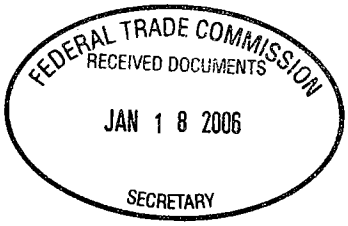
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



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

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF FTC/FDA/NIH-RELATED DOCUMENTS INCLUDED IN RESPONDENTS' EXHIBIT LIST

Complaint Counsel hereby oppose Respondents' Motion for Official Notice of FTC/FDA/NIH Documents Included in Respondents' Exhibit List, filed on January 6, 2006 ("Motion" or "Mot. for Off. Not."). Respondent's Motion seeks official notice of 23 documents and states that "Respondents seek official notice of these government documents out of an abundance of caution to permit removal of them from their exhibit list without forfeiting their right to rely upon them in their findings and conclusions and at trial." Mot. for Off. Not. at 1. Respondents' Motion makes it clear that Respondents do not merely seek to establish that the statements in the documents were made, but that the documents are relevant and material evidence that Respondents intend to use at trial. *Id.* at 1, 4. Respondents, however, have not shown that the documents are relevant and material to any disputed issue or that they should be

given any weight at all. Respondents' documents are not material facts, and to the extent that those documents are offered as "evidence," official notice does not obviate the necessity for listing the documents as exhibits. The documents are not relevant to whether Respondents violated the FTC Act, and relate instead to Respondents ' challenge of Federal Trade Commission ("FTC") substantiation policy for dietary supplement and weight-loss claims, which the Court has previously determined is not the issue to be litigated in this administrative trial. Complaint Counsel requests that the Court deny Respondents' Motion, and decide whether documents should be granted official notice as the issue arises during trial.

DISCUSSION

Commission Rule of Practice 3.43(d) states: "When any decision of an Administrative Law Judge or of the Commission rests, in whole or in part, upon the taking of official notice of a *material fact* not appearing in evidence of record, opportunity to disprove such notice fact shall be granted any party making timely motion therefor." 16 C.F.R. § 3.43(d) (emphasis added). It is clear from this provision that, as a preliminary matter, facts that are potentially the subject of official notice must be material. The Court can then take official notice of such material facts if they have sufficient indicia of trustworthiness.[1]

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[1] Respondents previously filed a Request for Official Notice of Portions of FTC Website on February 3, 2005. In its Order granting the previous Request, the Court noted that Federal Rule of Evidence 201(b) provides that "A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Order on Resp'ts' Req. for Official Notice, Dec. 5, 2005, at 1-2.

Respondents' present Motion seeking official notice of FTC, FDA, and NIH documents differs from Respondents' previous Request for Official Notice of Portions of FTC Website ("Previous Request"). In their Previous Request, Respondents only sought official notice that certain statements contained in the FTC's web pages were made, not that they were relevant or material. Previous Request at 4. Respondents' present Motion, however, seeks to establish the 23 FTC, FDA, and NIH documents as relevant and material evidence that Respondents intend to use at trial.[2]

Respondents repeatedly profess, without any supporting facts or argument, that the 23 documents are relevant and material evidence to their case. This is clear from repeated references in their Motion, which states:

> The FTC policy guidance documents, comments, and rulings are part of the public record and *reflect the agency's position* concerning the matters addressed within the documents. FDA's guidance and draft documents advocate the policies of the agency in matters *relevant to this proceeding*. Study applications and documents issued by the NIH are verifiable and may be officially noticed for the purpose of deciding issues that are *ultimately relevant to the resolution of this matter*.

Mot. for Off. Not. at 4 (emphasis added). Respondents' assertion that they seek official notice to allow them to delete the documents from their exhibit list without forfeiting their "right to rely

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[2] Three documents that are the subject of the present Motion were also the subject of the previous Request: RX-003, FTC Notice of Potential Illegal Marketing of Products that Claim to Cause Weight-Loss, Reduce the Risk of Disease, or Produce Other Health Benefits by Affecting the Stress-Related Hormone Cortisol; RX-017, Hearing Transcript of FTC Deception in Weight Loss Advertising; and RX-023, FTC Targets Products Claiming to Affect the Stress Hormone Cortisol. Although the Court granted Respondents' Request for official notice of these documents, it did so in connection with their use as exhibits to one of Respondents' motions for partial summary decision, not in connection with their use as trial exhibits, and it made no finding about the relevance or materiality of the documents.

upon them in their findings and conclusions and at trial" also shows that they intend to rely on the documents as "evidence."

Respondents have not shown, however, that the statements in the documents are relevant, material, and true, or that they should be given any weight. In its Order granting the Previous Request, the Court specifically noted that "Respondents do not seek official notice that the statements contained in the FTC's web pages are true, merely that such statements were made" and stated that:

> Respondents must demonstrate that the statements are relevant, material and true for them to have any weight. The documents will not be admitted into evidence, but may be cited to in briefs. Pursuant to Commission Rule 3.43, official notice relates to "a material fact not appearing in evidence of record." 16 C.F.R. § 3.43(d); *see also Sykes v. Apfel*, 228 F.3d 259, 272 (3rd Cir. 2000); *York v. AT&T Co.*, 95 F.3d 948, 958 (10th Cir. 1996).

Order on Resp'ts' Req. for Official Notice, Dec. 5, 2005. Without establishing the relevance of the documents under Rule of Practice 3.43, Respondents do not have the "right to rely upon them in their findings and conclusions and at trial."

The character of the 23 documents makes it clear that the Respondents are continuing to tilt at FTC substantiation policy, which the Court has held is not the issue to be litigated at trial. In a previous Order concerning Respondents' defenses, the Court stated:

> Respondents' defenses primarily challenge the Federal Trade Commission ("FTC") substantiation policy for dietary supplement and weight-loss claims. However, the issue to be litigated at the trial in this matter is whether Respondents violated the FTC Act's prohibition against false and misleading advertising.

See, e.g., Nov. 4, 2004 Order on Compl.Counsel's Mot. to Strike Resp'ts' "Additional Defenses" at 2. The documents that are the subject of Respondents' present Motion for official notice

evince Respondents' intention to challenge the FTC's substantiation policy at trial despite the Court's previous determinations.

The documents can be grouped into seven categories, the first five of which comprise FTC documents, and the last two of which comprise FDA and NIH documents.[3] These seven categories are as follows: (1) statements concerning FTC substantiation requirements, including a speech by a former Commissioner, who briefly served as Respondents' counsel, FTC policy statements, and a press release and warning letter relating to products not challenged in this case (documents 1, 2, 3, 4, and 15; RX-001, RX-003, RX-005, RX-006, RX-023); (2) documents relating to the FTC denial of two petitions for rulemaking presented by Corporate Respondents' current counsel in connection with FTC substantiation requirements (documents 8, 16, 17; RX-010, RX-032, RX-034); (3) an FTC workshop transcript and business education documents (documents 11, 13, 14; RX-015, RX-017, RX-018); (4) voluntary industry guidelines (documents 7 and 10; RX-009 and RX-013); (5) FTC staff comments in connection with the activities of other commissions and agencies (documents 5, 6, 22; RX-007, RX-008, RX-805); (6) FDA industry guidance documents (documents 9, 12, 21; RX-011, RX-016, RX-804); and (7) NIH grant applications and guidelines on obesity (documents 18, 19, 20, 23; RX-705, RX-706, RX-

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[3] Complaint Counsel set forth their objections to Respondents' exhibits, including the documents at issue here, in Complaint Counsel's Objections to Respondents' Final Exhibit List of December 2005, served on Respondents and the Court on January 4, 2006. Complaint Counsel set forth relevancy objections to RX-001, RX-007, RX-008, RX-009, RX-010, RX-013, RX-016, RX-017, RX-023, RX-032, RX-034, RX-705, RX-804, RX-805, and RX-806. Complaint Counsel set forth hearsay objections to RX-001, RX-007, RX-008, RX-009, RX-013, RX-016, RX-017. RX-032, RX-034, RX-705, RX-804, and RX-805. Complaint Counsel set forth objections under Fed. R. Evid. 403 (as incorporated in Rule 3.43(b)) in connection with RX-016, RX-032, RX-034, RX-705, RX-804, RX-805, and RX-806. Finally, Complaint Counsel objected to the authenticity of RX-806.

707, RX-806). Respondents have not shown how these documents are relevant to any disputed issues for this trial, as defined repeatedly by this Court in previous rulings. The categories are discussed further below.

(1) DOCUMENTS CONTAINING STATEMENTS CONCERNING FTC SUBSTANTIATION REQUIREMENTS [4]

All of the documents in this category implicate the FTC's deception and substantiation policies, but are not material evidence relevant to whether Respondents violated such policies. Complaint Counsel do not dispute the existence or accuracy of Documents 3 and 4 (RX-005 and RX-006), as the Commission policy statements on substantiation and deception. However, as the Court stated in its Nov. 4, 2004 Order on Compl. Counsel's Mot. to Strike Resp'ts' "Additional Defenses":

> The FTC's policy statement . . . does not control the outcome of the case and is not the standard against which Respondents' claims will be judged, except insofar as the policy has been adopted by relevant laws and controlling cases. *Heintz v. Jenkins*, 514 U.S. 291, 298 (1995); *Goswami v. American Collections Enterprise, Inc.*, 377 F.3d 488, 493, n.1 (5th Cir. 2004); *Newman v. Boehm, Pearlstwin & Bright, Ltd.*, 119 F.3d 477, 481 n.2 (7th Cir. 1997); *Amrep Corp. v. FTC*, 768 F.2d 1171, 1178 (10th Cir. 1985).

Nov. 4, 2004 Order at 2. Statements about FTC policy provide guidance, but do not substitute for relevant laws and controlling cases.

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[4] The documents are: 1. Remarks of Mary L. Azcuenaga Commissioner, Before the International Congress of Advertising and Free Market, "Freedom: XXI Century; The Century of The Consumer" (May 11, 1995) (RX-001); 2. FTC Notice of Potential Illegal Marketing of Products that Claim to Cause Weight-Loss, Reduce the Risk of Disease, or Produce Other Health Benefits by Affecting the Stress-Related Hormone Cortisol (Oct. 1, 2004) (RX-003); 3. FTC's Policy Statement Regarding Advertising Substantiation (RX-005); 4. FTC's Policy Statement on Deception, October 14,1983 (RX-006); and 15. FTC Targets Products Claiming to Affect the Stress Hormone Cortisol (RX-023).

In addition, statements in Document 1 (RX-001), made by former Commissioner Azcuenaga, who briefly served as Respondents' counsel, are non-binding on the FTC, and contain the following disclaimer: "The views I express today are my own and are not necessarily those of the Commission or of any other Commissioner." Furthermore, Respondents have failed to establish the relevance of any of the documents, including documents 2 and 15 (RX-003 and RX-023) which relate to a product that is not challenged in this case.

(2) DOCUMENTS RELATING TO DENIAL OF FTC RULEMAKING PETITIONS[5]

The documents in this category all relate to petitions previously proposed by Corporate Respondents' counsel, outside of the context of this case, requesting that the FTC conduct a rulemaking proceeding in connection with FTC substantiation policy. Because the petitions were denied, the documents are irrelevant to whether Respondents violated the FTC Act's prohibition against false and misleading advertising. Respondents' request for official notice of these documents suggests that Respondents will attempt to inject previously settled policy questions into this administrative adjudication and to convert this trial into a second forum for challenging the denial of the petitions. Respondents have not shown how the documents are relevant to any disputed issue.

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[5] The documents are: 8. FTC's Denial of Petition for Rulemaking filed on behalf of Dr. Julian Whitaker (RX-010); 16. FTC's Denial of April 16, 2003 Petition for Rulemaking filed on behalf of The First Amendment Health Freedom Association (RX-032); and 17. FTC's Denial of Whittaker Petition (RX-034).

(3) FTC TRANSCRIPT AND BUSINESS EDUCATION DOCUMENTS[6]

Complaint Counsel do not dispute the existence or accuracy of Documents 11 and 14 (RX-015 and RX-018), which are business education documents, but have objected to Document 13 (RX-017) on hearsay and relevancy grounds. The documents were published to assist industry members comply with existing laws and controlling cases. They are not material evidence and do not constitute the standard against which Respondents' claims will be judged. Accordingly, Respondents have not established the relevance of any of the documents to any disputed issue.

(4) VOLUNTARY INDUSTRY GUIDELINES[7]

The two documents in this category are voluntary guidelines for providers of weight loss products and services. Both of the documents contain the following statement regarding the voluntary guidelines: "They are not binding, do not represent legal standards or interpretation of any legal requirements, and are not sponsored or issued by any government agency." As voluntary guidelines, the documents do not constitute the standard against which Respondents' claims will be judged and are therefore not relevant to whether Respondents violated the FTC Act. Respondents have not shown how the documents are relevant to any disputed issue.

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[6] The documents are: 11. FTC's Dietary Supplements: An Advertising Guide For Industry (RX-015); 13. Hearing Transcript of FTC Deception in Weight Loss Advertising: A workshop (RX-017); and 14. FTC's Advertising Policies, Frequently Asked Advertising Questions: Answers for Small Businesses (FTC Brochure 2004) (RX-018).

[7] The documents are: 7. Report re: Partnership for Healthy Weight Management brochure, Voluntary Guidelines for Providers of Weight Loss Products or Services (RX-009); and 10. Report re: Partnership for Healthy Weight Management internet guide, Voluntary Guidelines for Providers of Weight Loss Products or Services (RX-013).

(5) FTC STAFF COMMENTS ON OTHER COMMISSIONS AND AGENCIES[8]

The three documents in this category are FTC staff comments in connection with the work of other commissions and agencies. Respondents have not shown how such documents are relevant to any disputed issue in this FTC matter.

(6) FDA INDUSTRY GUIDANCE DOCUMENTS[9]

The documents in this category relate to another government agency, the FDA, that is not involved in these proceedings, and do not relate to FTC substantiation standards as adopted by relevant laws and controlling cases. Respondents have not shown how the documents in this category are relevant to any disputed issue.

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[8] The documents are: 5. Letter from the Division of Advertising Practices to Commission on Dietary Supplement Labels regarding FTC staff comments on draft report of the Commission on Dietary Supplement Labels (RX-007); 6. Comments before the US FDA in the matter of Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Proposed Rule (RX-008); and 22. FTC's Staff Comments on FDA's Significant Scientific Agreement (RX-805).

[9] The documents are: 9. FDA's Guidance for Industry Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements written by the U.S. Food and Safety and Applied Nutrition Office of Special Nutritionals 02/14/2005 (RX-011); 12. FDA's Guidance for Industry / Structure/ Function Claims Small Entity Compliance Guide written by the U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition (RX-016); and 21. FDA's Draft Guidelines on Competent & Reliable (RX-804).

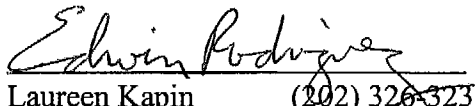
(7) NIH GRANT APPLICATIONS AND GUIDELINES ON OBESITY[10]

Respondents have not shown how the documents in this category, including grant applications and NIH guidelines, are relevant to any disputed issue in this FTC matter. The NIH Clinical Guidelines on obesity are non-binding guidelines of another agency having no bearing on FTC substantiation requirements as adopted by relevant laws and controlling cases.

CONCLUSION

Complaint Counsel oppose Respondents' Motion for Official Notice of FTC/FDA/NIH Documents because Respondents have failed to show that the documents are relevant, material, and true. In many instances, the documents are not relevant and are hearsay. Complaint Counsel request that, instead of granting official notice at this time, the Court consider the exhibits and any objections to them as they are presented in the context of trial.

Respectfully submitted,



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[10] Documents 18, 19, and 20 (RX-705, RX-706, and RX-707) are Respondents' grant applications. Document 23 is Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults by the National Institutes of Health (RX-806).

Complaint Counsel do not repeat the document titles of RX-705, RX-706, and RX-707, used in Respondents' publicly-filed Motion, out of an abundance of caution. Respondents have filed a Revised Motion for *In Camera* Treatment of Trial Exhibits ("*In Camera* Motion") that seeks *in camera* treatment of RX-705 and RX-706. The public record version of Respondents' *In Camera* Motion redacts all document descriptions, including the document descriptions of RX-705 and RX-706. Because of Respondents' apparent inconsistency in the treatment of their grant application document descriptions – publicly disclosing them in their Motion for Off. Not., but redacting them from their *In Camera* Motion – Complaint Counsel, out of an abundance of caution, do not use the grant application document descriptions in this document.

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Bureau of Consumer Protection
Federal Trade Commission
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Dated: January 18, 2006

CERTIFICATION OF REVIEWING OFFICIAL

I certify that I have reviewed the attached public filing, *Complaint Counsel's Opposition to Respondents' Motion for Official Notice of FTC/FDA/NIH-Related Documents Included in Respondents' Exhibit List*, prior to its filing to ensure the proper use and redaction of materials subject to the *Protective Order* in this matter and protect against any violation of that *Order* or applicable RULE OF PRACTICE.

James A. Kohm
Associate Director, Division of Enforcement
Bureau of Consumer Protection

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of January, 2006, I caused *Complaint Counsel's Opposition to Respondents' Motion for Official Notice of FTC/FDA/NIH-Related Documents Included in Respondents' Exhibit List*, to be filed and served as follows:

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

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

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

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

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