

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

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**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.,** )  
**BAN, L.L.C.,** )  
**DENNIS GAY,** )  
**DANIEL B. MOWREY, and** )  
**MITCHELL K. FRIEDLANDER,** )

**Respondents.** )

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**Docket No. 9318**

**PUBLIC DOCUMENT**

**COMPLAINT COUNSEL’S REPLY TO RESPONDENTS’ OPPOSITION TO  
MOTION TO STRIKE RESPONDENTS’ “ADDITIONAL DEFENSES”**

Pursuant to the Court’s September 21<sup>st</sup> *Order*, and RULE OF PRACTICE 3.22, Complaint Counsel submit their rebuttal to issues raised in Respondents’ *Opposition* to our *Motion to Strike Respondents’ Additional Defenses*. In their *Opposition*, Respondents disclaimed this Court’s authority; advanced a “controlling line of cases” largely unrelated to the FTC’s substantiation standard; described the FTC’s pre-*Complaint* activities as “final agency action” or a restraint on speech; stated admissions not made by Complaint Counsel; and raised new, vague allegations to apply the discredited defenses of laches and estoppel against the government. However, Respondents have not established that the alleged defenses are legally valid, supported by statements of fact, and/or at all material to the allegations of the *Complaint*. Respondents’ defenses have consumed our resources and those of the Court, and have needlessly compounded and confused the issues in this case. Respondents’ extraneous defenses should be stricken.

## DISCUSSION

Respondents' *Opposition* demonstrates that an *Order* striking the alleged defenses is appropriate in the circumstances of this case. As discussed below, the *Opposition* is fraught with contradictory arguments and incorrect statements. Respondents' arguments and statements do not effectively rebut the *Motion to Strike* or justify their campaign to try matters unrelated to the allegations of the *Complaint*.

### I. The Administrative Law Judge Has Authority to Strike the Alleged Defenses

Respondents first sought to justify their alleged defenses by disclaiming the Court's authority to rule on those defenses. *See* Resp'ts' Opp'n at 5 (Sept. 9, 2004) ("[I]n fact, the ALJ does not even have authority to resolve many of Respondents' defenses.") (hereinafter "Opp'n"). This argument runs contrary to Commission law, including cases cited by Respondents. This Court has authority to rule on the *Motion to Strike*.<sup>1</sup>

The questions before the Court are preliminary questions of legal sufficiency, pleading, and relevance. This is apparent from our *Motion to Strike*, which states that the alleged defenses are legally insufficient, fail to plead *facts* as required by RULE 3.12, or are irrelevant or immaterial to the issues raised in the *Complaint*. *See* Mot. to Strike at 2-4 (Aug. 20, 2004). Administrative

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<sup>1</sup> As a threshold matter, the *Motion to Strike* is properly before the Court. In their *Answers*, Respondents asserted defenses for trial and adjudication. *See, e.g.,* Answer, Resp't Basic Research, at 12-15 (July 30, 2004). Respondents preserved their defenses for future actions only if the defenses were not properly asserted here: "To the extent any of the foregoing grounds of defense may not properly be asserted and/or adjudicated in this proceeding, Respondent hereby states its intent to preserve such defenses for future proceedings." *Id.* at 15.

The *Opposition* incorrectly states that "[e]ach Respondent" presented identical allegations with respect to the alleged constitutional defenses. *See* Opp'n at 5, 15. Respondents Gay, Mowrey, and Friedlander made fewer allegations than the Corporate Respondents. *See* Answer, Resp't Gay, at 7-8 (July 30, 2004); Answer, Resp't Mowrey, at 6-8 (July 30, 2004); Answer, Resp't Friedlander, at 7 (July 30, 2004).

Law Judges have long ruled on these preliminary questions in the context of other motions to strike defenses, even when those defenses are asserted on statutory or constitutional grounds. *See, e.g., In re Metagenics, Inc.*, 1995 FTC LEXIS 2, \*2 (Jan. 5, 1995) (striking alleged defenses that proposed order would be arbitrary and capricious or would violate commercial free speech rights); *In re Volkswagen, Inc.*, Docket No. 9154, slip op. at 2, 5, 7 (July 8, 1981) (striking defenses relating to “reason to believe” and “public interest” as well as failure to engage in rulemaking and other constitutional issues) (attached to *Motion to Strike*); *see also In re General Motors Corp.*, Docket No. 9074, 1976 FTC LEXIS 237, \*1-2 (July 9, 1976) (striking defenses relating to “reason to believe” and “public interest”).

In their *Opposition*, Respondents described as “instructive” or “relevant” several other decisions in which Administrative Law Judges ruled on motions to strike constitutional or statutory defenses. *See* Opp’n at 4 (citing *In re Dura Lube Corp.*, Docket No. 9292, 1999 WL 33577395 (Aug. 31, 1999)); *id.* at 20 n.11 (citing *In re Kroger Co.*, No. 9102, 1977 FTC LEXIS 70, \*1 (Oct. 18, 1977)). These decisions, cited in the *Opposition*, further confirm that the Court has authority to rule on the issues identified in our *Motion*.<sup>2</sup>

Respondents overlooked this serious contradiction in their legal argument. They simply maintained that the Court cannot rule on the sufficiency of their constitutional and statutory defenses because, in their view, “[n]either the ALJ nor the Commission has any authority to

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<sup>2</sup> Respondents also pointed to *In re Gibson, et al.*, 90 F.T.C. 275 (1977), and *In re Boise Cascade Corp.*, Docket No. 9133, 1981 WL 389463 (Mar. 27, 1981), but neither of these decisions concerned a motion to strike defenses. The orders in *Gibson* and *Boise Cascade* both concerned motions to dismiss the *Complaint* for lack of “public interest,” which motions were potentially dispositive of the entire cases. The Commission denied both motions. *See id.* *Gibson* and *Boise Cascade* are poor precedents for Respondents’ argument and defenses.

uphold the FTC's regulatory scheme." Opp'n at 10.<sup>3</sup> With this statement, Respondents advanced a second, even greater, contradiction: They claimed that the *Motion to Strike* raised a "threshold legal issue that should be certified to the Commission," Opp'n at 10, even though this issue purportedly "fall[s] within the sole province of Article III courts." *Id.* Certification to the Commission would serve little purpose if the Commission lacked authority to rule on the issue. Respondents' contentions here are unsupported by citation to any authority, and are erroneous. Both the Court and the Commission may rule on constitutional and APA issues.<sup>4</sup>

Respondents also argued that the *Motion to Strike* is beyond the Court's authority because it presented "broad, policy-based arguments." Opp'n at 2. However, the *Motion to Strike* relied on legal argument. The word "policy" appears in the *Motion* solely as part of the title of the *Policy Statement Regarding Advertising Substantiation* appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839-42 (1984). *See* Mot. to Strike at 5, 9, 11. We cited this *Policy Statement* as an important component of a large body of legal guidance dating back several decades, which we will not revisit here. It is not a "broad, policy-based argument" to cite relevant legal authorities, including the *Advertising Substantiation Statement*.

As discussed above, this Court has the well-established authority to resolve preliminary

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<sup>3</sup> For this proposition, Respondents cited *Ticor Title Insurance Co. v. FTC*, 814 F.2d 731 (D.C. Cir. 1986). However, the *Ticor Title* opinion merely stated, in *dicta*, that "an agency will not *ordinarily* pass on the constitutionality of the *statute under which it operates*." *Id.* at 739 (emphasis added). It did not state that the Commission lacked authority to rule on constitutional issues. Indeed, the D.C. Circuit has expressly declined to adopt that conclusion. *See Ukiah Adventist Hosp. v. FTC*, 981 F.2d 543, 550 (D.C. Cir. 1993) ("we intimate no view on whether a constitutional challenge . . . would be committed exclusively to the courts of appeals").

<sup>4</sup> *See* cases cited *supra* page 3; *see also In re Trans Union Corp.*, Docket No. 9255, 2000 WL 257766 (Feb. 10, 2000), *cited in* Opp'n at 6.

questions of legal sufficiency, pleading, and relevance relating to defenses, including those asserted on grounds of due process, the *First Amendment*, or the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.* (“APA”). Respondents’ arguments to the contrary are incorrect.

## II. Respondents’ “Controlling Line of Precedent” Does Not Validate their Defenses

In their *Opposition*, Respondents offered several new permutations of their alleged constitutional defenses. First, they stated that the “overriding issue” is that due process requires the Commission “to promulgate a concrete, content-neutral standard against which an advertiser [specifically, ‘an advertiser of dietary supplements or weight-loss products’] may judge its commercial speech, before speaking.” Opp’n at 9, 10. Alternatively, the “overriding issue” is that due process requires the FTC to provide “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.” Opp’n at 10. In summary, Respondents question “[w]hether the Commission’s regulatory scheme governing dietary supplements and weight-loss claims is constitutional.” *Id.*

Respondents did not analyze the authorities discussed in Complaint Counsel’s *Motion*.<sup>5</sup> Instead, Respondents identified a separate, “controlling line of cases” to justify their due process defenses. *See* Opp’n at 14. One of these cases, the *Pearson* decision, was also offered to support their *First Amendment* and APA defenses. *See id.* at 18-19, 24-25. As discussed below, these cases are not a “line,” they are not “controlling,” and they are largely inapposite.

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<sup>5</sup> Respondents dismissed the holdings of three U.S. Courts of Appeals that have upheld the Commission’s substantiation standard in response to challenges of “vagueness.” *See* Opp’n at 13 n.6 (citing, without discussion, *Thompson Medical Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1145, 1156-57 (9<sup>th</sup> Cir. 1984); *Bristol-Meyers Co. v. FTC*, 738 F.2d 554, 561 (2d Cir. 1984)).

Respondents' first case is *Kolender v. Lawson*, 461 U.S. 352 (1983), in which the Supreme Court upheld a facial due process challenge to a state criminal statute that required persons who loiter or wander on the streets to provide a "credible and reliable" identification, and to account for their presence when questioned by an officer. 461 U.S. at 353, *cited in* Opp'n at 14. Respondents contend that the *Kolender* decision, and others in their "controlling line," "establish the following constitutional principal [sic]: that vague standards governing commercial speech . . . are unconstitutional." Opp'n at 14. However, the *Kolender* decision does not discuss or even refer to commercial speech.

Respondents' second case does discuss commercial speech, but it relates to the standards employed by the U.S. Food and Drug Administration ("FDA"), not the advertising substantiation standard applied by the Commission. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *cited in* Opp'n at 14. Respondents' reliance on *Pearson* is misplaced. The *Pearson* Court ruled that FDA had completely failed to give content to its "significant scientific agreement" standard, either through general guidance or on a case-by-case basis, and thus violated the APA. *Id.* at 660-661.<sup>6</sup> In contrast, the Commission has developed a large body of guidance that gives content to the competent and reliable scientific evidence standard. Indeed, the Commission has already considered the argument that Respondents presented in their *Opposition*. *See* Letter from Federal Trade Commission to Jonathan W. Emord, Esq. (Nov. 30, 2000) (attached to *Motion to Strike*). As the Commission has noted, the FDA's standards and regulatory regime are "fundamentally different from the FTC's law enforcement approach." *See id.* (citing 21 U.S.C. §§ 343(r)(1)(B)

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<sup>6</sup> Having ruled that FDA's failure to define its standard violated the APA, the *Pearson* court did not reach the *Fifth Amendment* argument. Respondents initially suggested otherwise. *Compare id.* at 660 with Opp'n at 14 (citing *Pearson* in *Fifth Amendment* argument).

and (r)(5)(D) and comparing FDA statutory framework to FTC law).<sup>7</sup>

*Pearson* is not “controlling,” and it cannot resuscitate Respondents’ invalid defenses. If the decisions of the U.S. Court of Appeals for the District of Columbia Circuit will control on appeal, as Respondents appear to suggest, see Opp’n at 14, then Respondents have not shown how their defenses can succeed in light of a decision from the D.C. Circuit that is directly on point—the decision validating the FTC’s advertising substantiation standard in *Thompson Medical Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986). See Mot. to Strike at 6, 9.

Respondents’ third case relates to the Commission’s advertising substantiation standard, but it represents the early, minority view among the Courts of Appeals. *American Home Prods. Corp. v. FTC*, 695 F.2d 681 (3d Cir. 1983) (“AHP”), cited in Opp’n at 14. We fully addressed this case in our *Motion*, and will not reiterate those arguments here. See Mot. to Strike at 9 n.6.

Respondents’ fourth and final case upheld a facial due process challenge to a state statute that required physicians to comply with the *Texas Abortion Facility Reporting and Licensing Act*. See *Women’s Med. Ctr. v. Bell*, 248 F.3d 411, 414, 422 (5<sup>th</sup> Cir. 2001), cited in Opp’n at 14. The statute at issue in *Bell* is patently distinguishable from the substantiation standard challenged in

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<sup>7</sup> The Commission further declared:

Only after investigation and review of the supporting science and a determination that the evidence is lacking will the FTC seek to stop advertising claims through a negotiated consent agreement or litigation. In cases where the FTC decides to challenge advertising claims as unsubstantiated . . . Commission staff will typically meet with the advertiser, explain staff’s assessment of the substantiation and provide an opportunity for the advertiser to respond before determining whether formal agency action is necessary. The Commission’s approach . . . is in no way analogous to the *Pearson* court’s characterization of the FDA practice as “simply saying no without explanation.”

*Id.* (citing *Pearson*, 164 F.3d at 660); see also Mot. to Strike at 7 (discussing present case).

the present case. *See Bell*, 248 F.3d at 422 (quoting provisions of statute, such as requirement that physicians “ensure that all patients . . . are cared for in a manner and in an environment that enhances each patient’s dignity and respect in full recognition of her individuality”). Contrary to what Respondents state in their *Opposition*, *Bell* is not part of a “line” of decisions starting with *Kolender*, *Pearson*, and *AHP*. These cases are unrelated. They do not “control” the outcome of the *Motion to Strike*, and they do not validate Respondents’ invalid defenses.

Respondents’ due process defense has no valid basis in fact or law. The *Complaint* has put Respondents on notice of the practices challenged by the Commission, and its allegations with respect to lack of substantiation may be readily understood in light of the Commission’s opinions, orders, statements, and publications on the substantiation standard. *See Mot. to Strike* 5-9.

Respondents can, or reasonably should, understand the issues, and they have a “full opportunity” to justify their conduct here. *See L.G. Balfour Co. v. FTC*, 442 F.2d 1, 19, 21 (7<sup>th</sup> Cir. 1971).

Respondents are being afforded due process. *See Southwest Sunsites, Inc. v. FTC*, 785 F.2d 1431, 1435 (9<sup>th</sup> Cir. 1986). The alleged due process defense is invalid, and should be stricken.<sup>8</sup>

### **III. The Commission’s Activities Before the Filing of the *Complaint* Are Not “Final Agency Action” and Do Not Violate the *First Amendment***

Next, Respondents sought to justify their defenses by characterizing the FTC’s processes as “final agency action” or a restraint on free speech. Respondents’ *Opposition* clarified that the “final agency action” or alleged restraint on free speech or occurred *before* the filing of the

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<sup>8</sup> In concluding their due process argument, Respondents make the following assertion: “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 . . . is unconstitutional.” Opp’n at 15; *see also id.* at 16-17. These words belie Respondents’ suggestion that the alleged due process issue “will escape judicial review.” Opp’n at 9.



Complaint. *See, e.g.*, Opp’n at 20 (“the Commission’s constitutional violation occurred before Respondents spoke”).<sup>9</sup> As discussed below, the alleged APA defenses are still invalid.

**A. The Commission’s Activities Before the Filing of the Complaint Are Not “Final Agency Action” Under the *Administrative Procedure Act***

In their *Opposition*, Respondents alleged that “the Commission’s policy choice to utilize vague commercial speech standards without procedural safeguards . . . constitutes final agency action and [sic] subject to immediate review.” Opp’n at 22. Respondents are mistaken.

Respondents’ argument here contravenes *FTC v. Standard Oil Co.*, 449 U.S. 232, 244 (1980). Simply recharacterizing the alleged defenses as not being “limited to the Commission’s issuance of a vague and ambiguous charging document,” Opp’n at 22, does not establish that there has been final agency action. The *Complaint* must be fully litigated, and a final *Order* must issue, for final action to occur. *See Standard Oil Co.*, 449 U.S. at 241; *see also* Mot. to Strike at 16.

Respondents disagree with this conclusion, again relying on non-Commission caselaw.

Respondents’ “final agency action” argument is based on three appellate decisions interpreting the determinations of the U.S. Environmental Protection Agency.<sup>10</sup> These three decisions arose in a

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<sup>9</sup> If Respondents had pled “the *facts* constituting the grounds of defense,” RULE 3.12(b)(1)(i), this allegation would have been apparent to Complaint Counsel in July. We noted in our *Motion* that Respondents “alleged no facts to support their broad, highly generalized” *First Amendment* claim. *See* Mot. to Strike at 15. Respondents incorrectly stated, twice, that we did not raise this issue. *See* Opp’n at 16, 23.

Respondents’ argument that the *Motion* “demonstrated sufficient notice of both the legal and factual bases” of the defenses completely misconstrues what we stated in our *Motion*—that the *inadequacies* of Respondents’ alleged defenses were obvious. At this late date, Respondents still have not alleged the specific facts and circumstances that support their contentions of undue delay, chilled speech, personal bias, and so forth. We are left to guess at these facts—facts supposedly already known to Respondents—while Respondents demand further discovery.

<sup>10</sup> *See* Opp’n at 22 (citing *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986), and *McLouth Steel Prods.*

factual context very different from the present case, so their holdings are inapposite.<sup>11</sup> However, the general legal principles discussed in the lead decision cited in Respondents' *Opposition*, the *Appalachian Power Co.* decision, may be instructive. The *Appalachian Power Co.* court stated:

In the administrative setting, "two conditions must be satisfied for agency action to be 'final': First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'"

208 F.3d at 1022 (citations omitted).

Applying these precepts to the present case, neither the Commission's adoption of an advertising substantiation standard nor the staff's use of that standard before the filing of the *Complaint* has "mark[ed] the 'consummation' of the agency's decisionmaking process," *id.*, as this litigation clearly attests. Second, no *Order* has been entered against Respondents to date. Consequently, this case bears no resemblance to the EPA determinations cited by Respondents.<sup>12</sup>

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*Corp. v. Thomas*, 838 F.2d 1317 (D.C. Cir. 1988)).

<sup>11</sup> See *Appalachian Power Co. v. EPA*, 208 F.2d at 1023-28 (noting that EPA's Periodic Monitoring Guidance "significantly broadened" underlying rule and imposed immediate requirement that states would have to follow in setting the terms of emission permits for electric power companies that required permits to continue operating); *Ciba-Geigy Corp. v. EPA*, 801 F.2d at 43 (recalling that EPA's revised labeling statement warned 20 registrants that agency would treat stocks of simazine as misbranded within forty days); *McLouth Steel Prods. Corp.*, 838 F.2d at 1317 (concluding that EPA's use of model to estimate contamination attributable to appellant's site was final determination subject to review).

<sup>12</sup> Comparison to administrative litigation in other agencies is more appropriate. For example, in *Rosenthal & Co. v. Bagley*, 581 F.2d 1258 (7<sup>th</sup> Cir. 1978), the Seventh Circuit considered and rejected an interlocutory declaratory judgment action against the Commodity Futures Trading Commission ("CFTC"), in which the appellant claimed that the CFTC's statutory scheme violated the *Seventh Amendment*. The *Bagley* court concluded that the wisest course was to "allow the agency to proceed to a final determination and let the judicial determination of the constitutional question await the judicial review of the final agency action." 581 F.2d at 1261.

Respondents' "final agency action" argument fares poorly under FTC jurisprudence. See, e.g., *Ticor Title Ins. Co.*, 814 F.2d at 731; see also Mot. to Strike at 15-17. The *Ticor Title* decision, cited in Respondents' *Opposition* and discussed *supra* note 3, is illustrative. Like Respondents here, the Ticor Title Insurance Company asserted constitutional and other defenses to an administrative complaint. During the ensuing litigation, Ticor Title sought a declaratory judgment that Section 5(b) of the FTC Act was unconstitutional because the exercise of law enforcement powers by an independent federal agency violated Article II of the *Constitution*. The District Court dismissed Ticor Title's claim, holding that it was not ripe for adjudication, and the Court of Appeals affirmed. In separate opinions, Judge Edwards determined that Ticor Title's action was premature due to failure to exhaust administrative remedies, 814 F.2d at 732-45, Judge Williams found judicial review premature because there was no final agency action, *id.* at 745-50, and Judge Green decided that Ticor Title's claim was not ripe for review. *Id.* at 750-58. Respondents' defenses are premature challenges to non-final agency action.

According to Respondents, "[i]t cannot be presumed that the FTC will act in good faith and respect a speaker's First and Fifth Amendment rights." Opp'n at 24. This statement ignores the presumption of regularity that attaches to agency activities, see *FCC v. Schreiber*, 381 U.S. 279, 296 (1965), as well as the judicial presumption "of honesty and integrity on the part of the Commission." *Southwest Sunsites, Inc.*, 785 F.2d at 1437. The Commission did *not* engage in "final agency action" when it sought information from Respondents,<sup>13</sup> provided advisory

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<sup>13</sup> See *North Carolina State Bd. v. FTC*, 615 F. Supp. 1155 (E.D.N.C. 1985) (concluding that issuance of compulsory process was not final agency action); *Dairymen Inc. v. FTC*, 684 F.2d 376, 379 (6<sup>th</sup> Cir. 1982) (holding that investigation was not subject to review).

opinions to them,<sup>14</sup> or engaged in unsuccessful consent negotiations with them.<sup>15</sup> Respondents' new arguments do not change the fact that there has been no final agency action to date. The alleged APA defenses are invalid, immaterial, and unripe for review.<sup>16</sup>

**B. Respondents' Additional *First Amendment* Arguments Are Invalid**

Complaint Counsel have already discussed Respondents' *First Amendment* argument based on FDA caselaw. Respondents maintain, however, that they have a valid *First Amendment* defense to "the FTC's substantiation doctrine" because the substantiation requirement, or the FTC's application of that requirement, regulates claims that may not be literally false. *See* Opp'n at 18, 19. This argument is incorrect because it overlooks a crucial point. The *First Amendment*

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<sup>14</sup> *See, e.g., Jerome Milton, Inc. v. FTC*, 734 F. Supp. 1416, 1419 (N.D. Ill. 1990) (concluding that letters from Commission and Commission staff relating to substantiation for advertised toothpaste claims were not final action, and rejecting contention that staff took final action "[b]ecause the filing of a complaint is not definitive, as *Standard Oil* makes clear") (citing *Standard Oil Co.*, 449 U.S. at 244).

<sup>15</sup> *See Bristol-Meyers Co. v. FTC*, 469 F.2d 1116, 1119-20 (2d Cir. 1972) (Mansfield, J., concurring) ("Consent negotiations are not a stage in adjudication but a means of establishing whether adjudication can be avoided altogether."); *see also Public Citizen v. Office of the U.S. Trade Rep.*, 970 F.2d 916, 919 (D.C. Cir. 1992) (holding that appellants could not identify final agency action prior to completion of trade agreement negotiations).

<sup>16</sup> As the above discussion suggests, Respondents already have evidence of the agency's actions to date, in the form of documents within their possession and witnesses in their employ. After this case is fully litigated before the Court and the Commission, Respondents will have the full record of these proceedings, and may choose to renew their APA challenge. "A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action." 5 U.S.C. § 704.

Respondents briefly suggested that the Commission's challenge to claims made for the Leptoprin and Anorex products were "mooted" by Respondents' reformulation of those products. *See* Opp'n at 27. However, it is well-settled that "discontinuance of past illegal practices does not necessarily render moot a controversy over an injunction against similar future actions." *Rubbermaid, Inc. v. FTC*, 575 F.2d 1169, 1172 (6<sup>th</sup> Cir. 1978).

does not protect false *or* deceptive commercial speech.<sup>17</sup>

At the outset, the Court should strike Respondents' alleged *First Amendment* defense to the false claims alleged in the *Complaint*. See Compl. ¶¶ 24, 26, 32, 41, 43. The *Complaint* alleges that Respondents made false establishment claims and falsely represented that Respondent Mowrey was a medical doctor. See *id.* As previously observed, false commercial speech has no constitutional protection, so the *First Amendment* is no defense to these allegations.

The Court should also strike Respondents' alleged *First Amendment* defense to the unsubstantiated claims alleged in the *Complaint*. See Compl. ¶¶ 16, 19, 22, 30, 35, 39. Unsubstantiated claims are deceptive commercial speech. “Unsubstantiated claims are deceptive because consumers expect that the advertiser has some basis for making the claim.” *American Fin. Servs. Ass’n v. FTC*, 767 F.2d 957, 980 n. 27 (D.C. Cir. 1985) (citing *Pfizer* and *In re Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 451, *aff’d*, 481 F.2d 246 (6<sup>th</sup> Cir. 1972)); see also *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9<sup>th</sup> Cir. 1994); *Thompson Medical Co.*, 791 F.2d at 193 (citing *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294 (7<sup>th</sup> Cir. 1979) and *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972)); *National Comm’n on Egg Nutrition v. FTC*, 570 F.2d 157, 172 (7<sup>th</sup> Cir. 1977). These decisions make clear that unsubstantiated claims are deceptive commercial speech. Respondents are not entitled to use the *First Amendment* to shield themselves from liability here.

Respondents also argue that “the Commission’s substantiation doctrine and competent and reliable scientific evidence standard are unconstitutional, because . . . they operate as a prior

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<sup>17</sup> “[O]ur cases make clear that the State may ban commercial expression that is *fraudulent or deceptive* without further justification.” *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) (emphasis added); see also Mot. to Strike at 11-12 (citing additional cases). Respondents’ *Opposition* provides no authority to the contrary.

restraint on protected commercial speech.” Opp’n at 17. This argument is incorrect for several reasons. First, the Supreme Court and other courts have repeatedly questioned whether the prior restraint doctrine applies to commercial speech. See *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 571 n.13 (1980) (noting that hardness of commercial speech may obviate need for prior restraint doctrine in this area); *Friedman v. Rogers*, 440 U.S. 1, 10 (1979); *Virginia State Bd. of Pharm. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 n.24 (1976) (noting that characteristics of commercial speech may make prohibition against prior restraints inapplicable); see also *In re San Juan Star Co.*, 662 F.2d 108, 115 (1<sup>st</sup> Cir. 1981); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) (questioning applicability of prior restraint doctrine to commercial speech). Second, the Commission’s substantiation standard is not a prior restraint. “The term ‘prior restraint’ is used ‘to describe administrative and judicial orders forbidding certain communications when issued in advance of the time that such communications are to occur.’” *Alexander v. United States*, 509 U.S. 544, 550 (1993); see *Northeast Women’s Ctr. v. McMonagle*, 939 F.2d 57, 63 (3d Cir. 1991) (“A prior restraint is a content-based restriction on speech prior to its occurrence.”). Temporary restraining orders and permanent injunctions—orders that actually forbid speech activities—are examples of prior restraints. See *id.* In contrast, the Commission’s substantiation standard and *Complaint* are not binding or self-enforcing, and thus are not official restrictions on speech. Lastly, Respondents have alleged no facts to show that speech has been restrained. The *Complaint* alleges that Respondents did, in fact, engage in speech—false and deceptive commercial speech, which Respondents employed to sell dietary supplements to American consumers. As set forth above, and in our *Motion to Strike*, Respondents have failed to establish that the *First Amendment* is a valid defense to the *Complaint*.

#### IV. Complaint Counsel Did Not Make Admissions Reported by Respondents

Respondents next sought to justify their alleged “reason to believe” and “public interest” determinations by stating several “admissions” that Complaint Counsel have not made. These purported concessions are strawmen. They do not validate Respondents’ defenses, which have already been shown to be invalid. *See* Mot. to Strike at 18-20 (discussing, *inter alia*, *In re Exxon Corp.*, 83 F.T.C. 1759, 1760 (1974)).

First, according to Respondents, our discovery responses show that “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.” Opp’n at 32. This argument rests on the unstated fallacy that Complaint Counsel did not consult non-testifying experts before the issuance of the *Complaint*. We consulted such experts, and the bases of their opinions are not “facts” subject to disclosure simply because Respondents characterize them as such. *See In re Telebrands Corp.*, Docket No. 9313, 2003 WL 23208989 (Dec. 23, 2003).<sup>18</sup>

Respondents advanced several other incorrect “admissions.” According to Respondents, “Complaint Counsel have . . . 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 . . . relied on by Respondents in making the claims at issue do not constitute adequate substantiation.” Opp’n at 31. This statement baldly mischaracterizes our

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<sup>18</sup> Similarly, Respondents reported that “Complaint Counsel *concedes* that when the Commission filed its Complaint . . . it did not even know the quantity and quality of support that the FTC Act required of Respondents’ advertisements under its substantiation doctrine.” Opp’n at 12 (emphasis in original). Again, this overlooks the fact that the Commission’s advertising substantiation standard is well-established and that Complaint Counsel consulted non-testifying experts in fully evaluating Respondents’ advertisements and alleged substantiation.

responses to Respondents' *Interrogatories*. Our responses stated that we would produce responsive information from expert witnesses regarding Respondents' alleged substantiation in accordance with the schedule for expert discovery set forth in the Court's *Scheduling Order*. We also objected to the provision of responsive information from non-testifying experts pursuant to RULE 3.31(c)(4)(ii). *See* Resp. to Resp't's First Set of Interrog. at 2-6 (Aug. 27, 2004).

Lastly, Respondents averred that "Complaint Counsel now admits that they are unable to say . . . whether the claims at issue are express or implied." Respondents failed to disclose that Complaint Counsel answered this question before the filing of the *Opposition*.<sup>19</sup>

The Court should accord no weight to Respondents' mischaracterizations.

**V. Respondents' Defenses of Laches or Equitable Estoppel Are Untenable and Invalid**

Lastly, Respondents contend that laches and equitable estoppel constitute valid defenses against the Commission "under appropriate circumstances." *Opp'n* at 35. Tellingly, Respondents did not explain in their *Opposition*, or allege in their *Answers*, what factual circumstances would possibly make these defenses valid in this case. Respondents merely advanced vague, legalistic allegations and stated that they would need discovery to uncover representations that purportedly were made directly to them. They then advanced an argument based on similarly speculative legal grounds. This Court should reject Respondents' new effort to advance these discredited defenses.

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<sup>19</sup> Based upon the evidence presently available to Complaint Counsel, the representations made by Respondents in promotional materials for the challenged products are strongly implied claims. As Respondents are aware, some words in the alleged claims were literally stated in promotional materials. For example, Respondents have used the words "visible" and "substantial" and "significantly overweight" in their advertising for the challenged products. Complaint Counsel's First Supp. Resp. to Resp't's' First Set of Interrog. (Sept. 3, 2004) (attached hereto).



As a threshold matter, Respondents' new allegations do not satisfy the fact pleading requirement of RULE 3.12. Respondents stated in their *Opposition*, for the very first time, that “[t]he FTC has made numerous explicit and tacit representations in the past concerning their regulatory scheme which Respondents have relied upon to their detriment.” Opp’n at 36. This does no more than state part, and only part, of the traditional requirements for equitable estoppel against a private party. *See Marks v. Newcourt Credit Group*, 342 F.2d 444, 456 (6<sup>th</sup> Cir. 2003) (stating requirements). Respondents did not: (1) identify the alleged misrepresentation by the government;<sup>20</sup> (2) allege facts to show that the FTC’s purpose was to invite action by Respondents; (3) allege that Respondents were, in fact, ignorant of the “true facts,” whatever those “facts” would be in the context of this case; and (4) allege facts to show reliance on the alleged misrepresentations. *See, e.g.*, Answer, Resp’t Basic Research, at 15 (alleging none of these facts); Opp’n at 35-37 (same); *cf. Marks*, 342 F.2d at 456 (stating factual requirements for equitable estoppel).<sup>21</sup> Respondents have had multiple opportunities to state the facts supporting laches and estoppel, and they have failed to do so. Respondents’ new, generic allegations do not validate the alleged defenses.

Respondents’ legal argument is based on similarly speculative grounds. Complaint Counsel stated in the *Motion to Strike* that laches and equitable estoppel are invalid defenses, and Respondents countered that “the issue is not as Complaint Counsel represents.” Opp’n at 36.

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<sup>20</sup> Presumably, Respondents would have objected if the Commission had simply cited the FTC Act in its Complaint without stating the challenged representations.

<sup>21</sup> Respondents complain that “Complaint Counsel also ignores so-called statutory laches,” but Respondents did not raise “statutory laches” as a separate defense. Complaint Counsel has previously addressed Respondents’ contentions with respect to delay under the APA. *See Mot. to Strike* at 15-18; *see also supra* at 8-12.

Respondents are incorrect. They cited *United States v. Philip Morris Inc.*, 300 F. Supp.2d 61 (D.D.C. 2004), for the proposition that laches and equitable estoppel are valid defenses. See Opp'n at 35. However, the *Philip Morris* court stated:

The essence of the Government's argument is that the equitable defenses of waiver, equitable estoppel, [and] laches . . . may not be asserted against the United States when, as here, "it is acting in its sovereign capacity to exercise public rights to protect the public interest. . . . *The case law overwhelmingly supports the Government's position.* . . . The case law is also clear that if equitable estoppel is ever to apply to the Government, the justification for it must be compelling and must go beyond the showing a party would have to make against an ordinary opponent in an ordinary case. . . . It is equally clear that, under the law of this Circuit, laches and unclean hands are both unavailable as a matter of law when, as here, the Government acts in the public interest.

*Id.* at 66 (citations omitted and emphasis added). Here, again, Respondents' argument is contradicted by the authority cited in their own *Opposition*.<sup>22</sup>

Neither the Supreme Court nor the D.C. Circuit has ever upheld a finding of equitable estoppel against the government. See *Office of Personnel v. Richmond*, 496 U.S. 414, 422 (1990) ("we have reversed every finding of estoppel that we have reviewed"); *Philip Morris Inc.*, 300 F. Supp.2d at 70. Respondents are reduced to suggesting that this defense may, for the first time, be valid here. That is insufficient to establish a valid defense. RULE 3.12 requires that Respondents articulate the *facts* that support their defenses. Respondents concede that if equitable estoppel were to become a valid defense, it would only be "in compelling circumstances," Opp'n at 36, but they have repeatedly failed to plead facts to allege that such circumstances exist in the present case. The weight of authority does not support the application of these defenses against the

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<sup>22</sup> Respondents also rely on *Resolution Trust Corp. v. Vanderweele*, 833 F. Supp. 1383, 1388 (N.D. Ind. 1993), and *dicta* in *Occidental Life Ins. Co. v. EEOC*, 432 U.S. 355, 373 (1977). This reliance is misplaced for the reasons aptly stated by the *Philip Morris* court. See 300 F. Supp.2d at 73-74.

Commission. See *FTC v. American Microtel, Inc.*, 1992 U.S. Dist. LEXIS 11046, \*3 (D. Nev. June 10, 1992); *In re Rentacolor, Inc.*, 103 F.T.C. 400, 418 (1983); *In re Metagenics, Inc.*, 1995 FTC LEXIS at \*3 (citing other cases). Such ill-asserted defenses are untenable or invalid as a matter of law, and should be stricken.<sup>23</sup>

## CONCLUSION

Throughout this litigation, Complaint Counsel has expended resources on otherwise unnecessary discovery and motions practice<sup>24</sup> because Respondents wish to try another case. In Respondents' "wished-for" case, the "overriding" issues are whether the Commission engaged in "repeated violations of Respondents' fundamental rights," or an "unyielding refusal to comply with the requirements of due process," or personal bias and animosity against Respondent Friedlander, among other alleged illegalities. See, e.g., Opp'n at 2, 8, 38. These allegations have absolutely no bearing on whether the Respondents actually violated the FTC Act by marketing dietary supplements with false or unsubstantiated claims.

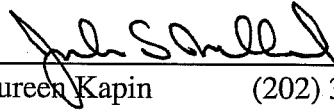
Respondents' alleged defenses are untenable and legally invalid, unsupported by factual statements, and/or irrelevant and immaterial. The alleged defenses have consumed the resources of Complaint Counsel and the Court, and may greatly, and unduly, expand the scope of the hearing on the Commission's *Complaint*. For the reasons set forth in our moving papers, we respectfully urge the Court to strike Respondents' defenses.

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<sup>23</sup> Complaint Counsel does not wish to reiterate, or waive, its previous arguments concerning Respondents' redundant, negative defenses and accusations of personal bias.

<sup>24</sup> See, e.g., Basic Research, LLC's Second Req. for Prod. of Documents, Resp't's Nos. 6, 8, 13, 20, 21, 23-29, 32-33, 35 (Sept. 9, 2004) (attached hereto); see also Basic Research, LLC's First Req. for Admissions, Resp't's Nos. 10-21, 25-26, 43-47 (Sept. 9, 2004) (attached hereto).

Respectfully submitted,



---

Laureen Kapin (202) 326-3237  
Walter C. Gross, III (202) 326-3319  
Joshua S. Millard (202) 326-2454  
Robin M. Richardson (202) 326-2798  
Laura Schneider (202) 326-2604

Division of Enforcement  
Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580

Dated: September 28, 2004

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

- (1) **Complaint Counsel's First Supp. Resp. to Resp't's' First Set of Interrogs. (Sept. 3, 2004).**
- (2) **Basic Research, LLC's Second Req. for Prod. of Documents (Sept. 9, 2004).**
- (3) **Basic Research, LLC's First Req. for Admissions (Sept. 9, 2004).**

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

**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.,  
BAN, L.L.C.,  
DENNIS GAY,  
DANIEL B. MOWREY, and  
MITCHELL K. FRIEDLANDER,**

**Respondents.**

**Docket No. 9318**

**PUBLIC DOCUMENT**

**COMPLAINT COUNSEL'S FIRST SUPPLEMENTAL RESPONSE TO  
RESPONDENT'S FIRST SET OF INTERROGATORIES**

On August 27, 2004, Complaint Counsel served its Response to Respondent Basic Research L.L.C.'s First Set of Interrogatories ("Respondent's Interrogatories"). Pursuant to Rule 3.22(f) of the Commission's Rule of Practice, the parties have held several conferences in an effort in good faith to resolve by agreement certain discovery issues. As a result of those conferences, and pursuant to Rule 3.35, Complaint Counsel serve the following supplemental response to Respondent's First Set of Interrogatories. Complaint Counsel reserves all applicable general objections set forth in Complaint Counsel's Response to Respondent's First Set of Interrogatories.

## **GENERAL RESPONSES**

1. Complaint Counsel's responses are made subject to all objections as to competence, relevance, privilege, materiality, propriety, admissibility, and any and all other objections and grounds that would require the exclusion of any statement contained herein if any requests were asked of, or if any statements contained herein were made by, or if any documents referenced here were offered by a witness present and testifying in court, all of which objections are reserved and may be interposed at the time of the hearing.
2. The fact that Complaint Counsel have answered or objected to any interrogatory or part thereof should not be taken as an admission that Complaint Counsel accept or admit the existence of any facts or documents set forth in or assumed by such interrogatory or that such answer or objection constitutes admissible evidence. The fact that Complaint Counsel have responded to any interrogatory in whole or in part is not intended and shall not be construed as a waiver by Complaint Counsel of all or any part of any objection to any interrogatory.
3. Complaint Counsel have not completed their investigation in this case, and additional facts may be discovered that are responsive to Respondent's interrogatories. Complaint Counsel reserve the right to supplement the responses provided herein as appropriate during the course of discovery.
4. As used herein, "Respondents" shall mean all Respondents named in the Complaint.
5. -As used herein, "Respondent's interrogatories" shall mean the interrogatories and all applicable instructions and definitions as set forth in Respondent's interrogatories.

### **Interrogatories and Responses**

#### **INTERROGATORY NO. 1** [Respondent's Interrogatory No. 1a, b, and c]

1. 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; and
  - c) describe all extrinsic evidence (that is, anything other than the Promotional Material itself) that was relied upon in determining what representations were conveyed

**Response:**

Complaint Counsel object to the extent that Respondent has included as many as five separate interrogatories under this one numbered interrogatory, the total number of discrete and separate interrogatories is understated. Complaint Counsel's responses are numbered according to the actual number of interrogatories posed. Accordingly, Complaint Counsel have renumbered the Interrogatories with Respondent's original number in brackets.

Complaint Counsel object to the extent that this Interrogatory seeks information prepared in anticipation of litigation or disclosure of the theories and opinions of Complaint Counsel (General Objection 2), information protected from disclosure by the deliberative process privilege (General Objection 3), information relating to the expert witnesses that Complaint Counsel intend to use at the hearing (General Objection 4), information relating to non-testifying expert witnesses (General Objection 5), or is otherwise inconsistent with Complaint Counsel's obligations under the Rules of Practice (General Objection 9).

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.

**Supplement:**

Subject to and without waiving these objections or the General Objections stated above, Complaint Counsel state as follows: The Complaint alleges that Respondents have represented the claims at issue "expressly or by implication."

Express claims are those that are literally stated in a piece of promotional material, and require no evidence whatsoever beyond the text of the promotional material itself. *Thompson Medical Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986). Implied claims are all other claims that are not expressly stated in the text of the promotional material. Such claims range from those that use language and imagery "virtually synonymous with an express claim, through language that literally says one thing but strongly suggests another, to language which relatively few consumers would interpret as making a particular representation." *Thompson Medical Co.*, 104 F.T.C. at 788-89.

Based upon the evidence presently available to Complaint Counsel, the representations made by Respondents in promotional materials for the challenged products are strongly implied claims. As Respondents are aware, some words in the alleged claims were literally stated in promotional materials. For example, Respondents have used the words "visible" and "substantial" and "significantly overweight" in their advertising for the Challenged Products. *See, e.g.*, Complaint 41 and accompanying Exhibits; Complaint Counsel's Response to Respondent's First Set of Interrogs., Interrog. 6 (Respondent's Interrog. 4).



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.

Dated: September 3, 2004

Respectfully submitted,

*Laureen Kapin*

Laureen Kapin (202) 326-3237  
Walter C. Gross (202) 326-3319  
Joshua S. Millard (202) 326-2454  
Robin M. Richardson (202) 326-2798  
Laura Schneider (202) 326-2604

Bureau of Consumer Protection

## CERTIFICATE OF SERVICE

I hereby certify that on this 3<sup>rd</sup> day of September, 2004, I caused *Complaint Counsel's First Supplemental Response To Respondent's First Set of interrogatories* to be served and filed as follows:

- (1) one (1) electronic copy via email and one (1) paper copy  
by first class mail to the following persons:

**Stephen E. Nagin**

Nagin Gallop Figuerdo P.A.  
3225 Aviation Ave.  
Miami, FL 33133-4741  
(305) 854-5353  
(305) 854-5351 (fax)  
[snagin@ngf-law.com](mailto:snagin@ngf-law.com)

**For Respondents**

**Jeffrey D. Feldman**

FeldmanGale  
201 S. Biscayne Blvd., 19<sup>th</sup> Fl.  
Miami, FL 33131-4332  
(305) 358-5001  
(305) 358-3309 (fax)  
[JFeldman@FeldmanGale.com](mailto:JFeldman@FeldmanGale.com)

**For Respondents**

**A.G. Waterhouse, LLC,  
Klein-Becker USA, LLC,  
Nutrasport, LLC, Sovage  
Dermalogic Laboratories,  
LLC, and BAN, LLC**

**Richard D. Burbidge**

Burbidge & Mitchell  
215 S. State St., Suite 920  
Salt Lake City, UT 84111  
(801) 355-6677  
(801) 355-2341 (fax)  
[rburbidge@burbidgeandmitchell.com](mailto:rburbidge@burbidgeandmitchell.com)

**For Respondent Gay**

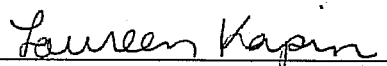
**Ronald F. Price**

Peters Scofield Price  
340 Broadway Centre  
111 East Broadway  
Salt Lake City, UT 84111  
(801) 322-2002  
(801) 322-2003 (fax)  
[rpf@psplawyers.com](mailto:rpf@psplawyers.com)

**For Respondent Mowrey**

**Mitchell K. Friedlander**

5742 West Harold Gatty Dr.  
Salt Lake City, UT 84116  
(801) 517-7000  
(801) 517-7108 (fax)  
**Respondent Pro Se**  
[mkf555@msn.com](mailto:mkf555@msn.com)



COMPLAINT COUNSEL

**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**

**BASIC RESEARCH, LLC'S SECOND REQUEST FOR PRODUCTION OF  
DOCUMENTS**

Respondent, Basic Research, L.L.C., by and through its undersigned counsel, and pursuant to 16 CFR §3.37(a), hereby requests Complaint Counsel to produce the documentary material and tangible things identified below for inspection and copying within fifteen (15) days at FeldmanGale, P.A., Miami Center, 19th Floor, 201 South Biscayne Blvd., Miami, Florida 33131, or such time and place as may be agreed upon by all counsel.

**DEFINITIONS**

Notwithstanding any definition below, each word, term, or phrase used in these Requests for Production is intended to have the broadest meaning permitted under the Federal Trade Commission's Rule of Practice.

1. "Challenged Products" shall mean each product referred to in the Complaint, including: Dermalin-APg, Cutting Gel, Tummy Flattening gel, Leptroprin, Anorex, and PediaLean, both individually and collectively.
2. "Commission," "you," and "your" shall mean the Federal Trade Commission, its employees, agents, attorneys, consultants, representatives, officers, and all other persons acting or purporting to act on its behalf.
3. "Communications(s)" shall mean the transmittal or exchange of information of any kind in any form, including oral, written, or electronic form.
4. "Complaint" shall mean the administrative complaint issued by the Federal Trade Commission and any amendments to that Complaint, in the above-captioned matter.
5. "Corporate Respondents" shall mean the following Respondents: Basic Research, LLC, A.G. Waterhouse, LLC, Klein-Becker, usa, LLC, Nutrasport, LLC, Söavage Dermalogic Laboratories, LLC and BAN, LLC, both individually and collectively as defined in the Complaint, including all of their operations under any trade names.
6. "Document" should be interpreted in the broadest sense permitted under the Federal Trade Commission's Rules of Practice, including but not limited to writings, drawings, graphs, charts, photographs, audio recordings, transcripts, videotapes, electronic mail, and other data compilations from which information can be obtained. The term "document" includes originals and all non-identical copies.

7. "Communication" or "communications" mean the act or fact of transmitting information, whether by correspondence, telephone line, computer media, meeting or any occasion of joint or mutual presence, as well as the transmittal of any document from one person to another.
8. "Each" and "any" shall mean and shall include the word "all" so as to have the broadest meaning whenever necessary to bring within the scope of any Specification all information and/or document(s) that otherwise might be construed to be outside its scope.
9. "Efficacy" shall mean the ability of the product to achieve the results for which it is advertised.
10. "Individual Respondents" shall mean: Respondents Dennis Gay, Daniel B. Mowrey, and Mitchell K. Friedlander, both individually and collectively, unless otherwise stated.
11. "Or" includes "and" and "and" shall include "or," so as to have the broadest meaning whenever necessary to bring within the scope necessary to bring within the scope of any Request for all information or documents that might otherwise be construed to be outside its scope.
12. "Person" or "Persons" shall mean: all natural persons, corporations, partnerships or other business associations, and each and every other legal entity, including all members, officers, predecessors, assigns, divisions, branches, departments, affiliates, and subsidiaries.
13. "Promotional Material" shall mean: any written or oral statement, advertisement, illustration, or depiction that is designed to effect a sale or create interest in the purchasing of goods or services, whether the same appears in a press release, video news release, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, sticker, free standing insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display,

instructional or education materials, packaging, package insert, package label, film, slide, radio or television broadcast or transmission, Internet or World Wide Web site, streaming video, electronic mail, audio program transmitted over a telephone system, script(s) used to make oral solicitations to consumers, or publications or broadcast in any other medium.

14. "Referring to" or "relating to" shall mean: discussing, describing, reflecting, containing, analyzing, studying, reporting, commenting, evidencing, constituting, setting forth, considering, recommending, concerning, or pertaining to, in whole or in part.

15. "Respondent(s)" shall mean" all Corporate Respondents and all Individual Respondents, both individually and collectively, unless otherwise stated.

16. "Safety" shall mean the ability of the product to be used without risk or adverse health consequences for the user.

### INSTRUCTIONS

1. Unless otherwise specified, the time period covered by these document production requests shall not be limited. All documents and tangible things responsive to the request – regardless of dates or time periods involved – must be provided.

2. Each document production request shall operate and be construed independently. Unless otherwise indicated, no paragraph limits the scope of any other paragraph.

3. All documents that in their original form were stapled, clipped, or otherwise attached to other documents should be produced in such form. A complete copy of each document should be submitted even if only a portion of the document is within the scope of the Request. Each page produced should be marked with a unique Bates tracking number.

4. Documents covered by this Request are those which are in your possession or under your actual or constructive custody or control.

5. This Request does not seek documents that were provided to you by the Corporate Respondents in response to formal investigative demands.

6. Responsive documents that are not produced because you claim a privilege must be identified on a privilege log. The log must identify the grounds for withholding the document, the date of the document, type (e.g., letter, meeting, notes, memo), nature and subject matter of the document, the author or originators, and the addressees/recipients. Each author or recipient who is an attorney should be noted as such. If only a part of a responsive document is privilege, all non-privileged portions of the document must be provided.

7. The First Request for Production is continuing in character so as to require you to produce additional information promptly upon obtaining or discovering different, new or further information before the close of discovery.

8. The use of the singular includes the plural, and the plural includes the singular.

9. The use of a verb in any tense shall be construed to include all other tenses.

10. The spelling of a name shall be construed to include all similar variants of such name.

#### DOCUMENT REQUESTS

1. All transcripts of or relating to the Respondents.

2. All documents listed in Complaint Counsel's Initial Disclosures.

3. All documents relating to submissions by the Federal Trade Commission in all prior weight loss cases.

4. All consent orders issued by the Federal Trade Commission in weight loss cases.

5. All documents relating to the contention that clinical testing does not support the representations made in the advertising of the Challenged Products.

6. All expert reports that the Federal Trade Commission has filed in other part three proceedings or proceedings under Section 13(b) of the FTC Act.
7. All depositions taken of the Federal Trade Commission substantiation experts in any weight loss cases.
8. All appellate briefs filed by the Federal Trade Commission in other part 3 proceedings or proceedings under Section 13(b) of the FTC Act.
9. All complaints relating to the Challenged Products, including consumer and non-consumer complaints.
10. All communications with the National Institute of Health (NIH) relating to the Respondents or Challenged Products.
11. All communications with the Food and Drug Administration (FDA) relating to the Respondents or Challenged Products.
12. All communications with or to Cytodyne Technologies, Inc., its agents, officers, employees, Brian Molloy, Steve Stern, Brian Benevento, or Mel Rich.
13. All documents relating to any request for rulemaking submitted to the Federal Trade Commission by Jonathon W. Emord, Esq.
14. All communications with or to former employees of the Corporate Respondents.
15. All communications with authors of any studies or publications submitted to the Federal Trade Commission by the Corporate Respondents.
16. All notes of conversations with authors of studies or publications submitted to the Federal Trade Commission by the Corporate Respondents.
17. All communications to or with consumers relating to the Challenged Products.



18. All communications to or with consumers relating to competitors of the Challenged Products.
19. All documents relating to the interpretations of the advertisements of the Challenged Products.
20. All documents relating to the expertise and training of the FTC Commissioners in advertising interpretation.
21. All documents relating to the expertise and training of the FTC Commissioners in the interpretation of scientific or medical studies.
22. All documents relating to studies contradicting or undermining the express or implied interpretations of the advertisements for the Challenged Products.
23. All Federal Trade Commission publications which set forth the substantiation standard applicable in this case.
24. All reported cases which set forth the substantiation standard applicable in this case.
25. All internal memorandums which set forth the substantiation standard applicable in this case.
26. All request for rulemaking relating to the substantiation standard applicable in this case.
27. All documents relating to requests by advertisers for clarification on the substantiation standards applicable in this case.
28. All documents relating to requests made by advertisers pursuant to 16 C.F.R. §1.1.

29. All documents relating to requests made to the Federal Trade Commission by advertisers seeking approval of advertising prior to dissemination.
30. All studies reviewed by the Federal Trade Commission relating to the Challenged Products.
31. All consumer surveys conducted by the Federal Trade Commission relating to the Challenged Products.
32. All documents which define or explain the meaning of "competent and reliable scientific evidence."
33. All documents which purport to establish what constitutes competent and reliable evidence for purposes of supporting efficacy claims of weight loss products.
34. All correspondence to or with the individuals who served on the panel of "Deception in Weight Loss Advertising: A Workshop," held on November 19, 2002.
35. All documents that reflect the Federal Trade Commission's understanding of what the Federal Trade Commission needs to have a "reason to believe."
36. All documents which support the Federal Trade Commission's analysis of the meaning of the claims made by Respondents about the Challenged Products.
37. All documents which reflect the meaning of the words "Rapid" and "Substantial."
38. All drafts or versions of any expert reports.
39. All document and things considered and/or relied upon by any expert in connection with his or her services in this action.
40. All documents and things generated by any expert in connection with his or her services in the instant action, including but not limited to, any videos, photographs, tests, test results, notes and memoranda.



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Jeffrey D. Feldman  
Gregory L. Hillyer  
FELDMANGALE, P.A.  
Miami Center – 19<sup>th</sup> Floor  
201 South Biscayne Blvd.  
Miami, Florida 33131  
Telephone: (305) 358-5001  
Facsimile: (305) 358-3309

**Counsel for Respondents 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. and Ban, L.L.C**

**CERTIFICATE OF SERVICE**

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

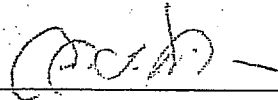
(1) One (1) copy via e-mail attachment in Adobe® “.pdf” format to Commission Complaint Counsel, Laureen Kapin, Joshua S. Millard, and Laura Schneider, all care of [lkapin@ftc.gov](mailto:lkapin@ftc.gov); [jmillard@ftc.gov](mailto:jmillard@ftc.gov); [richardson@ftc.gov](mailto:richardson@ftc.gov); [lschneider@ftc.gov](mailto:lschneider@ftc.gov) 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;

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

(3) 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.

(4) 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.

(5) One (1) copy via United States Postal Service to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84111, *pro se*.



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**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**

**BASIC RESEARCH, LLC'S FIRST REQUEST FOR ADMISSIONS**

Respondent, Basic Research, LLC, by and through its undersigned counsel and pursuant to 16 CFR §3.32 hereby requests that the Federal Trade Commission admit the following within fifteen (15) days of service hereof.

**DEFINITIONS**

1. "Commission" or "FTC" shall mean the Federal Trade Commission, its employees, agents, attorneys, consultants, representatives, officers, and all other persons acting or purporting to act on its behalf.

2. "Staff Counsel" shall mean any attorney(s) employed by the Federal Trade Commission, excluding the Commissioners, including without limitation Complaint Counsel in the above-captioned matter.
3. "Complaint" shall mean the administrative complaint issued by the Federal Trade Commission and any amendments to that Complaint, in the above-captioned matter.
4. "Challenged Products" shall mean each product referred to in the Complaint, including: Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Leptroprin, Anorex, and PediaLean, both individually and collectively.
5. "Challenged Advertisements" shall mean the advertising, both individually and collectively, for the Challenged Products referred to in the Complaint.
6. "Challenged Claims" shall mean the claims, both express and implied, appearing in the Challenged Advertisements and referred to in the Complaint.
7. "Respondent(s)" shall mean" all Corporate Respondents and all Individual Respondents, both individually and collectively, unless otherwise stated.
8. "Corporate Respondents" shall mean the following Respondents: Basic Research, LLC, A.G. Waterhouse, LLC, Klein-Becker, usa, LLC, Nutrasport, LLC, Söavage Dermalogic Laboratories, LLC and BAN, LLC, both individually and collectively as defined in the Complaint, including all of their operations under any trade names.
9. "Individual Respondents" shall mean: Respondents Dennis Gay, Daniel B. Mowrey, and Mitchell K. Friedlander, both individually and collectively, unless otherwise stated.
10. "Efficacy" shall mean the ability of the product to achieve the results for which it is advertised.

11. "Safety" shall mean the ability of the product to be used without risk or adverse health consequences for the user.

12. "Operating Manual" means the Federal Trade Commission Operating Manual.

### INSTRUCTIONS

The Requests for Admissions, as separately set forth below, shall be admitted unless, within fifteen (15) days after service, a sworn written answer or objection addressed to the Requests is served upon Basic Research, LLC and filed with the Secretary. Answers shall specifically deny the Request or set forth in detail the reasons why the Request cannot truthfully be admitted or denied. A denial shall fairly meet the substance of the Request, and when good faith requires that a party qualify its answer or deny only a part of the Request, so much of it as is true shall be specified, and the remainder shall be qualified or denied. Lack of information or knowledge shall not be given as a reason for failure to admit or deny unless a reasonable inquiry that the information known to or readily obtainable is insufficient to enable an admission or denial. If it is believed that a Request presents a genuine issue for trial, the Request may not, on that ground alone, be objected to; the Request may either be denied, or the reasons why the Request cannot be admitted or denied set forth.

### REQUESTS FOR ADMISSIONS

1. Admit that the Federal Trade Commission has not conducted any studies regarding the Efficacy of the Challenged Products.

2. Admit that the Federal Trade Commission has not conducted consumer surveys or other research relating to how reasonable consumers would interpret or understand the Challenged Advertisements.

3. Admit that the Federal Trade Commission has not conducted consumer surveys or other research relating to what types of substantiation reasonable consumers would expect the Respondents to possess in order to have a reasonable basis for the Challenged Claims in the Challenged Advertisements.

4. Admit that at the time the Complaint was filed, the Federal Trade Commission had no expert opinion as to what express and/or implied claims were made in the Challenged Advertisements.

5. Admit that at the time the Complaint was filed, the Federal Trade Commission had no expert opinion that Respondents lacked a "reasonable basis" for the Challenged Advertisements.

6. Admit that at the time the Complaint was filed, the Federal Trade Commission had no expert opinion to support the allegations in paragraphs 24, 26, 32, and 41 of the Complaint.

7. Admit that the interpretation of Challenged Advertisements used to support the filing of the Complaint was performed by Staff Counsel for the Federal Trade Commission.

8. Admit that the term "Rapid" can mean different things to different reasonable consumers.

9. Admit that the term "Substantial" can mean different things to different reasonable consumers.

10. Admit that at the time the Challenged Advertisements were published, the Federal Trade Commission had no pre-screening protocol for the approval of the Challenged Advertisements.



11. Admit that at the time the Challenged Advertisements were published, the Federal Trade Commission had no pre-screening protocol for determining the adequacy of the substantiation supporting the claims made in the Challenged Advertisements.
12. Admit that the Federal Trade Commission will not give advertisers definitive answers on the adequacy of their claim substantiation before advertisements are disseminated.
13. Admit that 16 C.F.R. §1.1 does not provide a pre-screening protocol for advertisers to receive approval of their advertising.
14. Admit that advice provided by the Federal Trade Commission under 16 C.F.R. §1.1 is not binding on the Federal Trade Commission.
15. Admit that the Federal Trade Commission is under no obligation to issue warning letters if it changes its position regarding advice previously provided under 16 C.F.R. §1.1.
16. Admit that in 2000, the Federal Trade Commission received a petition to adopt a rule for the pre-screening of dietary supplement advertisements.
17. Admit that in 2000, the Federal Trade Commission denied a petition to adopt a rule for the pre-screening of dietary supplement advertisements.
18. Admit that in 2000, the Federal Trade Commission denied a petition to adopt a rule for pre-screening of dietary supplement advertisements because it was impracticable.
19. Admit that the Federal Trade Commission, at one time, had a pre-screening protocol for approving advertisements prior to dissemination.
20. Admit that the Federal Trade Commission abolished its pre-screening protocol for approving advertisements prior to dissemination.
21. Admit that the Federal Trade Commission would pre-screen Respondents' advertisements in the event that a cease and desist order is issued against them.

22. Admit that the Federal Trade Commission defines, in each case, the substantiation needed to constitute a reasonable basis for the Challenged Advertising.

23. Admit that in the case of specific establishment claims, the only substantiation required of the advertiser is the substantiation specifically referenced by the advertiser in the advertisement.

24. Admit that what constitutes a "reasonable basis" changes from case to case.

25. Admit that the Federal Trade Commission coordinated the filing of the Complaint with the 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").

26. Admit that the Federal Trade Commission was asked by Congressional representatives to delay filing of the Complaint until the commencement of the Hearings.

27. Admit that J. Howard Beales III is not a medical doctor.

28. Admit that at the Hearings J. Howard Beales III was addressed as "Dr. Beales."

29. Admit that at the Hearings, when addressed as "Dr. Beales," Dr. Beales did not correct any member of Congress that he was not a medical doctor.

30. Admit that Dr. Wexler is not a medical doctor.

31. Admit that the Federal Trade Commission deems Dr. Wexler to be an expert on child obesity.

32. Admit that at the Hearings Dr. Wexler was addressed as "Dr. Wexler."

33. Admit that at the Hearings, when addressed as "Dr. Wexler," Dr. Wexler did not correct any member of Congress that he was not a medical doctor.

34. Admit that there is no Federal Trade Commission rule that prohibits a Ph.D. from being referred to as a "doctor."

35. Admit that the conclusion that Respondents did not possess or rely upon a reasonable basis that substantiated the accused advertising is premised upon the Respondents not having a specific type and amount of substantiation for its claims.

36. Admit that the Federal Trade Commission's authority is limited to determining whether the representations made in the Challenged Advertisements are in accord with the level of substantiation Respondents possessed.

37. Admit that it is the Federal Trade Commission's position that "competent and reliable scientific evidence" can mean different types and amounts of evidence in different cases.

38. Admit that the Federal Trade Commission has not defined "competent and reliable scientific evidence" to require any specific kinds, types or amounts of scientific studies.

39. Admit that the Federal Trade Commission has not defined "competent and reliable scientific evidence" to require any specific testing or research protocol or controls.

40. Admit that the Federal Trade Commission's position is that the state of the science renders all the representations made in the Challenged Advertisements unsupported.

41. Admit that it is the Federal Trade Commission's position that claims about the Safety and Efficacy of dietary supplements must be substantiated by competent and reliable scientific evidence.

42. Admit that it is the Federal Trade Commission's position that Respondents needed competent and reliable scientific evidence to substantiate the representations made in the Challenged Advertisements.

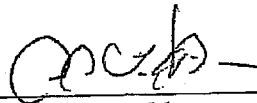
43. Admit that the FTC Commissioners have no formal training or expertise in advertising interpretation.

44. Admit that the FTC Commissioners are not given any formal training in advertising interpretation prior to being commissioned.

45. Admit that the FTC Commissioners have no formal training or expertise in the interpretation of science and/or medical studies.

46. Admit that the FTC Commissioners are not given any formal training in the interpretations of science and/or medical studies prior to being commissioned.

47. Admit that the attorneys for the Federal Trade Commission are bound to follow the procedures specifically discussed in the FTC Operating Manual.



Jeffrey D. Feldman  
Gregory L. Hillyer  
Chris Demetriades  
FELDMANGALE, P.A.  
Miami Center - 19<sup>th</sup> Floor  
201 South Biscayne Blvd.  
Miami, Florida 33131  
Telephone: (305) 358-5001  
Facsimile: (305) 358-3309

**Counsel for Respondents 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. and Ban, L.L.C**

**CERTIFICATE OF SERVICE**

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

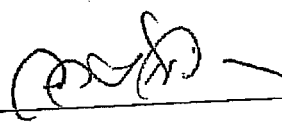
(1) One (1) copy via e-mail attachment in Adobe® “.pdf” format to Commission Complaint Counsel, Laureen Kapin, Joshua S. Millard, and Laura Schneider, all care of [lkapin@ftc.gov](mailto:lkapin@ftc.gov), [jmillard@ftc.gov](mailto:jmillard@ftc.gov), [rrichardson@ftc.gov](mailto:rrichardson@ftc.gov), [lschneider@ftc.gov](mailto:lschneider@ftc.gov) 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;

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

(3) 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.

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(5) One (1) copy via United States Postal Service to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84111, *pro se*.

  
\_\_\_\_\_

## CERTIFICATE OF SERVICE

I hereby certify that on this 20<sup>th</sup> day of September, 2004, I caused *Complaint Counsel's Reply to Respondents' Opposition to Motion to Strike Respondents' "Additional Defenses"* to be served and filed as follows:

- (1) the original, two (2) paper copies filed by hand delivery and one (1) electronic copy via email to:  
**Donald S. Clark, Secretary**  
Federal Trade Commission  
600 Penn. Ave., N.W., Room H-159  
Washington, D.C. 20580
- (2) two (2) paper copies served by hand delivery to:  
**The Honorable Stephen J. McGuire**  
Chief Administrative Law Judge  
600 Penn. Ave., N.W., Room H-104  
Washington, D.C. 20580
- (3) one (1) electronic copy via email and one (1) paper copy by first class mail to the following persons:


**Stephen E. Nagin**  
Nagin Gallop Figuerdo P.A.  
3225 Aviation Ave.  
Miami, FL 33133-4741  
(305) 854-5353  
(305) 854-5351 (fax)  
[snagin@ngf-law.com](mailto:snagin@ngf-law.com)  
**For Respondents**

**Jeffrey D. Feldman**  
FeldmanGale  
201 S. Biscayne Blvd., 19<sup>th</sup> Fl.  
Miami, FL 33131-4332  
(305) 358-5001  
(305) 358-3309 (fax)  
[JFeldman@FeldmanGale.com](mailto:JFeldman@FeldmanGale.com)  
**For Respondents**  
**A.G. Waterhouse, LLC,  
Klein-Becker USA, LLC,  
Nutrasport, LLC, Sovage  
Dermalogic Laboratories,  
LLC, and BAN, LLC**

**Ronald F. Price**  
Peters Scofield Price  
310 Broadway Centre  
111 East Broadway  
Salt Lake City, UT 84111  
(801) 322-2002  
(801) 322-2003 (fax)  
[rpf@psplawyers.com](mailto:rpf@psplawyers.com)  
**For Respondent Mowrey**

**Richard D. Burbidge**  
Burbridge & Mitchell  
215 S. State St., Suite 920  
Salt Lake City, UT 84111  
(801) 355-6677  
(801) 355-2341 (fax)  
[rburbidge@burbridgeandmitchell.com](mailto:rburbidge@burbridgeandmitchell.com)  
**For Respondent Gay**

**Mitchell K. Friedlander**  
5742 West Harold Gatty Dr.  
Salt Lake City, UT 84116  
(801) 517-7000  
(801) 517-7108 (fax)  
**Respondent Pro Se**  
[mkf555@msn.com](mailto:mkf555@msn.com)

  
\_\_\_\_\_  
COMPLAINT COUNSEL