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

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

COMPLAINT COUNSEL'S MOTION TO SUBMIT REPLY TO RESPONDENTS' OPPOSITION TO PENDING MOTION TO STRIKE RESPONDENTS' "ADDITIONAL DEFENSES"

Pursuant to Rule of Practice 3.22, Complaint Counsel seek leave to file a *Reply* in response to Respondents' *Opposition* to our *Motion to Strike Respondents' Additional Defenses*. Respondents' forty-page long *Opposition* raises new issues that were not fairly raised by the defenses alleged in their *Answers*. The *Opposition* also states, inaccurately, that Complaint Counsel has made certain concessions regarding Respondents' assertions, and introduces inaccuracies in the record and the status of the law. These matters were not discussed in our *Motion to Strike*, and so we request permission to file a *Reply* addressing these new matters.¹

Complaint Counsel has not concurrently filed its proposed *Reply* due to the complexity of the issues presented as well as the sheer number of matters raised. Respondents had twenty days in which to prepare their lengthy *Opposition*. Complaint Counsel will need a comparatively brief but nonetheless necessary period of time to formulate a complete response to Respondents' new issues, many of which raise issues with potential precedential effect. We will be able to submit the proposed *Reply* within five business days of an *Order* granting leave to file.

Respondents' Opposition contained the following new issues, among others: (1) Whether, as Respondents now contend, this Court lacks authority to rule on due process, First Amendment, and Administrative Procedure Act issues in the context of a Motion to Strike, when Respondents initially raised these issues as defenses for trial; (2) Whether, as Respondents now contend, the "controlling line of cases" for the alleged due process defense pertains to the standards employed by the FDA, or other entities, but not the FTC; (3) Whether, as Respondents now contend, the internal use of FTC advertising substantiation standards before the issuance of the Complaint actually constituted "final agency action" against Respondents, and a violation of the First Amendment; (4) Whether, as Respondents now contend, Complaint Counsel has made certain concessions regarding Respondents' assertions; and (5) Whether Respondents are entitled to assert laches or equitable estoppel against the FTC by raising new factual allegations in the Opposition, and will require discovery to uncover statements allegedly made directly to them, particularly when the weight of authority does not support the application of these defenses.

These five questions were not raised in Respondents' defenses or the rest of the *Answers*. Complaint Counsel could not have reasonably raised these questions in their *Motion to Strike*. At the time that we filed our *Motion*, few could have reasonably foreseen that Respondents would disclaim the Administrative Law Judge's authority to rule on defenses proffered for trial, rely upon FDA caselaw instead of FTC caselaw, characterize the staff's pre-*Complaint* processes as "final agency action" or a restraint on free speech; incorrectly describe our discovery responses as making certain concessions regarding Respondents' assertions, or introduce new factual allegations in the *Opposition*.

The RULES state that "[t]he moving party shall have no right to reply, except as permitted by the Administrative Law Judge or the Commission." RULE 3.22(c). Permission to file replies may be granted when such pleadings would prove "necessary or useful." *In re Basic Research, LLC*, 2004 WL 1771591 (July 20, 2004) (Chappell, J.). Replies have been permitted even in the absence of a formal motion. *See In re MSC Software Corp.*, Docket No. 9299, 2002 WL 509706 (Jan. 17, 2002); *see also In re Grolier, Inc.*, 97 F.T.C. 194, 196 (1981). In this case, because Respondents have raised new issues for the record, it is fair to allow an opportunity to respond. A response to the new issues raised in Respondents' *Opposition* would assist the Court in resolving the pending *Motion*. Unlike Respondents' previous replies, the proposed filing would not simply reiterate arguments set forth in the original moving papers.

Granting leave to file a reply is especially appropriate given the significance of this preliminary dispute. Respondents have propounded dozens of document requests related to their panoply of alleged defenses. *See, e.g.*, Basic Research, LLC's Second Request for Production of Documents (Sept. 9, 2004) (demanding, among other things, all documents relating to the individual Commissioners' professional expertise) (attached hereto). Their conduct already has had a profound impact on the course of this litigation and the discovery process; if this conduct is allowed to continue, it will also affect the scope of the hearing on the Commission's *Complaint*.²

In their *Opposition*, Respondents make their motivations quite plain. They wish to try a case completely dissimilar from that raised by the Commission's *Complaint*—a case in which the crux of the matter is not whether Respondents marketed dietary supplements with false or unsubstantiated claims, but whether the FTC engaged in "repeated violations of Respondents' fundamental rights," or an "unyielding refusal to comply with the requirements of due process," among other alleged illegalities. *See, e.g.*, Resp'ts' Opp'n at 2, 8.

CONCLUSION

For the reasons set forth above, Complaint Counsel respectfully request the opportunity to to file a *Reply* to address new matters that Respondents raised in defense of their alleged defenses.

A proposed order granting leave to file a Reply within five business days of said leave is attached.

Respectfully submitted,

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

Laura Schneider (202) 326-2604

Division of Enforcement Bureau of Consumer Protection Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C. 20580

Dated: September 13, 2004

ATTACHMENT TO COMPLAINT COUNSEL'S MOTION TO SUBMIT REPLY TO RESPONDENTS' OPPOSITION TO PENDING MOTION TO STRIKE RESPONDENTS' "ADDITIONAL DEFENSES"

(1) Basic Research, LLC's Second Request for Production of Documents (Sept. 9, 2004).

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In the Matter of	
BASIC RESEARCH, L.L.C., A.G. WATERHOUSE, L.L.C.,	
KLEIN-BECKER USA, L.L.C.,	
NUTRASPORT, L.L.C., SOVAGE DERMALOGIC LABORATORIES, L.L.C.,))
d/b/a BASIC RESEARCH, L.L.C., OLD BASIC RESEARCH, L.L.C.,	
BASIC RESEARCH, A.G. WATERHOUSE,))
BAN, L.L.C., d/b/a KLEIN-BECKER USA, NUTRA SPORT, and	DOCKET NO. 9318
SOVAGE DERMALOGIC LABORATORIES, DENNIS GAY,	
DANIEL B. MOWREY,	
d/b/a AMERICAN PHYTOTHERAPY RESEARCH LABORATORY, and))
MITCHELL K. FRIEDLANDER	
Respondents.) ·

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

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

DEFINITIONS

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

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

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

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

- 14. "Referring to" or "relating to" shall mean: discussing, describing, reflecting, containing, analyzing, studying, reporting, commenting, evidencing, constituting, setting forth, considering, recommending, concerning, or pertaining to, in whole or in part.
- 15. "Respondent(s)" shall mean" all Corporate Respondents and all Individual Respondents, both individually and collectively, unless otherwise stated.
- 16. "Safety" shall mean the ability of the product to be used without risk or adverse health consequences for the user.

INSTRUCTIONS

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

 Unless otherwise indicated, no paragraph limits the scope of any other paragraph.
- 3. All documents that in their original form were stapled, clipped, or otherwise attached to other documents should be produced in such form. A complete copy of each document should be submitted even if only a portion of the document is within the scope of the Request. Each page produced should be marked with a unique Bates tracking number.
- 4. Documents covered by this Request are those which are in your possession or under your actual or constructive custody or control.

- 5. This Request does not seek documents that were provided to you by the Corporate Respondents in response to formal investigative demands.
- 6. Responsive documents that are not produced because you claim a privilege must be identified on a privilege log. The log must identify the grounds for withholding the document, the date of the document, type (e.g., letter, meeting, notes, memo), nature and subject matter of the document, the author or originators, and the addressees/recipients. Each author or recipient who is an attorney should be noted as such. If only a part of a responsive document is privilege, all non-privileged portions of the document must be provided.
- 7. The First Request for Production is continuing in character so as to require you to produce additional information promptly upon obtaining or discovering different, new or further information before the close of discovery.
 - 8. The use of the singular includes the plural, and the plural includes the singular.
 - 9. The use of a verb in any tense shall be construed to include all other tenses.
- 10. The spelling of a name shall be construed to include all similar variants of such name.

DOCUMENT REQUESTS

- 1. All transcripts of or relating to the Respondents.
- 2. All documents listed in Complaint Counsel's Initial Disclosures.
- 3. All documents relating to submissions by the Federal Trade Commission in all prior weight loss cases.
 - 4. All consent orders issued by the Federal Trade Commission in weight loss cases.
- 5. All documents relating to the contention that clinical testing does not support the representations made in the advertising of the Challenged Products.

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

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

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

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Counsel for Respondents Basic Research, L.L.C., A.G. Waterhouse, L.L.C., Klein-Becker USA, L.L.C., Nutrasport, L.L.C., Sovage Dermalogic Laboratories, L.L.C. and Ban, L.L.C

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was provided to the following parties this 9^{7^k} day of September, 2004 as follows:

- (1) One (1) copy via e-mail attachment in Adobe[®] ".pdf" format to Commission Complaint Counsel, Laureen Kapin, Joshua S. Millard, and Laura Schneider, all care of lkapin@ftc.gov, jmillard@ftc.gov; rrichardson@ftc.gov; lschneider@ftc.gov with one (1) paper courtesy copy via U. S. Postal Service to Laureen Kapin, Bureau of Consumer Protection, Federal Trade Commission, Suite NJ-2122, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;
- (2) One (1) copy via United States Postal Service to Stephen Nagin, Esq., Nagin Gallop & Figueredo, 3225 Aviation Avenue, Suite 301, Miami, Florida 33131.
- (3) One (1) copy via United States Postal Service to Richard Burbidge, Esq., Jefferson W. Gross, Esq. and Andrew J. Dymek, Esq., Burbidge & Mitchell, 215 South State Street, Suite 920, Salt Lake City, Utah 84111, Counsel for Dennis Gay.
- (4) One (1) copy via United States Postal Service to Ronald F. Price, Esq., Peters Scofield Price, A Professional Corporation, 340 Broadway Centre, 111 East Broadway, Salt Lake City, Utah 84111, Counsel for Daniel B. Mowrey.
- (5) One (1) copy via United States Postal Service to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84111, pro se.

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A.G. WATERHOUSE, L.L.C.,	,)	
KLEIN-BECKER USA, L.L.C.,)	
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BAN, L.L.C.,) PUBLIC DOCUME	NT
DENNIS GAY,)	
DANIEL B. MOWREY, and)	
MITCHELL K. FRIEDLANDER,)	
)	
Respondents.)	
)	

ORDER GRANTING COMPLAINT COUNSEL'S MOTION FOR LEAVE TO SUBMIT REPLY TO RESPONDENTS' OPPOSITION TO PENDING MOTION TO STRIKE RESPONDENTS' ADDITIONAL DEFENSES

On September 13, 2003, Complaint Counsel moved for leave to file a *Reply* in response to Respondents' *Opposition* to Complaint Counsel's *Motion to Strike Respondents' Additional Defenses*. As Respondents have raised new issues for the record that may have precedential effect, it is fair to allow an opportunity to respond, and a response to the matters raised in Respondents' *Opposition* would assist the Court in resolving the pending *Motion to Strike*.

Accordingly, upon due consideration of the parties' submissions, it is hereby

ORDERED that Complaint Counsel's Motion to Submit Reply is GRANTED.

Complaint Counsel shall file their *Reply* within five business days of this *Order*.

ORDERED:		
	Stephen J. McGuire	
		Chief Administrative Law Judge

CERTIFICATE OF SERVICE

I hereby certify that on this Day day of September, 2004, I caused Complaint Counsel's Motion to Submit Reply to Respondents' Opposition to Pending Motion to Strike Respondents' Additional Defenses" to be served and filed as follows:

(1) the original, two (2) paper copies filed by hand delivery and one (1) electronic copy via email to:

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

- (2) two (2) paper copies served by hand delivery to:

 The Honorable Stephen J. McGuire
 Administrative Law Judge
 600 Penn. Ave., N.W., Room H-104
 Washington, D.C. 20580
- one (1) electronic copy via email and one (1) paper copy by first class mail to the following persons:

Stephen E. Nagin

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For Respondents

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COMPLAINT COUNSEL