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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

BASIC RESEARCH, LLC, a limited liability company; A.G. WATERHOUSE, LLC, a limited liability company; SOVAGE DERMALOGIC LABORATORIES, LLC, a limited liability company; THE CARTER-REED COMPANY, LLC, a limited liability company; DYNAKOR PHARMACAL, LLC, a limited liability company; DENNIS GAY, an individual; and MITCHELL K. FRIEDLANDER, an individual,

Plaintiffs,

v.

FEDERAL TRADE COMMISSION, a federal administrative agency, and THE UNITED STATES OF AMERICA,

Defendants.

COMPLAINT FOR DECLARATORY RELIEF

Case: 2:09cv00779
Assigned To : Jenkins, Bruce S.
Assign. Date : 8/31/2009
Description: Basic Research et al v. FTC et al

Magistrate Judge: _____

Plaintiffs and the Federal Trade Commission ("FTC") are parties to an Agreement that defines the rights and duties of Plaintiffs and the FTC respecting fat loss and weight loss claims for Plaintiffs' dietary supplements and establishes a clear and unambiguous standard Plaintiffs

agreed to satisfy when making those types of claims. The Parties' Agreement provides that Plaintiffs may make weight loss and fat loss claims for dietary supplement products if they have a "reasonable basis" to make those claims, defined in the Agreement as any one or more of the following: tests or analyses or research or studies, or other evidence, based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

FTC is now refusing to abide by the express terms of its Agreement and, instead, is demanding that Plaintiffs meet additional, extracontractual and subjective advertising substantiation requirements and conditions never agreed to and which are not contained anywhere within the four corners of the Agreement. FTC's insistence -- notwithstanding the plain and unambiguous language of the Agreement -- that its interpretation of the Agreement allows FTC to impose upon Plaintiffs additional, changing and undefined requirements and conditions not found within the four corners of the Agreement violates that Agreement and defeats Plaintiffs' bases for entering into the Agreement.

Furthermore, FTC has threatened Plaintiffs with imminent contempt litigation if Plaintiffs fail to satisfy FTC's extracontractual, undefined and changing requirements and conditions. Through its rejection and breach of the Agreement, FTC is depriving Plaintiffs of their rights and benefits under the Agreement, and is also, thereby, depriving Plaintiffs of their First Amendment right to free speech and their Fifth Amendment right to Due Process.

FTC's breach of the Agreement, the resulting constitutional violations (for which Plaintiffs have no extra-judicial remedy) and FTC's threat of imminent prosecution necessitate

the filing of this Action. Notwithstanding the seriousness of the present dispute with FTC, this Action is notable for the narrow scope of relief sought. Plaintiffs do not here ask the Court for an order directing FTC to take specific action, nor do Plaintiffs seek a Court order enjoining FTC from exercising its administrative authority, even if the exercise of that authority results in FTC taking some action against Plaintiffs should FTC decide such action is necessary and proper.

Rather, Plaintiffs seek in this Action very narrow and specific declarations concerning discrete legal questions, namely 1) the interpretation and meaning of the reasonable basis standard set forth in the Parties' Agreement. Specifically, Plaintiffs seek a declaration that the express terms of the Agreement permit Plaintiffs to make weight loss and fat loss claims in advertisements for dietary supplements when Plaintiffs' possess and rely upon a reasonable basis for those claims, which consists of any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. 2) Relatedly, Plaintiffs seek a judicial declaration that FTC is legally bound by the definition set forth in the Agreement and that FTC may not unilaterally alter that definition. 3) Finally, Plaintiffs seek a declaration that FTC's attempts to demand that Plaintiffs satisfy extracontractual requirements violate the Agreement and are invalid.

Due to FTC's express and imminent threats of prosecution, the present disputes between Plaintiffs and FTC concerning both the meaning of the Agreement between them, and whether FTC must abide by the Agreement, are causing an immediate and ongoing deprivation of Plaintiffs' First and Fifth Amendment rights, which depend upon FTC honoring its Agreement.

The judicial declarations here sought are necessary to resolve this dispute and permit the Parties to govern themselves accordingly.

I. PARTIES

1. Plaintiff Basic Research, LLC ("Basic Research"), is a limited liability company organized and existing under the laws of the State of Utah, with its principal place of business in Salt Lake City, Utah.

2. Plaintiff A.G. Waterhouse, LLC ("A.G."), is a limited liability company organized and existing under the laws of the State of Wyoming, with its principal place of business in Salt Lake City, Utah.

3. Plaintiff Sovage Dermalogic Laboratories, LLC ("Sovage"), is a limited liability company organized and existing under the laws of the State of Utah, with its principal place of business in Salt Lake City, Utah.

4. Plaintiff The Carter-Reed Company, LLC ("Carter-Reed"), is a limited liability company organized and existing under the laws of the State of Utah, with its principal place of business in Salt Lake City, Utah.

5. Plaintiff Dynakor Pharmacal, LLC ("Dynakor"), is a limited liability company organized and existing under the laws of the State of Utah, with its principal place of business in Salt Lake City, Utah.

6. Plaintiff Dennis W. Gay is a citizen of the State of Utah and Manager of each of the limited liability company Plaintiffs.

7. Plaintiff Mitchell K. Friedlander is a citizen of the State of Nevada who, as an advertising copywriter, has written language appearing in certain advertisements to which FTC

objects.

8. Plaintiffs Sovage, Carter-Reed and Dynakor are each affiliates of Plaintiff Basic Research.

9. Defendant Federal Trade Commission is a federal agency authorized by Congress to prohibit unfair and deceptive acts or practices affecting interstate commerce.

II. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 5 U.S.C. §§ 702 and 704, and 28 U.S.C. § 2201.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1402 and 5 U.S.C. § 703.

12. The adjudication and interpretation of a consent agreement with the FTC lies within the exclusive jurisdiction of the federal courts.

III. SUMMARY OF ACTION

13. Plaintiffs and the FTC are parties to a contract in the form of a settlement agreement negotiated by the Parties in 2006 (the "Agreement").

14. The Agreement is a legally binding contract between Plaintiffs and FTC. The Agreement was negotiated at arms-length, over the course of several months, by sophisticated parties. The Agreement is supported by good and valuable consideration, as more fully explained below. The Parties to the Agreement were free to negotiate whatever terms were mutually acceptable to them, or to forgo any Agreement whatsoever.

15. A dispute has arisen between the Parties concerning the meaning and interpretation of one of the fundamental provisions of the Agreement.

16. Among other things, the Agreement defines the rights and duties of Plaintiffs and

the FTC respecting fat loss and weight loss claims in advertisements for Plaintiffs' dietary supplements.

17. The Agreement expressly provides that Plaintiffs may make weight loss and/or fat loss claims for dietary supplements so long as Plaintiffs possess and rely upon a "reasonable basis" (as defined in the Agreement) for such claims.

18. The Agreement specifically provides that Plaintiffs have a "reasonable basis" to make weight loss and/or fat loss claims for dietary supplements so long as Plaintiffs possess and rely upon any one or more of the following: tests or analyses or research or studies or other evidence, based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. *See* Agreement, ¶ II.

19. The Parties understood and agreed when negotiating the language of the Agreement that the "reasonable basis" standard for weight loss and/or fat loss claims defined in the Agreement was specific, clear, and unambiguous, making compliance readily ascertainable. Indeed, absent agreement with FTC concerning a specific and clear standard against which their substantiation would be evaluated going forward, Plaintiffs would not have entered into the Agreement in settlement and resolution of then outstanding disputes between Plaintiffs and FTC, which included causes of action for, among other things, the unlawful web-based publication by FTC of Plaintiffs' trade secrets given to FTC in confidence in response to an administrative subpoena.

20. The Parties understood and agreed when negotiating the definition in the Agreement for the "reasonable basis" standard for weight loss and/or fat loss claims, that the

standard was fixed and did not vary on a case-by-case basis.

21. The Agreement precludes the FTC from imposing upon Plaintiffs, as a condition precedent to advertising, conditions that vary from or exceed those required by the plain and unambiguous language of the negotiated Agreement.

22. To that end, the Agreement specifically provides that:

> **No** agreement, understanding, representation or **interpretation not contained in the Order** or in the Agreement **may be used to vary or contradict the terms of the Order**. Agreement ¶ 6 (Emphasis added).

23. In accordance with FTC rules and practice, the Agreement was published and subject to public comment before being adopted by the Commission. It was entered and became final June 19, 2006. A copy of the Decision and Order formalizing the Agreement is attached hereto as Exhibit A and is incorporated by reference.

24. The Agreement, and the Order which formally adopted the Agreement, constitutes final agency action and establishes the standard under which Plaintiffs may, and are legally entitled to, safely operate.

25. So long as Plaintiffs satisfy the reasonable basis standard contained in the Agreement, they are entitled to make weight loss and/or fat loss claims for their dietary supplements and, as noted, FTC is expressly disallowed from imposing upon Plaintiffs additional extracontractual conditions or requirements.

26. FTC now refuses to abide by the clear and unambiguous terms of the Agreement. FTC is instead improperly attempting to impose upon Plaintiffs additional terms and conditions beyond, and not included within, the plain requirements of the Agreement. Among other things, FTC asserts that for certain of Plaintiffs' weight loss and/or fat loss claims Plaintiffs must meet

additional, ambiguous and changing requirements which are nowhere found in the Agreement. Contrary to the plain language of the Agreement, FTC now also asserts that the applicable substantiation standard for Plaintiffs' advertising claims is not the one defined in the Agreement negotiated by the Parties, but is instead found in some undefined combination of the "Agreement, arbitrary directives contrary to the terms of the Agreement, and FTC law." FTC maintains that satisfaction of the defined reasonable basis standard is not enough. According to FTC, Plaintiffs must change their advertising in response to the FTC staff's changing, subjective desires, which desires are expressed in demands that certain advertising content be removed or qualified without any reasonable or objective basis in the Agreement supporting the staff's demands.

27. In refusing to honor the express terms of its Agreement with Plaintiffs, FTC has now taken the position that Plaintiffs face liability and contempt sanctions if Plaintiffs place certain advertisements or make certain claims for their dietary supplements unless Plaintiffs first satisfy FTC's additional undefined and changing requirements and conditions found nowhere in the Agreement.

28. In these ways and other ways described more fully below, FTC is now in material breach of the Agreement. FTC's breach of the Agreement is manifested by, among other things, FTC's imposition of various unspecified, undefined, subjective and unconstitutionally vague requirements that are different from the plain and unambiguous reasonable basis standard negotiated and agreed upon by the Parties and incorporated into the Agreement.

29. By denying Plaintiffs the right to advertise, and by unilaterally imposing its additional requirements upon Plaintiffs, FTC is violating Plaintiffs' Constitutional rights,

guaranteed by the First and Fifth Amendments, and improperly imposing on Plaintiffs the burden of complying with illegal directives on threat of significant penalties. The FTC has imposed an effective prior restraint on Plaintiffs' First Amendment rights, unconstitutionally chilling Plaintiffs' protected commercial speech, and violating Plaintiffs' Fifth Amendment right to Due Process.

30. FTC's breach through demands to meet additional requirements beyond that required by the Agreement, its post-settlement attempts to re-write its Agreement with Plaintiffs, and its threats of prosecution, its coercion, and its cajolery designed to cause Plaintiffs to fear imminent prosecution unless they abandon speech allowable under the Agreement, constitute violations of Plaintiffs' free speech rights under the First Amendment to the United States Constitution; deprivation of Plaintiffs' rights to Due Process under the Fifth Amendment to the United States Constitution; and imposition of immediate, ongoing and irreparable injury to Plaintiffs, as evidenced by at least the following specific acts:

a. FTC's refusal to accept the tests, analyses, research, studies or other evidence submitted by Plaintiffs and which provide a reasonable basis for its advertising claims, even though those materials expressly satisfy the negotiated and agreed upon standard contained within the Agreement – i.e., any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results;

b. FTC's requirement, as evidenced by its express statement to Plaintiffs, in

violation of the Agreement, that satisfying the clear and unambiguous reasonable basis standard contained in the Agreement is not sufficient, but that more is required of Plaintiffs before they may make weight loss and/or fat loss claims for dietary supplements without fear of imminent prosecution by FTC;

c. FTC's position, as evidenced by its express statement to Plaintiffs, in violation of the Agreement, that there is no clearly defined level of substantiation that the FTC will accept in support of Plaintiffs' advertising claims;

d. FTC's requirement, as evidenced by its express statement to Plaintiffs, varying from and contradicting the express and agreed to terms of the Agreement, that Plaintiffs must "qualify" certain statements made in advertisements depending on some variable, undefined, subjective standard arbitrarily derived by FTC outside the four corners of its Agreement with Plaintiffs;

e. FTC's position, in violation of the Agreement, that Plaintiffs may not make statements in advertising, notwithstanding that those statements are supported by a reasonable basis as required by the Agreement, if FTC finds an expert who can identify criticisms of Plaintiffs' substantiation;

f. FTC's assertion, in violation of the Agreement, that Plaintiffs' advertisements for Akävar™ and Relacore™ violate the negotiated Agreement, notwithstanding that Plaintiffs have a reasonable basis for those advertisements;

g. FTC's demand, in violation of the Agreement, that Plaintiffs immediately cease and desist placing or running advertisements for Akävar™ and Relacore™, notwithstanding that Plaintiffs possess and rely upon a reasonable basis for those

advertisements; and

h. FTC's express threat, in violation of the Agreement, that Plaintiffs run advertisements for Akävar™ and Relacore™ at Plaintiffs' own peril, notwithstanding that Plaintiffs possess and rely upon a reasonable basis for those advertisements.

31. FTC's actions subject Plaintiffs to a direct and immediate dilemma requiring Plaintiffs to choose either not to speak as they are permitted by the Agreement, and thereby sacrifice their First Amendment rights, or to do so and face imminent prosecution from FTC.

32. FTC's actions have in fact chilled Plaintiffs' First Amendment right to freedom of speech in that Plaintiffs have changed advertisements and have withheld placing other advertisements, due to FTC's improper and unlawful threats, and its breach of the Agreement. Indeed, due to FTC's conduct and attempts to change the applicable scientific reasonable basis standard which Plaintiffs must meet, Plaintiffs have no way of knowing what advertisements they can run in the future. Thus, FTC's breach of the Agreement is having a general in terrorem effect, chilling Plaintiffs' First Amendment rights, not only with respect to current advertisements, but also with respect to any advertisements Plaintiffs may run in the future.

33. The FTC has also imposed an unconstitutional prior restraint on Plaintiffs' right to freedom of speech by asserting that Plaintiffs are acting in bad faith if they place advertisements without first submitting those advertisements to, and receiving approval for the advertisements from, the FTC.

34. In addition to violating Plaintiffs' First Amendment rights, FTC has also violated Plaintiffs' right to due process guaranteed by the Fifth Amendment.

35. The Fifth Amendment Due Process clause requires the FTC to abide by, conform

to and respect the conditions upon which Plaintiffs entered into the Agreement and the express terms thereof.

36. The Agreement, adopted as an FTC Order, establishes the standards Plaintiffs are entitled to rely upon in advertising their dietary supplements.

37. Plaintiffs have a constitutionally protected liberty right in the free expression of truthful commercial advertisements, unmolested by the FTC, when those advertisements are supported by a reasonable basis as defined in the Agreement; in their reputation as law-abiding advertisers with whom others may contract without fear of FTC enforcement; and in their right to pursue a living through the marketing and sale of dietary supplements (a core business activity of Plaintiffs) (hereinafter collectively, "liberty interests").

38. Plaintiffs have a property interest in the scientific research supporting their dietary supplement advertisements, in their investments in advertising and market research, in the revenue derived from their dietary supplement advertisements, and in the benefit of their bargain with the FTC, including that the Agreement gives Plaintiffs a right to make weight loss and/or fat loss claims for dietary supplements so long as Plaintiffs possess and rely upon a reasonable basis for their advertising claims which consists of any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results (hereinafter collectively, "property interests").

39. FTC has violated Plaintiffs' Fifth Amendment Due Process rights by depriving Plaintiffs of their liberty and property interests without due process of law by not adhering to the

terms of the Agreement negotiated and agreed upon by Plaintiffs and FTC.

40. The FTC has refused to approve advertisements supported by a reasonable basis as contained in the Agreement, as set forth below.

41. The FTC has not affirmatively disavowed any intention of bringing litigation against Plaintiffs based upon the unconstitutional and improper actions and positions noted above. To the contrary, FTC has very recently threatened to file an action against Plaintiffs for contempt of the Agreement, based upon Plaintiffs' failure to comply with the unconstitutionally vague, changing and undefined requirements and positions complained of above, which FTC now seeks to improperly impose upon Plaintiffs.

42. There is no issue of exhaustion of administrative remedies because Plaintiffs do not seek administrative review. Moreover, the enforcement of the Agreement and the declaration of constitutional rights here sought are matters within the exclusive jurisdiction of the federal courts.

43. The FTC will not concede here or elsewhere that it will require of Plaintiffs only what the Agreement requires, i.e., a reasonable basis for Plaintiffs' advertising claims, defined in the Agreement as any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

44. Thus, an actual, genuine and present dispute exists between the Parties concerning the meaning and interpretation of a critical portion of the Agreement.

45. Accordingly, Plaintiffs seek in this action pursuant to the Declaratory Judgment

Act (28 U.S.C. § 2201) the declarations described in greater detail below, but generally including declarations that:

a. The Agreement operates as a contract defining the rights and duties of the Parties thereto with respect to the subject matter of the Agreement;

b. The Agreement specifically identifies and defines what Plaintiffs must possess and rely upon to form a reasonable basis for weight loss and/or fat loss claims in advertising for Plaintiffs' dietary supplements;

c. The reasonable basis standard contained in the Agreement is clear and unambiguous;

d. The express terms of the Agreement permit Plaintiffs to make weight loss and/or fat loss claims in advertisements for dietary supplements so long as Plaintiffs possess and rely upon a reasonable basis for those claims, which consists of any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results; and

e. FTC has violated Plaintiffs' First and Fifth Amendment rights by demanding that Plaintiffs abide by restrictions on Plaintiffs' protected speech rights and depriving Plaintiffs of their property interests beyond the requirements of the Agreement.

46. Notably, Plaintiffs do not seek specific performance of the Agreement, nor any order directing FTC to comply with the terms of the Agreement or otherwise limiting the FTC's exercise of its administrative authority.

IV. FACTUAL BACKGROUND

A. Plaintiffs' Business

47. Plaintiffs manufacture, advertise, promote, distribute and sell dietary supplements, including a handful of supplements designed to promote weight loss or fat loss.

B. Prior Litigation Between The Parties

1. The Administrative Action

48. In June 2004, the FTC commenced an administrative action (the "Administrative Action") against some of the Plaintiffs, alleging that they had violated the FTC's substantiation requirements.

49. During the Administrative Action, FTC asserted that the respondents in that case were required to have "competent and reliable scientific evidence" before they could make weight loss or fat loss claims for their dietary supplements.

50. The term "competent and reliable scientific evidence" that was at issue in the Administrative Action had no specific definition or meaning. Rather, FTC asserted that what constituted "competent and reliable scientific evidence" changed from case to case, product to product, and advertisement to advertisement, depending on the claims that were being made.

51. Thus, the "competent and reliable scientific evidence" standard FTC was seeking to enforce in the Administrative Action was a subjective, variable standard.

52. Furthermore, FTC refused to identify any specific type, level, quantity or quality of "scientific evidence" that constituted "competent and reliable scientific evidence" under the substantiation standard it was seeking to enforce in the Administrative Action.

53. Thus, on a case-by-case ad and post hoc basis, the FTC imposed its subjective judgment of what constituted competent and reliable scientific evidence.

54. The FTC asserted in the Administrative Action that the "competent and reliable scientific evidence" standard it was seeking to enforce was a mandatory standard that applied, without limitation, to all weight loss and fat loss advertising claims for dietary supplements.

2. The Carter-Reed Action

55. Shortly after commencing the Administrative Action, FTC sent Plaintiff Carter-Reed a letter demanding that Carter-Reed immediately cease and desist making certain advertising claims for its Relacore™ product, one of the two products at issue in this action.

56. In connection therewith, FTC asserted that Carter-Reed's advertisements for Relacore™ were subject to the same vague and undefined "competent and reliable scientific evidence" standard FTC was seeking to enforce in the Administrative Action.

57. Thus, FTC was unlawfully trying to suppress Carter-Reed's commercial speech, protected by the First Amendment, through imposition of an unconstitutionally vague and undefined substantiation standard for advertising claims.

58. In December 2004, Carter-Reed filed a complaint against the FTC, in this Court, civil case number 2:04-CV-01142, styled *The Carter-Reed Company, LLC, v. The Federal Trade Commission* (the "Carter-Reed Action"), which case was assigned to the Honorable Dee Benson. Through that action Carter-Reed sought declaratory and injunctive relief, *inter alia*, to enjoin FTC from its unlawful attempts to suppress Carter-Reed's constitutionally protected commercial speech.

59. The FTC's substantiation standard at issue in the Carter-Reed Action was the

same vague, undefined, constantly changing "competent and reliable scientific evidence" standard FTC claimed in the Administrative Action, which was a mandatory requirement for all weight loss and fat loss claims. The FTC had previously asserted in the Administrative Action that it was a standard applicable to all products, but variable from product to product, depending on the specific claims made. Thus, FTC asserted that the competent and reliable scientific evidence standard which Carter-Reed was challenging as unconstitutionally vague was entirely subjective.

60. Notwithstanding the fact that FTC was asserting in the Administrative Action that its "competent and reliable scientific evidence" standard was mandatory, FTC took a different position in the Carter-Reed Action, asserting that the "competent and reliable scientific evidence" standard was merely a guideline.

61. The "competent and reliable scientific evidence" standard that was at issue in both the Administrative Action and the Carter-Reed Action provided few procedural safeguards, and constituted an unconstitutionally vague and subjective standard.

62. In the Carter-Reed Action, Carter-Reed complained about the FTC's threats against Carter-Reed based upon the allegation that Carter-Reed's advertising claims were not "adequately substantiated" and that the FTC was unlawfully attempting, on a case-by-case ad and post hoc basis, to impose upon Carter-Reed its unconstitutionally vague and subjective judgment of what constituted competent and reliable scientific evidence. *See* Carter-Reed Complaint ¶¶ 7 and 9. The FTC's position left Carter-Reed subject to perpetual threats of prosecution with no means to avoid unlawful and mistaken prosecution because Carter-Reed had no way to discern what FTC meant by "competent and reliable scientific evidence."

63. After the Carter-Reed Action was filed, but before it was voluntarily dismissed pursuant to the later Agreement with FTC, Carter-Reed's attorneys met in Washington, D.C. with Heather Hippsley, a staff attorney with FTC responsible for evaluating Carter-Reed's Relacore™ advertising. After lengthy discussion, Ms. Hippsley, acting on behalf of and as an agent of FTC authorized to do so, agreed during that meeting that Carter-Reed could run modified versions of its advertising for Relacore™ provided that Carter-Reed limited its fat loss claims to reduction of stress-induced belly fat, as opposed to belly fat in general. Carter-Reed agreed to that limitation and so modified its advertisements for Relacore™. Thereafter, Carter-Reed advertised and sold its Relacore™ product for more than two years without objection from FTC. During that same period, and in reliance on, among other things, Ms. Hippsley's statement as a representative of the FTC, Carter-Reed dismissed the Carter-Reed Action as part of the settlement of the FTC Action.

3. The Agreement

64. After Plaintiffs spent millions of dollars litigating with the FTC in the Administrative Action and the Carter-Reed Action, both actions were ultimately resolved through the Agreement described above.

65. The Agreement is a contract between the Plaintiffs and FTC. The terms of the Agreement exclusively govern Plaintiffs' weight loss and fat loss claims in advertising for Plaintiffs' dietary supplements.

66. Pursuant to the Agreement, FTC and Plaintiffs agreed to a specific, clear and unambiguous standard that identifies what Plaintiffs would be required to possess in order to have a reasonable basis for weight loss and/or fat loss claims for dietary supplements without

molestation by or interference from FTC, thus preventing the FTC from imposing any additional, vague, subjective, undefined and unarticulated extracontractual requirements on Plaintiffs.

67. Pursuant to the terms of the Agreement, Plaintiffs and FTC agreed, among other things, that in connection with the manufacturing, labeling, advertising, promotion, offering for sale, and sale or distribution of the products at issue in the Administrative Action, or any substantially similar products, that Plaintiffs would not represent that such products cause weight loss or fat loss unless at the time any such representations were made Plaintiffs "possess and rely upon a reasonable basis for the representation . . . ." (Agreement, ¶¶ I and II.)

68. Pursuant to the terms of the Agreement, Plaintiffs and FTC agreed that, by definition, Plaintiffs had a "reasonable basis" to make weight loss and/or fat loss claims when Plaintiffs possessed and relied upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. (Agreement, ¶ II).

69. As part of the consideration for the Agreement, and in order to obtain the clear and unambiguous reasonable basis standard contained in the Agreement, Plaintiffs paid the FTC the sum of Three Million Dollars ($3,000,000.00).

70. As further consideration for FTC's agreement that Plaintiffs would be entitled to make weight loss and/or fat loss claims when Plaintiffs possess a reasonable basis as defined by the clear and unambiguous language of the Agreement, Plaintiffs agreed to the following: (a) Carter-Reed dismissed, without prejudice, the Carter-Reed Action and (b) Plaintiffs waived the

damage claims they had against the FTC and members of FTC's staff, which claims related to FTC's violation of a protective order entered in the Administrative Action and violation of related federal statutes, which violations occurred by virtue of the FTC publishing on the Internet Plaintiffs' highly confidential financial and trade secret information, which publication was expressly prohibited by the terms of the protective order and federal law. FTC's violation of the protective order and related civil and criminal statutes was so egregious that had the FTC been a private litigant, serious sanctions and penalties would no doubt have been imposed. Indeed, the administrative law judge assigned to the Administrative Action indicated in a written opinion that the violation was so egregious that the FTC should consider as an appropriate sanction dismissing with prejudice the complaint filed by FTC in the Administrative Action.

71. Like any party to a contractual agreement, FTC must honor its contractual agreements, including the Agreement at issue here.

72. Under the Agreement FTC must accept substantiation that meets the reasonable basis standard defined in the Agreement, and FTC is not free to reject tests, analyses, research, studies, or other evidence Plaintiffs possess simply because FTC has decided, post hoc, that it now desires to impose additional extracontractual requirements and obligations that were not negotiated and agreed upon by the parties, and thus are not required, or even allowed, by the express terms of the Agreement.

73. Throughout its negotiations with FTC over what Plaintiffs must possess to have a "reasonable basis" to make weight loss and/or fat loss claims in advertising, Plaintiffs specifically refused to agree to any definition that would allow the FTC to continue to decide, on a case-by-case basis, what it felt constituted "competent and reliable scientific evidence," or

which would allow the FTC to continue to impose unconstitutionally vague, undefined, or unspecified additional obligations that are not expressly contained within the four corners of the Agreement. Rather, Plaintiffs demanded a fixed, defined standard, precisely to prevent FTC from deciding subjectively, on a case-by-case basis what limits, restrictions or qualifications FTC may have decided to apply to Plaintiffs' substantiation. Of course, the parties to the Agreement, including the FTC, ultimately agreed upon the clear, unambiguous and fixed standard set forth in the Agreement.

74. The Agreement, and the clear and unambiguous reasonable basis standard defined therein, does not allow the FTC to apply an extracontractual, evolutionary and dynamic standard that changes on a product to product or case-by-case basis, depending on FTC's whim or fancy.

75. Pursuant to the clear and express terms of the Agreement, the only relevant question is whether Plaintiffs possess and rely upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. Once Plaintiffs have met the reasonable basis standard contained in the Agreement, the FTC is contractually obligated to accept Plaintiffs' reasonable basis, and FTC is not free to impose additional extracontractual obligations as conditions precedent to Plaintiffs' advertising.

76. Moreover, by the Agreement's express terms, FTC and Plaintiffs agreed not to expand on or impose additional requirements or conditions beyond those "contained in the [Consent] Order."

77. After having bought its peace through a settlement that limited the reasonable

basis standard to the precise definition contained in the Agreement, Carter-Reed dismissed on or about August 21, 2006 its claims against FTC without prejudice. Plaintiffs also agreed not to pursue other valuable claims they possessed but which had not yet been asserted in litigation.

C. Post Agreement Conduct

78. Plaintiffs spent millions of dollars obtaining the clarification that is embodied in the Agreement, and have spent millions of dollars more developing and acquiring products and advertising in reliance on the Agreement.

79. In addition, Plaintiffs have expended an extraordinary amount of time and money developing and implementing a conscientious, scientific and copious compliance program that utilizes highly regarded, world-class outside experts who assist Plaintiffs with evaluating scientific substantiation to ensure compliance with the specific reasonable basis standard in the Agreement.

80. The products that are the subject of the unlawful and improper demands by FTC, which necessitate this Action, are a dietary supplement weight loss product called Akävar™ and a dietary supplement product called Relacore™, which is designed to assist with stress related belly fat. Plaintiffs have invested millions of dollars researching, developing and bringing these products to market. If they cannot be advertised as weight loss and fat loss products, respectively, Plaintiffs' entire investment in the products and advertising will be lost.

81. Plaintiffs have on staff highly qualified research scientists who review and analyze published studies, clinical trials, industry literature and journal articles, scientific data, and other evidence largely generated by independent third-parties. Plaintiffs' in-house experts evaluate the science to determine whether the ingredients studied may provide benefits to

consumers in commercial supplements and, if so, what specific claims about those potential dietary supplements are supported by the reviewed science. The in-house scientists also evaluate the scientific material to determine if it is based on the expertise of professionals in the relevant area, is based on scientific evidence conducted and evaluated by persons qualified to conduct and evaluate the science, and whether those experts conducted and evaluated the science following procedures generally accepted in the profession to yield accurate and reliable results.

82. In addition to its in-house scientists, Plaintiffs retain leading authorities in the study of obesity research to evaluate scientific evidence its in-house counsel deem supportive of weight loss and/or fat lass claims under the Agreement standard. Those outside authorities assist Plaintiffs' compliance efforts by independently evaluating the scientific evidence concerning the various dietary ingredients to determine whether the evidence was conducted and evaluated in an objective manner by qualified individuals using procedures generally accepted in the profession to yield accurate and reliable results.

83. In no instance since entering into the Agreement with FTC in 2006 have Plaintiffs introduced into the market any dietary supplement for weight loss or fat loss without following the aforementioned scientific vetting process for every advertising claim. In no instance has a weight loss or fat loss claim been made devoid of substantiation in the form of: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

84. By the time Plaintiffs bring a dietary supplement to market, the scientific evidence supporting the supplement's efficacy has been thoroughly vetted internally and with

outside experts. Plaintiffs bring no supplement to market unless, based on the scientific evidence, the advice of their staff scientists, and the advice of leading authorities retained by Plaintiffs, Plaintiffs are confident they have satisfied their obligations under the Agreement.

85. Largely as a result of this scientific vetting, Plaintiffs are confident that their consumers' expectations (set, of course, by Plaintiffs' advertising claims) for Plaintiffs' dietary supplements will be met or exceeded and therefore Plaintiffs can (and do) offer a 100% unconditional 30 day money-back guarantee on every supplement they sell – a guarantee they honor without exception.

86. As noted, two different specific dietary supplements marketed, sold and distributed by Plaintiffs are directly at issue in this case as a result of the FTC's unlawful attempts to require Plaintiffs to satisfy additional extracontractual requirements. They are: (1) Akävar™, a supplement containing a patented herbal combination of Yerbé Mate, Guarana and Damiana ("YGD"), proven to cause significant weight loss among test subjects who took the YGD combination 15 minutes before main meals and who were specifically instructed not to change their diet or exercise routines; and (2) a clinically proven stress and anxiety reduction supplement called Relacore™, that when used in conjunction with diet and exercise helps reduce stress-induced belly fat in subjects.

87. Plaintiffs' substantiation materials for these supplements consist of literally thousands of pages of studies, reviews, articles, clinical trials, in-house studies, data and other evidence supporting the weight loss and fat loss statements made by Plaintiffs in advertising for Akävar™ and Relacore™.

88. As required by Section XII of the Agreement, Basic Research filed with FTC on

or about September 28, 2006 a comprehensive Compliance Report setting forth in detail the manner and form in which Plaintiffs had complied with the terms of the Agreement.

89. As part of the compliance process, Basic Research supplied FTC with its advertisements containing weight loss or fat loss statements, together with the tests, analyses, research, studies, or other evidence that provided the reasonable basis for statements in the advertisements.

90. For every weight loss and fat loss claim made by Basic Research in its advertisements for Akävar™ and Relacore™, Basic Research supplied FTC with one or more tests, analyses, research, studies and other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

91. As an example, for illustrative purposes only, in the case of studies published in peer-reviewed journals, those studies on their face constitute tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. Indeed, the peer-review process itself ensures that the published science was "conducted and evaluated in an objective manner by persons qualified to do so" and relies upon "procedures generally accepted in the profession to yield accurate and reliable results."

1. The FTC Refuses To Follow Its Long Standing Advertising Guidance For Products That Help Curb Appetite

92. The FTC for years has published on its website advertising guidelines. These guidelines were adopted by FTC following input and review by a panel of experts with whom

FTC consulted to address issues with advertising for weight loss products.

93. The purpose of the FTC's advertising guidelines is to help persons or entities who promote weight loss or fat loss products, such as Plaintiffs, understand how to comply with the FTC Act.

94. As part of its advertising guidelines, FTC for years has identified on its website and in materials distributed to advertisers certain weight loss statements the FTC calls "Red Flag" claims. These are claims FTC says it considers scientifically infeasible and, therefore, *per se* false. FTC's "Red Flag Claim 2" is attached as Exhibit B and incorporated by reference.

95. In connection with its "Red Flag" claims, the FTC has expressly identified a specific statement that companies such as Plaintiffs may make in advertising for products that help curb appetite. Specifically, the FTC provides the following guidance on its official website:

> Some products may help curb appetite or cravings. For these products, its [sic] okay to say people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product.

96. One of the products at issue in this case is Akävar™.

97. Akävar™ is a product that is scientifically proven to help curb appetite.

98. Indeed, at times during its meetings with Plaintiffs FTC has conceded that Akävar™ works as an appetite suppressant – i.e., it helps curb appetite.

99. During the early part of 2007, Basic Research and Dynakor began advertising Akävar™ using the headline "Eat All You Want And Still Lose Weight."

100. Basic Research and Dynakor chose the "Eat All You Want And Still Lose Weight" headline in reliance on the FTC's own guidance on its website which clearly states that, for products such as Akävar™ which "may help curb appetite or cravings . . . its [sic] okay to say

people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product."

101. Despite the fact that FTC has previously admitted that Akävar™ may help curb appetite, and notwithstanding the statement on its own website that for such products "its [sic] okay to say people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product[,]" FTC has taken the position that Plaintiffs cannot say in advertisements that people using Akävar™ "can eat what they want and still lose weight" even though the advertisements make it clear "that people will not want to eat as much food as before they started using the product."

102. Indeed, FTC has now taken the contradictory position that the words "eat all you want and still lose weight" may not at all appear in any advertisement for Akävar™.

2. Akävar™ and Relacore™ Advertisements

103. Advertisements for Akävar™ and Relacore™ are directly at issue in this case. Contrary to the plain and unambiguous language of the Agreement, and in violation of Plaintiffs' First Amendment rights to free speech and Fifth Amendment rights to Due Process, FTC now asserts that Plaintiffs are required before they may advertise Akävar™ and Relacore™ to meet additional vague and undefined substantiation requirements not contained in, and beyond that which is required by, the Agreement.

104. FTC now takes the contradictory position that Plaintiffs do not have a reasonable basis for their claims of weight loss and fat loss for Akävar™ and Relacore™, respectively, even though FTC has expressly admitted to Plaintiffs that the materials submitted by Plaintiffs in support of those products satisfy the reasonable basis standard defined in the Agreement – i.e.,

FTC has expressly admitted that Plaintiffs' substantiation for Akävar™ and Relacore™ consists of one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

105. Provided below is a sampling of the literally thousands of pages of substantiation Plaintiffs possess and rely upon for Akävar™ and Relacore™ advertising claims -- substantiation rejected by FTC notwithstanding that Plaintiffs have satisfied the "reasonable basis" standard defined in the Agreement.

i. Akävar™

106. Akävar™ contains herbal ingredients that have been used for centuries in various ways and somewhat recently became recognized worldwide for their proven weight loss effects. These herbs, Yerbé Mate (a South American evergreen tree; botanical name *ilex paraguariensis*), Guarana (an Amazon shrub; botanical name *paulina cupana*), and Damiana (a shrub found in Latin America and West Indies; botanical name *turnera diffusa*) (collectively, "the YGD herbal combination") have been the subject of many studies over the past several years. The studies and reviews show that the YGD herbal combination produces weight loss by suppressing appetite and thus systemically reducing caloric intake automatically, without dieting or exercise.

107. One of the studies conducted by researchers on the YGD herbal combination, Andersen and J. Fogh, *Weight Loss and Delayed Gastric Emptying Following a South American Herbal Preparation in Overweight Patients*, 14 Journal of Human Nutrition and Dietetics 3, 243-50 (2001) ("Andersen/Fogh Study"), demonstrated significant weight loss in study participants

who were specifically instructed not to alter their ordinary dietary and exercise routines. Those participants taking the YGD herbal combination 15 minutes before their main meals lost 11.2 pounds in 45 days, which was 10.56 pounds more weight loss than the placebo group.

108. The Andersen/Fogh Study demonstrated that subjects in the experimental group lost substantial weight by doing nothing more than taking the YGD combination 15 minutes before their main meals.

109. Consistent with the results of the Andersen/Fogh Study, advertising for Akävar™ states that people who take Akävar™ 15 minutes before their main meals may lose weight without altering their ordinary diet and exercise routines – exactly what was shown in the Study.

110. The substantiation materials Plaintiffs submitted to the FTC include a Declaration of Dr. Soren Toubro, a medical doctor, leading nutrition researcher and weight loss expert at the University of Copenhagen. Dr. Toubro's Declaration is among the body of tests, analyses, research, studies, or other evidence supplied to FTC as evidence of Plaintiffs' "reasonable basis" for statements made in Akävar™ advertising.

111. Dr. Toubro reviews in his Declaration the Andersen/Fogh Study, which was a 2001 randomized, double blind, placebo controlled, peer-reviewed, published clinical study by two medical researchers documenting the weight loss effects of the YGD herbal combination. Dr. Toubro opines that the study was "well designed" and notes that, based on the results of the study, the YGD herbal combination compares favorably with prescription weight loss medications. Indeed, the Andersen/Fogh Study demonstrated that the YGD herbal combination produced better weight loss results than prescription weight loss medications, even though the Study participants were told not to alter their ordinary dietary and exercise routines, and without

the messy side effects which accompany prescription medications.

112. The Andersen/Fogh Study is a test or research or study, based on the expertise of professionals in the field, conducted and evaluated in an objective manner using procedures accepted in the profession to yield accurate and reliable results. It is precisely one of the types of evidence the Agreement contemplates Plaintiffs may possess and rely on for a reasonable basis to make weight loss statements in advertising, and is precisely the type of evidence which the FTC is contractually bound to accept for that purpose.

113. Dr. Toubro's conclusions concerning the Andersen/Fogh Study are also consistent with other studies and reviews of various YGD research studies showing the statistically-significant weight loss effects of the YGD herbal combination.

114. While Plaintiffs have relied upon and continue to rely on substantial amounts of tests, analyses, research, studies, or other evidence for statements made in advertising for Akävar™, Dr. Toubro's Declaration standing alone, like the Andersen/Fogh Study, meets the agreed upon reasonable basis standard set forth in the Agreement, and provides by itself a reasonable basis for Plaintiffs' advertising statements. Dr. Toubro's Declaration is an analysis based on the expertise of a professional in the field, conducted in an objective manner by a person qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. It is precisely the type of evidence the Agreement contemplates Plaintiffs may possess and rely on for weight loss statements in advertising, and is precisely the type of evidence the FTC is contractually bound to accept for that purpose.

115. FTC spoke with Dr. Andersen, of the Andersen/Fogh Study, concerning his study. Dr. Andersen confirmed to FTC that the Andersen/Fogh Study showed that study participants

lost weight simply by taking a pill containing the YGD herbal combination 15 minutes prior to main meals. Dr. Andersen also confirmed to FTC that study participants were specifically instructed to make no change to their diet and exercise routines.

116. In meetings with Plaintiffs and their attorneys, FTC expressly admitted that the Andersen/Fogh Study meets the reasonable basis standard set forth in the negotiated Agreement.

117. FTC also expressly admitted that the body of tests, studies, research, analyses and other evidence submitted by Plaintiffs in support of their advertising for Akävar™ literally satisfies the reasonable basis standard set forth in the negotiated Agreement.

118. Despite those admissions, and notwithstanding that Plaintiffs plainly possess for Akävar™ claims tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results, FTC now seeks unlawfully to impose upon Plaintiffs additional, vague and subjective extracontractual requirements contained nowhere in the four corners of the Agreement.

119. However, the FTC is contractually bound to accept the Andersen/Fogh Study, the Toubro analysis and the other materials submitted by Plaintiffs, and is prohibited from attempting to impose upon Plaintiffs, upon threat of prosecution and litigation, other requirements or obligations that are not contained within the four corners of the Agreement.

120. FTC's rejection of materials that satisfy the defined standard in the Agreement and demand that Plaintiffs satisfy extracontractual requirements constitutes a material breach of the Agreement. Through that material breach of the Agreement, FTC has violated, and is

continuing to violate, Plaintiffs' First Amendment right to freedom of speech and Fifth Amendment right to Due Process.

ii. Relacore™

121. Relacore™ contains herbs, vitamins, and minerals that, when taken in combination with diet and exercise, reduce stress, thereby resulting in a reduction in stress-induced visceral (belly) fat by decreasing levels of stress-induced cortisol. Higher levels of stress and anxiety are scientifically associated with higher levels of a hormone called "cortisol" in the body. High levels of stress-induced cortisol have many unhealthy effects, including increased retention of visceral (belly) fat. Numerous studies support the conclusion that decreases in stress and anxiety decrease stress-related cortisol levels in the body, which in turn results in a reduction in stress-induced visceral (belly) fat.

122. At least two well designed, published, peer-reviewed, placebo controlled scientific studies demonstrate that the active ingredients in Relacore™ reduce stress and anxiety.

123. The scientific materials Plaintiffs submitted to the FTC for Relacore™ include an Affidavit of Dr. Sten Madsbad, a professor of internal medicine and endocrinology at the University of Copenhagen and the Chief Physician in the Department of Endocrinology at Hvidover University Hospital at the University of Copenhagen. Dr. Madsbad explains in his Affidavit the science behind Relacore™ and opines that statements made in Plaintiffs' advertising for Relacore™ are substantiated by the scientific literature.

124. Dr. Madsbad conducted a comprehensive review of the relevant scientific literature relating to Relacore™. Among other things, Dr. Madsbad identified the following in his Affidavit: (1) fourteen separate studies and articles supporting the claim that stress increases

cortisol; (2) seventeen separate studies and articles supporting the claim that a stress-induced rise in cortisol increases visceral (belly) fat; and (3) sixty-one separate studies and articles supporting the claim that the active ingredients in Relacore™ reduce stress-induced cortisol production. Dr. Madsbad's detailed Affidavit, proceeding ingredient-by-ingredient, identifies voluminous studies and articles that support the claims made by Plaintiffs in advertising for Relacore™.

125. While Plaintiffs have relied and continue to rely on substantial amounts of tests, analyses, research, studies, or other evidence for statements made in advertising for Relacore™, Dr. Madsbad's Affidavit standing alone meets the reasonable basis standard set forth in the Agreement, as it is an analysis based on the expertise of a professional in the relevant area, that was conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

126. Dr. Madsbad's Affidavit is precisely the type of evidence the Agreement contemplates Plaintiffs may possess and rely on for weight loss and/or fat loss statements in advertising, and is precisely the type of evidence the FTC is contractually bound to accept for that purpose.

127. Notwithstanding that Plaintiffs' support for their Relacore™ product satisfies the reasonable basis standard defined in the Agreement, FTC now seeks unlawfully to impose upon Plaintiffs additional, vague and subjective extracontractual requirements contained nowhere in the four corners of the Agreement.

128. However, the FTC is prohibited from imposing upon Plaintiffs extracontractual requirements or obligations not contained within the four corners of the Agreement.

129. FTC's demand that Plaintiffs satisfy additional extracontractual requirements and

obligations constitutes a material breach of the Agreement. Through that material breach, FTC has violated, and continues to violate, Plaintiffs' First Amendment right to freedom of speech and Fifth Amendment right to Due Process.

3. The FTC Has Breached the Agreement and, through that Breach, Has Violated Plaintiffs' First Amendment Rights to Freedom of Speech and Fifth Amendment Rights to Due Process

130. After receiving Basic Research's Compliance Report and supporting materials, FTC requested substantial additional information, including information neither contemplated nor required under the terms of the negotiated Agreement. For example, the FTC demanded information concerning products manufactured, labeled, advertised, promoted, offered for sale, sold or distributed outside the United States by one or more of the Plaintiffs since the date the Agreement issued on June 19, 2006.

131. The FTC Administrative Action concerned only domestic sales of the products offered by Basic Research and the other named Respondents. The manufacture, labeling, advertising, promotion, offering for sale, sale or distribution of products outside the United States is not covered by the Agreement, has no significant effect on any of Plaintiffs' competitors in the United States, is governed by the laws of foreign countries and is not within the jurisdiction of the FTC. Thus, under the negotiated Agreement, the FTC was not, and is not, entitled to any information concerning products manufactured, labeled, advertised, promoted, offered for sale, sold or distributed by Plaintiffs outside the United States.

132. Despite the fact that FTC was not entitled to that information under the Agreement, the FTC essentially threatened to commence an action against Basic Research unless the information was provided. FTC's demand was a breach of the Agreement negotiated by the

Parties. Nonetheless, in an effort to avoid litigation with FTC, Basic Research provided under protest much of the additional information requested by FTC, including information neither contemplated nor required to be provided under the Agreement.

133. Despite the fact that Basic Research and its affiliated companies submitted to the FTC substantiation for their weight loss and fat loss advertising claims that meets and exceeds the reasonable basis standard contained in the Agreement, the FTC refused to honor the contract entered into by Plaintiffs and the FTC.

134. Notwithstanding Basic Research's demonstrated compliance with the Agreement, FTC has breached and continues to breach the Agreement. FTC's breach is material and has caused irreparable harm to Plaintiffs through the chilling effect FTC's unlawful conduct has had on Plaintiffs' exercise of its First Amendment right to freedom of speech and the FTC's violation of Plaintiffs' Fifth Amendment right to Due Process.

135. Even more troubling to Plaintiffs, FTC admits and acknowledges it is imposing different requirements upon Plaintiffs than the clear, unambiguous and objective standard negotiated between the Parties and defined in the Agreement. FTC has instead imposed additional extracontractual requirements and obligations not contained within the Agreement, and applied to Plaintiffs' advertising the same vague and undefined "standard" that was squarely at issue in the Carter-Reed Action, which standard FTC expressly disavowed as a "rule" in briefing submitted in that litigation to this Court.

136. FTC has expressed to Plaintiffs its position that even though the substantiation submitted for Akävar™ and Relacore™ meets the reasonable basis standard defined in the Agreement, Plaintiffs may only make "qualified" weight loss claims for Akävar™, and

"qualified" fat loss claims for Relacore™, and that FTC is requiring an additional, extracontractual, undefined level, degree, quality, and quantity of scientific evidence before Plaintiffs may make so-called "unqualified" statements concerning weight loss or fat loss in advertising for Akävar™ and Relacore™.

137. However, the Agreement contains no provision whatsoever which allows the FTC to impose a "qualified" or "unqualified" condition on Plaintiffs' weight loss and fat loss claims, a distinction which is subjective, vague and ambiguous, and which is exactly the type of vague standard the Agreement was designed to prohibit. In fact, the words "qualified" and "unqualified" appear nowhere in the Agreement. FTC's attempt to impose a "qualified" and "unqualified" distinction on Plaintiffs' weight loss and fat loss advertising is unlawful, and is directly contrary to the express and clear definition in the Agreement.

138. The Agreement is plain and unambiguous on its face. Once Plaintiffs have a reasonable basis for claims, as defined by the clear and unambiguous language set forth in the Agreement, FTC is obligated to accept that reasonable basis, and Plaintiffs are entitled to make weight loss and fat loss claims. There is no requirement that the claims be "qualified" as demanded by the FTC or that Plaintiffs meet additional requirements and obligations beyond those specifically identified in the Agreement.

139. The Agreement clearly and unequivocally states that Plaintiffs are entitled to make weight loss and fat loss claims for dietary supplements if Plaintiffs possess and rely upon any one of the following: tests or analyses or research or studies or other evidence, so long as they are "based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally

accepted in the profession to yield accurate and reliable results."

140. The very notion that different of Plaintiffs' advertising statements require different levels of substantiation, or that Plaintiffs must meet additional undefined requirements for certain unspecified advertising claims, does violence to the clear and unambiguous reasonable basis standard negotiated and agreed upon by the Parties and incorporated into the Agreement.

141. In further violation of Plaintiffs' rights under the Agreement, as well as Plaintiffs' First Amendment right to free speech and Plaintiffs' Fifth Amendment right to Due Process, FTC has simply refused even to consider some types of scientific evidence submitted by Basic Research in support of Plaintiffs' advertising statements because it is not the "type" of evidence FTC's staff attorneys prefer, even though the scientific evidence rejected by FTC fits squarely within the reasonable basis standard defined in the Agreement.

4. Unlawful and Unconstitutional Demands Made by the FTC, and Plaintiffs' Efforts to Avoid Litigation with the FTC, Even Though the FTC Was in Breach of the Agreement

i. The November 2, 2007 Letter

142. By letter dated November 2, 2007 ("November 2 Letter"), FTC informed Plaintiffs it had concluded that Plaintiffs were in violation of the Agreement. A copy of the November 2 Letter is attached hereto as Exhibit C and is incorporated by reference.

143. In the November 2 Letter, FTC stated it had concluded that certain of Plaintiffs' advertising claims, including claims for Akävar™ and Relacore™, were not supported by the additional requirements which FTC asserts it may impose upon Plaintiffs under the Agreement, even though those additional requirements are found nowhere in the Agreement. FTC demanded

that Plaintiffs "promptly revise their advertisements to comply with the" additional terms FTC sought to impose.

144. FTC's position concerning Plaintiffs' advertising for Relacore™ was particularly troubling to Plaintiffs as Carter-Reed had been running for approximately two years the modified version of its Relacore™ advertisement which contained the claim previously approved by FTC staff attorney Hippsley. Moreover, any dispute with FTC concerning the content and support for Relacore advertising had been resolved as part of the global settlement between the parties that resulted in the 2006 Agreement and dismissal of the Carter-Reed Action against FTC.

145. Not once in the intervening two years after the FTC had agreed that Carter-Reed could make the claim FTC now asserts violates the Agreement, did FTC raise any concern or objection to Plaintiffs' use of the modified Relacore™ advertisements.

146. Rather, the FTC first asserted that Relacore™ advertisements violated the Agreement only after Basic Research and Dynakor began advertising their Akävar™ product.

147. As explained above, Plaintiffs provided FTC with literally thousands of pages of scientific materials for Plaintiffs' advertising claims for these and all their dietary supplements for which Plaintiffs make weight loss or fat loss statements. That body of scientific materials included volumes of tests, analyses, and studies, as well as research and other evidence, as contemplated and required under the Agreement.

148. FTC's conduct, however, goes far beyond demanding that Plaintiffs meet different requirements than what is required by the clear and unambiguous reasonable basis standard negotiated and incorporated in the Agreement.

149. In its November 2 Letter, FTC also claimed that certain of Plaintiffs'

advertisements made or implied so-called "Red Flag" claims. As just one example, FTC asserted in its November 2 Letter that Plaintiffs' advertisements for Akävar™ implied that Akävar™ would cause substantial weight loss in **all users**. FTC's position is contradicted by the plain language in the advertisements, which read in relevant part:

> FACT: TESTS PROVE ***VIRTUALLY*** 100% SUCCESS!
>
> That's right. While no diet pill can possibly work for everybody (that's why there's a money-back guarantee) scientific documentation has confirmed that virtually everyone in the study who used Akävar™-20/50's active compound (23 out of 24 participants, to be exact) lost weight.
>
> (Emphasis added.)

150. FTC has confirmed it ran no copy testing of any kind to determine what, if any, unstated claims may or may not be implied to potential consumers in Plaintiffs' Akävar™ advertising. Instead, FTC's staff attorneys acknowledge they merely reviewed the advertisements themselves and apparently divined, without the benefit of any data or evidence, that Plaintiffs' potential consumers would take away from advertising for Akävar™ a number of unstated, so-called implied claims expressed nowhere in the text of the advertisements themselves and contradicted by the express language of the ads.

151. The vagueness and uncertainty of FTC's position and the peril at which it puts Plaintiffs is further illustrated by FTC's objections to Plaintiffs' Akävar™ advertising. The November 2 Letter objects to Plaintiffs' Akävar™ advertisement as follows:

> Explanation of Violation: Advertisements for Akävar represent that users can eat all they want and still lose weight, which conveys the implied claim that users can eat unlimited amounts of food and still lose weight. The Andersen/Fogh study does not constitute competent and reliable scientific evidence that users taking Akävar can eat unlimited amounts of food and still lose weight because the researchers did not monitor the caloric intake of those subjects who took the YGD compound and lost weight. (Emphasis added.)

152. This assertion by the FTC grossly misrepresents Plaintiffs' advertisements in that Plaintiffs never claimed in any advertising for Akävar™ that "users can eat unlimited amounts of food and still lose weight." Moreover, FTC's unsupported proposition is nonsensical on its face – no person can possibly eat unlimited amounts of food. It's physiologically impossible. Importantly, no reasonable consumer could ever believe such a claim, even if it were made.

153. Notwithstanding that Basic Research unquestionably had a reasonable basis for the weight loss and fat loss statements in its advertising, comprised of tests, analyses, research, studies, or other evidence, as specifically identified in the Agreement, Plaintiffs made every effort to address the concerns raised in FTC's November 2 Letter.

ii. The December 17, 2007 Meeting

154. On December 17, 2007, after responding to FTC's November 2 Letter and after submitting additional requested materials, Plaintiffs' counsel, in-house compliance officer, and Plaintiff Friedlander traveled to Washington, D.C., to meet with James Kohm, Associate Director of the Enforcement Division, Bureau of Consumer Protection at the FTC, and members of his staff.

155. During the December 17, 2007 meeting, Mr. Kohm, acting for and on behalf of the FTC, specifically stated that Plaintiffs could use the "Eat All You Want And Still Lose Weight" headline in Akävar™ advertisements if Plaintiffs made it clearer in the advertisements that consumers taking Akävar™ can "eat all they want and still lose weight" because they will want to eat less.

156. Although Basic Research believed its original Akävar™ advertising was more than adequately supported by a reasonable basis as defined in the Agreement, and made it clear

that consumers can eat all they want and still lose weight with Akävar™ because consumers will want to eat less, Basic Research nevertheless agreed to make, and did immediately make, the changes demanded by FTC at the December 17 meeting, including inclusion in all Akävar™ advertising of a prominent, brightly-colored box with the highlighted heading "STOP: READ THIS BEFORE YOU BUY AKÄVAR-20/50" in which the very clarification demanded by FTC was included: "Losing weight is all about reducing caloric intake, and Akävar™ is a new-generation calorie-restricting compound that lets you eat all you want… because you want to eat less." (This advertisement is sometimes hereinafter referred to as the "First Revised Akävar™ Advertisement." A copy of this advertisement is attached hereto as Exhibit D).

157. FTC also demanded at the December 17, 2007 meeting that Plaintiffs address a handful of questions relating to the tests, analyses, research, studies, or other evidence submitted for several of Plaintiffs' products. Plaintiffs provided everything requested and answered to the best of their abilities FTC's questions.

iii. The February 20, 2008 Letter

158. Notwithstanding Plaintiffs' changes to advertising for Akävar™ and submission of still more information and evidence requested by the Staff, FTC sent Plaintiffs a letter dated February 20, 2008 (the "February 20 Letter") (a copy of which is attached hereto as Exhibit E) wherein the FTC reversed course on comments made during the December 17, 2007 meeting and, instead, reverted back to its previous position that Plaintiffs lacked a reasonable basis for statements made even in the Akävar™ advertisements revised following the December meeting and incorporating the changes demanded by FTC at that meeting.

159. Furthermore, contrary to the express statement made by Mr. Kohm during the

December 17, 2008 meeting that Plaintiffs could use the "Eat All You Want And Still Lose Weight" headline if Plaintiffs made it clearer in the Akävar™ advertisement that consumers could eat all they want because they would want to eat less, the FTC asserted in the February 20 Letter that the revised Akävar™ advertisement violated the Consent Order because it used that specific headline.

160. The FTC's February 20 Letter also contradicts the statement on the FTC website that, for products that help curb appetite, "its [sic] okay to say people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product[,]" stating that "[i]t is staff's view that such claims are scientifically infeasible at the current time." *See* February 20 Letter n. 2. Thus, advertisers, such as Plaintiffs, are put in peril notwithstanding their adherence to the FTC's official guidance with respect to products that may help curb appetite.

161. Basic Research relied on the FTC's guideline, which is intended to help marketers understand how to comply with the FTC Act, and which is posted on the FTC's own website, when it selected the headline and marketing campaign for Akävar™, which is scientifically shown to cause weight loss by suppressing appetite – a fact expressly stated in the advertising for Akävar™.

162. Moreover, the statement "eat all you want and still lose weight" is fully supported by the tests, analyses, research, studies, or other evidence which Plaintiffs possess, including the Andersen/Fogh Study, in which participants taking the YGD herbal combination lost 11.2 pounds in 45 days, which weight loss was necessarily caused by an automatic reduction in caloric intake. In other words, the study participants ate all they wanted and still lost weight due

to the YGD herbal combination reducing their appetite for food.

163. FTC also stated in the February 20 Letter that Plaintiffs lacked a reasonable basis for stress-induced belly fat statements made in Relacore™ advertising.

164. Again, in an effort to avoid litigation (if at all possible), and notwithstanding that Plaintiffs easily met and exceeded the reasonable basis standard set forth in the Agreement, Plaintiffs responded to FTC's concerns by submitting still more evidence supporting their advertising claims and addressing still more concerns raised in FTC's correspondence.

iv. The March 14, 2008 Meeting

165. Plaintiffs' counsel and Mr. Friedlander again flew to Washington, D.C., and met with Mr. Kohm and other FTC staff attorneys on March 14, 2008.

166. FTC expressly stated during the March 14, 2008 meeting that Plaintiffs' tests, analyses, research, studies, or other evidence demonstrated that Akävar™ was an appetite suppressant. Specifically, Mr. Kohm, acting for and on behalf of the FTC, expressly acknowledged during the March 14, 2008 meeting that Plaintiffs' tests, analyses, research, studies, or other evidence demonstrated that Akävar™ was an effective appetite suppressant.

167. Notwithstanding that fact, the FTC reversed itself once again during the March 14, 2008 meeting and stated, for the first time, the FTC's new position that Plaintiffs' tests, analyses, research, studies or other evidence supported only so-called "qualified" weight loss claims for Akävar™.

168. At no time during the March 14, 2008 meeting did anyone from FTC ever indicate that Plaintiffs could only make "qualified" appetite suppressant claims for Akävar™.

169. Despite FTC's admission that Plaintiffs' substantiation demonstrated that

Akävar™ was an effective appetite suppressor; despite the fact that Mr. Kohm had expressly stated during the December 17, 2007 meeting that Plaintiffs could use the "Eat All You Want And Still Lose Weight" headline if Plaintiffs made it clearer in the Akävar™ advertisement that consumers could eat all they want because they would want to eat less; and despite the fact that the new Akävar™ advertisement contained the exact clarification the FTC had demanded during the December 17, 2007 meeting, FTC took the position during the March 14, 2008 meeting that the new advertisement violated the Consent Order.

170. FTC threatened in the March 14, 2008 meeting that it would initiate an enforcement action against Plaintiffs if they did not immediately pull all advertising for Akävar™ and run only advertisements containing "qualified" weight loss claims, which FTC defined during the March 14, 2008 meeting as advertisements that convey to potential consumers that Plaintiffs' substantiation is "preliminary," or some other word to that effect. FTC insisted Basic Research convey this message in its Akävar™ advertising despite the fact that the substantiation relied upon by Basic Research consists of much, much more than the one single study to which FTC was referring, and notwithstanding that Plaintiffs' tests, analyses, research, studies, or other evidence meets the reasonable basis standard under the Agreement.

171. During the March 14, 2008 meeting, the FTC asserted that Plaintiffs could not use the phrase "Eat All You Want And Still Lose Weight" as the headline for the Akävar™ advertisement. However, at no time during the March 14, 2008 meeting did the FTC ever state or otherwise suggest that the phrase "Eat all you want and still lose weight" could not appear, in any form, in the text of the advertisement, as opposed to appearing in the headline of the advertisement.

172. During the March 14, 2008 meeting, the Parties also briefly discussed the Relacore™ advertisement, and Plaintiffs agreed to provide additional tests, analyses, research, studies, or other evidence to the FTC, which Plaintiffs in fact subsequently provided.

v. Plaintiffs Pulled The New Akävar™ Advertisements

173. Although Plaintiffs strongly disagreed with the positions the FTC asserted during the March 14, 2008 meeting, but in a further effort to avoid litigation with the FTC, Basic Research pulled following the March 14, 2008 meeting all of its Akävar™ television advertising and pulled all print advertisements for which firm commitments had not been made. Plaintiffs promptly notified FTC of this decision. *See, e.g.,* Letter from Linda Goldstein to Jim Kohm, dated March 18, 2008 (the "March 18 Letter"), a copy of which is attached hereto as Exhibit F.

174. In the March 18 Letter, Plaintiffs stated, in part, "[d]uring our [March 14] meeting, you indicated that staff was satisfied that Basic Research had presented competent and reliable scientific evidence to support the fact that Akävar™ is an appetite suppressant. In light of the fact that Basic Research has established the efficacy of Akävar™ as an appetite suppressant, the FTC's own Red Flags guides would appear to permit Basic Research to make the claim "Eat All You Want" without any additional evidence or support so long as the advertisements make clear that consumers will not want to eat as much. We believe the qualifying language in the warning box clearly communicates this message. Accordingly, we would appreciate the opportunity to revisit this issue with you."

175. After FTC received the March 14 Letter, FTC reversed the position it had taken during the March 14, 2008 meeting that Basic Research had presented adequate tests, analyses, research, studies, or other evidence to support the fact that Akävar™ is an appetite suppressant.

In response to the March 14 Letter, FTC sent Plaintiffs a letter erroneously stating that "[w]hat we in fact said was we believe the YGD study does not constitute competent and reliable scientific evidence for an unqualified appetite suppressant claim." *See, e.g.,* Letter from Lem Dowdy and Melinda Claybaugh to Linda Goldstein, dated March 21, 2008 (the "March 21 FTC Letter"), a copy of which is attached hereto as Exhibit G.

176. The statement in the March 21 FTC letter that "[w]hat we in fact said was we believe the YGD study does not constitute competent and reliable scientific evidence for an unqualified appetite suppressant claim" is untruthful because at the March 14, 2008 meeting the FTC officials present never stated that the evidence was not competent and reliable but, in fact, expressed satisfaction that the evidence met the reasonable basis standard set forth in the Agreement.

177. Rather, the March 21 FTC Letter was the first time FTC ever told Plaintiffs that the Andersen/Fogh Study does not meet the reasonable basis standard set forth in the Agreement for an "unqualified" appetite suppressant claim, however the FTC defines an "unqualified" claim.

178. Notwithstanding that, through the March 21 FTC Letter the FTC reversed the position it had taken during the March 14, 2008 meeting, the FTC expressly admitted in the March 21 FTC Letter that Akävar™ may help curb appetite, the Andersen/Fogh Study "provides some evidence of an appetite suppressing effect for YGD, Basic Research may make qualified statements about appetite suppression . . ." *See, e.g.,* March 21 FTC Letter, Exhibit G hereto.

179. After the March 14, 2008 meeting, and in addition to pulling its existing Akävar™ advertisements, Basic Research also generated an entirely new advertisement for

Akävar™ (the "Second Revised Akävar™ Advertisement"), a copy of which is attached hereto as Exhibit H. This new advertisement complied with the FTC's demand that Plaintiffs not use the phrase "Eat All You Want And Still Lose Weight" as the headline for the advertisement.

180. The Second Revised Akävar™ Advertisement clearly stated that there was controversy surrounding the phrase "Eat All You Want And Still Lose Weight," and that Plaintiffs' primary study (the Andersen/Fogh Study, which is a well-controlled, double-blinded, peer-reviewed, published clinical trial) was not **universally** accepted in the scientific community. Basic Research provided a copy of the new advertisements to FTC on March 25, 2008.

vi. The March 27, 2008 Meeting

181. Plaintiffs' counsel and Mr. Friedlander flew to Washington, D.C., and met once again with FTC staff attorneys on March 27, 2008.

182. During the March 27, 2008 meeting, the FTC attorneys acknowledged that Plaintiffs' Akävar™ substantiation meets the reasonable basis standard specifically described in the Agreement. Specifically, FTC acknowledged that Plaintiffs' substantiation for Akävar™ was comprised of "tests, analyses, research, studies, or other evidence," that it was "based on the experience of professionals in the relevant area," and that it was science "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."

183. Notwithstanding this acknowledgment and admission, FTC expressly stated during the March 27, 2008 meeting that "just meeting the letter of the standard" is not enough.

184. Ostensibly for that reason, FTC stated at the March 27, 2008 meeting its position

that Plaintiffs' tests, analyses, research, studies, or other evidence for Akävar™ was somewhere between "no support" and the "gold standard." On that basis, FTC stated that any advertisement for Akävar™ or any other YGD herbal combination based supplement would be deemed by the FTC a violation of the Agreement unless that advertising: (1) indicated the "state" of the science supporting the product (i.e., that the science was "preliminary" or somewhere between no support and the gold standard); (2) contain only "qualified" weight loss claims; and (3) any appetite suppression claims had to be "qualified" as well.

185. FTC asserted during the March 27, 2008 meeting that the Second Revised Akävar™ Advertisement violated the Agreement because it did not adequately convey that the state of the science supporting the product was "preliminary," and did not adequately "qualify" the weight loss claim made in the advertisement.

186. FTC very clearly stated at the March 27, 2008, meeting that it would not permit Basic Research to run any advertisement for a YGD herbal combination supplement (such as Akävar™) that was not "qualified enough that the consumer understands the study is somewhere in between no support and the gold standard."

187. No such requirement exists in the Agreement.

188. FTC's unilateral imposition of this requirement was a further breach of the Agreement, which breach violates Plaintiffs' Fifth Amendment right to Due Process, and chills Plaintiffs' First Amendment right to freedom of speech.

189. During the March 27, 2008 meeting, FTC asserted that the clear and unambiguous reasonable basis standard negotiated by the Parties and included in the Agreement was a "fluid standard" that changes "depending on what the scientific evidence is – it's always different."

190. During the March 27, 2008 meeting, FTC further asserted that Plaintiffs' weight loss and fat loss statements in advertising violate the Agreement because FTC had located "experts who disagree with your experts."

191. The reasonable basis standard negotiated by the Parties and specifically described in the Agreement is, by definition, entirely independent of opinions that may or may not be held by others, including experts hired by FTC. The Agreement contains no requirement that there be a consensus among experts, unanimous expert opinion, or that there be absolute scientific certainty, in order for Plaintiffs to make weight loss and fat loss claims for dietary supplements. Rather, the Agreement very clearly requires a "reasonable basis" for claims, which is satisified when Plaintiffs' possess one or more of the following: tests or analyses or research or studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

192. FTC further stated that the Second Revised Akävar™ Advertisement violated the Agreement because, although it did not have the phrase "Eat All You Want And Still Lose Weight" as the headline for the ad, it did contain a postage stamp size picture of the First Revised Akävar™ Advertisement in the body of the advertisement, as the advertisement discussed the controversy surrounding that phrase.

193. During the March 27, 2008 meeting, FTC demanded that the postage stamp size picture of the First Revised Akävar™ Advertisement be removed from any future ads.

194. FTC concedes its staff attorneys' conclusions concerning the "net impression" of the Akävar™ advertisement are supported by no copy tests or other studies of any kind showing

what potential consumers take away from Plaintiffs' advertisement. Regardless, FTC demanded that Plaintiffs immediately cease and desist from running the Second Revised Akävar™ Advertisement, and threatened that Plaintiffs run the advertisement at their own peril.

195. FTC further stated at the March 27, 2008 meeting that FTC believed Plaintiffs had acted in bad faith because they had made a limited placement of the Second Revised Akävar™ Advertisement without first providing a copy to the FTC, and without first having received approval from the FTC for the advertisement. FTC demanded during the March 27, 2008, meeting that Plaintiffs pull their newly revised advertisements even though the advertisement, on its face, clearly states that the substantiation for Akävar™ is not universally accepted.

196. None of the requirements imposed by FTC during the March 27, 2008 meeting are found in the Agreement, and FTC's positions stated that day are directly contrary to the clear and unambiguous language in the Agreement, which provides a fixed, objective standard for the required reasonable basis.

197. Accordingly, FTC's unilateral imposition of these requirements was a breach of the Agreement, which breach immediately chilled and continues to chill Plaintiffs' exercise of its First Amendment right to freedom of speech and violates Plaintiffs' Fifth Amendment right to Due Process.

198. FTC took these positions at the March 27, 2008 meeting in direct violation and breach of the Agreement, notwithstanding FTC's admission that the Andersen/Fogh Study meets the reasonable basis standard set forth in the Agreement.

199. FTC similarly stated during the March 27, 2008 meeting its position that Plaintiffs' current advertisement for Relacore™, a copy of which is attached as Exhibit I,

violates the Agreement because Plaintiffs' voluminous support (consisting of tests or studies or research or analyses or other evidence) for statements in the advertisement does not allegedly meet the reasonable basis standard set forth in the Agreement. FTC demanded in violation of Plaintiffs' constitutional rights and breach of the Agreement, that Plaintiffs immediately cease and desist running advertisements for Relacore™, and threatened that Plaintiffs run the advertisement at their own peril.

200. The positions taken by the FTC during the March 27, 2008 meeting are contrary to the clear and unambiguous language in the Agreement, and constitute a breach of the Agreement, which breach chills Plaintiffs' exercise of its Plaintiffs' First Amendment right to freedom of speech and violates Plaintiffs' Fifth Amendment right to Due Process.

vii. The April 16, 2008 Meeting

201. After the March 27, 2008 meeting, FTC agreed to meet with Plaintiffs on Monday, April 7, 2008, to discuss, line by line, possible changes Plaintiffs could make to the Second Revised Akävar™ Advertisement, which would be acceptable to FTC.

202. At approximately 6:00 pm (EST) on Friday, April 4, 2008, after Plaintiffs' counsel and Plaintiff Friedlander had already made their travel arrangements for the meeting which was scheduled for April 7, 2008, FTC left a voice mail for Plaintiffs' counsel indicating, for the first time, that the Second Revised Akävar™ Advertisement was completely unacceptable, and that FTC expected Plaintiffs to submit yet another proposed revised advertisement to the FTC for its consideration. FTC further indicated in that voice mail message that the meeting which was planned for Monday morning (the 7th) would likely be of no benefit without such a revised ad having been first submitted to the FTC. Accordingly, FTC cancelled

the meeting which had been scheduled for April 7, 2008.

203. Although Plaintiffs' strongly disagreed with the positions taken, and demands made, by the FTC during the March 27, 2008, and in response to the FTC's newly stated position that Basic Research needed to submit a new advertisement prior to any additional meeting with FTC, Basic Research generated an entirely new advertisement for Akävar™ (the "Third Revised Akävar™ Advertisement"), a copy of which is attached hereto as Exhibit J. This new advertisement complied with the FTC's demand that Plaintiffs not use the picture of the First Revised Akävar™ Advertisement in the Akävar™ advertisement, and included further changes to the ad, which were all made in an attempt to placate, and avoid litigation with, the FTC.

204. Because Basic Research was faced with certain deadlines to place the Akävar™ advertisements with two of the print publications in which Basic Research advertises, which deadline fell after the April 7, 2008 date on which the FTC had previously agreed to meet with Plaintiffs (but which meeting was cancelled by FTC at the last minute), and which fell before Plaintiffs could arrange a new meeting time with the FTC, Basic Research placed the Third Revised Akävar™ Advertisement for publication only in two publications.

205. A copy of the Third Revised Akävar™ Advertisement was subsequently provided to the FTC on April 15, 2008. When this advertisement was provided to the FTC, Plaintiffs specifically informed the FTC that Basic Research had been required to make a limited placement of the advertisement due to the problems associated with the FTC having cancelled the meeting which had previously been scheduled for April 7, 2008.

206. Plaintiff Friedlander and Plaintiffs' counsel again traveled to Washington, DC, and met with FTC's staff attorneys on April 16, 2008.

207. During the April 16, 2008 meeting, the FTC asserted that the Third Revised Akävar™ Advertisement violated the Agreement.

208. The FTC further asserted that Plaintiffs were operating in bad faith by having made a limited placement of the Third Revised Akävar™ Advertisement without having first obtained the FTC's approval of the advertisement.

209. During the April 16, 2008 meeting, the FTC stated that although they believed Plaintiffs' tests, analyses, research, studies, or other evidence support a "qualified" appetite suppressant claim for Akävar™ (however it is that FTC defines a "qualified appetite suppressant claim"), and notwithstanding the FTC's statement on its own website that for products that help curb appetite "its [sic] okay to say people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product[,]" FTC nonetheless stated that Plaintiffs cannot use the phrase "eat what you want and still lose weight" anywhere in any Akävar™ advertisements because participants in the Andersen/Fogh Study were not specifically instructed to eat all they want.

210. During the April 16, 2008 meeting, the FTC asserted for the first time that it was the FTC's position that the phrase "eat all you want and still lose weight" could not, under any circumstances, appear in any Akävar™ advertisement.

211. During the April 16, 2008 meeting, the FTC asserted that the Third Revised Akävar™ Advertisement did not adequately "qualify" the state of the science.

212. The FTC further asserted during the April 16, 2008 meeting that the Third Revised Akävar™ Advertisement did not adequately "qualify" the weight loss claim for Akävar™.

213. During the April 16, 2008 meeting, the FTC stated that although Plaintiffs did not have to indicate in Akävar™ advertisements that there was a "controversy" surrounding the state of the science relating to Akävar™, that if Plaintiffs chose to present such a controversy in Akävar™ advertisements, the controversy could not be presented in a "balanced" manner.

214. Indeed, the FTC expressly stated during the April 16, 2008 meeting that one reason they had determined that the Third Revised Akävar™ Advertisement violated the Agreement was because the advertisement was "too balanced." FTC asserted that the advertisement was "too balanced" because the advertisement did not state that the science supporting weight loss claims for the YGD herbal compound was "preliminary," and did not specifically identify all of what the FTC asserted were various "flaws" in the Andersen/Fogh Study.

215. During the April 16, 2008 meeting, the FTC asserted that, with respect to any advertisement of Akävar™, "[a] message that the science is uncertain is the only message that complies with the [Agreement]."

216. During the April 16, 2008 meeting, the FTC asserted that even if the Third Revised Akävar™ Advertisement says "what is truthful, it may be false."

217. The FTC further asserted that the ads "may say things that are truthful, but that doesn't cut it."

218. During the April 16, 2008 meeting, the FTC asserted that the reasonable basis standard which governs Plaintiffs' advertising claims is not contained solely in the Agreement. Rather, the FTC asserted that the applicable standard is found in some unspecified combination of the "Agreement and FTC law."

219. The FTC asserted during the April 16, 2008 meeting that the Relacore™ advertisement violates the Agreement.

220. The positions taken by the FTC during the April 16, 2008 meeting constitute a material breach of the Agreement, which breach chills Plaintiffs' First Amendment right to freedom of speech and violates Plaintiffs' Fifth Amendment Due Process rights.

viii. FTC's May 12, 2008 Letter

221. On May 12, 2008, FTC sent Plaintiffs a letter wherein FTC stated unequivocally that the current Relacore™ advertisement violates the Agreement, and that Plaintiffs must immediately terminate that advertisement. A copy of the May 12, 2008 Letter is attached hereto as Exhibit K.

222. In the May 12, 2008 Letter, FTC states that the net impression of the Relacore™ advertisement is a claim that Relacore™ reduces belly fat.

223. Upon information and belief, FTC's interpretation of the net impression of the Relacore™ advertisement is based solely on the opinion of FTC's staff attorneys. That is, FTC has identified no consumer studies or surveys conducted by FTC to substantiate FTC's own determination concerning the messages communicated to consumers by the ads.

224. FTC's assertion that the net impression of the Relacore™ advertisement is that Relacore™ reduces belly fat is false.

225. Rather, the advertisement makes the claim that dieting can be stressful, stress increases cortisol, cortisol increases belly fat, Relacore™ reduces stress, and Relacore™, when taken in conjunction with diet and exercise, can help reduce stress-induced belly fat.

ix. The October 24, 2008 Letter

226. FTC sent Plaintiffs on October 24, 2008 a letter ("October 24 Letter"), together with a proposed contempt action Complaint, and a new proposed consent agreement, which proposed consent agreement omits the "reasonable basis" language contained in the Agreement. A copy of the October 24 letter is attached hereto as Exhibit L.

227. Despite the fact that FTC had approved the Relacore™ reduction of stress-related belly fat claim prior to the Parties entering into the Agreement, and despite the fact that FTC allowed the Relacore™ advertising to continue thereafter for two years, the October 24 Letter stated that the FTC had concluded that Plaintiffs violated the Agreement, and that unless Plaintiffs entered into the proposed new consent agreement before November 24, 2008, the FTC staff would recommend that the Department of Justice file the proposed Complaint.

228. As evidenced by FTC's proposed enforcement action complaint, and contrary to FTC's prior stated position that FTC interpreted Plaintiffs' Relacore™ advertisements make a claim that taking Relacore™ will help decrease belly fat in general, FTC now appears to acknowledge that the Relacore™ advertisement makes the more limited claim that dieting can be stressful, stress increases cortisol, cortisol increases belly fat, Relacore™ reduces stress, and Relacore™, when taken in conjunction with diet and exercise, can help reduce stress-induced belly fat.

x. The November 6, 2008 Meeting

229. In hopes of avoiding litigation, Plaintiffs' counsel met once again with FTC staff on November 6, 2008.

230. During this meeting, Mr. Kohm expressly acknowledged on behalf of FTC that Plaintiffs and FTC have a fundamental disagreement concerning the meaning and interpretation

of the reasonable basis standard contained in the Agreement.

231. During this meeting, Plaintiffs' counsel explained that Plaintiffs believe the Affidavit of Dr. Madsbad (discussed in ¶¶ 129-132 above) meets the express terms of the reasonable basis standard set forth in the Agreement, and that Plaintiffs did not understand why the FTC asserts that the Affidavit of Dr. Madsbad does not meet the agreed upon reasonable basis standard. In particular, Plaintiffs' counsel explained that Dr. Madsbad had done what anyone writing a review article for a medical journal would do in connection with preparing such an article – namely, Dr. Madsbad, who is clearly a professional in the relevant field, conducted a review of the relevant scientific literature, that there is no evidence that review was biased, and reached a conclusion based upon his objective review of the relevant scientific literature.

232. In response, FTC staff stated that Dr. Madbad's Affidavit does not meet the agreed upon reasonable basis standard contained in the Agreement because FTC has an expert who disagrees with Dr. Madsbad's conclusion.

233. During this meeting, FTC specifically stated that they have concluded that Plaintiffs are in violation of the Agreement, that the only possible way to get Plaintiffs to comply with FTC's own requirements and conditions is to bring an enforcement action against Plaintiffs, and that unless Plaintiffs entered into the proposed new consent agreement prior to November 24, 2008, FTC would commence an enforcement action.

234. In response to the changing and evolving positions taken by FTC over the course of the meetings described above and in the correspondence sent by FTC, Plaintiffs undertook at great expense an effort to obtain further evaluation of its substantiation for Akävar™ and Relacore™ by other world-class, independent experts. While Plaintiffs were unequivocally

certain they had already satisfied their contractual obligations under the plain language of the Agreement, Plaintiffs undertook this additional review: 1) to further satisfy themselves that the science upon which they relied met the standard in the Agreement; 2) to confirm that the scientists who had evaluated the science for Plaintiffs were qualified experts in the field capable of objectively reviewing the science; 3) to ensure Plaintiffs were fully and fairly considering the objections raised by FTC; and 4) to try to persuade FTC to reconsider their positions in light of the opinions Plaintiffs hoped to obtain from preeminent scientists in the field of obesity research.

235. Among others, Plaintiffs retained Dr. Frank Greenway, Medical Director and Professor at Pennington Biomedical Center, Louisiana State University. Dr. Greenway has received more than 150 grants and contracts relating to obesity research, has published more than 200 scientific papers, including peer-reviewed articles, reviews, book chapters, and abstracts, and has been an invited speaker at 75 major conferences and symposia. The Pennington Biomedical Center is one of the world's leading nutritional research centers. The Pennington Biomedical facility has more than 80 faculty members and over 600 physicians, scientists, and support personnel who focus their research efforts on 10 research program areas: Epidemiology and Prevention, Physical Activity and Health, Cancer, Diabetes, Obesity, Neurodegeneration, Genomics and Molecular Genetics, Stem Cell and Developmental Biology, Neurobiology, and Nutrient Sensing and Signaling.

236. Dr. Greenway reviewed both Dr. Toubro's opinion and the Andersen/Fogh Study itself, and provided Plaintiffs with a written opinion in which Dr. Greenway concludes that the YGD studies "had valid study designs that should allow one to rely upon the results." Dr. Greenway further states that his "opinion is congruent with that of Dr.

Toubro." Dr. Greenway further concluded that the weight loss demonstrated in the 45 day portion of the Andersen/Fogh Study "was due to a reduction in food intake, and not to an increase in exercise."

237. Plaintiffs also consulted with Dr. George Bray, Boyd Professor at the Pennington Biomedical Research Center of Louisiana State University in Baton Rouge, Louisiana, and Professor of Medicine at the Louisiana State University Medical Center in New Orleans. Dr. Bray is widely recognized as one of the world's leading experts in obesity research. Indeed, during the administrative action involving some of the Plaintiffs and FTC, the FTC's own expert in that case, Dr. Robert Eckel, testified that Dr. Bray has "exquisite qualifications[,]" "has a tradition of academic excellence in the area of obesity research[,]" and that he, Dr. Eckel, would argue that Dr. Bray's credentials are "second to none." Dr. Bray founded the North American Association for the Study of Obesity (NAASO now The Obesity Society), and he was the founding editor of its journal, Obesity Research, as well as co-founder of the International Journal of Obesity and the first editor of Endocrine Practice, the official journal of the American College of Endocrinologists. Dr. Bray has been President of NAASO, of the American Society for Clinical Nutrition, of the International Association for the Study of Obesity and the American College of Endocrinology. Dr. Bray has authored over 1,700 scientific papers, ranging from peer-reviewed articles, reviews, books, book chapters and reviews, and has given over 200 invited lectures. Prior to his tenure at LSU, Dr. Bray was professor of medicine and professor of physiology/biophysics and chief of diabetes and clinical nutrition at the University of Southern California.

238. With respect to the Andersen/Fogh Study, Dr. Bray has reported to Plaintiffs it is his expert opinion, that:

- The study was well designed and controlled;
- The study was conducted in an objective manner;
- Dr. Andersen and Dr. Hessel were qualified to design and conduct the study; and
- The procedures employed in the study are generally accepted in this profession to yield accurate and reliable results.

239. Dr. Bray further states that he knows Drs. Greenway and Toubro personally and professionally and that they are imminently well qualified to analyze the Andersen/Fogh Study. Dr. Bray concludes that based upon his review of the relevant materials and his general expertise YGD "reduces food intake and results in lower caloric intake among subjects who take the herbal combination before main meals. Another way to say this is that YGD helps curb appetite."

240. Dr. Bray has also reported that he has reviewed the Akävar™ advertisements and that, although he claims no expertise in consumer advertising, from a scientific standpoint he does not see any untruthful statements in the advertisements.

241. To assist Plaintiffs with their further review of Relacore™, Plaintiffs also retained Dr. Arne Astrup, the head of the Department of Human Nutrition of the University of Copenhagen. Dr. Astrup is the immediate past president of the International Association for the Study of Obesity, and is widely recognized as one of the word's leading experts in obesity research.

242. Among other things, Dr. Astrup reviewed Dr. Madsbad's Affidavit and

Plaintiffs' scientific substantiation for Relacore™. Thereafter, Dr. Astrup provided Plaintiffs with a letter in which he concluded that:

- The substantiation upon which Basic Research relies for Relacore™ easily satisfies the competent and reliable scientific evidence standard set forth in the Consent Agreement;
- Dr. Madsbad is unquestionably a qualified expert in the relevant field, and is imminently well qualified to offer the analyses and opinions contained in his Affidavit;
- Dr. Madsbad employs in his Affidavit the most common procedure utilized in the relevant field for assessing the accuracy and reliability of a scientific proposition – identification and independent review of the most relevant scientific literature on the issue;
- Dr. Madsbad's Affidavit demonstrates an objective analysis of the studies, tests, reviews and other relevant scientific literature;
- Dr. Madsbad's Affidavit satisfies the competent and reliable scientific evidence standard set forth in the Consent Agreement;
- Dr. Madsbad's opinions are well-supported;
- Relacore™ reduces stress; and
- Because Relacore™ reduces stress, Relacore™ reduces stress-related cortisol, which in turn causes a reduction in stress-related visceral fat, particularly when used in connection with a diet and, to a lesser extent, exercise.

243. Dr. Astrup has reported that he has reviewed advertisements for Relacore™ and that, although he claims no expertise in consumer advertising, from a scientific

standpoint he does not see any untruthful statements in the advertisements.

xi. The June 12, 2009 Meeting

244. Plaintiffs' counsel once again met with FTC staff on June 12, 2009.

245. During this meeting Mr. Dowdy and Ms. Claybaugh specifically reiterated their determination that Plaintiffs have violated, and are in violation of, the Consent Agreement through its advertisements for the Akävar™ and Relacore™ products.

246. During this meeting, FTC staff stated that Plaintiffs had violated the Consent Agreement by making "unqualified" weight loss claims for Akävar™, and that Plaintiffs' scientific substantiation for the Akävar™ product does not support an unqualified weight loss claim. FTC staff stated that Plaintiffs' scientific substantiation for the Akävar™ product supports only a "qualified" weight loss claim. Mr. Dowdy went on to explain FTC staff's position on what constitutes a "qualified" weight loss claim, specifically stating that "a qualified weight loss claim is a 'may' or 'might,' not a 'will'."

xii. The July 8, 2009 Meeting

247. Plaintiffs' counsel once again met with FTC staff on July 8, 2009. Dennis Murphy from the FTC's Bureau of Economics was also present.

248. During this meeting, FTC staff reiterated their position that Plaintiffs' substantiation for the Akävar™ product did not support the "Eat All You Want & Still Lose Weight" claim because the participants in the Andersen/Fogh Study were not told to eat all they want. FTC staff further stated that Plaintiffs cannot say the words "eat all you want" – period, and that the phrase "eat all you want and still lose weight" was too strong to adequately qualify.

249. During this meeting, FTC staff also raised new concerns about the Andersen/Fogh

Study which staff had never previously raised. FTC staff stated that there exist what staff called "anomalies" with the Andersen/Fogh Study, which staff said, in their opinion, calls into question the reliability of the Andersen/Fogh Study. FTC staff explained that these anomalies included the fact that the placebo group did not lose enough weight, there were no reported dropouts in the study, and that the experimental group lost too much weight.

250. During this meeting, FTC staff also stated that they had other criticisms of the Andersen/Fogh Study, including the duration of the study, the number of participants in the study, and the fact that the study was designed by Dr. Hessell.

251. During this meeting, FTC staff further explained that the fact there were no reported side effects during the delayed gastric emptying portion of the study "is surprising." Staff further stated that, given the various anomalies they believe exist with respect to the Andersen/Fogh Study, a reasonable scientist would not conclude it is a reliable study.

252. During this meeting, FTC staff further indicated that the Andersen/Fogh Study does not support the Akävar™ advertising claims because the product has ingredients in addition to those that were tested in the Andersen/Fogh Study.

253. During this meeting, with respect to the Relacore™ product, FTC staff stated that although science demonstrates there is a correlation between higher levels of cortisol and higher levels of belly fat, "cause and effect" between higher levels of cortisol and higher levels of belly fat has not been established.

254. During this meeting, FTC staff stated that the Relacore™ ads violate the Consent Agreement

xiii. <u>The July 20, 2009 Meeting</u>

255. Plaintiffs' counsel again met with FTC on July 20, 2009. Present on behalf of the FTC was David Vladeck, Director of FTC's Bureau of Consumer Protection, as well as Mr. Kohm and his staff.

256. Plaintiffs submitted to Mr. Vladeck in advance of the meeting a "white paper" setting forth much of the substantiation provided to FTC's staff and presenting argument designed to persuade the Bureau of Consumer Protection to close its investigation into Akävar™ and Relacore™ without the need for formal action or litigation.

257. During the July 20 meeting, FTC's Bureau Director stated that the Relacore™ advertisements and Akävar™ advertisements violate the Consent Agreement.

258. The Bureau of Consumer Protection thereafter formally rejected Basic Research's positions and forwarded to the Commission a recommendation to file an action against Basic Research.

259. Basic Research subsequently requested and attended on August 28, 2009 and August 31, 2009 meetings with the Commissioners of the FTC, each of whom rejected the positions here asserted by Basic Research concerning the reasonable basis standard defined in the Agreement, and FTC's additional, undefined, changing and vague extracontractual requirements nowhere found in the Agreement. Notwithstanding that there is no administrative exhaustion of remedies requirement for the relief here sought, Plaintiffs have presented their position concerning the Agreement to every level of the FTC from the compliance staff, to the Bureau Director, to the Commission itself. There is no other administrative body or officer at FTC authorized or able to change the positions FTC has taken and which are the subject of this Action. Accordingly, there is a present, existing dispute between FTC and Plaintiffs concerning

the matters addressed herein, which dispute cannot be resolved absent judicial intervention.

260. Despite, and contrary to, the clear and unambiguous language of the Agreement, the FTC's present position appears to require a "consensus" or an "absolute" view, obtained in some undefined way that is not set forth in the plain language of the Agreement. Indeed, the FTC is imposing upon Plaintiffs caveats, obligations, and standards that go far beyond the express terms of the Agreement.

261. However, the Agreement requires the FTC to accept Plaintiffs' tests, analyses, research, studies, or other evidence once those tests, analyses, research, studies, or other evidence meet the reasonable basis standard set forth in the Agreement.

262. The Agreement does not permit the FTC to impose additional requirements and obligations that are not contained within the four corners of the Agreement.

263. The Agreement does not give the FTC a license to violate Plaintiffs' First Amendment right to freedom of speech and its Fifth Amendment right to Due Process.

264. The FTC has repeatedly told Plaintiffs that the FTC considers Plaintiffs' advertisements to be in violation of the Agreement, and that the FTC will commence an enforcement action if Plaintiffs do not modify their advertisements.

265. Plaintiffs have diligently sought to avoid litigation with the FTC. They have done so even though the positions taken, and the threats made, by the FTC constituted a breach of the Agreement and a violation of Plaintiffs' First Amendment right to freedom of speech and Plaintiffs' Fifth Amendment right to Due Process.

266. Rather than leading to a peaceful resolution with the FTC, however, the Plaintiffs' attempts to appease the FTC simply emboldened the FTC, who responded by retracting positions

they had previously taken, and then making new, even contradictory, demands that are not supported by the Agreement.

FIRST CLAIM FOR RELIEF
Declaratory Relief

267. Plaintiffs hereby incorporate by reference the preceding paragraphs as though fully set forth herein.

268. An actual controversy has arisen and does now exist between Plaintiffs and the FTC with respect both to the meaning and interpretation of the reasonable basis standard defined in the Agreement and the FTC's demands that Plaintiffs satisfy extracontractual requirements before they may engage in weight loss or fat loss advertising.

269. Plaintiffs contend that the Agreement allows them to make weight loss and fat loss claims for dietary supplements if Plaintiffs have a reasonable basis supporting those claims. Pursuant to the express terms of the Agreement, Plaintiffs have a reasonable basis, and are therefore entitled, to make weight loss and fat loss claims so long as Plaintiffs possess and rely upon one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

270. FTC, on the other hand, contends that the reasonable basis standard which governs Plaintiffs' advertising claims is not contained in the Agreement. FTC asserts that the applicable standard is an extracontractual variable or flexible standard that changes on a case-by-case basis, and that Plaintiffs are required at FTC's direction, as it sees fit to provide from time to time, to meet additional extracontractual requirements that are not contained in, and go beyond,

the explicit reasonable basis standard contained in the plain and unambiguous language of the Agreement.

271. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration of their rights and obligations with respect to the Agreement, and of the meaning and interpretation of the reasonable basis standard set forth in the Agreement, and specifically a declaration that:

a. The Agreement operates as a contract defining the rights and duties of the Parties thereto vis-à-vis the subject matter of the Agreement;

b. The Agreement defines what Plaintiffs must possess and rely upon for weight loss and fat loss claims in advertising for dietary supplements;

c. The reasonable basis standard contained in the Agreement is clear and unambiguous;

d. The express terms of the Agreement permit Plaintiffs to make weight loss and fat loss claims in advertisements for dietary supplements if Plaintiffs possess and rely upon a reasonable basis for those claims. Pursuant to the express terms of the Agreement, Plaintiffs have a reasonable basis when they possess and rely upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

SECOND CLAIM FOR RELIEF
Declaratory Relief – First Amendment
Freedom of Speech

272. Plaintiffs hereby incorporate the preceding paragraphs by reference as though

fully set forth herein.

273. Plaintiffs' advertising for weight loss and fat loss supplements is constitutionally protected commercial speech under the First Amendment. Plaintiffs' advertising for these supplements is neither false nor misleading. Under, *inter alia*, *United States v. Armour*, 402 U.S. 673 (1971) and *U.S. v. Wayne County, Michigan,* 1994 WL 739020 (E.D. Mich. Dec. 22, 1994), FTC is legally foreclosed from either demanding or arguing that Plaintiffs must satisfy extracontractual conditions precedent before Plaintiffs may publish weight loss and/or fat loss advertising claims.

274. FTC violated Plaintiffs' First Amendment right to freedom of speech when FTC first demanded Plaintiffs "promptly revise" all advertising for weight loss and fat loss supplements, based not on the negotiated and agreed upon reasonable basis standard expressly set forth in the Agreement, but instead insisting upon satisfaction of extracontractual requirements and conditions that are not contained anywhere within the four corners of the Agreement.

275. FTC further violated Plaintiffs' First Amendment right to freedom of speech when FTC later demanded Plaintiffs immediately cease and desist all advertising for the weight loss and fat loss supplements at issue, by rejecting the clear and unambiguous reasonable basis standard contained in the Agreement, and by demanding that Plaintiffs meet some undefined extracontractual requirements and conditions that are not contained anywhere within the four corners of the Agreement. The FTC staff attorneys thus have established themselves as content censors, who demand adherence to a blanket ban against Plaintiffs' constitutionally protected commercial speech on threat of prosecution. That blanket ban is presumptively unconstitutional

under the First Amendment.

276. Although the Agreement requires Plaintiffs to have, rely on and supply FTC with tests, analyses, research, studies, or other evidence which meet the negotiated and agreed upon reasonable basis standard expressly set forth in the Agreement, the Agreement negotiated and entered into by FTC and Plaintiffs does not give FTC the option to substitute for the agreed upon reasonable basis standard its own subjective, undefined, evaluative criteria set forth in FTC's correspondence to Plaintiffs and expressed by FTC's staff attorneys during in-person meetings with Plaintiffs' attorneys and representatives. FTC's application of such subjective, undefined, evaluative criteria constitutes an exercise of unbridled censorial discretion over the content of Plaintiffs' constitutionally protected speech. FTC's actions violate Plaintiffs' First Amendment right to freedom of speech.

277. FTC has communicated its intention to commence immediately the litigation it has repeatedly threatened. As discussed above, Plaintiffs have presented their position in this dispute to every level of the FTC. FTC has rejected Plaintiffs' arguments. There is no other person or body at FTC authorized to change FTC's position and concede the points at issue here.

278. FTC's actions described above create a direct and immediate dilemma for Plaintiffs, to either sacrifice their First Amendment rights, or to exercise their First Amendment rights and face litigation by FTC.

279. Plaintiffs accordingly seek a declaration that FTC's actions, including FTC's insistence that Plaintiffs meet requirements and conditions not contained within the four corners of the Agreement, constitute a present and ongoing violation of Plaintiffs' First Amendment right to freedom of speech.

THIRD CLAIM FOR RELIEF
Declaratory Relief – Fifth Amendment
Due Process

280. Plaintiffs hereby incorporate the preceding paragraphs by reference as though fully set forth herein.

281. Plaintiffs have a constitutionally protected liberty interest in the free expression of truthful commercial advertisements, unmolested by the FTC, when Plaintiffs possess tests, analyses, research, studies, or other evidence which meet the "reasonable basis" standard set forth in the Agreement; in their reputation as a law-abiding advertiser with whom others may contract without fear of FTC enforcement; and in their right to pursue a living through the marketing and sale of weight and fat loss dietary supplements (a core business activity of Plaintiffs, developed through an extraordinary investment of time and money).

282. Plaintiffs have a property interest in the scientific research supporting their weight loss and fat loss advertisements, in their investments in advertising and market research, in the revenue derived from their weight loss and fat loss advertisements, and in the benefit of their bargain with the FTC, including that the Agreement gives Plaintiffs a right to make weight loss and fat loss claims for dietary supplements, so long as Plaintiffs possess and rely upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

283. Plaintiffs relinquished their continued right to litigate in the then pending Administrative Action and Carter-Reed cases when Plaintiffs agreed to negotiate and enter into

an Agreement with FTC that finally and completely settled the issues existing between FTC and Plaintiffs. Among other things, Plaintiffs surrendered their right to a public hearing and determination of the baseless claims brought against them in the FTC Administrative Proceeding. Plaintiff Carter-Reed also dismissed its lawsuit and claims against FTC which were designed to address FTC's unconstitutional and improper "rule" imposing a vague and undefined standard for substantiating weight loss and fat loss advertising claims. Plaintiffs also paid the FTC the sum of $3,000,000, and agreed to waive and release their significant damages claims against FTC and its staff, which claims arose from FTC's unlawful publication of Plaintiffs' highly confidential and trade secret information on the Internet.

284. Plaintiffs surrendered these rights and rights to litigate in order to obtain a clear, definite and precise definition of the scientific basis Plaintiffs would have to have and rely on for advertising statements relating to weight loss and fat loss for dietary supplements.

285. The Fifth Amendment Due Process clause requires FTC to abide by, conform to and respect the conditions upon which Plaintiffs entered into that Agreement and the express terms thereof.

286. FTC must construe the Agreement as written, not as that document might have been written, and not as FTC may have written an order had FTC successfully established its factual claims and legal theories through further litigation in the FTC Administrative Proceeding.

287. FTC has violated Plaintiffs' Fifth Amendment Due Process rights by depriving Plaintiffs of their liberty and property interests without due process of law by not adhering to the terms of the Agreement negotiated and agreed upon by Plaintiffs and FTC.

288. There is no administrative process Plaintiffs can utilize to compel the FTC to

honor Plaintiffs' rights under the Agreement.

289. Plaintiffs accordingly seek a declaration that FTC's actions, including FTC's insistence that Plaintiffs meet requirements and conditions not contained within the four corners of the Agreement, constitute a present and ongoing violation of Plaintiffs' Fifth Amendment Due Process rights.

FOURTH CLAIM FOR RELIEF
Declaratory Relief

290. Plaintiffs hereby incorporate by reference the preceding paragraphs by reference as though fully set forth herein.

291. An actual controversy has arisen and does now exist between Plaintiffs and the FTC with respect to whether FTC is in breach of the Agreement.

292. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration of their rights and obligations with respect to the Agreement and specifically a declaration that:

a. The Agreement defines what Plaintiffs must possess and rely upon to have a reasonable basis for weight loss and fat loss claims in advertising for dietary supplements;

b. The reasonable basis standard contained in the Agreement is clear and unambiguous;

c. Pursuant to the express terms of the Agreement, Plaintiffs are entitled to make weight loss and fat loss claims in advertisements if Plaintiffs have a reasonable basis to make those claims;

d. Pursuant to the express terms of the Agreement, Plaintiffs have a reasonable basis to make weight loss and fat loss claims when Plaintiffs possess and rely

upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results;

e. The reasonable basis standard set forth in the Agreement is not a variable or flexible standard;

f. The Agreement does not require that there be a consensus or general consensus in the scientific community before Plaintiffs can make advertising claims;

g. By refusing to abide by and honor the terms of the Agreement, and instead unilaterally imposing upon Plaintiffs additional terms and requirement found nowhere in the Agreement, FTC is in material breach of the Agreement.

293. In connection with the relief Plaintiffs seek through this particular claim, Plaintiffs do not seek an order of specific performance, or any other order which directs FTC to comply with the terms of the Agreement. Indeed, Plaintiffs do not seek an order of specific performance or any other order with directs FTC to comply with the terms of the Agreement. Nor do Plaintiffs seek any order enjoining FTC from exercising its administrative authority, even if the exercise of that authority results in FTC taking some action against Plaintiffs should FTC decide such action is necessary and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. On the First Claim for Relief, for a declaration that:

a. The Agreement operates as a contract defining the rights and duties of the

Parties thereto vis-à-vis the subject matter of the Agreement;

b. The Agreement defines what Plaintiffs must possess and rely upon for weight loss and fat loss claims in advertising for dietary supplements;

c. The reasonable basis standard contained in the Agreement is clear and unambiguous;

d. The express terms of the Agreement permit Plaintiffs to make weight loss and fat loss claims in advertisements for dietary supplements if Plaintiffs have a reasonable basis. Pursuant to the express terms of the Agreement, Plaintiffs have a reasonable basis when Plaintiffs possess and rely upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results;

2. On the Second Claim for Relief, a declaration that FTC's actions, including FTC's insistence that Plaintiffs meet requirements and conditions not contained within the four corners of the Agreement, constitute a present and ongoing violation of Plaintiffs' First Amendment right to freedom of speech;

3. On the Third Claim for Relief, a declaration that FTC's actions, including FTC's insistence that Plaintiffs' meet requirements and conditions not contained within the four corners of the Agreement, constitute a present and ongoing violation of Plaintiffs' Fifth Amendment Due Process rights;

4. On the Fourth Claim for Relief, a declaration that:

a. The Agreement defines what Plaintiffs must possess and rely upon to have a reasonable basis for weight loss and fat loss claims in advertising for dietary supplements;

b. The reasonable basis standard contained in the Agreement is clear and unambiguous;

c. Pursuant to the express terms of the Agreement, Plaintiffs are entitled to make weight loss and fat loss claims in advertisements if Plaintiffs have a reasonable basis to make those claims;

d. Pursuant to the express terms of the Agreement, Plaintiffs have a reasonable basis when Plaintiffs possess and rely upon any one or more of the following: tests or analyses or research or studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results;

e. The reasonable basis standard set forth in the Agreement is not a variable or flexible standard;

f. The Agreement does not require that there be a consensus or general consensus in the scientific community before Plaintiffs can make advertising claims;

g. By refusing to abide by and honor the terms of the Agreement, and instead unilaterally imposing upon Plaintiffs additional terms and requirement found nowhere in the Agreement, FTC is in material breach of the Agreement.

5. For costs of suit incurred herein; and

6. For such other relief as the Court deems just and proper.

DATED this 31st day of August, 2009.

BURBIDGE MITCHELL & GROSS

Richard D. Burbidge
Robert J. Shelby
Robert P.K. Mooney
Attorneys for Plaintiffs

EXHIBIT A

UNITED STATES OF AMERICA

BEFORE

FEDERAL TRADE COMMISSION

DOCKET NO.

D09318

IN THE MATTER OF:

BASIC RESEARCH, LLC, ET AL.

ORDER

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

Commissioners: **Deborah Platt Majoras, Chairman**
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

In the Matter of	
BASIC RESEARCH, L.L.C.,	
a limited liability corporation,	
A.G. WATERHOUSE, L.L.C.,	
a limited liability corporation,	
KLEIN-BECKER USA, L.L.C.,	
a limited liability corporation,	
NUTRASPORT, L.L.C.,	
a limited liability corporation,	
SOVAGE DERMALOGIC LABORATORIES, L.L.C.,	
a limited liability corporation,	
BAN, L.L.C.,	**DOCKET NO. 9318**
a limited liability corporation, also doing	
business as BASIC RESEARCH, L.L.C.,	**DECISION AND ORDER**
OLD BASIC RESEARCH, L.L.C.,	
BASIC RESEARCH, A.G. WATERHOUSE,	
KLEIN-BECKER USA, NUTRA SPORT, and	
SOVAGE DERMALOGIC LABORATORIES,	
DENNIS GAY,	
individually and as an officer	
of the limited liability corporations,	
DANIEL B. MOWREY,	
also doing business as	
AMERICAN PHYTOTHERAPY RESEARCH	
LABORATORY, and	
MITCHELL K. FRIEDLANDER	

The Federal Trade Commission having issued its Complaint charging the 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., BAN, L.L.C., (d/b/a Basic Research, L.L.C., Old Basic Research, L.L.C., Basic Research, A.G. Waterhouse, Klein-Becker USA, Nutra Sport, and Sovage Dermalogic Laboratories), Dennis Gay, Daniel B. Mowrey, (d/b/a American

Phytotherapy Research Laboratory), and Mitchell K. Friedlander named in the caption hereof with violations of Section 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. § 45(a) and 52 as amended, and Respondents having been served with a copy of that Complaint, together with a notice of contemplated relief, and Respondents having filed answers to the Complaint, denying the allegations set forth therein; and

Respondents, their attorneys, and Counsel for the Commission having thereafter executed an Agreement Containing Consent Order, an admission by Respondents of all the jurisdictional facts set forth in the Complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged as such in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers, releases, and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(c) of its Rules; and

The Commission having considered the matter and having thereupon accepted the executed Consent Agreement and placed such Agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure described in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following Order:

1. Respondent Basic Research, L.L.C., is a Utah limited liability company with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

2. Respondent A.G. Waterhouse, L.L.C., is a Wyoming limited liability company with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

3. Respondent Klein-Becker USA, L.L.C., is a Utah limited liability company with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

4. Respondent Nutrasport, L.L.C., is a Utah limited liability company with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

5. Respondent Sovage Dermalogic Laboratories, L.L.C., is a Utah limited liability company with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

6. Respondent BAN, L.L.C., is a Utah limited liability company with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

7. Respondent Dennis Gay is an officer of the limited liability companies. His principal place of business is the same as that of the limited liability companies.

8. Respondent Daniel B. Mowrey is an individual also doing business as American Phytotherapy Research Laboratory. His principal office or place of business is located at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

9. Respondent Mitchell K. Friedlander is an individual whose principal office or place of business is the same as that of Mowrey.

10. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

11. Respondents waive:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law, which the parties agree will not be entered;

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; provided that this waiver does not affect respondents' rights to assert any defenses in any Commission action not enforcing this order;

d. Respondents further waive and release any claim respondents may have against the Federal Trade Commission and the employees, agents, or representatives of the FTC arising from this enforcement action; and

e. Respondents shall cause a dismissal of the litigation entitled *Carter-Reed Company, LLC v. Federal Trade Commission*, pending in the United States District Court for the District of Utah, Civil No. 2:04cv001142DB, and agree that it will not be re-filed to challenge or contest the validity of this Order, or any FTC agency action that has been taken against respondents prior to this agreement.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

3. "Endorser" and "endorsement" shall mean as defined in 16 C.F.R. 2.55.0(b).

4. "Food" and "drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

5. Unless otherwise specified, "respondents" shall mean 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., d/b/a Basic Research, L.L.C., Old Basic Research, L.L.C., Basic Research, A.G. Waterhouse, Klein-Becker USA, Nutra Sport, and Sovage Dermalogic Laboratories, Dennis Gay, Daniel B. Mowrey, and Mitchell K. Friedlander, and each of the above's successors and assigns, and their officers, agents, representatives, and employees.

6. "Substantially similar product" shall mean any product that is substantially similar in ingredients, composition, and properties.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Leptoprin, Anorex, PediaLean, or any substantially similar product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of the names "Cutting Gel," "Tummy Flattening Gel," "Anorex" and "PediaLean," or other trade names, or through the use of endorsements, that such product causes weight or fat loss, unless at the time the representation is made, respondents possess and rely upon a reasonable basis for the representation, which shall consist of competent and reliable scientific evidence.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, drug, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of trade names or endorsements, about the effect of such food, drug or dietary supplement on any disease, or about the effect of such food, drug or dietary supplement on the structure or function of the human body or other health benefits or weight loss

benefits, unless at the time the representation is made respondents possess and rely upon a reasonable basis for the representation, which shall consist of competent and reliable scientific evidence.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of endorsements or trade names, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Leptoprin, Anorex, or any other product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of endorsements:

A. That respondent Daniel B. Mowrey is a medical doctor; or

B. The profession, expertise, training, education, experience or qualifications of Mowrey or any other endorser.

V.

IT IS FURTHER ORDERED that payment shall be made to the Federal Trade Commission the sum of three million dollars ($3,000,000). This payment shall be made in the following manner:

A. Basic Research, L.L.C. shall make the payment, on behalf of all respondents, by wire transfer or certified or cashier's check made payable to the Federal Trade Commission, the payment to be made no later than fifteen (15) days after the date that this order becomes final; *provided* that all respondents are primarily liable, jointly and severally, for the payment amount, including any default payment amount if the payment is in default, unless and until payment is made in full.

B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable.

C. The funds paid, together with any accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of any of the products challenged in the complaint in connection with the acts or practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty or punitive assessment.

D. Respondents relinquish all dominion, control and title to the funds paid, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of either respondent, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

VI.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VII.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VIII.

IT IS FURTHER ORDERED that respondents Dennis Gay, Daniel B. Mowrey, and Mitchell K. Friedlander, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment, or of their affiliation with any new business or employment. The notice shall include the respondents' new business address and telephone number and a description of the nature of the business or employment and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondents shall, for three (3) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. Copies of all advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. Any tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that reasonably contradict, qualify or call into question the representation or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

X.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XI.

IT IS FURTHER ORDERED that respondents shall notify the Commission at least thirty (30) days prior to any change in the respondent corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XII.

IT IS FURTHER ORDERED that respondents shall, within ninety (90) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XIII.

This order will terminate on June 19, 2026, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark

Donald S. Clark
Secretary

SEAL:
ISSUED: June 19, 2006

EXHIBIT B

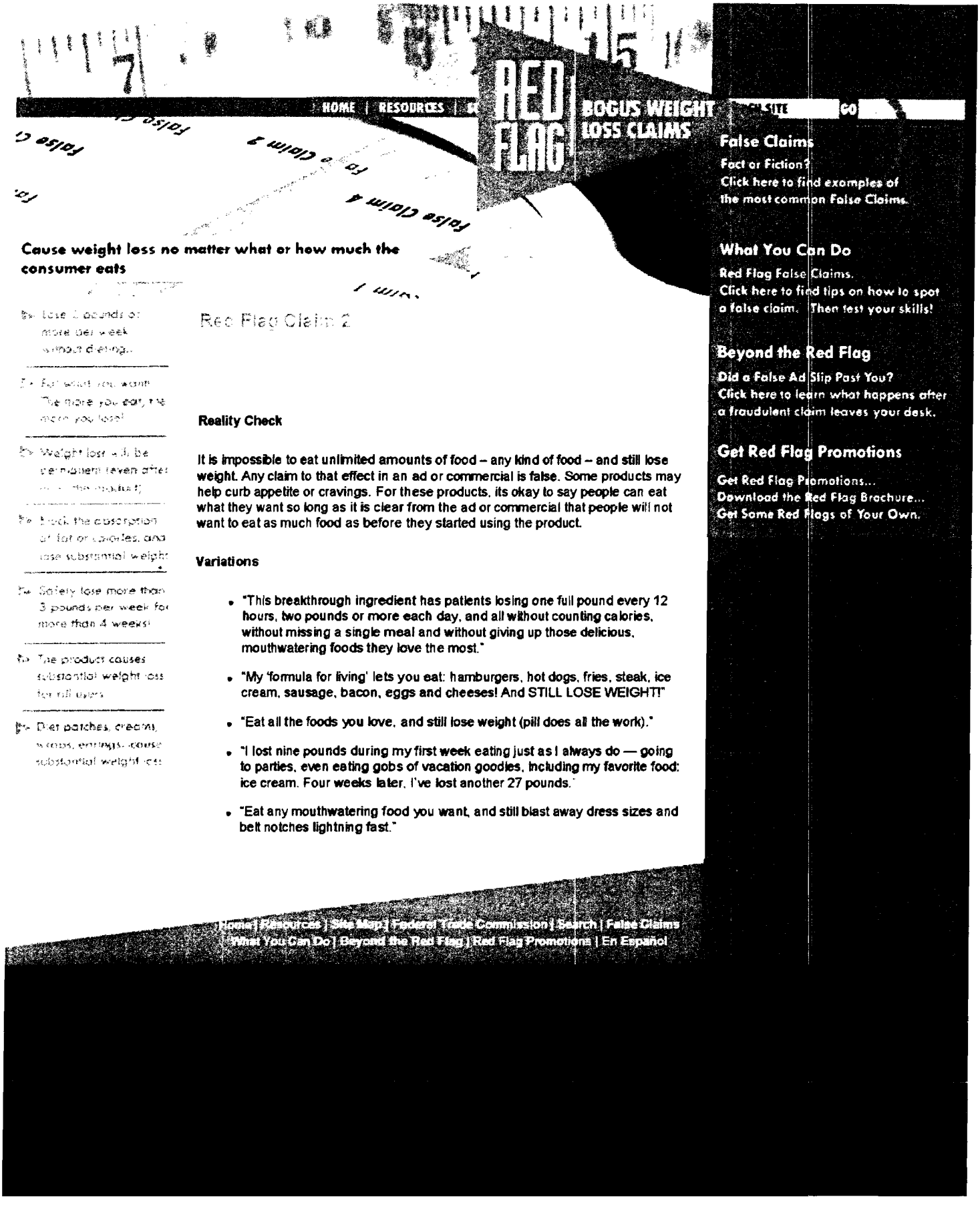
HOME | RESOURCES |
RED FLAG
BOGUS WEIGHT LOSS CLAIMS
False Claims
Fact or Fiction?
Click here to find examples of the most common False Claims.
What You Can Do
Red Flag False Claims.
Click here to find tips on how to spot a false claim. Then test your skills!
Beyond the Red Flag
Did a False Ad Slip Past You?
Click here to learn what happens after a fraudulent claim leaves your desk.
Get Red Flag Promotions
Get Red Flag Promotions...
Download the Red Flag Brochure...
Get Some Red Flags of Your Own.
Cause weight loss no matter what or how much the consumer eats
Red Flag Claim 2
Reality Check
It is impossible to eat unlimited amounts of food – any kind of food – and still lose weight. Any claim to that effect in an ad or commercial is false. Some products may help curb appetite or cravings. For these products, its okay to say people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product.
Variations
"This breakthrough ingredient has patients losing one full pound every 12 hours, two pounds or more each day, and all without counting calories, without missing a single meal and without giving up those delicious, mouthwatering foods they love the most."
"My 'formula for living' lets you eat: hamburgers, hot dogs, fries, steak, ice cream, sausage, bacon, eggs and cheeses! And STILL LOSE WEIGHT!"
"Eat all the foods you love, and still lose weight (pill does all the work)."
"I lost nine pounds during my first week eating just as I always do — going to parties, even eating gobs of vacation goodies, including my favorite food: ice cream. Four weeks later, I've lost another 27 pounds."
"Eat any mouthwatering food you want, and still blast away dress sizes and belt notches lightning fast."
Home | Resources | Site Map | Federal Trade Commission | Search | False Claims | What You Can Do | Beyond the Red Flag | Red Flag Promotions | En Español

EXHIBIT C

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

Bureau of Consumer Protection
Division of Enforcement

Lemuel Dowdy
Attorney

Direct Dial:
(202) 326-2981

Fax:
(202) 326-2559

November 2, 2007

VIA EMAIL AND U.S. MAIL
Linda A. Goldstein, Esq.
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, New York 10036

Re: *In the Matter of Basic Research, LLC, et al.*, FTC Docket No. 9318

We have completed our review of Respondents' compliance report and supplemental supporting materials and determined that Respondents have violated two provisions of the Commission's Order issued on June 19, 2006. The purpose of this letter is to set forth the claims that violate Paragraphs II and III of the Order, present our analysis of Respondents' purported substantiation for the claims, and inform Respondents that they must promptly revise their advertisements to comply with the Order.[1]

I. Introduction

This letter focuses primarily on the deficiencies of the Andersen/Fogh[2] and Antonio[3] studies, upon which Respondents rely most heavily as support for their products claims. Before we turn to those studies, however, we first address three of Respondents' other often-mentioned

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[1] We did not review or seek Respondents' substantiation for all of the Respondents' advertising claims covered by the Order. The claims identified here do not constitute an exhaustive list of all statements by Basic Research that may violate the Order.

[2] T. Andersen and J. Fogh, *Weight Loss and Delayed Gastric Emptying Following a South American Herbal Preparation in Overweight Patients*, 14 Journal of Human Nutrition and Dietetics 3, 243–50 (2001).

[3] J. Antonio, et al., *Effects of a Standardized Guggulsterone Phosphate Supplement On Body Composition in Overweight Adults: A Pilot Study*, 50 Current Therapeutic Research 4, 220-27 (1999).

substantiation materials, which we have determined do not constitute competent and reliable scientific evidence. First, the Consumer Study[4] does not constitute such evidence in support of Respondents' weight loss claims for three primary reasons: (1) the study only lasted 28 days; (2) the study required the subjects to weigh and measure themselves and report the data to the researchers; and (3) by the fourth week of the study, only 44% of the subjects followed the researchers' dosage instructions.[5]

Second, Respondents claim that consumer testimonials provide a reasonable basis for their product claims. It is clear from FTC case law, however, that testimonials do not constitute competent and reliable scientific evidence. *See, e.g., Removatron Int'l Corp.*, 111 F.T.C. 206, 234 (1988) ("It is well settled that testimony of satisfied users of a product is of little evidentiary value in determining the adequacy of substantiation for an advertising claim of effectiveness of a product or device."), *aff'd*, 884 F.2d 1489 (1st Cir. 1989).

Third, the ghrelin study conducted by Daniel Mowrey and Natalie Chevreau[6] is not competent and reliable scientific evidence because it involved only five subjects in an uncontrolled setting.

II. Violations of Paragraph II of the Order

Paragraph II of the Order prohibits unsubstantiated representations about the weight loss benefits of any food, drug or dietary supplement. In violation of Paragraph II of the Order, Basic Research represents the weight loss benefits of several products without possessing and relying upon competent and reliable scientific evidence. The Andersen/Fogh study does not constitute competent and reliable scientific evidence to support claims A through C. Indeed, the fact that the article reporting the study does not contain a statistical analysis calls into question the

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[4] C.H.S. Ruxton, et al., *Effects of an Over-the-Counter Herbal Weight Management Product (Zotrim) on Weight and Waist Circumference in a Sample of Overweight Women: a Consumer Study*, 35 Journal of Nutrition & Food Science 5, 243-50 (2005).

[5] We note that the expert panel advising the authors of the meta-analysis of ephedrine weight-loss studies (the Rand Report) determined that treatment durations shorter than eight weeks were insufficient to assess weight loss. *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*, Evidence Report/Technology Assessment No. 76 (Prepared by the Southern California Evidence-Based Practice Center, RAND, Paul Shekelle, MD, PhD, Task Order Director, under contract with HHS Agency for Healthcare Research and Quality) (Feb. 2003).

[6] "Effect of the IPT Combination and Methylxanthines on Plasma Ghrelin Levels in Women Subjects." (BR0004424 to BR0004430).

reliability of the study as support for any weight loss claim.[7] Similarly, miscellaneous other materials Respondents submitted to support claim D do not constitute competent and reliable scientific evidence substantiating that claim. We discuss the unsubstantiated claims, which are implied claims conveyed by Respondents' advertising, and the inadequacy of Respondents' substantiation in more detail below.[8]

A. Unsubstantiated Claim: Akavar allows users to eat unlimited amounts of food and still lose weight.[9]

Explanation of Violation: Advertisements for Akavar represent that users can eat all they want and still lose weight, which conveys the implied claim that users can eat unlimited amounts of food and still lose weight. The Andersen/Fogh study does not constitute competent and reliable scientific evidence that users taking Akavar can eat unlimited amounts of food and still lose weight because the researchers did not monitor the caloric intake of those subjects who took the YGD compound and lost weight. In fact, the authors proposed further

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[7] While our primary concerns about the Andersen/Fogh study are set forth in the body of the letter, we have some additional reservations about Respondents' reliance on that study. First, the length of the study, 45 days, may be insufficient to assess weight loss, as noted in footnote 5, above. Second, the preparations of yerba mate, guarana, and damiana used in the study may differ from those in Respondents' products, even though the amount of the ingredients may be the same in both. The Dietary Supplement guidelines note (at 18) that marketers should not rely solely on clinical trials using different extract preparations as competent and reliable evidence of efficacy. Different preparations of the same plant may contain widely divergent amounts of active compounds. The part of the plant used and the method of preparation (which can range from powdering dried crude herbs to sophisticated extraction techniques using a variety of solvents) can result in very different end products. Third, Respondents' inclusion of ingredients in addition to the YGD compound, particularly DHEA, which is an endogenous hormone and a precursor to male and female sex hormones, may cause additional effects that cannot be attributed to YGD alone.

[8] We note that claims A through C are "Red Flag" claims. *See* the FTC's publication "Red Flag Bogus Weight Loss Claims" ("Red Flags") located at http://www.ftc.gov/bcp/conline/pubs/buspubs/redflag.pdf. It is staff's view that such claims are scientifically infeasible at the current time. Nonetheless, this letter assesses the substantiation materials Respondents rely upon most heavily.

[9] Most of the Akavar ads contain this claim: "EAT ALL YOU WANT AND STILL LOSE WEIGHT." *See, e.g.*, 30- and 60-second television commercials; www.dynakorpharmacal.com (last visited October 31, 2007); www.akavardirect.com (last visited October 31, 2007); BR0004968; BR0004972.

research to understand the effect, if any, of the YGD compound on appetite and caloric intake.

If the respondents could substantiate a claim that the product reduces appetite, a claim that people using the product can eat what they want would not necessarily violate the Order so long as the advertising discloses clearly and conspicuously that users will not want to eat as much food as before they started using the product. As explained above, however, the Respondents have not substantiated a claim that the product reduces appetite. Even if the Respondents could substantiate such a claim, we do not believe the Akavar advertising discloses clearly and conspicuously that the product will cause people to want to eat less food. For example, in the 30-second commercial, the words "EAT ALL YOU WANT AND STILL LOSE WEIGHT," are repeated aloud and on screen. However, the closest the commercial comes to suggesting that people will want to eat less food is the phrase "Caloric Restricting Compound," which appears on screen twice, but is not said aloud or explained. Similarly, Akavar's print ads include the claim "AUTOMATIC CALORIC RESTRICTION,"[10] accompanied by the statement that "Study participants were specifically told not to alter their eating habits and they still lost weight." These vague references to caloric restriction do not convey to consumers that Akavar will cause them to want to eat less food. Indeed, they may suggest that such restriction is not necessary. Appetite is not the only factor in food intake. If consumers interpret not altering their eating habits to mean consuming the same quantity of food, weight loss would not be expected to occur.

B. Unsubstantiated Claim: Akavar causes substantial weight loss in all users.[11]

Explanation of Violation: Respondents' Akavar ads imply that all Akavar users will experience substantial weight loss. However, no weight loss product causes weight loss in all users. Akavar websites (but not Akavar television commercials) do contain a statement that no diet pill can work for everyone, but this statement is completely overwhelmed by more prominent claims touting 100% success.

C. Unsubstantiated Claim: Estrin-D causes permanent weight loss.[12]

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[10] *See, e.g.*, BR0004972.

[11] One website selling Akavar states: "YOU WILL NOT FAIL THIS TIME" and "FACT: TESTS PROVE VIRTUALLY 100% SUCCESS!" That's right. While no diet pill can possibly work for everybody (that's why there's a money-back guarantee) scientific documentation has confirmed that virtually everyone in the study who used Akavar's active compound (23 out of 24 participants, to be exact) lost weight." *See* www.akavardirect.com (last visited October 31, 2007).

[12] Marketing materials for Estrin-D state: "In other words, the active ingredients in Estrin-D caused easy, automatic, permanent weight loss without calorie-counting and without

Explanation of Violation: The Andersen/Fogh study does not constitute competent and reliable scientific evidence to support the claims that customers taking Estrin-D will experience permanent weight loss for two reasons. First, the longest segment of the study was 12 months, which is not long enough to support a "permanent" weight loss claim. Second, during the 12-month segment, 22 subjects took the YGD compound in an uncontrolled setting. As a result, the study does not constitute competent and reliable scientific evidence substantiating this claim.

D. Unsubstantiated Claim: Relacore causes a reduction in abdominal fat.[13]

Explanation of Violation: This claim is not supported by competent and reliable scientific evidence. Respondents' substantiation materials do not include studies of Relacore itself or, with one inconsequential exception, any studies showing that any of the ingredients in Relacore cause a reduction in abdominal fat.[14] Instead, Respondents' substantiation rests on the theoretical chain of reasoning that the purported mood elevating or stress reducing effects of the ingredients in Relacore reduces cortisol levels, which, in turn, reduces abdominal fat. (*See* July 23rd letter at 21).

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diet rebound." *See, e.g.*, www.thebodyforum.com/?p=EstrinD (last visited October 31, 2007); www.estrin-d.com/estrin-d-faq3.php (last visited October 31, 2007); BR0000441.

[13] Relacore's product carton states: "Relacore's natural anti-stress, mood elevating formula can help alter the underlying stress-related causes of excess belly fat. . . leaving you happier, full of energy, and with that flat, youthful tummy you thought you'd never see again" Other ads state: But now there's Relacore. Relacore helps control cortisol and helps us lose stubborn belly fat. . . FAST!" (BR0000748) Similarly, the homepage of www.relacore.com (last viewed October 31, 2007) states: "Can an all-natural 'feel good pill' help shrink your 'Belly FAT?' The answer may surprise you. (Click here to find out more.)" When consumers click, the following language appears: "But now you can beat stress-induced belly fat with Relacore, the breakthrough all-natural anti-anxiety, mood elevating pill that, in conjunction with a sensible diet and exercise program, helps control stress-induced cortisol production, thereby helping reduce belly fat."

[14] Respondents have submitted at least one study suggesting that DHEA may reduce abdominal fat in elderly adults. It is clear from a 2003 review that, at that time, there was a major conflict among DHEA studies as to whether DHEA causes changes in body composition. *See* K. Ketan, et al., *Dehydroepiandrosterone: Is There A Role for Replacement?* 78 Mayo Clin. Proc., 1257-1273 (2003). In addition, a recent two-year study found no differences in body composition between elderly adults taking DHEA and those receiving a placebo. *See* K.S. Nair et al., *DHEA in Elderly Women and DHEA or Testosterone in Elderly Men*, 355 New Engl. J. Med. 16, 1647-59 (2006).

Respondents have not, however, presented competent and reliable scientific evidence that Relacore, even if it does elevate mood or reduce stress, also reduces cortisol and belly fat. It is not clear that reducing stress or elevating mood leads to less cortisol and less abdominal fat.[15] For example, it is well known that many anti-depressant prescription drugs actually cause weight gain.[16]

In addition, although some studies suggest that elevated cortisol levels are associated with abdominal fat, a cause and effect relationship has not been established conclusively. For example, an article reporting a study on cortisol levels in middle-aged and older men states: "It remains unknown, however, whether excess cortisol secretion is primarily a cause, or is rather a consequence of human obesity itself.[17] In addition, Dr. Malcolm Low, MD, Ph.D., senior scientist and Associate Director, Center for the Study of Weight Regulation and Associated Disorders, Oregon Health & Science University, Portland, has been quoted as stating: "For the average person who has gained a bit too much weight, the problem isn't that he or she makes too much cortisol. It is probably that this person eats too much fast food and doesn't exercise. Even if such people have elevated cortisol, it is because they have excess body fat, not because there was too much cortisol to begin with. The medical condition of excess cortisol is unusual."[18]

In summary, the Relacore weight loss claims are not supported by competent and reliable scientific evidence because Respondents' substantiation materials do not demonstrate that elevating mood or reducing stress (assuming Relacore produces such effects) necessarily reduces a person's levels of cortisol or abdominal fat. In addition, Respondents have not demonstrated that stress-related increases in cortisol levels lead to an increase in abdominal fat.

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[15] Indeed, one study Respondents submitted states: "It is not yet clear whether measures which relieve chronic psychological stress can be broadly useful for controlling visceral obesity . . ." M.F. McCarty *Modulation of adipocyte lipoprotein lipase expression as a strategy for preventing or treating visceral obesity*. (BR0009727, BR0009731).

[16] *See* M. Fava, *Weight Gain and Antidepressants*, 61 J. Clin. Psychiatry Supp. 11, 37-41 (2000).

[17] G. Travison et al., *Cortisol levels and measures of body composition in middle-aged and older men*, 67 Clinical Endocrinology, 71-77 (2007).

[18] *See* article "Stress Hormone: No Link to Obesity?" located at http://www.medicinenet.com/script/main/art.asp?articlekey=57726 (last visited October 31, 2007).

III. Violations of Part III of the Order

Part III of the Order prohibits misrepresentations of the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research. We have determined that certain implied claims in Respondents' advertisements relating to the Andersen/Fogh study and the Antonio study violate Part III. We discuss the claims and their proposed substantiation below.

A. **Misrepresentation**: Respondents' advertisements for Akavar misrepresent the Andersen/Fogh study by claiming that this test proves that Akavar causes weight loss.[19]

Explanation of Violation: This claim misrepresents the conclusions of the Anderson/Fogh study. Instead of concluding that the study proves that the tested compound causes weight loss, the article reporting the Andersen/Fogh study states that the study's results should be considered preliminary: "[T]his herbal preparation may prove to be an additional new method for facilitating weight loss. Further clinical studies with dietetic monitoring of energy intake, dietary quality, satiety ratings, body weight and body composition are now indicated . . . ."

B. **Misrepresentation**: Respondents' advertisements for Akavar misrepresent the Andersen/Fogh study by claiming that the one-year portion of the study was randomized and controlled.[20]

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[19] A website selling Akavar states: " FACT: TESTS PROVE VIRTUALLY 100% SUCCESS . . . In a controlled, randomized clinical trial (the only type of proof accepted by the both [sic] scientific and medical communities) doctors tested a group of overweight patients. And among those that took the active, patented Akavar 20/50 compound, 23 out of 24 people lost a substantial amount of weight . . . In other words, Akavar 20/50 caused automatic weight loss without calorie counting and with diet rebound." *See* www.dynakorpharmacal.com (last visited October 31, 2007).

[20] A website selling Akavar states: "In a controlled randomized clinical trial (the only type of proof accepted by the both [sic] scientific and medical communities) doctors tested a group of overweight patients. And among those that took the active, patented Akavar compound, 23 out of 24 people lost a substantial amount of weight. But there's more! Not one of the subjects who continued taking the active Akavar weight-loss compound for a period of one full year experienced rebound weight gain. Not one! In other words Akavar caused easy, automatic weight loss without calorie counting and without diet rebound." *See* www.dynakorpharmacal.com (last visited October 31, 2007).

Explanation of Violation: In fact, the one-year portion of the study was not randomized or controlled.

C. **Misrepresentation**: Respondents' advertisements for Estrin-D and Zotrin misrepresent the results of the Andersen/Fogh study by claiming subjects receiving the YGD compound lost weight because they reduced their caloric intake.[21]

Explanation of Violation: In fact, however, the Andersen/Fogh study did not establish the mechanism leading to the weight loss in the group taking the YGD compound. Indeed, as already discussed, the authors proposed further research to understand the effect, if any, of the YGD compound on appetite and caloric intake.

D. **Misrepresentation**: Respondents' advertisements for Estrin-D misrepresent the Andersen/Fogh study by claiming that menopausal women who received the YGD compound lost more weight than menopausal women who received a placebo.[22]

Explanation of Violation: This claim misrepresents the Andersen/Fogh study because the study as reported does not identify the ages of the individual female subjects, or which of the them were menopausal. Therefore, Dr. Mowrey must have drawn his own conclusions as to which women in the study were menopausal based solely on their age when constituting his "subgroup of 15 perimenopausal and menopausal women." Age is not an accurate method of identifying menopausal women because women do not reach menopause at the same age. Generally speaking, most North American women reach menopause sometime between the ages of 45 and 55, but menopause can occur as early as age 40 or as late as age 60. Additionally, menopause can be induced surgically (by removing ovaries) at any age.

E. **Misrepresentation**: Respondents' advertisements for Estrin-D misrepresent the results of the Andersen/Fogh study by claiming that the study proves that the YGD compound

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[21] An Estrin-D ad states: "In other words, the active ingredients in Estrin-D reduced caloric intake automatically." www.estrin-d.com/estrin-d-faq3.php (last visited October 31, 2007).

The Zotrin product package states: "Reduces daily caloric intake automatically." (BR0000924-25).

[22] "Relevant to this summary is an analysis of the weight change of the subgroup of 15 perimenopausal and menopausal women . . . . Seven of these women were randomly assigned to receive the treatment that consisted of . . . . Eight of these women . . . took capsules containing a placebo. . . . At the end of the 45 days, the YGD-treated group lost an average of 3.16 Kilos (8 lbs.) whereas the placebo group lost only an average of 0.16 kg (0.3 lbs)." http://www.estrin-d.com/estrin-d-studies.php (Last visited October 31, 2007).

causes permanent weight loss or causes users to maintain weight loss for one year.[23]

Explanation of Violation: As discussed above, the one-year portion of the Andersen/Fogh study was uncontrolled. Therefore, any claim that this portion of the study represents proof of permanent weight loss or weight maintenance is false.

F. **Misrepresentation**: Respondents' advertisements for Leptoprin SF misrepresent the Antonio study by claiming that the study represents proof of weight loss.[24] Respondents' advertisements for Stim-Free and ProVactin contain similar misrepresentations.[25]

Explanation of Violation: There are several problems with the Antonio study. First, there were only six subjects in each of the three study groups. Most scientists agree that study populations of this size are too small to produce reliable results.[26] The problem with the small study group size was compounded by large differences between the experimental group and the placebo group with respect to age, percentage of fat at baseline, and fat mass at baseline.

Second, the difference in overall weight loss between the group taking guggulsterone phosphate and the control and placebo groups was not statistically significant. The study's abstract specifically states that between-group differences in weight loss were not statistically significant. Although Respondents assert that Dr. Mowrey found evidence to the contrary, we do

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[23] *See* footnote 14, above.

[24] A website selling Leptoprin-SF states: "After Six Weeks, the Study Results Were Independently Reviewed and Verified. The Leptoprin-SF group experienced a significant decrease in overall body weight — an incredible 830% greater than the group who participated in the diet and exercise program alone!" and "Clinical Studies Don't Lie. In a recent clinical trial, subjects who were given the active Leptoprin-SF compound (in conjunction with modest caloric restriction and exercise) experienced eleven times (1100%) more weight loss and 63% more fat loss than those on diet and exercise alone." *See* www.leptoprin.com (Last visited August 13, 2007); BR0000557-559.

[25] The Stim-Free and ProVactin packages state: "What else does this scientifically validated study clinical trial confirm? Simply this: there's a 100% stimulant-free, clinically proven way to lose excess pounds of spongy fat and flab." (BR0000343, BR0000671).

[26] *See* L.M. Hsu, *Random Sampling, Randomization, and Equivalence of Contrasted Groups in Psychotherapy Outcome Research*, 57 Journal of Consulting and Clinical Psychology 1, 131-137 (1989). *See also* Stephen D. Simon, Statistical Evidence in Medical – Trials What do the data really tell us? 4 (Oxford University Press 2006).

not believe that Dr. Mowrey's information is reliable. The researchers who conducted the study published a correction to state that the difference between the guggulsterone phosphate group and the other groups was statistically significant with respect to fat mass, but the correction did not change the statement about the lack of significant between-group differences in weight loss.

Apparently, Dr. Mowrey relies on a statement in the U.S. Patent application for the guggulsterone phosphate compound claiming that there was a significant between-group difference in weight loss. This statement is not reliable. It is part of a one-paragraph summary of the study that appears in an application dated October 27, 1998, months before the study was reported in April 1999 and corrected in November 1999.

Finally, we disagree with the statement in your June 21st letter that a Utah federal district court judge made favorable statements about the Antonio study in his "Findings of Fact and Conclusions of Law and Order" issued in *Basic Research, LLC v. Cytodyne Technologies, Inc.* In fact, the judge referred to a study of an ephedrine product that was published in the April, 2000 issue of Current Therapeutic Research. As you know, the Antonio study appeared in that publication's April, 1999 issue.

IV. Conclusion

In closing, we believe that the Respondents have committed, and continue to commit, serious violations of the Order. We strongly encourage Respondents to take steps to ensure that their current advertising complies with the Order. We will give such steps appropriate weight in assessing whether to recommend enforcement action and the remedies the Commission should seek in any such action. At the same time, Respondents should recognize that they have been under a legal duty to comply with the Order since June 2006, and that compliance at this point will not necessarily avoid an enforcement action. Please inform us, within two weeks of the date of this letter, of the steps Respondents will take to comply with the Order. The opinions expressed in this letter are those of the staff, and do not necessarily reflect the views of the Commission or of any Commissioner.

Sincerely,

Lemuel Dowdy

EXHIBIT D

AKAVAR

BODY

EAT ALL YOU WANT & STILL LOSE WEIGHT™?

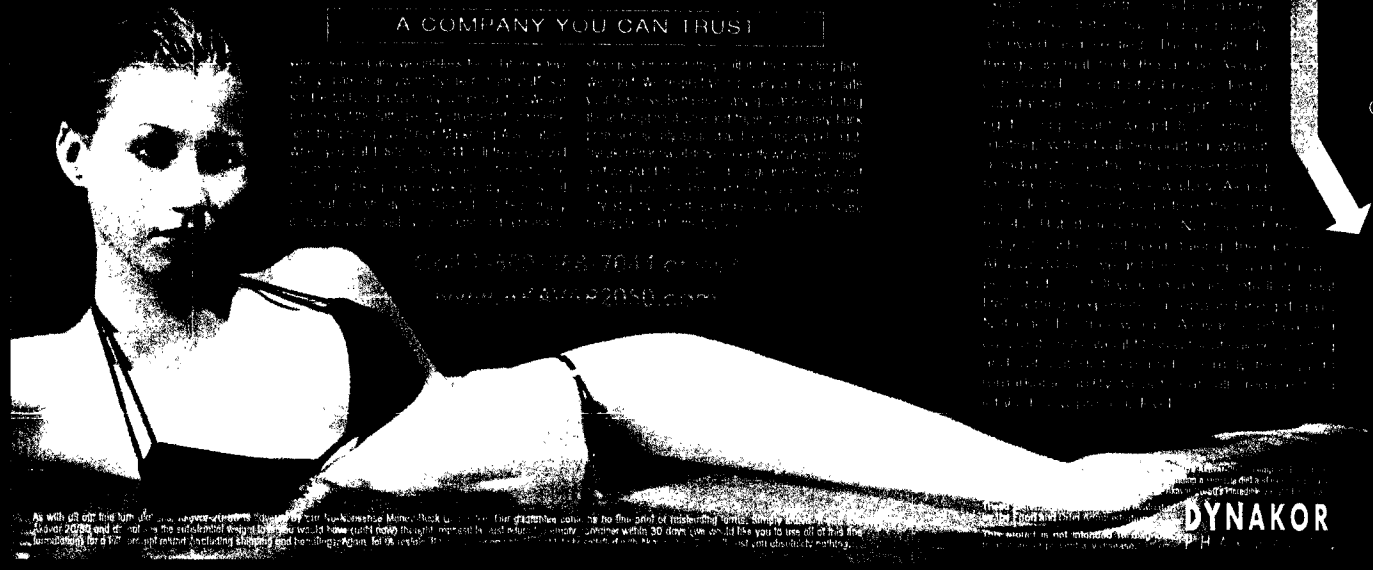
(And we couldn't say it in print if it wasn't true!)

INTRODUCING... AKÄVAR™ 20/50 "Fastest, Easiest Weight Loss Ever"

STOP: READ THIS BEFORE YOU BUY AKÄVAR™-20/50

"Eat All You Want And Still Lose Weight"™... They're the eight most provocative words in the English language (at least for those of us who've tried diet after diet and failed). But can anyone really eat all they want and still lose weight? The answer might surprise you. Losing weight is all about reducing caloric intake, and Akavar is a new-generation calorie-restricting compound that lets you eat all you want... because you want to eat less. In other words, by altering your desire to overeat (what scientists call "increasing satiety"), you reduce your caloric intake automatically, and you lose weight worry free. "dieting"... without calorie counting... without complex meal plans, frozen foods or feeling starved... and, best of all, without even trying.

A COMPANY YOU CAN TRUST



AKÄVAR™-20/50: HOW IT WORKS

FACT (Akavar 20/50 literally causes excess fat to be pulled from bulging parts of your body!

As Akavar™ 20/50 restricts caloric intake to below your daily caloric requirement, you literally pull excess fat from all over your body, including your waist, hips, thighs and buttocks (the body's natural fat storage sites)... leaving your body thinner, trimmer and sexier than you ever thought possible!

FACT Clinical trial shows success

That's right! While no diet pill can possibly work for everyone (that's why there's a money-back guarantee), the peer-reviewed clinical trial revealed that virtually everyone in the study who used Akavar 20/50's active compound (23 out of 24 participants, to be exact) lost a significant amount of weight.

FACT The secret is the formula

Akavar-20/50 is the only weight-loss compound that works automatically. There is absolutely no need to count calories, no need to consciously lower your caloric intake, no need for expensive, pre-packaged meals... and no need to give up your favorite foods! Why? Because Akavar-20/50 reduces caloric intake automatically

$39.99 FOR A FULL 60 CAPSULE SUPPLY

CALL 1-800-388-7011
AKAVAR2050.COM

DYNAKOR

EXHIBIT E

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, NW
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February 20, 2008

Via Email and U.S. Mail

Linda A. Goldstein, Esq.
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, NY 10036

Re: *In the Matter of Basic Research, LLC, et al.*, FTC Docket No. 9318

Dear Ms. Goldstein:

The purpose of this letter is to respond to the matters you raised at our meeting on December 17, 2007, and your December 26th letter and revised Akavar ad. We apologize for the delay in responding to you after our December 17th meeting. We gave careful consideration the matters you raised at the meeting and we consulted several sources to assist us in analyzing the relevant issues.

A. Akavar Advertisements

In our November 2nd letter, we identified claims in Akavar advertisements that we believe violate the Order.[1] At our meeting, we specifically discussed the following claim: "EAT ALL YOU WANT AND STILL LOSE WEIGHT (And we couldn't say it in print if it wasn't true!)"[2] At that time, you stated that the Andersen/Fogh study substantiates this claim because that study shows that the YGD compound caused users to reduce their caloric intake (*i.e.*, eat less) and, in

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[1]As recently as two weeks ago, we have seen television and point-of-sale Akavar ads that contain the same violative claims we identified in our November 2nd letter.

[2]We note that this claim is a "Red Flag" claim. *See* the FTC's publication "Red Flag Bogus Weight Loss Claims" ("Red Flags") located at http://www.ftc.gov/bcp/conline/pubs/buspubs/redflag.pdf. It is staff's view that such claims are scientifically infeasible at the current time.

turn, to lose weight.[3] We do not believe that the Andersen/Fogh study supports the claim ("Eat all you want and still lose weight") for two reasons. First, the subjects in the study were not told to eat all they wanted; they were told not to change their normal food habits. This distinction matters because many people, including persons who are overweight, do not normally eat all they want. If people believe they can eat all they want and lose weight with Akavar, they may change their normal food habits and eat more. Therefore, the study, in which subjects were told to maintain their normal food habits, does not support a claim that Akavar causes weight loss for users who eat all they want.

Second, the researchers did not confirm that the subjects taking the active Akavar compound lost weight by eating less food. They did not definitively conclude how the YGD compound caused the experimental group to lose more weight than the placebo group. Rather, they surmised, albeit without supporting data, that the subjects taking the Akavar compound lost more weight than the placebo group because they reduced their caloric intake. They did not conclude that caloric restriction was the only possible cause of additional weight loss in the experimental group, but instead called for further studies to determine the method of action.[4] This call for additional research implicitly acknowledges that other modes of action were possible.

Even if Respondents did have adequate substantiation supporting the claim that Akavar will allow users to eat all they want and still lose weight, the revised advertisement does not adequately disclose that users can eat all they want and still lose weight because they will want to eat less. The headline is prominent and dramatic, and the additional question mark at the end of the headline and text box with purportedly qualifying statements are not sufficiently prominent and dramatic to disclaim the headline. Additionally, the statements in the test box are not close enough to the headline to insure that they will be read along with the headline.

Additionally, we note three problems with the revised Akavar ad that we raised with respect to earlier Akavar ads. First, the advertisement conveys the unsubstantiated claim that Akavar causes substantial weight loss in all users.[5] This claim is strongly implied by words in the advertisement that focus specifically on the likelihood of success (*i.e.*, "Clinical trial shows success") coupled with statements that "virtually everyone" or "23 out of 24 participants" in the

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[3]We wish to reiterate the position we took in our letter of November 2, 2007, that we have several reservations with respect to the Andersen/Fogh study and, therefore, question its reliability as support for any weight loss claim.

[4]Your letter of February 5, 2008, cites Dr. Greenway's opinion that a reduction in food intake, not increased exercise, caused the observed weight loss in the Andersen/Fogh study. Dr. Greenway's opinion is flawed because it appears to be based on the incorrect assumption that a reduction in caloric intake or increased exercise are the only means by which the experimental group in the Andersen/Fogh study could have lost weight. According to the sources we consulted, however, decreasing appetite (leading to reduced caloric intake) is not the only method of action by which the YGD compound could have caused weight loss.

[5]This claim is also a Red Flag claim. See note 2.

study who used the Akavar compound lost weight.[6] Statements in the advertisements that Akavar "automatically"reduces caloric intake also convey the claim that the product works for all users.[7]

Second, the advertisement makes the unsubstantiated claim that Akavar prevents weight gain for one year. This claim is conveyed by statements describing the one-year portion of the Andersen/Fogh study:

> Not one of the subjects who continued taking the active Akavar 20/50 weight loss compound for a period of one year (in an uncontrolled "real life" setting) experienced rebound weight gain. Not one! In other words, Akavar 20/50 caused easy, automatic weight loss without calorie counting and without diet rebound . . . .

An uncontrolled study does not constitute competent and reliable scientific evidence that Akavar prevents weight gain for one year. Moreover, it is likely that any mention of the one-year portion of the Andersen/Fogh study will imply that Akavar prevents weight gain for one year.

Third, we notice that the advertisement misrepresents the instructions given to study subjects by claiming they were told "not to change their normal eating habits or exercise routine." The article reporting the Andersen/Fogh study does state that subjects were told not to change their normal food habits, but does not state that subjects were told not to change their exercise routines.

B. <u>The Antonio Study</u>

As we have discussed, our primary concern regarding the Antonio study is that the study groups were too small to produce reliable results related to fat mass loss or weight loss.[8] At our meeting in December, you took the position the between-group results related to fat mass are reliable, despite the small size of the groups, because they were statistically significant.

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[6]In fact, these phrases are very similar to an example of this Red Flag claim given in the FTC publication "Red Flag--Bogus Weight Loss Claims": "Everyone in our study lost substantial weight. Failure is impossible."

[7]Several statements in the advertisement claim that Akavar automatically reduces a users's caloric intake. For example, the text under the heading "The secret is in the formula" reads: Akavar-20/50 is the only weight-loss compound that works automatically. There is absolutely no need to count calories, no need to consciously lower your caloric intake, no need for expensive pre-measured meals . . . and no need to give up your favorite foods! Why? Because Akavar-20/50 reduces caloric intake . . . automatically."

[8]Even if the study groups were of sufficient size, the study would not support weight loss claims because the difference in overall weight loss between the group taking the guggulsterone phosphate compound and the other two groups (control and placebo) was not significant.

Upon further consideration, we continue to believe that the fat mass findings, despite their statistical significance, are undermined by the small study group size because small groups are more susceptible to covariate imbalances. Such imbalances occur when the control group differs from the experimental group in important characteristics that might influence the outcome measure. In other words, when a study uses sample sizes of less than 10, the chances are relatively high that an imbalance exits between the study groups with respect to individual characteristics that might affect the outcome. If this imbalance is present (for instance, 2 individuals in the experimental group have characteristics that could cause sudden weight loss and no individuals with these characteristics are in the placebo group), the observed difference in outcome (a statistically significant difference in weight loss between the experimental group and the placebo group) may be due to characteristics of the two individuals in the experimental group rather than the effect of the tested treatment. As one author explained:

> Randomization helps ensure that both measurable and immeasurable factors are balanced out across both the standard and the new therapy, assuring a fair comparison . . . Randomization relies on the law of large numbers. With small sample sizes, covariate imbalance may still sneak in. A study [citation omitted] showed that total sample size less than 10 could have a 50% chance or higher of having a categorical covariate with levels twice as large in one group than the other.[9]

Your letter of February 5, 2008 related to this issue does not address the potential problem of covariate imbalances in studies involving study groups of less than 10, such as the Antonio study. In the Antonio study, for example, factors affecting weight loss (such as increased exercise or illness) may not have been evenly randomized between the small study groups. For this reason, the purported weight loss effect of the product may have stemmed from variation between groups rather than the product. Results based on small study groups sizes may be clinically insignificant or otherwise unsuitable for extrapolation to the general population despite a finding of statistical significance. Therefore, we believe the Antonio study does not substantiate any of Respondents' fat mass or weight loss claims.

C. Abdominal Fat Loss Claims for Relacore

As we stated in our November 2, 2007 letter, Respondents' fat loss claims for Relacore are not supported by competent and reliable scientific evidence. Respondents addressed this at the December 17th meeting by asserting that, several years ago, FTC staff in the Division of Advertising Practices ("DAP") stated that they would not challenge claims that Relacore reduces belly fat in people with stress-induced belly fat. We have spoken with DAP staff about this and they have no such recollection. Moreover, they state that they told Respondents that Relacore's fat loss claims lacked adequate substantiation.

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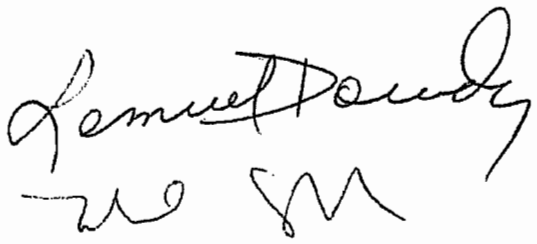
[9]Stephen D. Simon, Statistical Evidence in Medical Trials: What do the Data Really Tell Us? 4 (2006).

D. Interactivity and safety of DHEA

We have repeatedly noted our concern that DHEA, an ingredient in Akavar, Estrin-D, and Relacore, may negatively interact with other ingredients in those products and potentially counteract any purported weight loss effects. You questioned this concern at our meeting in December, and although we have not found evidence that DHEA will counteract any weight loss effect purportedly caused by Respondents' products, DHEA may nonetheless produce unintended negative effects in some people.[10]

In short, despite the matters you raised at the December 17th meeting and since then, we continue to believe that Respondents' advertising has violated the Order as explained in our November 2nd letter and Respondents should promptly cease making all of the violative claims to bring current advertising for Akavar, Leptoprin-SF, ProVactin, Stim-Free, and Relacore into compliance with the Order. Please respond within ten days from the date of this letter.

Sincerely,



Lemuel Dowdy and
Melinda Claybaugh

[10] *See* www.nlm.nih.gov/medlineplus/druginfo/natural/patient-dhea.html (discussions under the headings "Side Effects and Warnings"and "Interactions" address possible negative effects).

EXHIBIT F

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Linda A. Goldstein
Manatt, Phelps & Phillips, LLP
Direct Dial: (212) 790-4544
E-mail: lgoldstein@manatt.com

March 18, 2008

Jim Kohm
Federal Trade Commission
601 Pennsylvania Avenue NW
Washington, DC 20510

Re: Basic Research, LLC

Dear Jim:

Thank you again for taking the time to meet with us last week. We found the meeting to be highly productive and are hopeful that by continuing to share an open and constructive dialogue regarding the competent and reliable scientific evidence that Basic Research has for the claims it is making in its advertisements we will be able to reach an amicable resolution of all outstanding concerns.

As we discussed yesterday, I do wish to confirm that as a gesture of its good faith, and in order to facilitate continued discussions regarding the Akavar advertisements in a non-adversarial matter, Basic Research has agreed to pull the current advertisements for Akavar containing the headline "Eat All You Want and Still Lose Weight." As I explained to you yesterday, while Basic Research has made every effort to pull the current advertising, because of the substantial lead times involved in the placement of print advertisements, it was not able to pull all print advertising that had previously been placed. As you requested, the following is a list of the advertisements that could not be pulled and the dates these ads will appear:

USA Weekend - 3/16/08
Better Homes and Gardens - 3/18/08
Country Home - 3/18/08
First For Women - 3/17/08
Traditional Home - 3/18/08
Womans World - 3/17/08
American Profile - 4/06/08
Country Living - 4/08/08
Family Circle - 4/18/08
Latina - 4/15/08
Marie Claire - 4/15/08
Redbook – 4/15/08
TV Guide - 3/28/08

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Country Home – 4/22/08

We also wish to advise you that there were a few multi-product ads containing an abbreviated advertisement for Akavar that also could not be pulled. The following is a list of those advertisements and their scheduled issue dates:

Soaps in Dept - 3/17/08
Womans World - 3/31/08
Better Homes and Gardens - 4/15/08
National Enquirer - 3/28/08
Womans World - 4/28/08

We also wish to confirm that all television advertising for Akavar has been cancelled. This has resulted in a significant financial cost to Basic Research as it does not currently have other television advertisements for Akavar to substitute for the commercials that have been pulled.

Please be advised while Basic Research has, as a gesture of good faith, agreed to pull the television and print advertisements that contain the headline, "Eat All You Want and Still Lose Weight" Basic Research continues to believe that this statement, when presented[1] in conjunction with disclosure of the fact that consumers will want to eat less is fully consistent with the guidance provided by the Federal Trade Commission in its Red Flags brochure. Specifically, in that brochure the FTC expressly states as follows: "Some products may help curb appetite or cravings. For these products it is OK to say people can eat what they want as long as it is clear from the advertisement or commercial that people will not want to eat as much food as before they started using the product." During our meeting, you indicated that staff was satisfied that Basic Research had presented competent and reliable scientific evidence to support the fact that Akavar is an appetite suppressant. In light of the fact that Basic Research has established the efficacy of Akavar as an appetite suppressant, the FTC's own Red Flags guides would appear to permit Basic Research to make the claim "Eat All You Want" without any additional evidence or support as long as the advertisements make clear that consumers will not want to eat as much. We believe the qualifying language in the warning box clearly communicates this message. Accordingly, we would appreciate the opportunity to revisit this issue with you..

As we discussed, we will be furnishing to you under separate cover, additional information regarding both Akavar and Relacore which we hope will answer some of the outstanding issues raised during our meeting as well as copies of proposed revised advertisements for Akavar and the current revised ads for Relacore. We appreciate your

[1] Basic Research is also in the process of revising the website, and has removed the headline from the site.

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willingness to review these advertisements in light of the information we will be gathering for you.

Thank you again for your continued consideration.

Sincerely,

Linda A. Goldstein

LAG:mec

80418504.1

EXHIBIT G

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, NW
WASHINGTON, DC 20580

Division of Enforcement
Bureau of Consumer Protection

Lemuel W. Dowdy
Attorney

Direct Dial: (202) 326-2981

March 21, 2008

Sent Via Email and First Class Mail
Linda A. Goldstein, Esq.
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, NY 10036

Re: *In the Matter of Basic Research, LLC, et al.*, FTC Docket No. 9318

Dear Linda:

This letter responds to an assertion in your letter dated March 18th, which we received yesterday. You claim that, at our last meeting, we "indicated that staff was satisfied that Basic Research had presented competent and reliable scientific evidence to support the fact that Akavar is an appetite suppressant." What we in fact said was we believe the YGD study does not constitute competent and reliable evidence for an unqualified appetite suppression claim. However, in that the study provides some evidence of an appetite suppressing effect for YGD, Basic Research may make qualified statements about appetite suppression so long as the claim accurately describes the limited scientific basis for this effect.

The Red Flag guidance you referred to contemplates that marketers relying upon evidence of appetite suppression to make "eat all you want" claims (with the clear and conspicuous disclaimer that users will want to eat less) will have competent and reliable evidence for an unqualified appetite suppression claim. The YGD study does not constitute such evidence.

Additionally, as we discussed on the phone yesterday, Melinda and I will be able to meet with you on the morning of Thursday, March 27th. Please let us know what time to expect you and give us the advertisements you wish to discuss sufficiently in advance so we can review them. Please contact us if you have any questions.

Sincerely,

Lemuel Dowdy and
Melinda Claybaugh

EXHIBIT H

Product Update

What Makes Akävar®-20/50 Different?

Open any box of diet pills and what's the first thing you see? That's right, some complicated, calorie-restricted diet plan. Let's face it, if you could follow the diet plan you probably wouldn't need the pills, would you? Well you won't find a diet plan in a box of Akävar. According to the folks at Dynakor, that's what makes Akävar so different. "Whether it's Akävar's ability to delay gastric emptying or its influence on the 'hunger hormone,' ghrelin, Akävar acts as a sort of 'Super Appetite Suppressant,' reducing your caloric intake 'automatically' so you don't have to worry about what to eat, how much to eat and when you can eat it," says Akävar spokesperson, Gina Gay. "Simply take Akävar 15 minutes before main meals and you lose weight. What could be easier?"

[In Plain English]

advertisement

Extra: Controversial Diet Pill Rocks Weight-Loss Market

Miracle Pill or... Diet Scam?

AKÄVAR-20/50: Millions are taking it... Millions more are talking about it

"All I did was take a capsule before meals and I lost weight. That's it. It couldn't have been easier."

With millions of Americans struggling to get thin, you would think the release of a published, peer-reviewed clinical trial showing that virtually anyone can lose weight by simply swallowing a pill 15 minutes before meals would be instantly embraced by the scientific and medical communities.

You would expect front page news stories screaming, "Fat Cure Revealed" or "Miracle Diet Pill Discovered." Instead, the release of Akävar®-20/50 (the patented European weight-loss breakthrough) has created a firestorm of controversy.

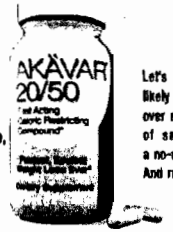
On one side you have experts who believe claims like "Eat All You Want and Still Lose Weight" and "Automatic Weight Loss" go much too far. On the other hand, you have experts who believe the weight-loss claims are fully substantiated. Still others express complete outrage. But while critics and experts debate, consumers continue their love affair with this controversial diet pill as Akävar flies off the shelf at retailers across the country. So which side is right? Or does the truth reside somewhere in the middle?

Interestingly enough, both sides seem to agree on three critical points: First, the study clearly shows that virtually everyone (23 out of 24, to be exact) lost a substantial amount of weight simply by taking the Akävar compound before main meals. Second, the participants lost the weight even though they were told not to change their normal eating habits or exercise routine. Finally, the double-blind design of the study is the "gold standard" for scientific research.

The controversy seems to begin with the question "How much science is enough science?" Some say, for example, that one study is never enough. Others, like Catherine Collins, chief dietitian at St. George's Hospital in London, complain that the number of participants in the study was too small... adding, "One of those people could have been fasting for a wedding (and) that kind of thing could throw the numbers off."

"Nonsense," says Dr. Daniel Mowrey, Ph.D., who reviewed the substantiation for Dynakor Pharmacal® Akävar's maker. "The study was peer reviewed, double-blind and well controlled. If it wasn't competent, the study wouldn't have been published. As for the comment about someone fasting for a wedding, you could just as easily argue that the numbers were thrown off because one of the participants was abducted by aliens... ridiculous."

The other flash point of the debate seems to be the advertisement's provocative headline, "Eat All You Want and Still Lose Weight." The skeptics say "impossible." But Gina Gay, spokesperson for Akävar, points to the Federal Trade Commission's own website where there seems to be a specific exemption for a weight-loss product like Akävar... a product that curbs appetite (or as the ad says,"reduces your caloric intake automatically"). "In fact," she continues, "while the FTC doesn't endorse any product, its guidelines specifically state that it's okay to say 'people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product.' This is exactly what happens when you take Akävar... you can eat what you 'want' because you want to eat less... you take two capsules before meals... you lose weight... it's that simple."



Trying to find Akävar?

Akävar is available at retailers nationwide, directly from Dynakor at [illegible] or online at [illegible]

Let's face it... nothing works for everyone. That's why the controversy is likely to continue. But when so many people are buying a product over and over again there must be something to it. As they say, thousands of satisfied customers can't be wrong. Also, Akävar comes with a no-questions-asked money-back guarantee, so what have you got to lose? And really, if all you have to do to lose weight is remember to take a couple of capsules before each meal, well, it's certainly worth a try. See you in the diet aisle!

EXHIBIT I

LOSING WEIGHT BUT STILL HAVE BELLY BULGE?

Getting rid of stubborn belly fat takes more than diet and exercise... Popular "feel-good" pill may be solution.

You diet... you exercise... you're popping the latest diet pill... *and*... you're even losing weight. But take a look in the mirror... you still have that unsightly belly bulge. Twenty pounds lighter and you still look... fat! How in the world can that be possible?

As it turns out, the same diet that's helping you lose weight might actually be causing you to retain figure-destroying belly fat. That's because dieting is stressful. You worry about what to eat... when to eat... how much to eat. All that worry leads to "diet stress."

- Do you tend to retain belly fat even when you lose weight?
- Does dieting make you stressed out and anxious?
- Are you accumulating belly fat that just won't go away?
- Do you overeat in response to daily stress?
- Do you suffer "mid-afternoon fatigue" when dieting?
- Do you have difficulty falling asleep at night when dieting?

And, as we all know by now, stress increases that nasty little stress hormone, cortisol, and cortisol increases belly fat. That's why you can go on a diet, lose weight, but still look thick around the middle.

So what are we to do? Millions of women are turning to weight-control adjuncts or "add-ons." These so-called adjuncts are not really diet pills in the true sense of the word. Instead, they help traditional diet and exercise programs reduce tummy bulge by controlling the cortisol increase generated by diet-related stress and anxiety... the same stress and anxiety that can lead to stubborn belly fat retention (not to mention that all-time diet killer: "Nervous Binge Eating").

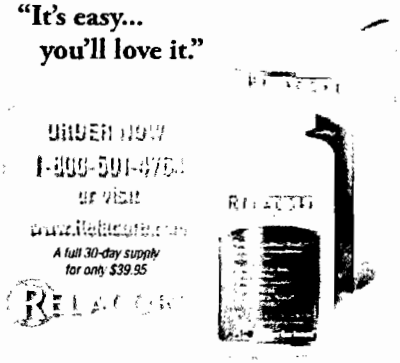
Over the past five years, the most popular "Belly Fat" pill has been Relacore® (from the Carter-Reed Company™). Relacore has sold more than 12.7 million bottles worldwide and is affectionately called "America's #1 Selling 'Belly Fat' Pill." Relacore has a great track record... and it wouldn't be America's #1 selling "Belly Fat" pill five years running if people didn't love it.

Let's face it, you not only want to lose weight, you want to look good... and looking good means a thinner waist and flatter tummy.

So if you're ready to go on a diet, or if you're already losing weight and having a hard time getting rid of your stubborn belly bulge, try this exceptional tummy-flattening, weight-control "adjunct," Relacore.

As they say in all the TV ads...

"It's easy... you'll love it."



RELACORE® Your satisfaction is 100% guaranteed. If, for any reason, you are not totally satisfied with the power of Relacore, simply return the empty container within 30 days for a full, prompt, no-question-asked refund.

EXHIBIT J

HEALTH

Could this be the fastest, easiest weight loss ever?

Pop A Pill Before You Eat & Lose Weight

"All I did was take two capsules before meals and I lost weight. That's it. It couldn't have been easier."

Millions are taking it... Millions more are talking about it... The incredible story behind this controversial European weight-loss breakthrough.

published, peer-reviewed clinical trial shows that practically anyone can lose weight by simply swallowing a pill 15 minutes before their main meals. With virtually every man and woman in America struggling to get thin, you would think this study would be instantly embraced by the scientific and medical communities.

Instead, the release of this patented European "miracle pill" has created a firestorm of controversy. Some experts feel claims like "Eat All You Want and Still Lose Weight" are over-the-top. Others are convinced the weight-loss claims are fully substantiated by the study. While the experts debate, consumers continue their love affair with this controversial European weight-loss breakthrough.

Interestingly enough, both sides seem to agree on three critical points: First, the study clearly shows that virtually everyone (23 out of 24, to be exact) lost a substantial amount of weight simply by taking the active Akāvar-20/50 compound before main meals. Second, the participants lost the weight even though they were told not, that's right, *not* to change their normal eating habits or exercise routine. Finally, the double-blind design of the study is the "gold standard" for scientific research.

Nevertheless, some experts claim that one study – even a published, peer-reviewed, double-blind study – is not enough proof to form a consensus. Others, like Catherine Collins, chief dietitian at St. George's Hospital in London, complain that the number of participants in the study is too small... adding, "One of those people could have been fasting for a wedding (and) that kind of thing could throw the numbers off."

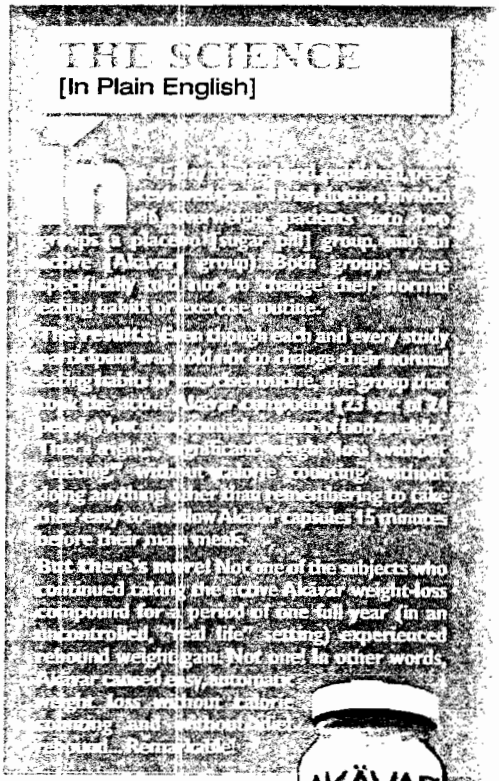
But Dr. Daniel Mowrey, Ph.D., who reviewed the substantiation on Akāvar's behalf, feels Ms. Collins' objection is utter nonsense, adding, "The study was peer-reviewed, double-blind and well controlled. If it wasn't competent, the study would never have been published. As for the comment about someone fasting for a wedding, you could just as easily argue that the numbers were thrown off because one of the participants was abducted by aliens... ridiculous."

And then there's the ad's provocative "Eat All You Want and Still Lose Weight" headline. The skeptics say "impossible." But Gina Gay, spokesperson for Akāvar, points to the Federal Trade Commission's own website where there seems to be a specific exemption for a weight-loss product like Akāvar... a product that curbs appetite (or as the ads say, "reduces your caloric intake automatically"). "In fact," she continues, "while the FTC doesn't endorse any product, its guidelines specifically state that it's okay to say 'people can eat what they want so long as it is clear from the ad or commercial that people will not want to eat as much food as before they started using the product.' This is exactly what happens when you take Akāvar... you can eat what you 'want' because you want to eat less... just take two capsules before meals... you lose weight... it's that simple."

Let's face it... nothing works for everyone. But when so many people are buying a product over and over again there must be something to it. As they say, "thousands of satisfied customers can't be wrong." Also, Akāvar comes with a no-questions-asked money-back guarantee, so basically you get to try it for free. And really, if all you have to do to lose weight is remember to take a couple of capsules before each meal, well, it's certainly worth a try. See you in the diet aisle!

While the published clinical trial using the active Akāvar-20/50 compound resulted in significant weight loss WITHOUT diet and exercise, adding a sensible diet and exercise program to your weight-loss regimen should only enhance Akāvar's weight-loss results. And remember, individual results will always vary.

THE SCIENCE
[In Plain English]



But there's more! Not one of the subjects who continued taking the active Akāvar weight-loss compound for a period of one full year (in an uncontrolled, "real life" setting) experienced rebound weight gain. Not one! In other words, Akāvar caused [illegible] weight loss without calorie [illegible]. Remarkable!

Trying to find Akāvar?

Akāvar is available at retailers nationwide, directly from Dynakor at 1-8[illegible]-544-2823 or online at www.AKAVAR2[illegible].com

Cost: about $40.00

EXHIBIT K

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, NW
WASHINGTON, DC 20580

Division of Enforcement
Bureau of Consumer Protection

Lemuel W. Dowdy
Attorney

Direct Dial: (202) 326-2981

May 12, 2008

Via Email and First Class Mail
Linda A. Goldstein, Esq.
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, New York 10036

Re: *In the Matter of Basic Research, LLC, et al.*, FTC Docket No. 9318

Dear Linda:

The purpose of this letter is to reiterate our conclusions regarding the respondents' abdominal fat reduction claims for Relacore. We stated in our letter to you, dated March 19, 2008, that the materials you had provided do not constitute competent and reliable scientific evidence substantiating any claim that Relacore reduces abdominal fat. We also stated, when we met with you, the other Basic Research attorneys and Mr. Friedlander on April 7, 2008, that the additional studies you submitted with your letter dated March 31, 2008 do not substantiate any claim that Relacore reduces abdominal fat. Thus, as we have previously stated, none of the purported substantiation you have submitted for Relacore substantiates any claim that Relacore reduces or helps reduce abdominal fat.

Sincerely,

Melinda Claybaugh
Lemuel Dowdy

EXHIBIT L

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, NW
WASHINGTON, DC 20580

Division of Enforcement
Bureau of Consumer Protection

Lemuel W. Dowdy
Attorney

Direct Dial: (202) 326-2981

October 24, 2008

SENT VIA EMAIL

Linda A. Goldstein, Esq.
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, New York 10036

Re: *In the Matter of Basic Research, LLC, et al.*, FTC Docket No. 9318

Dear Ms. Goldstein:

Pursuant to our compliance investigation in the above-captioned matter, we have concluded that Respondents Basic Research and Dennis Gay have violated the Commission Order issued June 19, 2006, in connection with sales of Relacore and Relacore PM. We believe that these law violations warrant civil penalties and injunctive relief. We are enclosing a proposed Consent Decree that we are prepared to recommend to the Commission in settlement of this matter. In the event we do not reach a negotiated settlement before **November 24, 2008**, we plan to recommend that the Commission forward the enclosed complaint to the Department of Justice for filing.

The Consent Decree does not specify a civil penalty because, without additional information from the Respondents, we cannot negotiate an appropriate civil penalty amount. In particular, we require the following information from June 19, 2006 to present:

1. Information related to international sales of Relacore, as requested in Question 1 of our letter dated September 4, 2008. Your objection to providing this information lacks merit, and we cannot negotiate a settlement unless the Respondents submit the requested sales information.

2. Advertisements and packaging used or disseminated in connection with the international marketing or sales of Relacore, and an English translation of any such advertisements or packaging in a language other than English.

3. The total number of Relacore units sold *not* excluding returns.

4. Gross revenues from Relacore sales (*i.e.*, total sales, without excluding returns of product and related refunds).

5. Gross profits from Relacore sales (*i.e.*, gross revenues less the cost of the product).

6. The basis of Respondent's net profit figure of -$5,632,282 (*i.e.*, itemization of the costs subtracted from gross revenues).

We also request the following information related to the ownership and management of Basic Research because we may recommend naming additional defendants as part of the settlement or complaint recommendation we forward to the Commission.

7. The names, addresses, officers, directors, owners, members, managers, and states of incorporation of Covarix, LLC and Western.

8. The names, addresses, officers, directors, owners, members, managers, and states of incorporation of Bydex Management and PC Management.

We would be happy to meet with you to discuss the proposed Consent Decree. If the Respondents are not interested in negotiating a settlement of this matter, please advise us as soon as possible. The opinions expressed in this letter are those of the staff and not necessarily those of the Commission or of any Commissioner.

Under Section 21(f) of the FTC Act, 15 U.S.C. § 57b-2(f), all documents and information provided voluntarily in lieu of compulsory process in law enforcement investigations will be exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. § 552(b)(3)(B). Furthermore, under Commission Rule 4.10(d), any material you provide which is marked **"CONFIDENTIAL"** will be given the same confidential treatment as material provided in response to compulsory process. The Commission's procedures concerning public disclosure and confidential treatment can be found at 15 U.S.C. §§ 46(f) and 57b-2(f), and Commission Rules 4.10 - 4.11, 16 C.F.R. §§ 4.10 - 4.11. If you decide to withhold all or any portion of any responsive material for any reason, including an applicable privilege or judicial order, you must identify each item withheld and state individually for each item: the names, addresses, positions, and organizations of all authors and recipients of the item; a description of the subject matter the item contains; and the specific reason(s) for withholding the item.

Please submit the requested information within ten days. If you have any questions regarding this letter, please contact either of us.

Sincerely,

Lemuel Dowdy and
Melinda Claybaugh

Encs.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA, **Plaintiff,** **v.** **BASIC RESEARCH, L.L.C., and DENNIS W. GAY,** **Defendants.**	**COMPLAINT FOR CIVIL PENALTIES, INJUNCTIVE AND OTHER RELIEF** **CIV. ACTION NO.**

Plaintiff, United States of America, acting upon the notification and authorization to the Attorney General by the Federal Trade Commission ("Commission"), for its Complaint alleges that:

1. Plaintiff brings this action under Sections 5(l), 13(b) and 16(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § § 45(l), 53(b) and 56(a), to obtain monetary civil penalties, a permanent injunction, rescission or reformation of contracts, restitution, the refund of moneys paid, the disgorgement of ill-gotten gains, and other equitable relief from Defendants for their violations of a final Commission order to cease and desist.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this matter under 28 U.S.C. § § 1331, 1337(a), 1345 and 1355 and under 15 U.S.C. § § 45(l), 53(b) and 56(a).

3. Venue in the United States District Court for the District of Utah is proper under

15 U.S.C. § 53(b) and under 28 U.S.C. § § 1391(b-c) and 1395(a).

4. The acts and practices of Defendants alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS

5. Defendant Basic Research, L.L.C. is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Drive, Salt Lake City, Utah 84116. Basic Research, alone and through affiliated entities, including Carter-Reed, L.L.C., manufactures and sells a variety of products, including dietary supplements purporting to promote weight loss. Basic Research transacts business in this district.

6. Defendant Dennis W. Gay is the CEO of Basic Research, L.L.C. Individually or in concert with others, he formulates, directs, controls, or participates in the acts or practices alleged in this complaint. Gay's principal office or place of business is located at 5742 W. Harold Gatty Drive, Salt Lake City, Utah 84116. Defendant Gay transacts business in this district.

7. At all times material herein, Defendants, through affiliated entity Carter-Reed, L.L.C., have been engaged in the manufacturing, advertising, labeling, offering for sale, sale, and/or distribution of dietary supplements to the public, including but not limited to Relacore and Relacore PM (together, "Relacore"). Relacore contains, among other things, Vitamin C, Vitamins B6 and B12, calcium, magnesium, and extracts of passion flower, magnolia, and ginseng. Consumers are directed to take up to 6 capsules per day. Defendants have sold Relacore to consumers in bottles ranging from approximately $30 to $70 each.

PRIOR COMMISSION PROCEEDING

8. In a Commission proceeding bearing Docket No. 9318, the Commission charged corporate defendant Basic Research and several of its related limited liability corporations, as

well as individual defendant Gay, with violating Section 5 of the FTC Act, 15 U.S.C. § 45. Pursuant to a settlement, the Commission, on June 19, 2006, issued a final order ("Order") against Defendants. Among other things, the Order prohibits Defendants from making certain representations about their products without sufficient scientific substantiation. The Order remains in full force and was served upon Defendants, who have acknowledged receipt of the Order.

9. The Commission's Order, attached to this Complaint as Exhibit A, includes the following provisions:

ORDER

DEFINITIONS

> 2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
>
> ***
>
> II.
>
> IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, drug, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of trade names or endorsements, about the effect of such food, drug or dietary supplement on any disease, or about the effect of such food, drug or dietary supplement on the structure or function of the human body or other health benefits or weight loss benefits, unless at the time the representation is made respondents possess and rely upon a reasonable basis for the representation, which shall consist of competent and reliable scientific evidence.

DEFENDANTS' ADVERTISING FOR RELACORE

10. On numerous occasions since June, 2006, Defendants, through Carter-Reed, L.L.C., have disseminated or caused to be disseminated advertisements for Relacore, including but not limited to, product packaging (Exhibit B), Internet advertisements at www.carter-reedcompany.com and www.relacore.com (Exhibits C and D), and a print advertisement (Exhibit E). These advertisements include the following statements:

Product Packaging (Exhibit B):

Helps Shrink Your stress-related "Belly Fat"

***

Research has shown there's a link between stress, tension, and excess belly fat . . . high levels of cortisol – a nasty little stress hormone – can cause pound after pound of excess body fat to accumulate around your waist and tummy . . . a health-threatening, figure-destroying condition affecting an estimated 47 million Americans, mostly women.

But now there's Relacore – the breakthrough, all-natural, anti-anxiety, mood elevating pill that, in conjunction with a sensible diet and exercise program, helps reduce stress-induced cortisol production, thereby helping to reduce belly fat.

***

The Belly Fat Connection
Relacore is the most significant advancement in belly fat control in more than a decade. Relacore's natural anti-stress, mood-elevating formula can help alter the underlying stress-related causes of excess belly fat . . . leaving you happier, full of energy, and with that flat, youthful tummy you thought you'd never see again.

Internet Advertisement from www.carter-reedcompany.com (Exhibit C):

Relacore is America's #1 "Belly Fat Pill." Excess tummy flab is not your fault: That's the startling conclusion reached by scientists who discovered stress is the likely cause of stubborn belly fat. But instead of simply identifying the problem, this time they may have found a solution!

***

But now you can beat stress-induced belly fat with Relacore, the breakthrough all-natural anti-anxiety, mood elevating pill that, in conjunction with a sensible diet and exercise program, helps control stress-induced cortisol production, thereby helping reduce belly fat.

***

Relacore is the best way to control the accumulation of stress-related cortisol and belly fat because the formula nips the problem of stress and anxiety in the bud, so to speak.

***

People who have taken Relacore PM in conjunction with proper diet and exercise have reported a visible reduction in stress-related belly fat in a few short weeks.

Internet Advertisement from www.relacore.com (Exhibit D):

LOSING WEIGHT BUT STILL HAVE BELLY BULGE? Getting rid of stubborn belly fat takes more than diet and exercise . . . Popular "feel-good" pill may be solution.

You diet . . . you exercise . . . you're taking the latest diet pill .. . *and* . . . you're even losing weight. But take a look in the mirror . . . you still have that unsightly belly bulge. Twenty pounds lighter and you still look . . . fat! How in the world can that be possible?

***

As it turns out, the same diet that's helping you lose weight might actually be causing you to retain figure-destroying belly fat. That's because dieting is stressful. You worry about what to eat . . . when to eat . . . how much to eat. All that worry leads to "diet stress."

***

And as we all know by now, stress increases that nasty little stress hormone cortisol and cortisol increases belly fat. That's why you can go on a diet, lose weight, but still look thick around the middle.

***

So if you're ready to go on a diet or if you're already losing weight and having a hard time getting rid of your stubborn belly bulge, try this exceptional tummy-flattening, weight control "adjunct" Relacore.

Print Advertisement (Exhibit E):

Can a natural "feel good pill" help shrink your BELLY FAT? The

answer may surprise you.

***

So if everyday life makes you stressed out and anxious . . . if you've been accumulating belly fat that just won't go away . . . if you're overeating in response to daily stress, and you're sick and tired of diet failure, it's time to try Relacore – the most significant advancement in belly fat control in more than a decade. Relacore is the natural anti-stress, mood elevating pill that can help positively alter the underlying cause of excess belly fat . . . leaving you happier, full of energy, and with that flat, youthful tummy you thought you'd never see again.

CAUSE OF ACTION

11. Through the means described in Paragraph 10, Defendants, directly or through Carter-Reed, L.L.C., in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of Relacore, have represented on numerous occasions, expressly or by implication, that Relacore reduces abdominal fat, including but not limited to representations that Relacore:

a. reduces stress-induced abdominal fat more than diet and exercise alone; and

b. reduces abdominal fat in persons who are dieting and exercising but are retaining abdominal fat because of the stress of dieting.

12. Defendants have made the representations set forth in Paragraph 11 without possessing and relying upon a reasonable basis for the representations, consisting of competent and reliable scientific evidence.

CIVIL PENALTIES AND EQUITABLE RELIEF

13. Each dissemination by Defendants of an advertisement containing any representation in violation of the Commission's Order constitutes a separate violation for which Plaintiff seeks monetary civil penalties.

14. Section 5(l) of the FTC Act, 15 U.S.C. § 45(l), as modified by Section 4 of the

Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, and Section 1.98(c) of the FTC's Rules of Practice, 16 C.F.R. § 1.98(c), authorizes this Court to award monetary civil penalties of not more than $11,000 for each violation of the Commission's Order.

15. Under Section 5(l) and 13(b) of the FTC Act, 15 U.S.C. § § 45(l) and 53(b), this Court is authorized to issue a mandatory injunction and such other and further equitable and ancillary relief as it may deem appropriate in the enforcement of the Commission's Order and the FTC Act, including disgorgement and restitution to prevent and remedy any violations of any provision of law enforced by the Commission.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court, pursuant to 15 U.S.C. §§ 45(l) and 53(b), and pursuant to the Court's own equitable powers:

(1) Enter a permanent injunction to prevent future violations of the FTC Act and the Commission's Order by Defendants;

(2) Award Plaintiff monetary civil penalties from Defendants for each violation of the Commission's Order alleged in this Complaint;

(3) Award such equitable relief as the Court finds necessary; and

(4) Award Plaintiff the costs of bringing this action, as well as such other relief as the Court may determine to be just and proper.

DATED:

FOR THE FEDERAL TRADE COMMISSION:

WILLIAM BLUMENTHAL
General Counsel

JAMES A. KOHM
Associate Director for Enforcement

ROBERT M. FRISBY
Assistant Director for Enforcement

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EUGENE M. THIROLF
Director
Office of Consumer Litigation

KENNETH L. JOST
Assistant Director
Office of Consumer Litigation

[Insert Name]
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA, **Plaintiff,** **v.** **BASIC RESEARCH, L.L.C. and DENNIS W. GAY,** **Defendants.**	**CIV. ACTION NO.**

CONSENT DECREE

WHEREAS Plaintiff, the United States of America, has commenced this action by filing the Complaint herein; defendants, Basic Research, L.L.C. and Dennis W. Gay, have waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of the merits of any issue of fact or law;

THEREFORE, on the joint motion of plaintiff and defendants, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

1. This Court has jurisdiction over the subject matter and the parties. Venue in the District of Utah is proper under 15 U.S.C. § 53(b) and under 28 U.S.C. §§ 1391(b) and (c) and 1395(a).

2. The Complaint states a claim upon which relief may be granted against Defendants under Sections 5(l), 13(b), and 16(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(l), 53(b), and 56(a).

3. The acts and practices of Defendants were, and are, in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Consent Decree. Defendants also waive any claims that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Consent Decree.

5. Each party shall bear its own costs and attorneys' fees.

6. Entry of this Consent Decree is in the public interest.

DEFINITIONS

1. "Competent and reliable scientific evidence" means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "Corporate Defendant" means Basic Research, L.L.C., and its successors and assigns.

3. "Defendants" means the Individual Defendant and the Corporate Defendant, individually, collectively, or in any combination.

4. "FTC" or "Commission" means the Federal Trade Commission.

5. "FTC Order" means the Decision and Order issued by the Federal Trade Commission on June 19, 2006 in Docket No. 9318 (In the Matter of Basic Research, L.L.C., et

al.), a copy of which is attached hereto as Exhibit A and made part of this Consent Decree.

6. "Individual Defendant" means Dennis W. Gay.

7. The terms "and" and "or" in this Consent Decree shall be construed conjunctively or disjunctively, as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

8. The term "including" in this Consent Decree means "including, without limitation."

I.
CIVIL PENALTY

IT IS FURTHER ORDERED that:

A. Pursuant to Section 5(l) of the FTC Act, 15 U.S.C. § 45(l), a judgment for a monetary civil penalty is hereby entered against Defendants, jointly and severally, in the amount of [$INSERT]. Defendants shall pay this civil penalty within five (5) days after the date of entry of this Consent Decree by electronic fund transfer in accordance with the instructions provided by: The Office of Consumer Litigation, Civil Division, U.S. Department of Justice, Washington, D.C. 20530;

B. This judgment represents a civil penalty owed to the United States Government, is not compensation for actual pecuniary loss, and, therefore, is not subject to discharge under the Bankruptcy Code pursuant to 11 U.S.C. § 523(a)(7). Defendants agree that the facts as alleged in the complaint filed in this action shall be taken as true, without further proof, in any subsequent civil litigation filed by the Plaintiff to enforce its rights to any payment or money judgment pursuant to this Order;

C. Defendants relinquish all dominion, control, and title to the funds paid to the fullest extent permitted by law. Defendants shall make no claim to or demand return of the funds,

directly or indirectly, through counsel or otherwise;

D. In the event of any default in payment, interest shall accrue pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment;

E. Pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(1), any consumer reporting agency may furnish a consumer report concerning Defendants to Plaintiff or to the FTC, which shall be used for purposes of collecting and reporting on any delinquent amount arising out of this Order.

II.
PROHIBITION AGAINST VIOLATING THE FTC ORDER

IT IS FURTHER ORDERED that Defendants and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent Decree by personal service or otherwise, are hereby permanently enjoined from ever violating, directly or through any corporation, subsidiary, division, or other device, any provision of the FTC Order; *provided, however*, that, in the event that the FTC Order is hereafter modified, Defendants' compliance with that Order as so modified will not be deemed a violation of this Part.

III.
PROHIBITED UNSUBSTANTIATED REPRESENTATIONS

IT IS FURTHER ORDERED that Defendants and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent Decree by personal service or otherwise, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any

product, service, or program, in or affecting commerce, including but not limited to Relacore, are hereby permanently enjoined from making any representation, including through endorsements or trade name, expressly or by implication:

A. That such product, service, or program

1. reduces stress-induced abdominal fat more than diet and exercise alone; and

2. reduces abdominal fat in persons who are dieting and exercising, but are retaining abdominal fat because of the stress of dieting; or

B. About the benefits, performance, efficacy, safety or side effects, of any product, service, or program;

unless the representation is true and not misleading and, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.
FOOD AND DRUG ADMINISTRATION

IT IS FURTHER ORDERED that nothing in this Consent Decree prohibits Defendants from making:

A. Any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.
COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Consent Decree:

A. Within ten (10) days of receipt of written notice from a representative of Plaintiff or the Commission, Defendants each shall submit additional written reports, which are true and accurate and sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and provide entry during normal business hours to any business location in each Defendant's possession or direct or indirect control to inspect the business operation;

B. In addition, Plaintiff and the Commission are authorized to use all other lawful means, including but not limited to:

1. obtaining discovery from any person, without further leave of the court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, 45, and 69;

2. posing as consumers and suppliers to Defendants, their employees, or any other entity managed or controlled in whole or in part by any Defendant, without the necessity of identification or prior notice; and

C. Defendants each shall permit representatives of Plaintiff and the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

Provided however, that nothing in this Consent Decree shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or

deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

VI.
COMPLIANCE REPORTING BY DEFENDANTS

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Consent Decree be monitored:

A. For a period of ten (10) years from the date of entry of this Consent Decree:

1. The Individual Defendant shall notify the Commission of the following:

a. Any changes in such Defendant's residence, mailing addresses, and telephone numbers, within ten (10) days of the date of such change;

b. Any changes in such Defendant's employment status (including self-employment), and any change in such Defendant's ownership in any business entity, within ten (10) days of the date of such change. Such notice shall include the name and address of each business that such Defendant is affiliated with, employed by, creates or forms, or performs services for; a detailed description of the nature of the business; and a detailed description of such Defendant's duties and responsibilities in connection with the business or employment; and

c. Any changes in such Defendant's name or use of any aliases or fictitious names;

2. Defendants shall notify the Commission of any changes in structure of the Corporate Defendant or any business entity that any Defendant directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited

to: incorporation or other organization; a dissolution, assignment, sale, merger, or other action; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; or a change in the business name or address, at least thirty (30) days prior to such change, *provided* that, with respect to any proposed change in the business entity about which a Defendant learns less than thirty (30) days prior to the date such action is to take place, such Defendant shall notify the Commission as soon as is practicable after obtaining such knowledge.

B. One hundred eighty (180) days after the date of entry of this Order and annually thereafter for a period of five (5) years, Defendants each shall provide a written report to the FTC, which is true and accurate and sworn to under penalty of perjury, setting forth in detail the manner and form in which they have complied and are complying with this Order. This report shall include, but not be limited to:

1. For the Individual Defendant:

   a. such Defendant's then-current residence address, mailing addresses, and telephone numbers;

   b. such Defendant's then-current employment status (including self-employment), including the name, addresses, and telephone numbers of each business that such Defendant is affiliated with, employed by, or performs services for; a detailed description of the nature of the business; and a detailed description of such Defendant's duties and responsibilities in connection with the business or employment; and

   c. Any other changes required to be reported under Subsection A of

this Section.

2. For all Defendants:

a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to the Section titled "Distribution of Order;" and

b. Any other changes required to be reported under Subsection A of this Section.

C. Each Defendant shall notify the Commission of the filing of a bankruptcy petition by such Defendant within fifteen (15) days of filing.

D. For the purposes of this Order, Defendants shall, unless otherwise directed by the Commission's authorized representatives, send to the Commission by overnight courier all reports and notifications required by this Order, at the following address:

Associate Director for Enforcement
Federal Trade Commission
600 Pennsylvania Avenue, N.W., Room NJ-2122
Washington, D.C. 20580
RE: *U.S. v Basic Research, L.L.C., et al.*

Provided that, in lieu of overnight courier, Defendants may send such reports or notifications by first-class mail, but only if Defendants contemporaneously send an electronic version of such report or notification to the Commission at: DEBrief@ftc.gov.

E. For purposes of the compliance reporting and monitoring required by this Order, Plaintiff and the Commission are authorized to communicate directly with each Defendant.

VII.
RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of thirteen (13) years from the date of entry of this Consent Decree, the Corporate Defendant and any business where (1) the Individual Defendant is the majority owner or an officer or director of the business, and (2) the business engages in, or assists others engaged in, the advertising, marketing, promotion, offering for sale, distribution, or sale of any product, service, or program, and their agents, employees, officers, and corporations, and those in active concert or participation with them who receive actual notice of this Consent Decree by personal service or otherwise, are hereby restrained and enjoined from failing to create and/or retain the following records:

A. Accounting records that reflect the cost of goods or services sold, revenues generated, and the disbursement of such revenues;

B. Personnel records accurately reflecting: the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

C. Customer files containing the names, addresses, phone numbers, dollar amounts paid, quantity of items or services purchased, and description of items or services purchased, to the extent such information is obtained in the ordinary course of business;

D. Complaints and refund requests (whether received directly, indirectly, or through any third party) and any responses to those complaints or requests;

E. Copies of all sales scripts, training materials, advertisements, or other marketing materials;

F. Copies of each advertisement, including videotapes and audiotapes, if applicable, containing any representation covered by this Consent Decree; all materials that were relied upon in disseminating such representation; and all tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and

G. All records and documents necessary to demonstrate full compliance with each provision of this Consent Decree, including but not limited to, copies of acknowledgments of receipt of this Consent Decree required by the Sections titled "Distribution of Consent Decree" and "Acknowledgment of Receipt of Consent Decree " and all reports submitted to the FTC pursuant to the Section titled "Compliance Reporting."

VIII.
DISTRIBUTION OF CONSENT DECREE

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Consent Decree, Defendants shall deliver copies of the Consent Decree as directed below:

A. Corporate Defendant: The Corporate Defendant must deliver a copy of this Consent Decree to (1) all of its principals, officers, directors, and managers; (2) all of its employees, agents, and representatives who engage in conduct related to the subject matter of the Consent Decree; and (3) any business entity resulting from

any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Consent Decree upon such Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.

B. Individual Defendant as Control Person: For any business that the Individual Defendant controls, directly or indirectly, or in which he has a majority ownership interest, he must deliver a copy of this Consent Decree to (1) all principals, officers, directors, and managers of that business; (2) all employees, agents, and representatives of that business who engage in conduct related to the subject matter of the Consent Decree; and (3) any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Consent Decree upon such Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.

C. Individual Defendant as employee or non-control person: For any business where the Individual Defendant is not a controlling person of a business but otherwise engages in conduct related to the subject matter of this Consent Decree, he must

deliver a copy of this Consent Decree to all principals and managers of such business before engaging in such conduct.

D. Defendants must secure a signed and dated statement acknowledging receipt of the Consent Decree, within thirty (30) days of delivery, from all persons receiving a copy of the Consent Decree pursuant to this Section.

IX.
ACKNOWLEDGMENT OF RECEIPT OF CONSENT DECREE

IT IS FURTHER ORDERED that each Defendant, within five (5) business days of receipt of this Consent Decree as entered by the Court, must submit to the Commission a truthful sworn statement acknowledging receipt of the Consent Decree.

X.
RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain Jurisdiction of this matter for purposes of construction, modification, and enforcement of this Consent Decree.

SO ORDERED this _____ day of _____, 200__.

_____
UNITED STATES DISTRICT JUDGE

FOR THE FEDERAL TRADE COMMISSION:

WILLIAM BLUMENTHAL
General Counsel

JAMES A. KOHM
Associate Director for Enforcement

ROBERT M. FRISBY
Assistant Director for Enforcement

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KENNETH L. JOST
Assistant Director
Office of Consumer Litigation

[Insert Name]
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice

FOR THE DEFENDANTS:

_____

[Insert Name and Title]
On behalf of Basic Research, LLC

_____

DENNIS GAY

_____

LINDA A. GOLDSTEIN
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, New York 10036
Tel: (212) 970-4544
Fax: (212) 790-4545
Attorney for Defendants

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

FILED
U.S. DISTRICT COURT
2009 AUG 31 P 3:38
DISTRICT OF UTAH
BY: DEPUTY CLERK

I. (a) PLAINTIFFS
BASIC RESEARCH, LLC; A.G. WATERHOUSE, LLC; SOVAGE DERMALOGIC LABORATORIES, LLC;CARTER-REED COMPANY, LLC; DYNAKOR PHARMACAL, LLC; DENNIS GAY;MITCHELL FRIEDLANDER

(b) County of Residence of First Listed Plaintiff SALT LAKE COUNTY
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
See Attachment

DEFENDANTS
FEDERAL TRADE COMMISSION; and THE UNITED STATES OF AMERICA

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
28 U.S.C. 2201
Brief description of cause:
Declaratory Judgment

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

DATE 31 Aug 09 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP

Case: 2:09cv00779
Assigned To : Jenkins, Bruce S.
Assign. Date : 8/31/2009
Description: Basic Research et al v. FTC et al