UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES WASHINGTON, D.C.

In the Matter of

BASIC RESEARCH, LLC A.G. WATERHOUSE, LLC KLEIN-BECKER USA, LLC NUTRASPORT, LLC SOVAGE DERMALOGIC LABORATORIES, LLC BAN LLC d/b/a BASIC RESEARCH LLC OLD BASIC RESEARCH, LLC 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, Respondents.



PUBLIC

Docket No. 9318

RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF FTC/FDA/NIH DOCUMENTS INCLUDED IN RESPONDENTS' EXHIBIT LIST

Pursuant to FTC Rule of Practice 3.43(d), all Respondents hereby respectfully move that his Honor take official notice of the listed FTC, FDA, and NIH documents included in the Respondents' Exhibit List. Respondents seek official notice for 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. Rule 3.43(d) of the Commission's Rules of Practice provides that the Administrative Law Judge and the Commission may take official notice of material facts that do not appear in evidence of the record, as long as the other party is given the opportunity to disprove such noticed facts

upon a timely motion. 16 C.F.R. § 3.43(d). The standard of official notice is parallel to that of judicial notice, provided for under Rule 201 of the Federal Rules of Evidence, and courts have consistently recognized that administrative agencies' ability to take official notice is even broader than the court's ability to take judicial notice.¹

Accordingly, Federal Trade Commission ALJs, as well as the Commission itself, have frequently taken official notice of facts in order to relieve the parties engaged in administrative adjudication of the duty to present formal evidence. As a matter of course, ALJs and the Commission have taken official notice of extra-record facts derived from government agency studies and publications, government guidelines and regulations, government records, and Congressional reports. Official notice has been deemed particularly appropriate when it is being sought for facts that do not concern the immediate parties ("legislative facts"), but are "general facts that help the tribunal decide questions of law and policy and discretion."

¹ See generally Kenneth C. Davis and Richard J. Pierce, Jr., II Administrative Law Treatise (3d ed. 1994) §§ 10.5 & 10.6 (discussing cases and observing that administrative agencies operating under the Administrative Procedures Act enjoy broader discretion to take notice of contested material facts than do courts operating under the Federal Rules of Evidence).

² Beauty-Style Modernizers, Inc., 83 F.T.C. 1761, 1779 (1974) (taking official notice of a Federal Reserve Board publication).

³ Skylark Originals, Inc., 80 F.T.C. 337, 350 (1972) (taking official notice of Federal Trade Commission guidelines); Marcor, Inc., 90 F.T.C. 183, 185 (1977) (taking official notice of a change in a Federal Reserve Board regulation).

⁴ Avnet, Inc., 82 F.T.C. 391, 484 n.31 (1973) (taking official notice of U.S. census data).

⁵ Rueben H. Donnelley Corp., FTC Dkt. No. 9079, Order Admitting Congressional Report as an Exhibit, November 15, 1978 (ALJ Timony) (taking official notice of four findings taken from a report of the Committee on Government Operations of the United States House of Representatives on Airline Deregulation and Aviation Safety), citing Stasiukevick v. Nicholls, 168 F.2d 474, 479 (1st Cir. 1948) ("The official report of a legislative or congressional committee is admissible in evidence in a judicial proceeding, as an exception to the hearsay rule, where the report, within the scope of the subject matter delegated to the committee for investigation, contains findings of fact on a matter which is at issue in the judicial proceeding. Indeed, the court could properly take judicial notice of the report, without its formal introduction into evidence.")

⁶ Davis and Pierce, Jr., II Administrative Law Treatise at §§ 10.5 p. 141 (contrasting "legislative facts" with "adjudicative facts," which "usually answer the questions of who did what, where, when, how, why, with what motive or intent"). See also United States v. Gould, 536 F.2d 216, 220 (8th Cir. 1976) ("Legislative facts are established truths, facts or pronouncements that do not change from case to case but apply universally, while adjudicative facts are those developed in a particular case.").

In light of existing precedent, Respondents seek to have his Honor take official notice of the following government agency publications, studies, and guidelines:

- 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 1 I, 1995) (exhibit 16 in support of Motion for Partial Summary Decision and Separate Statement of Undisputed Fact to instant case *FTC v. Basic Research* 9318) (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).
- 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).
- 7. Report re: Partnership for Healthy Weight Management brochure, Voluntary Guidelines for Providers of Weight Loss Products or Services (RX-009).
- **8.** FTC's Denial of Petition for Rulemaking filed on behalf of Dr. Julian Whitaker (RX-010).
- 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).
- 10. Report re: Partnership for Healthy Weight Management internet guide, Voluntary Guidelines for Providers of Weight Loss Products or Services (RX-013).
- 11. FTC's Dietary Supplements: An Advertising Guide For Industry (RX-015).
- 12. FDA's Guidance for Industry / Structure/ Function Claims Small Entity Compliance Gulde written by the U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition (RX-016).

- 13. Hearing Transcript of FTC Deception in Weight Loss Advertising: A workshop Note FTC 4917 defines "substantial weight loss as 1 lb./day (RX-017).
- **14.** FTC's Advertising Policies, Frequently Asked Advertising Questions: Answers for Small Businesses (FTC Brochure 2004) (RX-018).
- 15. FTC Targets Products Claiming to Affect the Stress Hormone Cortisol (RX-023).
- **16.** FTC's Denial of April 16,2003 Petition for Rulemaking filed on behalf of The First Amendment Health Freedom Association (RX-032).
- 17. FTC's Denial of Whittaker Petition (RX-034).
- 18. SBIR Applications filed by Dr. Chevereau for PediaLean Study (RX-705).
- 19. SBIR Study Application (RX-706).
- **20.** Application entitled for 6-month randomized and controlled trial to determine the feasibility and efficacy of an after-school obesity prevention program in 13-15 year olds (RX-707).
- 21. FDA's Draft Guidelines on Competent & Reliable (RX-804).
- 22. FTC's Staff Comments on FDA's Significant Scientific Agreement (RX-805).
- 23. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults by the National Institutes of Health (RX-806).

Each document identified above is reliable on its face. 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. For the aforementioned reasons we respectfully request that his Honor take official notice of the materials identified above.

Respectfully submitted,

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Pro se.

Dated: January 6, 2006

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES WASHINGTON, D.C.

In the Matter of

BASIC RESEARCH, LLC A.G. WATERHOUSE, LLC KLEIN-BECKER USA, LLC **NUTRASPORT, LLC** SOVAGE DERMALOGIC LABORATORIES, LLC BAN LLC d/b/a BASIC RESEARCH LLC OLD BASIC RESEARCH, LLC 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. Respondents.

PUBLIC

Docket No. 9318

ORDER GRANTING RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF FTC/FDA/NIH DOCUMENTS INCLUDED IN RESPONDENTS' EXHIBIT LIST

On January 6, 2006, Respondents filed a motion for official notice of FTC/FDA/NIH documents included in Respondents' Exhibit List pursuant to the specifications set out in the Commission's Rule of Practice 3.43(d). Respondents have satisfied the requirements for official notice in light of the Commission's course of practice and adjudicative precedent. Respondents identified a set of documents authorized, produced, or used as guidance by the Federal Trade Commission, the Food and Drug Administration, and the National Institutes of Health. In light of the Commission's existing standard under Rule 3.43(d), it is proper to grant the identified documents official notice. Accordingly, Respondents' Motion is GRANTED.

It is hereby ordered that the documents identified in Respondents' Motion are granted official notice.

ORDERED:	
	Stephen J. McGuire Chief Administrative Law Judge
Date:	Cinci Administrative Law Judge

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES WASHINGTON, D.C.

In the Matter of

BASIC RESEARCH, LLC A.G. WATERHOUSE, LLC KLEIN-BECKER USA, LLC **NUTRASPORT, LLC** SOVAGE DERMALOGIC LABORATORIES, LLC BAN LLC d/b/a BASIC RESEARCH LLC OLD BASIC RESEARCH, LLC 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, Respondents

Docket No. 9318

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of January, 2006, I caused Respondents' Motion for Official Notice of FTC/FDA/NIH Documents Included in Respondents' Exhibit List to be filed and served as follows:

1) an original and one paper copy filed by hand delivery and one electronic copy in PDF format filed by electronic mail to

Donald S. Clark Secretary U.S. Federal Trade Commission 600 Pennsylvania Avenue, N.W. Room H-159 Washington, D.C. 20580 Email: secretary@ftc.gov 2) two paper copies delivered by hand delivery to:

The Hon. Stephen J. McGuire Chief Administrative Law Judge U.S. Federal Trade Commission 600 Pennsylvania Avenue, N.W. Room H-112 Washington, D.C. 20580

3) one paper copy by first class U.S. Mail to:

James Kohm Associate Director, Enforcement U.S. Federal Trade Commission 601 New Jersey Avenue, N.W. Washington, D.C. 20001

4) one paper copy by first class U.S. mail and one electronic copy in PDF format by electronic mail to:

Laureen Kapin Joshua S. Millard Laura Schneider Walter C. Gross III Lemuel W.Dowdy Edwin Rodriguez U.S. Federal Trade Commission 600 Pennsylvania Avenue, N.W. Suite NJ-2122 Washington, D.C. 20580 Email: lkapin@ftc.gov jmillard@ftc.gov lschneider@ftc.gov wgross@ftc.gov ldowdy@ftc.gov erodriguez@ftc.gov

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Svetlana N. Walker