, e.g.*, RX-131; RX-134; RX-137; RX-138 (Attachment B). Respondents asked those questions in repeated attempts to determine exactly what advertising Respondents could engage in while the investigation was pending. Respondents received no substantive response from the Commission or its staff. *See* RX-135 (Attachment C).

Upon issuance of a civil investigative demand compelling the production of all corroborative science possessed by Respondents, FTC evaluated the information but did not disclose the criteria used for the evaluation and did not disclose the scientists who advised it, the scientific reports it received from those scientists, or even the precise content of, or reasons for, its scientific findings.

Thereafter, the Commission's undisclosed evaluation yielded a determination that Respondents' scientific evidence was not competent and reliable. *See* RX-126 (Attachment D). Yet even then the Commission would not inform Respondents of what scientific evidence it expected from them or what disclaimers or qualifications for the ads it would deem a sufficient corrective. Instead, the Commission has proceeded in secret on these points, leaving Respondents to engage in a guessing game with no real way of ever knowing what the FTC expects from them.

III. PERTINENT RULES

FTC Rule of Practice Section 3.23(b) (16 C.F.R. § 3.23) states, in pertinent part,

> *Appeals upon a determination by the Administrative Law Judge.* Except as provided in paragraph (a) of this section, applications for review of a ruling by the Administrative Law Judge may be allowed only upon request made to the Administrative Law Judge and a determination by the Administrative Law Judge in writing, with justification in support thereof, that the ruling involves a controlling question of law or policy as to which there is substantial ground for difference of opinion and that an immediate appeal from the ruling may materially advance the ultimate termination of the litigation or subsequent review will be an inadequate remedy. Applications for review in writing may be filed, not to exceed fifteen (15) pages exclusive of those attachments required below, within five (5) days after notice of the Administrative Law Judge's determination. Additionally, the moving party is required to attach the ruling or part thereof from which appeal is being taken and any other portions of the record on which the moving party is relying. Answer thereto may be filed within five (5) days after service of the application for review. The Commission may thereupon, in its discretion, permit an appeal. Commission review, if permitted, will be confined to the application for review and answer thereto, without oral argument or further briefs, unless otherwise ordered by the Commission.

IV. LEGAL ANALYSIS

Failure of the Commission to define in a meaningful way what the "competent and reliable scientific evidence" standard requires of Respondents denies Respondents their Fifth Amendment right to due process. The failure of the Commission to provide guidance concerning what disclaimers or qualifications will suffice to cure any perceived misleadingness is a violation

of Respondents' First Amendment rights. Respondents have a constitutional right that trumps administrative process or convenience to use the Pre-Complaint evidence in support of those affirmative defenses. Thus, the pre-Complaint evidence is wholly relevant to the case. Moreover, there will be no surprise to Complaint Counsel. Respondents made Complaint Counsel aware of their intent to rely on constitutional affirmative defenses from the beginning of the case. *See, e.g.*, Respondents' Motion for Partial Summary Decision Adverse to Petitioner on Validity of Petitioner's "Competent & Reliable Scientific Evidence" Standard, or in the Alternative, for Certification to the Commission, filed Jan. 28, 2005.

A. The Pre-Complaint Evidence Precluded by the Order is Relevant to Respondents' First Amendment Affirmative Defense

Claims in advertising are protected by the First Amendment as commercial speech so long as the claims are not inherently misleading. *See Bolger v. Youngs Drugs Products Corp.*, 463 U.S. 60, 67-68 (1983); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995). Under the First Amendment commercial speech standard, only inherently misleading claims may be restricted by the state. *Id.* The Supreme Court repeatedly has expressed in its commercial speech jurisprudence that disclosure is favored over suppression. *See 44 Liquormart v. Rhode Island*, 507 U.S. 484, 509 (1996)); *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 144 (1994); *Peel v. Attorney Registration and Disciplinary Comm'n*, 496 U.S. 91, 99-111 (1990). The Supreme Court repeatedly has expressed that less-speech-restrictive alternatives to outright suppression *must* be used if available. *Id.*

The Supreme Court has held that the use of disclaimers to correct potential misleadingness is an obvious, less-speech-restrictive alternative to outright suppression. Thus,

potentially misleading claims must be permitted with reasonable disclaimers designed to eliminate misleading connotations. *See In re R.M.J.*, 455 U.S. at 203 ("Restrictions on...advertising may be no broader than reasonably necessary to prevent the deception."); *Ibanez*, 512 U.S. at 144-46; *Peel*, 496 U.S. at 99-111 (1990). Under *Pearson v. Shalala*, 164 F. 3d 650, 656 (D.C. Cir. 1999), inconclusive science renders a claim, at worst, only "potentially misleading," constitutionally requiring resort to a disclaimer as a less-speech-restrictive alternative to claim restriction.

The issue in this FTC adjudicative proceeding is whether the scientific evidence supporting Respondents' claims rises to the level of "competent and reliable scientific evidence" sufficient to satisfy FTC that the claims are not deceptive. That standard must be defined by this agency in a manner consistent with existing First Amendment precedent. The First Amendment doest not allow suppression or punishment of parties who communicate impliedly deceptive but not fraudulent claims. Potentially misleading claims, i.e., those capable of a misleading connotation, may not be deemed unlawful but must be allowed into the market with such qualifications or disclaimers as are necessary to eliminate misleadingness. *See Peel*, 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206; *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988).

The Commission's advertising substantiation standard must distinguish potentially from inherently misleading claims and must rely on qualifications or disclaimers to eliminate misleadingness in all instances where the claims are, at worst, only potentially misleading. Finally, the comparative weight of its evaluative criteria must be explained either case-by-case in adjudicated findings and conclusions (not just in consent orders) or in a general rule. Thus, evidence concerning Respondents' efforts, during the pre-Complaint investigation by the Commission, to obtain guidance from the Commission and its staff concerning the substantiation

standards and potential qualifications or disclaimers that would be acceptable to the Commission are relevant and material to Respondents' affirmative defense based on the lawful exercise of First Amendment rights.

Under the First Amendment, any restraint on speech must be lifted at the earliest possible moment if an obvious, less-speech-restrictive alternative can be found to achieve the government's legitimate ends. *See Freedman v. Maryland*, 380 U.S. 51, 58-59 (1965) ("Any restraint imposed in advance of a final determination on the merits must...be limited...to the shortest fixed period compatible with sound judicial resolution."). Delay in receipt of justice in the presence of government speech suppression is the bane of the First Amendment and cannot be tolerated. See generally *New York Times Co. v. United States*, 403 U.S. 713, 714-15 (1971); *Elrod v. Burns*, 427 U.S. 347, 374 (1976); *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963) (holding that judicial determination of a prior restraint on the freedom of expression must be "almost immediate").

Consequently, Respondents' efforts to ascertain from the Commission and its staff exactly what type of scientific evidence and disclaimers the Respondents would need to satisfy the Commission is important evidence relating to the timeline in this administrative proceeding, which commenced in Part II and continued in Part III under the Commission's Rules of Practice. That evidence is relevant because it shows that the FTC has refused to limit its suppression of Respondents' speech to the shortest fixed period possible but that it has delayed in providing justice to Respondents. Thus, the pre-Complaint evidence is wholly relevant to Respondents' First Amendment affirmative defense. It is manifest and plain error to exclude evidence that would support affirmative constitutional defenses. The Chief ALJ's Order warrants immediate review by the Commission if it is not voluntarily withdrawn.

B. The Pre-Complaint Evidence Precluded by the Order is Relevant to Respondents' Fifth Amendment Affirmative Defense

It is a basic principle of due process that a law is void for vagueness if its prohibitions are not clearly defined. *Grayned v. Rockford*, 408 U.S. 105, 108 (1972). Vague laws offend several important values: (1) laws must give the person of ordinary intelligence a reasonable opportunity to know what is prohibited so that he may steer between lawful and unlawful conduct, (2) if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them, and (3) "where a vague statute 'abut[s] upon sensitive areas of basic First Amendment freedoms,' it 'operates to inhibit the exercise of [those] freedoms.'" *Id.* at 108-09 (quoting *Baggett v. Bullitt*, 377 U.S. 360, 372 (1964); *Cramp v. Bd. of Public Instruction*, 368 U.S. 278, 287 (1961)). Importantly, "stricter standards of permissible statutory vagueness may be applied to a [law] having a potentially inhibiting effect on speech." *Smith v. California*, 361 U.S. 147, 151 (1959). Under the Fifth Amendment, a law is unconstitutionally vague if it does not provide regulatees with sufficient information to discern how to conform their conduct to the requirements of the law. *See Grayned*, 408 U.S. at 105; *Zauderer v. Ohio*, 471 U.S. 626 (1985).

The Fifth Amendment requires the Commission to inform Respondents of what science is needed to meet the "competent and reliable scientific evidence standard" so that Respondents may discern how to conform their conduct to the requirements of the Rule. Despite the fact that the Commission must provide Respondents (and all regulates) with specific guidance, the FTC has chosen not to reveal what objective criteria it uses to evaluate scientific evidence submitted to it in response to access letters and civil investigative demands that call into question scientific corroboration for advertised diet supplement and weight-loss claims. Moreover, the FTC frequently disagrees with regulatees concerning whether the science they have marshaled in

support of claims is "competent and reliable," *See, e.g.*, *In re Schering Corp.*, 118 F.T.C. 1030 (1994); *In re Metagenics*, 124 F.T.C. 483 (1997); *In re Nature's Bounty*, 130 F.T.C. 206 (1995), but does not apprise regulates of the science it expects them to possess before making the claims or before continuing to make the claims.

Respondents are unable to discern from FTC precedent what principles guide the agency in making its determinations on the corroborative sufficiency of science supporting claims in advertising for diet and weight-loss supplements. Therefore, prior to the filing of the Complaint on June 16, 2004, Respondents specifically asked the Commission on numerous instances exactly what type of scientific evidence they would need to satisfy the Commission and what disclaimers would satisfy the Commission. *See, e.g.*, RX-134; RX-137; RX-138 (Attachment B). Respondents received no substantive response from the Commission. *See* RX-135 (Attachment C). Upon issuance of a civil investigative demand compelling the production of all corroborative science possessed by Respondents, FTC evaluated the information but did not disclose the criteria used for the evaluation and did not disclose the scientists who advised it, the scientific reports it received from those scientists, or even the precise content of, or reasons for, its scientific findings. Thereafter, the agency's undisclosed evaluation yielded a determination that Respondents' scientific evidence was not "competent and reliable." *See* RX-126 (Attachment D).

In the absence of principles to guide them, Respondents are entirely at a loss to know whether, if ever, the scientific evidence they possess will satisfy FTC's substantively undefined standard for advertised claims in the challenged advertisements. The lack of a comparable, clear definition for "competent and reliable scientific evidence" makes it impossible for Respondents to discern what level, degree, quality, quantity, and kind of scientific evidence FTC will consider

necessary and sufficient support for any particular claim. Moreover, Respondents cannot determine how best to qualify the claims to address any concerns the FTC may have about the extent to which the science provides evidence of the claimed benefits. In short, FTC's criteria for evaluating claims and its weighing of those criteria are hidden from Respondents and other advertisers of diet and weight-loss supplements.

The Commission did not provide Respondents with sufficient information to discern how to conform their conduct to the requirements of the law. The absence of defined criteria is a constitutional violation. Respondents effectively are deprived of their liberty and property rights in their chosen commercial speech and advertising because they cannot discern in advance, through the exercise of reason, what FTC will and will not accept as scientific corroboration for claims. This affirmative defense is central to defending Respondents' interests. Thus, evidence in support of this defense is wholly relevant and material to this adjudicative proceeding. Respondents are entitled to present this relevant evidence in support of their affirmative defense. *See Blinder, Robinson & Co. v. SEC*, 837 F.2d 1099, 1112 (D.C. Cir. 1988); *NLRB v. Process & Pollution Control Co.*, 588 F.2d 786, 790-91 (10th Cir. 1978); *Northcutt v. Califano*, 581 F.2d 164, 167 (8th Cir. 1978).

If your Honor does not believe he is empowered to rule on constitutional issues, the alternative request for an immediate interlocutory appeal to the full Commission is warranted and should be granted.

C. This Case Is Ripe for Interlocutory Review

Applications for review of an Administrative Law Judge's ruling may be allowed upon a determination that (1) the ruling involves a controlling question of law or policy as to

which there is substantial ground for difference of opinion and (2) an immediate appeal from the ruling may materially advance the ultimate termination of the litigation or subsequent review will be an inadequate remedy. FTC Rule of Practice Section 3.23(b). Both factors are met in this instance.

1. The Order Presents a Controlling Question of Law

Your Honor's Order involves "a controlling question of law or policy as to which there is substantial ground for difference of opinion." A question is deemed controlling "if it may contribute to the determination, at an early stage, of a wide spectrum of cases." *Rambus Inc.*, 2003 F.T.C. LEXIS 49 at *9 (Mar. 26, 2003) (citing *Automotive Breakthrough Sciences, Inc.*, 1996 F.T.C. LEXIS 478 at *1 (Nov. 5, 1996)).

If ALJs are permitted to exclude evidence of unconstitutional acts on the part of the Commission because the events occurred before a certain point in time (i.e., prior to filing of the Complaint), then *all* Respondents before the FTC are placed in the same situation as Respondents, precluded from defending themselves before the Commission. The Constitutional rights of all present and future Respondents are in jeopardy, and, thus, interlocutory review of those issues will contribute to the determination of a wide spectrum of cases.

The difference of opinion in this case lies in the application of *In re Exxon Corporation*, 83 F.T.C. 1759, 1760 (1974), to the present case. The issue in *Exxon* was whether Congress interfered with the FTC's judicial function to the point where the Commission was pressured to take enforcement action despite the fact that the enforcement actions were not in the public interest. The ALJ refused to permit evidence concerning "matters that go to the mental processes of the Commissioners." In this case, however, Respondents do not wish to use the pre-Complaint evidence to probe the mental processes of the Commissioners. Rather, Respondents

wish to use the evidence to support their constitutionally-based affirmative defenses. In *Exxon*, the ALJ explained that the issue to be litigated was "whether the alleged violation ha[d] in fact occurred." That is precisely the issue Respondents wish to address with their pre-Complaint evidence, as Respondents argue that it is impossible to violate an unconstitutional law. Thus, there is a legitimate difference of opinion on how to apply *Exxon* to a case like the instant case.

2. Subsequent Review of the Record Will Be an Inadequate Remedy

Subsequent review of the record in this case will be an inadequate remedy because an appellate court may review only the administrative record from the agency proceedings. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419-420 (1971). If the pre-Complaint evidence is excluded, that evidence will not become part of the administrative record. Therefore, following the completion of the hearing, Respondents would be prevented from appealing the exclusion of the pre-Complaint evidence because that evidence would not be part of the record. Thus, immediate review of the Order precluding pre-Complaint evidence is the only means by which Respondents can obtain review of the ruling. Interlocutory review is therefore warranted in this instance.

V. CONCLUSION

In the absence of clear criteria for discerning whether a claim is backed by "competent and reliable scientific evidence," Respondents could not reasonably anticipate whether FTC would agree with them that their science would be adequate support for prospective advertising claims and could not know whether any particular disclaimer could eliminate FTC concerns that would otherwise arise. FTC's refusal to supply Respondents with guidance when asked violated Respondents' First and Fifth Amendment rights. Respondents should be entitled to present relevant and material evidence in support of that affirmative defense. Respondents respectfully

request that your Honor certify those portions hereinabove mentioned of the January 10, 2006 Order for interlocutory review under Rule 3.23(b) or, in the alternative, to reconsider and to reverse that Order.

Respectfully Submitted,

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Date submitted: January 23, 2006

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
WASHINGTON, D.C.

In the Matter of

BASIC RESEARCH, LLC **A.G. WATERHOUSE, LLC** **KLEIN-BECKER USA, LLC** **NUTRASPORT, LLC** **SOVAGE DERMALOGIC LABORATORIES, LLC** **BAN LLC d/b/a BASIC RESEARCH LLC** **OLD BASIC RESEARCH, LLC** **BASIC RESEARCH, A.G. WATERHOUSE,** **KLEIN-BECKER USA, NUTRA SPORT, and** **SOVAGE DERMALOGIC LABORATORIES** **DENNIS GAY** **DANIEL B. MOWREY d/b/a AMERICAN** **PHYTOTHERAPY RESEARCH** **LABORATORY, and** **MITCHELL K. FRIEDLANDER,** **Respondents.**	**PUBLIC VERSION** **Docket No. 9318**

CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of January, 2006, I caused the public version of Respondents' Application for Review of the January 10, 2006 Order that Excludes Relevant Evidence Concerning the FTC's Pre-Complaint Investigation and Abridges Respondents' Constitutional Rights to be filed and served as follows:

1) an original and one paper copy filed by hand delivery and one electronic copy in PDF format filed by electronic mail to

Donald S. Clark
Secretary
U.S. Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-159
Washington, D.C. 20580

Email: secretary@ftc.gov

2) two paper copies delivered by hand delivery to:

The Hon. Stephen J. McGuire
Chief Administrative Law Judge
U.S. Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-112
Washington, D.C. 20580

3) one paper copy by first class U.S. Mail to:

James Kohm
Associate Director, Enforcement
U.S. Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20001

4) one paper copy by first class U.S. mail and one electronic copy in PDF format by electronic mail to:

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Svetlana N. Walker

Attachment A

further examination on the area Mowrey was unable to address. Opposition at 14.

With respect to Complaint Counsel's request to preclude Respondents from presenting testimony at trial concerning the manufacture of the challenged products, Complaint Counsel's motion is **DENIED**. Respondents shall make Michael Meade available for deposition for the limited topic of the manufacture, including the manufacturers, of the challenged products. The deposition shall be limited to two hours and shall be completed within 10 business days or a date mutually agreed upon that is at least 20 days prior to the start of trial.

D. Testimony on the pre-Complaint Investigation

Respondents' Final Witness List indicates that the intended testimony for Dennis W. Gay, Carla Fobbs, and Mitchell K. Friedlander includes "the investigation by the Federal Trade Commission ("FTC") and the impact of the investigation and proceedings." Respondents' Final Witness List at 2. Complaint Counsel seeks to preclude testimony from these and any other witnesses concerning the FTC's investigation and its impact on grounds that such testimony is irrelevant to the issues to be tried. Motion at 19.

Respondents argue they are entitled to call Gay, Fobbs, and Friedlander to testify concerning Respondents' efforts, during the pre-Complaint investigation by the Commission to obtain guidance from the Commission concerning the Commission's substantiation standards. Opposition at 15. Respondents further state such testimony is relevant to Complaint Counsel's pre-Complaint protocol; Respondents' good faith voluntary submission of materials in support of their claims; Complaint Counsel's reasonable basis for issuing the Complaint; and the costly and time-consuming efforts undertaken by Respondents to comply with the pre-Complaint investigation and post-Complaint defense of the charges brought by the Commission. Opposition at 15-16.

By previous Orders, Respondents have been repeatedly instructed that, "the issue to be litigated at the trial in this matter is whether Respondents violated the FTC Act's prohibition against false and misleading advertising." Order on Complaint Counsel's Motion to Strike Respondents' Additional Defenses, 2004 FTC LEXIS 211, *3 (Nov. 4, 2004). *See also* Order Denying Basic Research's Motion to Compel, 2004 FTC LEXIS 210, *10 (Nov. 4, 2004) ("[t]he issue to be tried is whether Respondents disseminated false and misleading advertising, not the Commission's decision to file the Complaint").

The pre-Complaint investigations are clearly irrelevant to the present matters before the Court. *See In re Exxon Corp.*, 83 F.T.C. 1759, 1760 (1974). "Once the Commission has . . . issued a complaint, the issue to be litigated is not the adequacy of the Commission's pre-complaint information or the diligence of its study of the material in question but whether the alleged violation has in fact occurred. *Id.*

Pursuant to Commission Rule 3.43, "[i]rrelevant, immaterial, and unreliable evidence shall

be excluded." 16 C.F.R. § 3.43. To the extent Respondents seek to introduce evidence on Complaint Counsel's pre-Complaint protocol, Complaint Counsel's reasonable basis for issuing the Complaint, or the costs to Respondents to comply with the pre-Complaint investigation and post-complaint defenses, such evidence is irrelevant and shall be excluded. In this respect, Complaint Counsel's motion is **GRANTED in part.**

With respect to other proffered evidence, Complaint Counsel, as the party with the burden on its motion *in limine*, has not clearly articulated the evidence sought to be excluded or the reasons therefor. Accordingly, Complaint Counsel's motion is **DENIED in part.** As to such other evidence, Respondents must be prepared to demonstrate at trial the relevance to the issues raised in the Complaint and Respondents' valid defenses thereto. Complaint Counsel may then raise its specific objections.

E. Testimony on Safety Claims

Respondents' Final Witness List indicates that the intended testimony for Complaint Counsel's Expert Witnesses, Steven Heymsfield, M.D. and Robert Eckel, M.D. includes testimony regarding "safety claims made in advertisements for dietary supplements and/or weight control products." Respondents' Final Witness List at 4-5. Complaint Counsel asserts the Complaint in this case does not allege any false or deceptive advertising with regard to safety claims and thus any such testimony is irrelevant to the issues to be tried. Motion at 22.

Respondents assert that they will rely on Complaint Counsel's representation in its Motion that "the Complaint in this case does not allege any false or deceptive advertising with respect to safety claims." Opposition at 16 (quoting Motion at 22). Based on Complaint Counsel's representation, Respondents agree not to question Complaint Counsel's experts concerning safety claims in connection with the challenged advertisements. Opposition at 16. But, Respondents state they reserve the right to examine any knowledgeable witness concerning the use and reliance on anecdotal evidence and case reports in the context of safety issues generally. Opposition at 16.

Based on these representations, with respect to Complaint Counsel's request to limit Respondents from questioning Heymsfield and Eckel concerning safety claims made in advertisements for dietary supplements and/or weight control products, the Motion is **GRANTED.** With respect to any other safety related issues that might be raised during trial, the Court will rule on the admissibility of such evidence at the appropriate time.

F. "Without limitation" Term

On Respondents' Final Witness List, Respondents have used the term "without limitation" to preface each description of intended testimony. Complaint Counsel argues that the "without limitation" preface is an apparent effort to allow Respondents to delve into more subject areas than listed. Motion at 23. Complaint Counsel seeks an order striking the phrase, "without limitation," and limiting Respondents to testimony that within reason falls within the subject

Attachment B

Confidential Material Subject to Protective Order

Redacted

Attachment C

Confidential Material Subject to Protective Order

Redacted

Attachment D

Confidential Material Subject to Protective Order

Redacted