UNITED STATES OF AMERICA
BEFORE 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 LABORATORIES, L.L.C.,
d/b/a BASIC RESEARCH, L.L.C.,
OLD BASIC RESEARCH, L.L.C.,
BASIC RESEARCH, A.G. WATERHOUSE,
BAN, L.L.C.,
d/b/a 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.

DOCKET NO. 9318

RESPONDENTS' OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO STRIKE RESPONDENTS' ADDITIONAL DEFENSES

Respondents Basic Research, LLC, A.G. Waterhouse, LLC, Klein-Becker USA, LLC, Nutrasport, LLC, Sövage Dermalogic Laboratories, LLC, Ban, LLC, Dennis Gay, Daniel B. Mowrey, Ph.D and Mitchell K. Friedlander (collectively "Respondents"), hereby file their Opposition to Complaint Counsel's Motion to Strike Respondents' Additional Defenses, and in support thereof state as follows.

I. INTRODUCTION

Respondents have raised both Constitutional and non-Constitutional defenses to the law enforcement action the Federal Trade Commission ("FTC" or "Commission") initiated against them on June 15, 2004. On July 30, 2004, after the Administrative Law Judge ("ALJ") denied Respondents' motions challenging the Commission's pleading, Respondents answered the Administrative Complaint. Respondents' Answers contain several Additional Defenses predicated on the Commission's repeated violations of Respondents' fundamental rights that underlie this proceeding. Certain of the FTC's past and present actions violate Respondents' rights under the First and Fifth Amendments to the U.S. Constitution and constitute arbitrary and capricious action under the Administrative Procedures Act ("APA"). Respondents asserted these and other defenses in a clear, concise manner that comports with Rule of Practice 3.12(b)(1)(i).

On August 20, 2004 Complainant moved to strike Respondents' Additional Defenses. That motion asserts broad, policy-based arguments that exceed the authority of the ALJ and preclude his jurisdiction to resolve them. These arguments must be certified to the Commission. *See In the Matter of Herbert R. Gibson, Sr., et al.*, 90 F.T.C. 275, 275, 1977 WL 189044, at *1 (Oct. 12, 1977) ("It is well established that an administrative law judge lacks authority to rule on and must certify motions to dismiss . . . and other motions containing questions pertaining to the Commission's exercise of administrative discretion.").

Complaint Counsels' other arguments concerning the validity of Respondents' Additional Defenses are inconsequential with respect to the outcome of this administrative action. Motions to strike—such as the instant one filed by Complaint Counsel—are disfavored and are properly denied except in the most limited of circumstances (which are not present, here). It is doubtful the United States Constitution and the Administrative Procedures Act (both of which police the

very powers the Commission asserts against Respondents) ever could be deemed "irrelevant" to an agency's law enforcement action. Because the Commission relies on its vague "substantiation doctrine" and subjective, *post* and *ad hoc* "competent and reliable scientific evidence" standard to regulate Respondents' commercial speech, both the U.S. Constitution and the APA are directly relevant to these enforcement proceedings.

At most, Complaint Counsel argues that it is *futile* to assert the challenged defenses before the Commission, and that Respondents should be *denied* the opportunity to develop a record to support their defenses in this proceeding. Even if Respondents simply were preserving defenses for appeal, Complaint Counsel utterly fails to demonstrate: (1) any prejudice to the FTC if Respondents' Additional Defenses are adjudicated, and not stricken, and (2) no prejudice to Respondents if Respondents are deprived of an opportunity to develop a record in this proceeding. Accordingly, Complaint Counsel's attempts to summarily remove these issues from this case in the interest of "economy" and "efficiency" are misplaced or facetious.

Finally, with respect to the form of the Additional Defenses, Complaint Counsel contends that a few are not properly pled. They criticize Respondents allegedly for not meeting the requirements of the FTC's Rules of Practice 3.12(b). The purpose of this Rule, however, is to sufficiently apprise Complaint Counsel of the grounds of each defense. Respondents complied with that purpose. Complaint Counsel has no difficulty appreciating the basis of Respondents' defenses as evidenced by their long discussions about the merits of each defense.

Because Complaint Counsel's Motion to Strike demonstrates sufficient notice of both legal and factual bases for Respondents' Additional Defenses, the Motion to Strike should be denied. Alternatively, leave to amend should be granted to cure any perceived deficiency.

II. ARGUMENT

A. Motions to Strike Defenses are Disfavored.

Motions to strike defenses are "viewed with disfavor." *FTC v. Commonwealth Marketing Group, Inc.*, 72 F.Supp.2d 530, 545 (1999); *In The Matter Of Dura Lube Corporation, et al.*, 1999 WL 33577395 *1 (F.T.C.). They should be denied, "unless the insufficiency of the defense is 'clearly apparent.'" *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 188 (3rd Cir. 1986)). Consequently, to succeed on a Motion to Strike, Complaint Counsel must show that the challenged allegations "are so unrelated to the [Respondents'] claims as to be unworthy of any consideration as a defense and that [Complaint Counsel] is prejudiced by the presence of the allegations in the pleading." *Id.* (citing *Great West Life Assur. Co. v. Levithan,* 834 F.Supp. 858, 864 (E.D.Pa 1993)). *Accord In the Matter Of Dura Lube Corporation, et al.*, 1999 WL 33577395 at *1 (F.T.C. Aug. 31, 1999) (to prevail on motion to strike, Complaint Counsel must show that defense (1) is unmistakably unrelated or so immaterial as to have no bearing on the issues; and (2) prejudices Complaint Counsel by threatening an undue broadening of the issues or by imposing an undue burden on Complaint Counsel).

Complaint Counsel fails to make their requisite showing under 16 C.F.R. § 3.43(a). The *Dura Lube* case is instructive. There (as here) the ALJ was presented with a motion to strike in which Complaint Counsel contended that Respondents' defenses should be stricken because allegedly they: (1) were irrelevant or immaterial, and serve only to confuse the issues; (2) were invalid as a matter of law; and/or (3) did not comply with FTC procedural Rule 3.12(b).

Complaint Counsel's motion to strike was denied with the comment that, although certain cases have held that issues of law or fact that are wholly irrelevant or immaterial can be resolved on a motion to strike, other cases have held that it is inappropriate to adjudicate such issues in

this manner. *Dura Lube*, 1999 WL 33577395 at *1-2. The ALJ held that decisions considering both the relevance of the defenses and the potential for prejudice to Complaint Counsel were more persuasive. *Id.*, citing *Home Shopping Network*, 1995 FTC LEXIS 259 (motions to strike will not be granted "unless their presence unduly prejudices the opposing party") and *Synchronal Corp. et al.*, 1992 FTC LEXIS 61, *1 (Mar. 5, 1992) ("a motion to strike will be denied not only if there are disputed questions of fact or law but also when there is a showing that permitting the defense to stand would not prejudice the plaintiff"). Because in *Dura Lube* the ALJ found that Complaint Counsel failed to meet both requirements, it was inappropriate to strike the challenged portions of the Answer, including a blanket denial of a preamble. *See* 1999 WL 33577395 at *1-2. Similarly, because there was no identified prejudice to Complaint Counsel, the ALJ permitted the defenses to stand, notwithstanding the requirements of Rule 3.12(b). *Id.*

Applying these basic tenets to the present proceeding, the Motion to Strike is meritless. None of Respondents' Additional Defenses are unrelated or immaterial to this proceeding and are unworthy of consideration (in fact, the ALJ does not even have authority to resolve many of Respondents' defenses). The Motion to Strike also is meritless because Complaint Counsel has not identified any undue prejudice to them as a consequence of issues raised by Respondents' Answers. Complaint Counsel's Motion to Strike should be denied.

B. Fifth Amendment—Due Process is a Valid Defense.

1. Respondents Properly Raise A Fifth Amendment Defense To This Administrative Proceeding.

Respondents' first challenged defense is denial of Due Process, under the Fifth Amendment to the United States Constitution. In asserting this defense Respondents complied with Rule of Practice 3.12(b). Each Respondent plainly and concisely alleges that:

> This enforcement action is based upon regulatory standards governing the quantity and quality of substantiation Respondent must possess at the time it

> makes express and implied claims in advertisements. The standards fail and have failed to provide reasonable persons, including Respondent, with fair notice as to whether contemplated claims in advertisements, including those at issue in this proceeding, are and were permissible and/or allow and have allowed the Commission and/or its representatives to enforce the standards pursuant to their personal or subjective predilections. The regulatory standards are thus unconstitutionally vague on their face and/or as applied to Respondent's prior and contemplated advertising activity and, therefore, violate Respondent's rights to due process under the Fifth Amendment to the Constitution of the United States. The Complaint and enforcement action based upon such standards must therefore be dismissed.

In moving to strike, Complaint Counsel does *not* claim Respondents cannot raise a Fifth Amendment defense. A Fifth Amendment challenge to an improper regulatory approach by a federal agency is a valid defense, particularly when the regulatory scheme is developed improperly and as a consequence, is vague. *See, e.g., In the Matter of Trans Union Corp.*, 2000 WL 257766 (Feb. 10, 2000) (Commission, in law enforcement action under Fair Credit Reporting Act, ordered by D.C. Circuit to hear Respondent's defense that "the FCRA's definition of consumer report is unconstitutionally vague under the Fifth Amendment.").[1] In fact, Complaint Counsel's motion confirms Respondents' right to raise Constitutional defenses. *See* Motion to Strike at 11, n. 7 (citing *In re Superior Ct. Trial Lawyers Ass'n,* 107 F.T.C. 510 (1986) and *In re Rodale Press, Inc.*, 71 F.T.C. 1184 (1967), in which Constitutional defenses to the Commission's action were raised *and addressed on the merits* by the Commission).

Complaint Counsel also does *not* contend Respondents failed to comply with Rule of Practice 3.12(b) in asserting their Fifth Amendment defense. In fact, they argue their position that the Commission's "substantiation" and "competent and reliable scientific evidence"

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[1] In *Thompson Medical Company, Inc. v. F.T.C.*, 791 F.2d 189 (D.C. Cir. 1986), after stating the Court's preference for FTC orders that are "unequivocally legal," the D.C. Circuit expressly noted that the FTC's utilization of vague standards to regulate commercial speech repeatedly are "attacked on vagueness grounds," and often force the FTC to go through a "lengthy and uncertain appellate process . . . ." *Id.*, at 195-96.

doctrines—which regulate dietary supplement and weight-loss claims and form the subject of Respondents' defense—provide "fair notice," are sufficiently "definite," and provide advertisers with a meaningful "opportunity" to be heard. *See* Motion at Strike at 5, 8, and 10.

What Complaint Counsel challenge is the *substance* of Respondents' Fifth Amendment defense. They seek to dismiss or summarily avoid Respondents' Constitutional defense by arguing it is "spurious." Motion to Strike at 4. Complaint Counsel contends the defense "flies in the face of Commission opinions, orders, and policy statements or publications . . . ." *Id.*, at 9. Complaint Counsel notes that their client "carefully considered and rejected arguments remarkably similar to those presented here by Respondents when it denied a formal petition for rulemaking pursuant to RULE OF PRACTICE 1.9." *Id.* at 9, n.5 (citing Letter from Federal Trade Commission to Jonathon W. Emord, Esq. (Nov. 30, 2000), Attachment 3 to Motion to Strike).

In essence, superficially reasoning by analogy rather than by cogent analysis, Complaint Counsel contends that raising a Fifth Amendment defense in this proceeding, to the Commission's advertising "substantiation" doctrine for dietary supplement and weigh-loss claims *is futile*. Complaint Counsel accuse Respondents of "burying their heads in the sand with respect to the Commission's *long-standing* substantiation standard," and argue that "[i]t defies credulity for Respondents to suggest that this administrative proceeding violates the tenets of due process." Motion to Strike at 7-8, 10. What hubris!

In a haughty manner unbecoming them, Complaint Counsel later opine that Respondents should not be permitted to raise defenses that seek to "try the prosecutor." Motion to Strike at 15-16. They contend it would be unfair if their client were forced to justify public policies and law enforcement decisions, or to even permit Respondents to develop record evidence

concerning their Constitutional defenses. *Id.* at 19-20. This argument is preposterous and, frankly, insulting to the intelligence of the Administrative Law Judge.

Under the Fifth Amendment *the Commission's unyielding refusal to comply with the requirements of due process*[2] is not a trifling matter of little consequence. The issue is *not* whether Respondents will have an opportunity to argue their "substantiation provides a reasonable basis for their claims." Motion to Strike at 10. Although Respondents *do* question whether the Commission's challenged law enforcement doctrine that regulates dietary supplement and weight-loss claims provides a meaningful opportunity to vindicate Respondents' Constitutional rights, the overriding issue is whether the Fifth Amendment, by itself or in conjunction with the First Amendment, requires the FTC to provide advertisers—*before they risk speaking and being subjected to coercive law enforcement action under the Commission's substantiation doctrine*—(1) a concrete, content-neutral commercial speech standard against which to judge their commercial speech, and/or (2) procedural safeguards that distinguish protected speech (whether fully protected or potentially misleading commercial speech) from unprotected speech (whether false or inherently misleading commercial speech).[3]

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[2] The ALJ should be incredulous about Complaint Counsel's remark that "Respondents have been *fully appraised* of the nature and details of their alleged violations of the FTC Act." Motion to Strike at 10 (emphasis added). The ALJ surely is mindful that—to this day—the FTC has *refused* to apprise Respondents, both in its charging document and in discovery, of *how* it interprets Respondents' advertisements (utilizing, instead, vague, subjective, and relative terms with no concrete meaning); *what* standard forms the basis of its advertising interpretation; *why* Respondents' evidence supporting their advertisements is insufficient to support the Commission's challenged, but still unarticulated claims; *what* forms the basis of its conclusion; and *what* Respondents supposedly needed to say, but did not say, to avoid consumer confusion and law enforcement liability. Such administrative adjudication by surprise is the inevitable, inherent by-product of the Commission's constitutionally infirm proceeding.

[3] If an advertised claim is *false* or *inherently misleading*, and therefore not entitled to First Amendment protection, Complainant need not rely on the substantiation doctrine. It can proceed under a "falsity theory" that extends to *all* materially misleading claims, including potentially misleading claims, *which are likely to mislead a substantial number of consumers acting* (continued...)

Respondents contend that, *before* the Commission can take coercive law enforcement action against an advertiser of dietary supplements or weight-loss products under any advertising substantiation doctrine, the Commission is constitutionally obligated to promulgate **a concrete, content-neutral standard** against which an advertiser may judge its commercial speech, before speaking, and/or must institute **procedural safeguards** that provide an advertiser the opportunity to correct—without liability for engaging in protected commercial speech, even if potentially misleading—what the Commission might claim, *after-the-fact*, is misleading. All basic factors necessary for Respondents to prevail on their constitutional challenge to the FTC's seriously flawed law enforcement scheme are present, here.[4]

Respondents and all others similarly situated are without knowledge of precisely which claims will survive—and which ones will fail—the Commission's advertising substantiation doctrine. Because there is no discernable limit to the Commission's discretion to initiate law enforcement action, and because there are no procedural safeguards to enable Respondents and others similarly situated to correct claims the Commission after-the-fact might deem violative of its flawed substantiation doctrine, such advertisers *unavoidably* will be subject to *unlawful* agency action that will *escape* judicial review, which clearly violates the First and Fifth

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reasonably under the circumstances, without raising First or Fifth Amendment concerns. *See* 15 U.S.C. § 55(a)(1); FTC's October 14, 1983 Policy Statement on Deception, appended to *In re Cliffdale Assocs.*, 103 F.T.C. 110 (1984).

[4] The FTC is an agency that exercises discretionary authority with little, or no, checks and balances. It institutes coercive enforcement actions under its advertising substantiation doctrine, with vague standards that confer unbridled discretion to regulate commercial speech, *ad* and *post hoc*. The Commission refuses to implement a prescreening mechanism or other procedural safeguards less restrictive of commercial speech (which Complaint Counsel acknowledges in the Motion to Strike at page 9, footnote 5). The Commission's adherence to an intentionally vague regulatory scheme with no procedural safeguards unduly threatens and curtails constitutionally protected freedoms, including Respondents' rights under the First Amendment.

Amendments of the U.S. Constitution. If this isn't so, as Complaint Counsel contends, the simplistic argument by Complaint Counsel would stand constitutional law on its head. For the reasons discussed below, the coerce action now being taken against Respondents under the flawed advertising substantiation doctrine is un-Constitutional and is void *ab initio.*

2. Complaint Counsel's Motion To Strike Raises A Constitutional Question That Should Be Certified To The Commission.

Whether the Commission's regulatory scheme governing dietary supplement and weight-loss claims is constitutional is a threshold legal issue that should be certified to the Commission and reviewed by the D.C. Circuit. Indeed, the first question raised by Complaint Counsel's motion is whether it raises factual or legal issues that the ALJ can properly resolve, or questions touching upon matters of administrative discretion, which have to be certified to the Commission for resolution. *See Herbert R. Gibson,* 90 F.T.C. at 275 ("It is well established that an administrative law judge lacks authority to rule on and must certify . . . motions containing questions pertaining to the Commission's exercise of administrative discretion.").

Neither the ALJ nor the Commission has any authority to uphold the FTC's regulatory scheme, including the standards employed by the FTC to implement Sections 5 and 12 of the Federal Trade Commission Act (the "FTC Act"), as constitutional. *See Weinberger v. Salfi*, 422 U.S. 748, 764-67 (1975); *Ticor Title Ins. Co. v. F.T.C.,* 814 F.2d 731, 739 n. 11 (D.C. Cir. 1986) ("agency is without jurisdiction or competence to decide the constitutional question"). This basic separation of powers is not unique to the FTC. Under the U.S. Constitution, no policymaking and law enforcement body has the power to resolve whether their interpretation or exercise of authority is constitutional. The constitutionality of the FTC's regulatory scheme and standards it imposes on interstate commerce, and the constitutionality of any law enforcement action thereunder, are questions of law that fall within the sole province of Article III courts.

As to whether the FTC's regulatory scheme, including its standards governing commercial speech, are *unconstitutional*, the ALJ can obviously make this recommendation to the Commission, but the ALJ has no authority to rule that the Commission, in its policymaking capacity, has violated the Fifth Amendment. The FTC's regulatory scheme and the standards the FTC uses to regulate commercial speech are matters of administrative discretion. Congress delegated to the Commission the power to implement Sections 5 and 12 of the FTC Act, and the Commission has implemented the FTC Act as it has seen fit. Whether the FTC's regulatory scheme and commercial speech standards are constitutional is something far beyond the authority of the ALJ to resolve. In fact, even Complaint Counsel acknowledges that the Commission would have to essentially capitulate and declare its own regulatory scheme and commercial speech standards unconstitutional. The ALJ has no authority to resolve this issue.

In other words, the ALJ has no authority, one way or the other, to resolve the *substantive* issue raised by Complaint Counsel's Motion to Strike Respondents' Fifth Amendment defense—that is, whether "Respondents have received, and continue to receive, the notice and opportunity for hearing required by law." Motion to Strike at 5. *See In the Matter of Boise Cascade Corp.*, 97 F.T.C. 246 (1981) (certifying to Commission issues touching upon Commission's power and discretion to initiate law enforcement action). The substantive issue underlying whether "Respondents' argument is untenable" or "invalid as a matter of law," Motion to Strike at 8, is a question that must be certified to the Commission and reviewed by the D.C. Circuit.[5]

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[5] Although Complaint Counsel contends that Respondents' constitutional challenge is futile, the Commission has in no uncertain terms recognized its obligation to zealously guard protected freedoms in discharging its duties to protect consumers under the FTC Act:

> We bow to no one in our concern and responsibility to protect the public from any invasion of its Constitutional rights, particularly those associated with the rights of freedom of speech and expression. In today's increasingly computerized society

(continued...)

3. Complaint Counsel's Fifth Amendment Argument Has No Merit, And This Proceeding Should Be Terminated.

Complaint Counsel argues the Commission has given Respondents "fair notice of its substantiation standard." Motion to Strike at 5. The Commission's "Policy Statement Regarding Advertising Substantiation," and/or the Commission's prior "opinions, cease and desist orders, consent decrees, complaints, and publications," Complaint Counsel contends, provide advertisers of dietary supplements and weight-loss products with sufficient notice of "the appropriate type and level of substantiation for the advertising claims challenged in the *Complaint*." *Id.*

Remarkably, in the next breath, Complaint Counsel *concedes* that when the Commission filed its Complaint and brought this law enforcement action, it did <u>not</u> even know the quantity and quality of support that the FTC Act required of Respondents' advertisements under its substantiation doctrine. Rather, what its substantiation doctrine required is determined after-the-fact based on what "*experts in the field* believe is reasonable to support the advertised claim . . . ." Motion to Strike at 7 (emphasis added). By necessity, Complaint Counsel argues, the Commission relies upon medical or scientific experts to determine on an *ad* and *post hoc* basis the level and amount of support required of "the challenged advertisements." *Id.*

Complaint Counsel refers to this after-the-fact determination of the controlling legal standard and the Commission's reliance on so-called "experts" to set the standard governing

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> with the ever-increasing involvement of Government in the lives of its citizens, we would be derelict in our duties as public officials and citizens if we were not especially zealous to protect the individual from any encroachment by Government on his fundamental freedoms. But we are also equally mindful of the importance of protecting individual citizens from any misleading and deceptive representations contained in the barrage of advertising to which he is daily subject in the promotion of the myriad of products offered for sale in the market-place.

In re Rodale Press, Inc., 71 F.T.C. 1184 (1967).

commercial speech after advertisers have spoken, as the Commission's long-standing "competent and reliable scientific evidence" test or "substantiation standard." Motion to Strike at 7-8. At trial, Complaint Counsel admits that they will try to introduce "expert" testimony on what is "competent and reliable" and will continue to argue, "that competent and reliable scientific evidence is required to establish a reasonable basis for the challenged claims." *Id.* at 7.

Complaint Counsel contends that Respondents' Fifth Amendment defense is "invalid as a matter of law," relying on a line cases that have little, or no, bearing on Respondents' Constitutional defenses.[6] In these cases, circuit courts upheld the FTC's use of the "competent and reliable scientific evidence" standard governing the rights of *adjudicated wrongdoers* in the context of *narrow fencing in provisions*, which, pursuant to the FTC's regulatory scheme, *obligated* the Commission to provide the wrongdoer with a *binding opinion* as to whether a future advertisement would violate the FTC's cease and desist order. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965) (holding that vague FTC cease and desist orders are less troublesome because wrongdoers can force the FTC to prescreen their ads).

In stark contrast, here, there is no adjudicated wrongdoer (although it is apparent that the FTC perceives all respondents subject to its heavy-handed law enforcements efforts as guilty until proven innocent). There is no cease and desist order governing the rights and liabilities of the parties. There is no narrow fencing in provision designed to prevent future violations of the FTC Act by an adjudicated wrongdoer. And there is no provision requiring the FTC to provide innocent advertisers with even non-binding advisory opinions before they run advertisements. In

[6] *See* Motion to Strike at 8-9, citing *Bristol-Meyers Co. v. FTC*, 738 F.2d 554 (2nd Cir. 1984); *Thompson Medical Co.*, 791 F.2d 189 (D.C. Cir. 1986); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1145, 1156-57 (9th Cir. 1984).

fact, Complaint Counsel acknowledges that the Commission has specifically denied rulemaking petitions requesting such procedural safeguards. *See* Motion to Strike at 9, n. 5.

The controlling line of cases is *Kolender v. Lawson,* 461 U.S. 352 (1983), *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) ("*Pearson I*"), *American Home Products Corp. v. Federal Trade Commission*, 695 F.2d 681 (3rd Cir. 1983), and *Women's Medical Center of Northwest Houston v. Bell*, 248 F.3d 411 (5th Cir. 2001). These cases establish the following constitutional principal, which informed Justice Brennan's concurring opinion in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985):[7] that vague standards governing commercial speech—such as the FTC's competent and reliable scientific evidence standard, which broadly applies to law abiding advertisers and unavoidably relies on after-the-fact opinions of third parties—are unconstitutional, especially where, as here, the government has no procedures protecting speakers from coercive law enforcement action.

Complaint Counsel attempts to sweep the Commission's ongoing constitutional violation under the rug by arguing that "[t]he weight of authority does not support" Respondents' Fifth Amendment defense. *See* Motion to Strike at 9. However, the controlling authority in the D.C. Circuit, *Pearson I*, runs directly contrary to Complaint Counsel's argument.

In fact, since *Pearson I*, the Commission has openly refused to conform its regulation of commercial speech to the requirements of the U.S. Constitution. It has repeatedly denied its obligation to provide (1) a concrete, content-neutral standard governing commercial speech against which advertisers of dietary supplements and weight-loss products can judge their

[7] Justice Brennan plainly recognized that the government's refusal to prescreen an advertisement "wholly undermines one of the basic justifications for allowing punishment for violations of imprecise commercial regulations—that a businessperson can clarify the meaning of an arguably vague regulation by consulting with government administrators." *Id.* at 668.

advertisements, and/or (2) procedural safeguards affording advertisers the opportunity to correct what the FTC might consider potentially misleading speech *before* they speak or become subject to coercive law enforcement action. Rather, the Commission has taken the constitutionally infirm position that it can utilize an admittedly vague commercial speech standard, and provide no procedural safeguards limiting the FTC's otherwise unbridled discretion to bring coercive law enforcement action based on an advertiser's exercise of a fundamental liberty, irrespective of whether the advertiser's speech is protected commercial speech and whether any perceived risk of consumer confusion could have been avoided by the FTC under the FTC Act.

If the ALJ refuses to certify the Fifth Amendment issue to the Commission, Respondents will adjudicate at the appropriate time and in an appropriate forum whether the Commission's speech entrapment scheme—which the Commission adopted, as a policymaker under the FTC Act before Respondents' challenged advertisements ran, which the Commission enforces as speech police, prosecutor, judge and jury, and which the Commission is now bringing to bear on Respondents by virtue of its Complaint—is unconstitutional. It is hardly the "precise type" of due process envisioned by our founding fathers. And it is certainly <u>not</u> the type of process permitted by the Fifth Amendment, which is the basis of Respondents' first defense.

C. First Amendment—Freedom of Speech is a Valid Defense.

Respondents' second challenged defense is the First Amendment—Freedom of Speech. In asserting this defense, each Respondent plainly and concisely alleges that:

> The Commission's Complaint, enforcement action and the relief sought abridge Respondent's rights under the First Amendment to the Constitution of the United States because the Commission seeks to restrict, restrain and/or prohibit protected commercial speech, because the Commission seeks to restrict, restrain and/or prohibit protected commercial speech through the use of *ad hoc* and non-defined terms and advertising substantiation lacking any measurable degree of definiteness, and because the Commission's actions are premised at least in part upon alleged representations made "by implication" that the Commission has

labeled false or misleading without relying on extrinsic evidence. In proceeding this way, the Commission has failed to choose and/or rejected alternate means to achieve its interests that are less restrictive of protected speech.

Again, Complaint Counsel does not contend that Respondents did not comply with Rule of Practice 3.12(b) in asserting this defense. Rather, Complaint Counsel again erroneously seeks to dismiss or summarily resolve a constitutional defense. *See* Motion to Strike at 4.

As before, Complaint Counsel's motion should be certified to the Commission, as the ALJ does not have the authority to resolve whether the Commission's regulatory scheme and commercial speech standards violate the U.S. Constitution. Once again, the only real points made by Complaint Counsel is that raising a constitutional defense before the Commission is *futile*, and that Respondents should not be permitted to *develop a record* on their constitutional defenses, because it would put on trial the law enforcement scheme the Commission has used since *Thompson Medical Co.*, 104 F.T.C. 648 (1984), when it issued its Policy Statement on Advertising Substantiation.[8] Complaint Counsel's Motion to Strike simply ignores why the Commission's substantiation doctrine and competent and reliable scientific evidence standard violate the First Amendment. As set out below, Complaint Counsel does not assert germane or correct statements of the law, and therefore their motion provides no basis for dismissing or adjudicating, let alone summarily adjudicating, Respondents' First Amendment defense.

If the ALJ refuses to certify the threshold Fifth Amendment issue to the Commission, Respondents will adjudicate at the appropriate time and in an appropriate forum whether the

[8] The difference between the "reasonable basis test" announced by the Commission in *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972), and the Commission's substantiation doctrine is not just semantics. A product claim, logically, either has, or does not have, a reasonable basis. One would not ask *how much reasonable basis?* However, in its Policy Statement on Advertising Substantiation, which was appended to *Thompson Medical*, 104 F.T.C. 648, 840 (1984), the Commission made clear that the call of the question under *Pfizer* is *how much evidentiary support does and must a product claim have?*

Commission's substantiation doctrine and competent and reliable scientific evidence standard are unconstitutional, because (1) they operate as a prior restraint on protected commercial speech; (2) they are based on a policy of suppression, not based on a policy of correcting potentially misleading speech; (3) they do not materially advance the FTC's stated interest of protecting consumers from confusion; and (4) there is a far less restrictive method of regulating potentially misleading commercial speech. For now, it is enough to rebut Complaint Counsel's arguments that Respondents' First Amendment defense is "invalid" or "untenable."

1. The First Amendment Protects Against Prior Restraints On Protected Commercial Speech.

The FTC Act does not give the Commission a license to ban protected speech, including potentially misleading speech. *See 44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484, 511 (1996); *Peel v. Attorney Disciplinary Commission,* 469 U.S. 91, 100 (1991); *In re RMJ,* 455 U.S. 191, 203 (1982); *Bates v. State Bar of Arizona,* 433 U.S. 350, 357 (1980).[9] Even if a product claim has the potential to mislead, it has "constitutional protection." *Brief of Federal Trade Commission as Amicus Curiae* in *Peel v. Attorney Displincary Commission,* 469 U.S. 91 (1991).

[9] In *44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484 (1996), the Supreme Court unanimously struck down a state ban on disfavored commercial speech (liquor price advertising), but disagreed on the continuing validity of *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York,* 447 U.S. 557 (1980). Despite this disagreement, the Court reaffirmed that a government policy of suppression is unlawful: "It is the State's interest in protecting consumers from 'commercial harms' that provides 'the typical reason why commercial speech can be subject to greater governmental regulation than noncommercial speech.' *Cincinnati v. Discovery Network, Inc.,* 507 U.S. 410, 426, 113 S.Ct. 1505, 1515, 123 L.Ed.2d 99 (1993). Yet bans that target truthful, nonmisleading commercial messages rarely protect consumers from such harms. Instead, such bans often serve only to obscure 'underlying governmental policy' that could be implemented without regulating speech. *Central Hudson,* 447 U.S., 566, n.9, 100 S.Ct., at 2351, n.9. In this way, these commercial speech bans not only hinder consumer choice, but also impede debate over central issues of public policy. *See id.,* at 575, 100 S.Ct., at 2356 (Blackmun, J., concurring in judgment)." *44 Liquormart,* 571 U.S. at 502-03.

It is irrelevant whether the government tries to directly ban protected speech by way of a pre-approval system, or indirectly ban protected speech by burdening it with a threat of coercive law enforcement action. Both means operate as an unconstitutional prior restraint. "The Government's content-based burdens must satisfy the same rigorous scrutiny as its content-based bans." *United States v. Playboy Entertainment Group, Inc.,* 529 U.S. 803, 812 (2000).

In *Zauderer,* 471 U.S. at 646, the Supreme Court was clear that government must develop tools that will distinguish between truthful and non-deceptive speech, on the one hand, and untruthful and deceptive speech, on the other. The rationale is rooted in the precept that "disclosure of truthful information is more likely to make a positive contribution to decision making than is concealment of such information." *Ibanez v. Florida Department of Business and Professional Regulation*, 512 U.S. 136 (1994).

2. The First Amendment Is A Valid Defense To The FTC's Substantiation Doctrine.

In *Pearson I*, the D.C. Circuit narrowly defined the circumstances under which the Food and Drug Administration ("FDA") could suppress speech, and the D.C. Circuit's holding applies equally to the FTC. The D.C. Circuit held that the government could <u>not</u> suppress potentially misleading health or safety product claims, except "when the [FTC] has determined that *no* evidence supports [a health or safety] claim," or "when the [FTC] determines that 'evidence in support of the claim is qualitatively weaker than evidence against the claim—for example, where the claim rests on *only one or two old studies,"* but then only when the government can "demonstrate *with empirical evidence* that disclaimers similar to the one [the court] suggested . . . would bewilder consumers and fail to correct for deceptiveness." *Pearson I*, 164 F.3d at 659-60 (emphasis original); *Whitaker v. Thompson*, 248 F. Supp. 1, 10 (D.C. Cir. 2002).

The D.C. Circuit *rejected* the FDA's argument that health and safety claims lacking *sufficient* scientific evidence could be deemed "inherently misleading." *Pearson I,* 164 F.3d at 655 ("We think this contention is almost frivolous."). Rather, product claims that are simply supported by *some* credible evidence are protected speech, even if they are potentially misleading. *See Pearson I*, 164 F.3d at 659; *Whitaker*, 8 F. Supp. at 10; *Pearson v. Shalala*, 130 F. Supp. 2d 105, 118 ((D.D.C. 2001) ("*Pearson II*") ("The question which must be answered under *Pearson* is whether there is any 'credible evidence'" supporting the claim); *Pearson v. Shalala*, 141 F. Supp. 2d 105, 110-11 (D.D.C. 2001) ("*Pearson III*") (reconsideration denied).

By intention or design, the FTC's substantiation doctrine, in asking *how much evidentiary support do product claims have and need*, regulates protected commercial speech. The Commission made this clear in *Pfizer*, when it held that the substantiation doctrine applied even to entirely *truthful* claims if an advertiser did not have enough support *when* the truthful claims were made.[10] 81 F.T.C. at 67-68. Unlike the falsity theory of liability, where the FTC has to prove that when the advertiser spoke, the challenged speech was unprotected as an element of its case-in-chief, *the substantiation doctrine has no such requirement*. The doctrine applies whether the advertisers' express or implied claims are true or false, and whether or not the advertiser has credible evidence to support those claims. In fact, the FTC's articulation of the doctrine in its Policy Statement on Advertising Substantiation make clear that the call of the question is not whether product claims have *some* evidentiary support—but whether they have *enough* to

[10] Again, if an advertiser asserts a claim that is in fact false or inherently misleading, and therefore not protected by the First Amendment, the FTC has no need to rely upon the substantiation doctrine. *See supra* note 3.

substantiate the claims according to the *Commission's view* of contemporary science *after* evaluating the case and receiving testimony from *friendly* medical or scientific experts.

Of course, the conclusion that the FTC's substantiation doctrine regulates protected speech does not mean that it is *per se* unconstitutional. Rather, it means that the threat of after-the-fact coercive law enforcement action posed by the FTC's regulatory scheme is subject to First Amendment challenge and must survive judicial scrutiny under the First Amendment of the U.S. Constitution.[11] *Pearson II*, 130 F. Supp. at 2d at 113 (citing *Pearson I*, 164 F.3d at 655).

3. The Commission's Law Enforcement Action Against Respondents, And Any Coercive Action Ordered Under The Substantiation Doctrine, Is Unconstitutional, An Issue Ripe For Adjudication.

Because the Commission's constitutional violation occurred *before* Respondents spoke, any order against Respondents based on the Commission's substantiation doctrine and competent and reliable scientific evidence standard would be unconstitutional. Moreover, because the Commission has brought a Complaint against Respondents under the legal theory that Respondents' scientific evidence does not "substantiate" their express or implied product claims, and because Respondents are challenging final agency action which occurred before Respondents ran their advertisements (the Commission's policy decision to utilize vague commercial speech standards with no procedural safeguards protecting First Amendment freedoms), Respondents' constitutional challenge is ripe for immediate adjudication. The ALJ

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[11] For this reason, the relevant FTC authority relating to the assertion of the First Amendment as a defense is *In re Kroger Co.*, 1977 FTC LEXIS 70 (F.T.C.), and <u>not</u> *In re Metagenics, Inc.*, 1995 FTC LEXIS 2 (F.T.C.). While the First Amendment does not sanction false or misleading advertisements, it also does <u>not</u> sanction unlawful regulatory schemes governing protected commercial speech, even if potentially misleading. The short shrift given to the First Amendment by the FTC in *Metagenics*, which did <u>not</u> develop, let alone address, the constitutionality of the Commission's substantiation doctrine, is inconsistent with the precedent cited in *Kroger* and subsequent First Amendment decisions, including the recent Supreme Court decisions *44 Liquormart, Peel* and *Zauderer,* and *Pearson I, Pearson II* and *Pearson III.*

should certify the substantive issues raised by Complaint Counsel's Motion to Strike, and direct the parties to brief the threshold constitutional question before the Commission.

D. Violation of Administrative Procedures Act is a Valid Defense.

Respondents' next challenged defenses are asserted under the APA (5 U.S.C. §§ 701, 706). Respondents plainly and concisely allege that the Commission's utilization of a vague regulatory scheme to prosecute Respondents constitutes improper agency action:

> The Complaint and this enforcement action are based upon regulatory standards governing the quantity and quality of substantiation Respondent must possess at the time it makes express and implied claims in advertisements. The standards fail and have failed to provide reasonable persons, including Respondent, with fair notice as to whether contemplated claims in advertisements, including those at issue in this proceeding, are and were permissible and/or allow and have allowed the Commission and/or its representatives to enforce the standards pursuant to their personal or subjective predilections. The regulatory standards are unconstitutional; therefore, this enforcement action constitutes agency action that is arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, contrary to constitutional right, and/or without observance of procedure required by law.

Similarly, Respondent Mitchell K. Friedlander alleges that the Commission's law enforcement action under the substantiation doctrine is arbitrary and capricious:

> The Complaint and administrative enforcement action in this cause constitutes arbitrary and capricious agency action under 5 United States Code, Section 701, in that the Federal Trade Commission's action against Respondents seeks to punish and prohibit protected commercial speech through the use of ad hoc and non-defined terms and advertising substantiation standards that lack any measurable degree of definiteness.

As with Respondents' constitutional defenses, Complaint Counsel's argument that these non-constitutional defenses have no merit and should be stricken should be certified to the Commission. Just as the ALJ has no authority to resolve whether the Commission's policy decision to regulate commercial speech with vague standards and no procedural safeguards is constitutional, the ALJ has no authority to resolve whether the Commission's chosen regulatory scheme governing dietary supplement and weight-loss claims violates the APA.

However, even if addressed, Complaint Counsel's arguments have no merit.

1. The Commission's Regulatory Scheme Governing Respondents' Commercial Speech Constitutes Final Agency Action.

Complaint Counsel first argues that Respondents' APA defenses do not challenge final agency action, by mischaracterizing these defenses as limited to the Commission's issuance of a vague and ambiguous charging document—the Complaint. *See* Motion to Strike at 16. Citing *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232 (1980), Complaint Counsel argues that it can evade the ALJ's review of its deficient charging document, because Complaint Counsel contends that it is "legally invalid" to assert a defense challenging non-final agency action. *See id.* ("Accordingly, it is *not* subject to review until administrative adjudication concludes.").

Complaint Counsel ignores the gravamen of Respondents' APA defenses, which directly challenge the Commission's regulatory scheme governing dietary supplemental and weight-loss claims—the by-product of which is vague and ambiguous charging documents. *See supra* note 2. Unquestionably, the Commission's policy choice to utilize vague commercial speech standards without procedural safeguards protecting First Amendment freedoms constitutes final agency action and subject to immediate review. *See Appalachian Power Co. v. EPA,* 208 F.3d 1015, 1021 (D.C. Cir. 2000); *Ciba-Geigy v. EPA,* 801 F.2d 430, 438 (D.C. Cir. 1986) (agency interpretation of guiding statute "with the expectation that regulated parties will conform to and rely on this interpretation, is final agency action fit for judicial review."); *McClouth Steel Products Corp v. Thomas*, 838 F.2d 1317,1321 (D.C. Cir. 1988) (EPA model used to determine contamination constituted final action, because "despite its claim that it is open to 'new approaches' to delisting decisions . . . , EPA has evidenced almost no readiness to reexamine the basic propositions that make up the VHS model.") (citation omitted).

2. Respondents' APA Defenses Are Adequately Pled.

Next, Complaint Counsel contends that Respondents' APA defenses "restate" arguments raised in connection with Respondents' constitutional defenses, which Complaint Counsel did not challenge under Rule of Practice 3.12(b)(1)(i). Yet, Complaint Counsel contends that, unlike Respondents' constitutional defenses, Respondents' APA defenses "flagrantly disregard RULE 3.12(b)(1)(i)." Motion to Strike at 16. This is silly.

Complaint Counsel's failure to challenge Respondents' constitutional defenses under Rule of Practice 3.12(b), coupled with the incorporation of Complaint Counsel's "notice" arguments in moving to strike Respondents' APA defenses, necessarily concedes that Complaint Counsel is fully apprised of the factual and legal basis of Respondents' APA defenses. Under these facts, not only have Respondents properly pled their APA defenses, Complaint Counsel has obviously not shown any prejudiced as a result of Respondents' pleading.

3. Respondents' APA Defenses Bear Directly On The Commission's Attempt To Hold Respondents' Liable For Allegedly Failing To Comply With The Commission's Substantiation Doctrine.

The Administrative Procedure Act declares unlawful agency action that is arbitrary, capricious and contrary to law. 5 U.S.C. § 706(2)(A). As part of any action governed by the APA, a court must examine the agency's actions to determine whether they constitute an abuse of discretion. An agency's decision may be overturned under the APA when it "has failed to respond to specific challenges that are sufficiently central to its decision." *International Fabricare Institute v. E.P.A.*, 972 F.2d 384, 389 (D.C.Cir. 1992).

With respect to agency action that regulates First Amendment activity, clarity and predictability are indispensable for government compliance with the APA, and the absence of either defines arbitrary and capricious enforcement. *Dickson v. Secretary of Defense*, 68 F.3d 1396, 1404 (D.C. Cir. 1995) ("The arbitrary and capricious standard of the APA 'mandates that

an agency take whatever steps it needs to provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision'") (citing *Pension Benefit Guaranty Corp. v. LTV Corp*, 496 U.S. 633, 654 (1990)). The significant constitutional concerns of speech regulation underscore the court's "duty of holding agencies to certain minimal standards of rationality" under the APA. *Whitaker v. Thompson*, 248 F. Supp. 1, 11 (D.D.C. 2002).

The absence of clear standards guiding the discretion of the public official vested with the authority to enforce the FTC Act invites abuse by enabling the official to administer the policy on the basis of impermissible factors and in a manner that is arbitrary, capricious and contrary to law. It cannot be presumed that the FTC will act in good faith and respect a speaker's First and Fifth Amendment rights. Rather, constitutional mandates require that the limits the FTC claims are implicit in its law be made explicit, by textual incorporation, binding judicial or administrative construction. *United Food & Commercial Workers Union, Local 1099 v. Southwest Ohio Reg'l Transit Auth.*, 163 F.3d 341, 359 (6th Cir. 1998) (citations omitted). Similarly, a statute or ordinance offends the First Amendment when it grants a public official "unbridled discretion" such that the official's decision to limit speech is not constrained by objective criteria, but may rest on "ambiguous and subjective reasons." *Id.*

In *Pearson I*, the D.C. Circuit avoided the Fifth Amendment issue by finding that the FDA's regulatory scheme as applied in that case violated the APA. It held that the FDA acted arbitrarily and capriciously in employing the amorphous standard of "significant scientific agreement" in relation to screening health claims on dietary supplement labels. The phrase had no definition. According to *Pearson I*, the FDA was required to give content to the phrase because "[i]t simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved." 164 F.3d at 653. Moreover, the D.C.

Circuit cautioned that, even if the FDA were to subsequently provide guidance under its regulatory scheme, such that its regulatory scheme becomes "sufficiently well-defined to satisfy the APA," it might still not be sufficiently definite to satisfy "the First or Fifth Amendment." *Id.* at 660, n. 11. While "the APA may allow the agency to provide guidance in implementation, the First or Fifth Amendment may require the agency to define its standard up front." *Id.*

Whether under the APA or the First and Fifth Amendments, the FTC can fair no better in employing the phrase "competent and reliable scientific evidence," than the FDA faired in using the phrase "significant scientific agreement," particularly given that the FTC's definition fluctuates depending upon the situation, and even then, based on the ill defined "expertise of professionals in the relevant area." Such ambiguity gives the FTC unbridled authority to determine what is "competent and reliable" on an *ad* and *post hoc* basis, and presents advertisers such as Respondents with a real and perpetual threat of prosecution for every ad that they publish regardless of the good faith they employed in determining that the ad had sufficient substantiation under the circumstances. *Pearson I* prohibited the FDA from regulating labeling claims with such borderless standards. The FTC should be held to no lesser burden.

Whether the Commission's law enforcement action against Respondents comports with the Commission's obligations under the APA and the U.S. Constitution goes to the very heart of the case. If the Commission intends to proceed against Respondents under the substantiation doctrine, it must (despite its manifest reluctance) rely upon standards that it clearly and concretely articulated *before* Respondents ran their advertisements, or provide Respondents with an opportunity to correct their allegedly misleading speech *before* being subject to coercive law enforcement action under that amorphous theory of liability.

E. Unreasonable Administrative Delay is a Proper Additional Defence and Should Not be Stricken.

Respondents' unreasonable delay defense is proper, and should not be stricken. Congress has determined that, as a matter of public policy, administrative agencies such as the FTC must act in a reasonable time frame. *See, e.g.,* 5 U.S.C. § 555(b) ("With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it"). *See also* 5 U.S.C. § 706(1) (authorizing the reviewing court to compel agency action that is unreasonably delayed). The United States Supreme Court has likewise condemned delay by administrative agencies, stating that "[w]e do not mean that delay in the administrative process is other than deplorable. It is deplorable if, as the Court of Appeals thought, the company was hampered in the presentation of its defenses . . ." *NLRB v. J.H. Rutter-Rex Mfg. Co.*, 396 U.S. 258, 265 (1969).

Other courts have also made it clear that unreasonable delay by administrative agencies is not to be tolerated. *See, e.g., NLRB v. Mountain Country Food Store, Inc.*, 931 F.2d 21 (8th Cir. 1991) (refusing to enforce an NLRB order on grounds that, in light of the NLRB's delay and the change in circumstances which had occurred, the NLRB had unreasonably delayed in seeking to enforce the order); *Public Citizen Health Research Group v. FDA,* 724 F. Supp. 1013, 1020 (D.D.C. 1989) (finding that the administrative "agency's discretion is not unbounded[,]" and that the FDA had unreasonably delayed in promulgating a regulation).

Here, the FTC has unreasonably delayed in bringing this action, which unreasonable delay was due, at least in part, to political purposes wholly unrelated to the merits of this case. In particular, assuming *arguendo* that the Commission had a reason to believe there was a violation of law and that bringing this action is in the public interest, there is absolutely no reason the FTC could not have brought this action in 2003, 2002 or 2001. Instead, the FTC deliberately delayed

commencing this action so that the filing of the complaint in this matter could be coordinated and timed with the commencement of Congressional hearings held on June 16, 2004, before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, United States House of Representatives ("the Hearings"). Such deliberate delay has resulted in a change of circumstances, which change goes to the heart of at least a portion of the relief sought in the complaint. For example, the Complaint alleges Respondents have falsely advertised two products containing ephedrine alkaloids—Leptoprin and Anorex. However, as a result of the FDA's ban on ephedra based products, Respondents no longer advertise, market, distribute or sell any ephedra based products, including Leptoprin and Anorex. Thus, the FTC's unreasonable delay has resulted in a material change of circumstances—*i.e.*, the claims concerning Leptoprin and Anorex are moot. *See, e.g., Mountain Country Food Store*, 931 F.2d at 22 (where there had been a change of circumstances rendering the basis of the NLRB's order moot, enforcement of the order "would be nothing short of punitive . . ."). Here, as in *Mountain Country*, any order with respect to the Anorex and Leptoprin would simply be punitive and not remedial.

While Complaint Counsel's desire to avoid the unreasonable delay issue is understandable, in order for the courts to review the issue of undue delay the litigants must be able to present evidence and make a proper record for the courts. *See, e.g., Panhandle Cooperative Ass'n, Bridgeport, Nebraska v. EPA*, 771 F.2d 1149, 1152 (8th Cir. 1985) (denying relief sought with respect to issue of delay on grounds that there was not an adequate record for review, and stating that "[t]he reason that the record is barren on this point is Panhandle never raised the delay issue before the EPA"). If this Court strikes the unreasonable delay defense and precludes Respondents from conducting necessary and appropriate discovery on the delay issue, Respondents would effectively be precluded from obtaining the information needed to create an

adequate record for review by the courts. Such a result would be a clear violation of Respondents' rights to due process. Respondents' unreasonable delay defense is a proper defense, and the motion to strike the defense should be denied.[12]

F. Respondents' Reason to Believe and Public Interest Defenses are Proper and Should Not be Stricken.

Respondents acknowledge that the Commission has held that, as a general rule, the filing of a complaint is dispositive of whether the Commission has determined it has a reason to believe a violation of law has occurred, and whether the Commission has determined that the proceeding is in the public interest. However, the law is clear that "the Commission's reason to believe determination may be reviewed for abuse of discretion or in extraordinary circumstances."[13] *In re Hoechst Marion Roussel, Inc.*, 2000 WL 33944047 F.T.C. (Sept. 14, 2000). *See also Standard Oil Co. of Cal. v. FTC*, 596 F.2d 1381, 1386 (9th Cir. 1979) *rev'd on*

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[12] Complaint Counsel refers the ALJ to *Gibson v. FTC*, 682 F.2d 554, 460 (5th Cir. 1982) as support for the proposition that a four year investigation cannot, as a matter of law, constitute undue delay, because longer investigations have been held to not be a violation of due process. Complaint Counsel's argument misses the mark on several fundamental points. First, the *Gibson* court expressly noted that "the delay must be credited in part to the Gibsons themselves." *Id.* at 560. Here, there is no assertion that the FTC's delay is attributable to the Respondents. Second, the issue in *Gibson* was whether the delay itself constituted a violation of due process. There was no discussion of an intervening change in circumstances that occurred during the delay. Third, the *Gibson* court apparently found that there was an adequate record with respect to the issue of delay, such that the Court could rule on the issue. Here, however, Complaint Counsel seeks to prevent Respondents from being able to develop the record, which would allow this Court to review the delay issue, and which would be necessary to allow a reviewing court to review the delay issue. *Gibson* is wholly inapposite to this case.

[13] In *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232 (1980), the Supreme Court held that the Commission's denial of the respondent's motion to dismiss the complaint on grounds that the Commission had not made a determination on the issue of "reason to believe" was not a final ruling and that, therefore, the respondent had not exhausted its administrative remedies and could not collaterally attack the FTC proceeding. *Id.* at 245. As discussed below, the Supreme Court went on to make it clear that the respondent was entitled to raise, in the FTC proceeding, the issue of whether the Commission had complied with the statutory requirement that the Commission make a determination as to whether there was a reason to believe a violation of law had occurred. *Id.* Respondents are following this procedure.

other grounds 449 U.S. 232 (1980) (court found that issue of whether the Commission in fact made a determination that there was a reason to believe a violation of law had occurred was subject to review). Similarly, the Commission's supposed determination that this proceeding is in the public interest can be reviewed in "extraordinary circumstances." *In re Brake Guard Products, Inc.*, 125 F.T.C. 138, 247 (1998).

The Supreme Court has made it clear that the APA "empowers a court of appeals to 'hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law[, and that] a court of appeals reviewing a cease-and-desist order has the power to review alleged unlawfulness in the issuance of a complaint." *Standard Oil Co. of Cal.*, 449 U.S. at 245. Because a court of appeals has such power, litigants must be allowed to create a record, which would be necessary for an appellate court to review the issue of the unlawful issuance of a complaint. *See id.* (Supreme Court noted that where the record is incomplete, the appellate court can order the Commission to take additional evidence on the issue of whether the issuance of a complaint was lawful in order to create an adequate record on appeal).

Here, Respondents respectfully submit that the FTC did not make the necessary determination that there was a reason to believe a violation of law had occurred, or that this proceeding is in the public interest. Thus, Respondents submit that the FTC has abused its discretion and that extraordinary circumstances exist, which require a denial of Complaint Counsel's Motion to Strike.[14] Indeed, if this Court strikes the reason to believe and public

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[14] In asserting that the Commission has abused its discretion and that extraordinary circumstances exist, Respondents do not suggest that the Commission's vague standard on this issue passes constitutional muster. Respondents simply inquiry, how could the Commission have "reason to believe" that a violation of the FTC Act occurred in this case, and that this action was "in the public interest," when it cannot even articulate the legal standard that Respondents supposedly violated, as evidenced by its charging document or interrogatory responses, but instead must wait for the testimony of friendly experts?

interest defenses and prevents Respondents from doing discovery on these issues, the Court will be preventing Respondents from being able to create a record on an issue that the Supreme Court has expressly held is one which can be reviewed by the appellate courts.

That the Commission has abdicated its obligation to make, and in fact has not made, the necessary determinations concerning "reason to believe" and the "public interest" is demonstrated by Complaint Counsel's recent responses to interrogatories served in this case. As the Court is aware, the Complaint in this matter alleges, *inter alia*, that Respondents have made certain express and/or implied advertising claims, that Respondents did not have a reasonable basis on which to makes those advertising claims, and that Respondents lack adequate substantiation to support the advertising claims. Respondents filed a motion for a more definite statement requesting that Complaint Counsel be required to define and clarify certain terms in the Complaint, including the Commission's vague description of the claims at issue, and the term reasonable basis as it relates to adequate substantiation for those claims. The ALJ denied the motion for more definite statement, ruling that "[a]ny necessary clarification of these terms may be obtained during the normal course of discovery." Order Denying Motions For A More Definite Statement And Motion To Dismiss The Complaint For Lack Of Definiteness at 4.

In light of the ALJ's ruling that Respondents could seek, and therefore expect to obtain, the necessary clarification through discovery, Respondent Basic Research served interrogatories requesting, *inter alia*, that Complaint Counsel disclose certain basic and fundamental facts relating to their allegations in this case. For example, Respondent Basic Research propounded the following interrogatory:

> With respect to each representation that you claim in your Complaint was made by one or more Respondents in Promotional Materials for the Challenged Products, please:

> a) state whether you contend that the representation was express or implied;
> b) identify the person or persons who interpreted the Promotional Material in question and determined what representations it conveyed;
> c) describe all extrinsic evidence (that is, anything other than the Promotional Material itself) that was relied upon in determining what representations were conveyed;
> d) describe the nature, quantity, and type of substantiation that you contend Respondents needed in order to possess and rely upon a reasonable basis to make the representation; and
> e) describe the factual basis for your contention that Respondents did not possess and rely upon a reasonable basis that substantiated the representation.

Basic Research's First Set of Interrogatories, Interrogatory No. 1(a)-(e). After setting forth their objections to this interrogatory, Complaint Counsel provided no information whatsoever:

> Subject to and without waiving these objections or the General Objections stated above, Complaint Counsel state that its Complaint alleges that Respondents have represented the claims at issue "expressly or by implication" and that information responsive to this request will be produced in accordance with the schedule for expert discovery set forth in the Court's Scheduling Order . . . . Subject to and without waiving these objections or the General Objections stated above, Complaint Counsel state that the evidence submitted by Respondents does not amount to competent and reliable scientific evidence typically required by Commission jurisprudence to support claims relating to health or safety. Complaint Counsel further state that information responsive to this request will be produced in accordance with the schedule for expert discovery set forth in the Court's Scheduling Order.

Complaint Counsel's Response To Respondent's First Set Of Interrogatories, Response to Interrogatory No. 1(a)-(c), and No. 1(e). In providing this response Complaint Counsel essentially admit that even though the Commission was required to make a determination that there was a reason to believe a violation of law had occurred in order to authorize the filing of the complaint, Complaint Counsel cannot articulate the factual predicates of their claims, and that such information can only be determined through expert testimony.[15] In light of such

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[15] Complaint Counsel have also admitted that they cannot, more than two months into this litigation, after more than four years of investigating Respondents, state the factual basis for the assertions that the scientific studies, analysis, research and tests relied on by Respondents in (continued...)

assertion, it is impossible for the Commission to have determined that there was a reason to believe a violation of law had occurred, or that this proceeding is in the public interest. Otherwise stated, in order for the Commission to make the necessary determinations concerning a "reason to believe" and the "public interest," the Commission would have to have known, at the time the Complaint was filed, whether the claims at issue are express or implied. However, Complaint Counsel now admits that they are unable to say, more than two (2) months after filing the complaint and four (4) years after investigating Respondents, whether the claims at issue are express or implied. If Complaint Counsel's assertions on this point are true, then it is not possible for the Commission to have made the necessary and fundamental determinations concerning the "reason to believe" and the "public interest" mandated by 15 U.S.C. § 45(b).

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making the claims at issue do not constitute adequate substantiation. For example, Basic Research's Interrogatory No. 2 asked Complaint Counsel the following:

> For each study, analysis, research, or test provided to you by any Respondent as substantiation for representations made concerning the Challenged Products during your investigation leading to the Complaint, please state whether you contend such study, analysis, research, or test does not constitute adequate substantiation for the representation for which it was asserted, and describe the basis and circumstances under which you made that determination, including without limitation the identity of the person who made the determination, when they made it, their qualifications to make such a determination, and the factual basis and reasoning underlying that determination.

Basic Research's First Set of Interrogatories, Interrogatory No. 2. After stating a variety of objections to this interrogatory, Complaint Counsel provided the following response:

> Subject to and without waiving these objections or the General Objections stated above, Complaint Counsel state that the evidence submitted by Respondents as substantiation for representations made concerning the Challenged Products does not constitute adequate substantiation. Complaint Counsel further state that additional information responsive to this request will be produced in accordance with the schedule for expert discovery set forth in the Court's Scheduling Order.

Complaint Counsel's Response To Respondent's First Set Of Interrogatories, Response to Interrogatory No. 2 (denominated by Complaint Counsel as Response to Interrogatory No. 5).

Similarly, in order for the Commission to make the necessary determinations concerning a "reason to believe" and the "public interest," the Commission would have had to have known, at the time the complaint was filed, why the scientific studies relied on by Respondents are not competent and reliable, and what level of substantiation would be required to support the claims at issue. Yet Complaint Counsel assert they cannot yet state why the scientific studies at issue are not competent and reliable, and that they still cannot articulate the nature, quantity and type of substantiation that would be required in order to make the claims at issue. Assuming once again that Complaint Counsel's assertions on this point are true, where Complaint Counsel are unable to state the factual basis for the claim that Respondents did not possess and rely upon a reasonable basis that substantiated the claims, it is impossible for the Commission to have made the requisite determinations concerning a "reason to believe" and the "public interest."

Complaint Counsel's responses to Respondent Basic Research's interrogatories make it clear that the Commission did not make the necessary determinations concerning "reason to believe" and the "public interest." The Commission therefore abused its discretion when it authorized the complaint to be filed, and extraordinary circumstances exist which require that the motion to strike the "reason to believe" and "public interest" defenses be denied.

G. "Puffery" is a Valid Defense to Allegations that Respondents Violated the FTC Act.

Puffery "is exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely." *The Clorox Company Porta Rico v. The Proctor & Gamble Commercial Company*, 228 F.3d 24, 38 (1st Cir. 2000). Puffery includes claims that are either "vague or highly subjective." *Cook, Perkiss & Liehe v. Northern California Election Service, Inc.*, 911 F.2d 242, 246 (9th Cir. 1990). Puffery is a well-recognized defense to FTC claims of deceptive

advertising. *See, e.g., Sterling Drug, Inc. v. Federal Trade Commission*, 741 F.2d 1146, 1150 (9th Cir. 1984). In fact, Complaint Counsel does not contend otherwise.

Instead, Complaint Counsel mistakenly argues that the "puffery" defense raised by all of the Respondents except for Gay and Friedlander is not a valid affirmative defense because it is already a "negative defense" to Complaint Counsel's charge that the statements made were misleading. This argument is without merit and should be rejected, as RULES OF PRACTICE 3.12(b) provides that an answer shall contain:

> (i) a concise statement of the facts constituting each ground of defense;
>
> (ii) specific admission, denial or explanation of each fact alleged in the Complaint or, if the Respondent is without knowledge thereof, a statement to that effect. . . .

Thus, Respondents are authorized by this rule to set forth a concise statement of the facts constituting each ground of defense <u>in addition</u> to admitting and denying the specific allegations of the Complaint. The rule does not limit this pleading requirement to "affirmative defenses" as does Rule 8(c) of the Federal Rules of Civil Procedure. In their puffery defense, the Respondents complied with Rule 3.12(b) by setting forth a concise statement of the facts constituting their puffery defense. Because Respondents are authorized to allege facts constituting each ground of defense and are not limited to pleading technical affirmative defenses, Complaint Counsel's argument should be rejected.

H. Complaint Counsel's Motion to Strike the Lack of Dissemination, Causation and Interstate Commerce Defenses Should be Denied.

Complaint Counsel's Motion to Strike the Lack of Dissemination, Causation and Interstate Commerce Defenses is predicated entirely on the assertion that these are "negative" defenses. However, even assuming *arguendo* that these are "negative" defenses, as just discussed, the law is clear that "negative defenses" are properly asserted in an answer. In any event, such defenses can be stricken only if Complaint Counsel demonstrates that they will be

prejudiced by the continuation of the defenses. *See, e.g., In re Synchronal Corp.*, 1992 WL 12001793 F.T.C. (March 5, 1992) (denying motion to strike defense where Complaint Counsel failed to show that any prejudice would result from the continuation of the defense).

Here, Complaint Counsel does not assert, and cannot demonstrate, that they would be prejudiced by the continuation of any "negative defense." On the contrary, by asserting that these defenses are negative defenses, Complaint Counsel admits that the issues raised by these defenses are relevant and are properly before this Court. As such, and in light of the absence of any prejudice to Complaint Counsel, the motion to strike the defenses of lack of dissemination, lack of causation and lack of interstate commerce must be denied.

I. Laches and Equitable Estoppel Constitute Valid Additional Defenses.

Contrary to Complaint Counsel's argument, the agency is not immune from defenses based on laches and equitable estoppel. Because these equitable defenses are potentially available to Respondents, this Court should recognize the Motion to Strike for what it is—a preemptive strike designed to foreclose the ability of respondents to gather the very evidence they need to assert and validate their defenses based on sound principles of equity.

Recent case law stands for the proposition that laches and equitable estoppel are available to defendants in proceedings instituted by the Federal government under appropriate circumstances. *See, e.g., U.S. v. Phillip Morris,* 300 F.Supp.2d 61 (D.D.C. 2004). First, with respect to the affirmative defense of equitable estoppel, the Supreme Court has expressly refused to decide that the defense cannot be pled against the United States. *Office of Personnel Management v. Richmond,* 496 U.S. 414, 423 (1990) (although acknowledging arguments in favor of rule against the defense, the Court did not adopt it and stated"[w]e leave for another day whether an estoppel claim could ever succeed against the Government"); *Heckler v. Community Health Services of Crawford County, Inc.,* 467 U.S. 51, 60, (1984) ("[w]e have left the issue

[whether equitable estoppel applies] open in the past and do so again today"). In *ATC Petroleum v. Sanders*, 860 F.2d 1104, 1111 (D.C. Cir. 1988), the D.C. Circuit held that "the fundamental principle of equitable estoppel applies to government agencies, as well as private parties." While the court noted in *Phillip Morris* that equitable estoppel would apply only in compelling circumstances, the very purpose of discovery is to allow a party to adduce evidence in support of their claims. Significantly, recent circuit court decisions have continued to recognize that the government may be equitably estopped from proceeding where the government has committed affirmative misconduct. *See Rumsfeld v. United Technologies Corporation*, 315 F.3d 1361, 1377 (Fed. Cir. 2003); *Zacharin v. United States*, 213 F.3d 1366, 1371 (Fed. Cir. 2000); *Linkous v. United States*, 142 F.3d 271 (5th Cir. 1998).

The FTC has made numerous express and tacit representations in the past concerning their regulatory scheme which Respondents have relied upon to their detriment. These form the substance of the disputes primarily at issue—whether what the FTC contends to be its regulatory scheme is constitutionally fit. Those representations and the circumstances under which those representations were made are relevant to this litigation and may validate Respondents' estoppel argument. By foreclosing the defense at this early stage of discovery before the Respondents have had the opportunity to investigate and develop their legal defenses, Respondents will be deprived of their ability to fully defend against the FTC's charges.

With respect to whether laches applies in the context of governmental action, the issue is not as Complaint Counsel represents. In *Occidental Life Ins. Co. v. EEOC,* 432 U.S. 355, 373, 97 S.Ct. 2447, 53 L.Ed.2d 402 (1977), the Supreme Court found laches to be potentially applicable to suits by government agencies on a case by case basis. Following that decision, the district court in *Resolution Trust Corp. v. Vanderweele,* 833 F.Supp. 1383, 1388 (N.D.Ind.1993)

held that no precedent foreclosed equitable defenses including laches and equitable estoppel as a matter of law when the Government asserts rights on behalf of the public at large. Significantly, the very case cited by Complaint Counsel in support of its argument, predates *Vanderweele* and questions the very assertion upon which the FTC relies. *See United States v. Ruby Co.*, 588 F.2d 697, 705 n. 10 (9th Cir. 1978) ("The traditional rule is that the doctrine of laches is not available against the government in a suit by it to enforce a public right or protect a public interest. 30A C.J.S. Equity s 114 (1965). It may be that this rule is subject to evolution as was the traditional rule that equitable estoppel would not lie against the government").

Complaint Counsel also ignores so-called statutory laches. However, statutory laches based upon Sections 555(b) and 706(1) of the APA is a valid defense. Section 555(b) requires that "[w]ith due regard for the convenience and necessity of the parties or their representatives and <u>within a reasonable time</u>, each agency shall proceed to conclude a matter presented to it." [Emphasis Added.] Section 706(1) authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed." In *Houseton v. Nimmo*, 670 F.2d 1375, 1377-78 (9th Cir. 1982), the Ninth Circuit held that these two sections read together authorized a court to dismiss agency action unreasonably delayed "when the delay is unreasonable and results in serious prejudice to one of the parties." *Accord Woodruff Community Hospital v. Sullivan*, 1992 W.L. 133087 *11 (C.D. Cal. 1992); *but see United States v. Popovich*, 820 F.2d 134, 138 (5th Cir. 1987). Respondents have alleged that there was unreasonable delay in bringing this action that seriously prejudiced them. Whether laches applies is a question of fact that should be decided on evidence at a hearing. Respondents should not be denied the opportunity to develop this defense.

J. Defenses based on Vague Allegations and Personal Bias Constitute Valid Additional Defenses.

Respondent Friedlander's defenses based on vagueness and personal bias are similar to and depend on grounds relating to the constitutionality of the Commission's regulatory scheme, and to the defenses based on whether the FTC's decision to open this prosecution met the "reason to believe" and "public interest" thresholds. Those arguments are adopted here.

It is incumbent upon the FTC to discharge its duties in compliance with constitutional procedures and constitutional mandates. Accordingly, the FTC's decision to proceed without having in place constitutional adequate standards or safeguards, including its refusal to provide those standards and safeguards during the proceeding constitute defenses which Respondent Friedlander should be allowed to explore. This Court should allow Respondent Friedlander's Additional Defenses centered on the unfairness of applying a constitutional infirm and vague regulatory scheme against him to stand.

Similarly, Respondent Friedlander should be allowed to explore whether the Commission properly met the "reason to believe standard" and sufficiently determined that its prosecution decision was in the public interest. Part of that inquiry centers on whether the Commission's action were motivated by bias against him personally. Because the Commission is obligated to proceed only when it has a reason to believe a violation of the FTC Act has occurred and when prosecution is in the public interest, Complaint Counsel's unsupported assertion that allegations of personal bias are "impertinent" and "scandalous" miss the point. *See Sierra Club v. Tri-State Transmission and Generation Ass'n* 173 F.R.D 275, 285 (D. Colo. 1997) (in refusing to strike allegations as being "impertinent" and "scandalous," court noted that "impertinent" allegations were those having no bearing on issues in a case and scandalous "allegations" were those that degraded a party's moral character, contained repulsive language, or detracted from the dignity

of the court). Because Respondent Friedlander's Additional Defenses pertain to issues germane to the proceeding, they are not impertinent. Further, because they do not degrade Mr. Murris' character, contain no repulsive language and do not detract from the dignity of the court or the Commission, the defenses are not "scandalous." Finally, the presence of Respondent Friedlander's allegations does not prejudice Complaint Counsel and for that additional reason should not be stricken. *Id.*

K. Respondents' Denial of Preamble Should Stand.

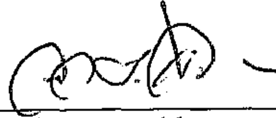
Corporate Respondents' denial of the Preamble should be allowed to stand for there is no valid justification for striking the denial. Complaint Counsel cites the older case of *In re Volkswagen* in which the ALJ considered specific defenses before him and based his decision to strike a denial of preamble on them. Significantly, the case reflects an older view of administrative practice when the issue how the ALJ should address motion to strike additional defenses was more uncertain. Far more instructive and appropriate is the approach adopted by the ALJ in *In re Dura Lube* 1999 WL 33577395 (F.T.C.), a recent case where the ALJ established generalized practices and guidelines governing affirmative defenses and denials. In *Dura Lube*, the ALJ applied the general test concerning additional defenses and concluded that absent a showing of prejudice by the FTC, a denial of a preamble should be allowed to stand.

Here, Complaint Counsel have cited no prejudice in support of their motion. Accordingly, because they have shown no prejudice, Respondents' denial of preamble should be allowed to stand.

III. CONCLUSION

In light of the foregoing, Complaint Counsel's Motion to Strike should be denied.

Respectfully submitted,



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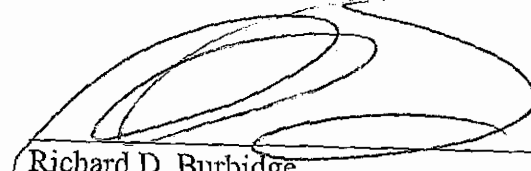
DATED this 9TH day of September, 2004.

BURBIDGE & MITCHELL



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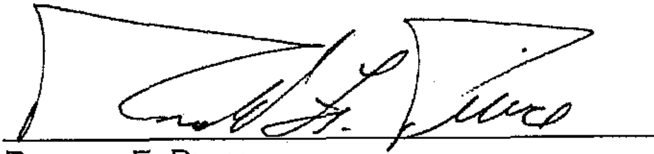

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was provided to the following parties this 9th day of September, 2004 as follows:

(1) One (1) original and one (1) copy by Federal Express to Donald S. Clark, Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(2) One (1) electronic copy via e-mail attachment in Adobe® ".pdf" format to the Secretary of the FTC at Secretary@ftc.gov;

(3) Two (2) copies by Federal Express to Administrative Law Judge Stephen J. McGuire, Federal Trade Commission, Room H-104, 600 Pennsylvania Avenue N.W., Washington, D.C. 20580;

(4) One (1) copy via e-mail attachment in Adobe® ".pdf" 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. Postal Service to Laureen Kapin, Bureau of Consumer Protection, Federal Trade Commission, Suite NJ-2122, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(5) One (1) copy via U. S. Postal Service to Elaine Kolish, Associate Director in the Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580

(6) One (1) copy via United States Postal Service to Stephen Nagin, Esq., Nagin Gallop & Figueredo, 3225 Aviation Avenue, Suite 301, Miami, Florida 33131.

(7) One (1) copy via United States Postal Service 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.

(8) One (1) copy via United States Postal Service 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.

(9) One (1) copy via United States Postal Service to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84111, Pro Se.

____

CERTIFICATION FOR ELECTRONIC FILING

I HEREBY CERTIFY that the electronic version of the foregoing is a true and correct copy of the original document being filed this same day of September 9, 2004 via Federal Express with the Office of the Secretary, Room H-159, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.