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.,	)	**Docket No. 9318**
BAN, L.L.C.,	)	**PUBLIC DOCUMENT**
DENNIS GAY,	)	
DANIEL B. MOWREY, and	)	
MITCHELL K. FRIEDLANDER,	)	
	)	
Respondents.	)	

COMPLAINT COUNSEL'S RESPONSE TO BASIC RESEARCH LLC'S FIRST REQUEST FOR ADMISSIONS

Pursuant to Rule 3.32 of the Commission's Rules of Practice, Complaint Counsel serve the following answers to Respondent Basic Research LLC's First Request For Admissions ("Respondent's Admissions"). Complaint Counsel's provision of a response to any request for admission shall not constitute a waiver of any applicable objection, privilege, or other right. Where required in order to respond to these Requests For Admissions, Complaint Counsel represents that it has undertaken good faith efforts to identify the information that would allow it to admit or deny such requests.

GENERAL OBJECTIONS

1. Complaint Counsel object to Respondent's requests for admissions to the extent they fail to seek an admission of the truth of matters relevant to the pending proceedings. Rule 3.32, Admissions.

2. Complaint Counsel object to Respondent's requests for admissions to the extent they fail to relate to statements or opinions of fact or of the application of law to fact and thereby exceed the scope of Rule 3.32 Admissions.

3. Complaint Counsel object to Respondent's requests for admission to the extent they seek information prepared in anticipation of litigation or which seek disclosure of the theories and opinions of Complaint Counsel or Complaint Counsel's consultants or agents, on the grounds that such information is protected from disclosure by the attorney work product privilege and the provisions of Rule 3.31(c)(3). *Stouffer Foods Corp.*, No. 9250, Order Ruling on Stouffer Foods' Application for an Order Requiring the Production of Documents (Feb. 11, 1992); *Kraft, Inc.*, No. 9208, Order Ruling on Respondent's Motion for Documents in the Possession of Complaint Counsel (July 10, 1987).

4. Complaint Counsel object to Respondent's requests for admission to the extent they seek information protected from disclosure by the deliberative process privilege. *Stouffer Foods Corp.*, No. 9250, Order Ruling on Stouffer Foods' Application for an Order Requiring the Production of Documents (Feb. 11, 1992); *Kraft, Inc.*, No. 9208, Order Ruling on Respondent's Motion for Documents in the Possession of Complaint Counsel (July 10, 1987); *see also* Rule 4.10(a)(3).

5. Complaint Counsel object to Respondent's requests for admission to the extent they seek information relating to the expert witnesses that Complaint Counsel intend to use at the hearing on the ground that the timing for identification of such witnesses and discovery relating to their opinions and testimony is established in the Scheduling Order Pursuant to Rule 3.21(c). *Schering Corp.*, No. 9232, Order re Interrogatories and Request for Production of Documents (Feb. 6, 1990); *Kraft, Inc.*, No. 9208, Order Ruling on Respondent's Motion for Documents in the Possession of Complaint Counsel (July 10, 1987).

6. Complaint Counsel object to Respondent's requests for admission to the extent that they seek information relating to non-testifying expert witnesses because Respondent has not made the proper showing that they are entitled to such information pursuant to Rule 3.31(c)(4)(ii). *Schering Corp.*, No. 9232, Order Denying Discovery and Testimony by Expert Witness (Mar. 23, 1990); *Telebrands Corp.*, No. 9313, Order Denying Respondents' Motion To Compel The Production of Consumer Survey Information, (Dec. 23, 2003).

7. Complaint Counsel object to Respondent's requests for admission to the extent that they seek information obtained from or provided to other law enforcement agencies, and to the extent that they seek information obtained in the course of investigating other marketers of dietary supplements and weight loss products, on the grounds that such documents are protected from disclosure by the law enforcement evidentiary files privilege and disclosure of such documents would be contrary to the public interest.

8. Complaint Counsel object to Respondent's requests for admission to the extent that, when read with the definitions and instructions, are so vague, broad, general, and all inclusive that they do not permit a proper or reasonable response and are, therefore, unduly burdensome and oppressive.

9. Complaint Counsel object to the Instructions and Definitions to the extent that they impose an obligation greater than that imposed by the Commission's Rules of Practice and the provisions of any Pretrial Scheduling Order.

10. Complaint Counsel object to Respondent's requests for admission to the extent that they seek information ascertained from or the identity of confidential informants as disclosure of such information would be contrary to the public interest.

11. Complaint Counsel object to Respondent's Complaint Counsel object to Respondent's Requests for Admissions to the extent they fail to distinguish between the "Federal Trade Commission" and Complaint Counsel and thereby seek information in the possession of the Commissioners, the General Counsel, or the Secretary in his capacity as custodian or recorder of any information in contravention of Rule 3.35(a)(1) because such documents are not in the possession, custody or control of Complaint Counsel.

GENERAL RESPONSES

1. Complaint Counsel's responses are made subject to all objections as to competence, relevance, privilege, materiality, propriety, admissibility, and any and all other objections and grounds that would require the exclusion of any statement contained herein if any requests were asked of, or if any statements contained herein were made by, or if any documents referenced here were offered by a witness present and testifying in court, all of which objections are reserved and may be interposed at the time of the hearing.

2. The fact that Complaint Counsel have responded to any request for admission in whole or in part is not intended and shall not be construed as a waiver by Complaint Counsel of all or any part of any objection to any request for admission.

3. Complaint Counsel have not completed their investigation in this case, and additional facts may be discovered that are responsive to Respondent's interrogatories. Complaint Counsel reserve the right to supplement the responses provided herein as appropriate during the course of discovery.

4. As used herein, "Respondents" shall mean all Respondents named in the Complaint.

5. As used herein, "Respondent's requests for admission" shall mean the requests for admission and all applicable instructions and definitions as set forth in Basic Research, LLC's First Request For Admissions.

Requests For Admission and Responses

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

Response:

Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel admit that they have not conducted any studies regarding the Efficacy of the Challenged Products.

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

Response:

Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel objects to this request as vague and overbroad as it pertains to "other research." Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that they have not, as of this date, conducted "consumer surveys" relating to "how reasonable consumers would interpret or understand the Challenged Advertisements" and denies this request as to "other research."

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

Response:

Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel objects to this request as vague and overbroad as it pertains "other research." Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that they have not, as of this date,

conducted "consumer surveys" relating to "what types of substantiation reasonable consumers would expect the Respondents to possess in order to have a reasonable basis for the Challenged Claims in the Challenged Advertisements" and denies this request as to "other research."

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel denies.

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel denies.

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel denies.

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that they reviewed, analyzed and interpreted the Challenged Advertisements in connection with the filing of the Complaint but denies that they were the only individuals who did so in connection with the filing of the complaint.

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. The issue in this case is not whether there are multiple reasonable meanings of the term "Rapid." A respondent can be held liable where multiple interpretations of a claim are possible only one of which is deceptive. Stouffer Foods Corp., 118 F.T.C. at 799; Kraft., Inc. 114 F.T.C. at 120-21 n.8; Thompson Medical, 104 F.T.C. at 789 n.7.

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. The issue in this case is not whether there are multiple reasonable meanings of the term "Substantial." A respondent can be held liable where multiple interpretations of a claim are possible only one of which is deceptive. Stouffer Foods Corp., 118 F.T.C. at 799; Kraft., Inc. 114 F.T.C. at 120-21 n.8; Thompson Medical, 104 F.T.C. at 789 n.7.

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

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening protocol." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response.

11. Admit that at the time the Challenged Advertisements were published, the Federal Trade Commission had no pre-screening protocol for determining the adequacy of the substantiation supporting the claims made in the Challenged Advertisements.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening protocol." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response.

12. Admit that the Federal Trade Commission will not give advertisers definitive answers on the adequacy of their claim substantiation before advertisements are disseminated.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Subject to and without waiving this objection, Complaint Counsel denies this request to the extent that FTC staff may, under certain circumstances, as part of the post-order compliance process, provide advice as to whether a proposed course of action, if pursued, will constitute compliance with a Commission Order. See 16 C.F.R. §2.41 (d).

13. Admit that 16 C.F.R. § 1.1 does not provide a pre-screening protocol for advertisers to receive approval of their advertising.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening protocol." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response. Subject to and without waiving these objections, Complaint Counsel asserts that the text of 16 C.F.R. § 1.1 speaks for itself but admits this request to the extent that the text of the regulation does not contain the term "pre-screening protocol."

14. Admit that advice provided by the Federal Trade Commission under 16 C.F.R. § 1.1 is not binding on the Federal Trade Commission.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Subject to and without waiving this objection, Complaint Counsel asserts that the text of 16 C.F.R. § 1.1 speaks for itself and that the regulatory framework governing Advisory Opinions cannot properly be understood except by reference to the framework as a whole which includes not only but §1.1 but §§ 1.2-1.4. Complaint Counsel admits this request to the extent that the text of §§ 1.3(b) and (c) provide that the Commission may reconsider, rescind, or revoke advice given by the Commission or its staff. Section 1.3(b) goes on to provide that "Notice of such rescission or revocation will be given to the requesting party so that he may discontinue the

course of action taken pursuant to the Commission's advice. The Commission will not proceed against the requesting party with respect to any action taken in good faith reliance upon the Commission's advice under this section, where all the relevant facts were fully, completely, and accurately presented to the Commission and where such action was promptly discontinued upon notification of rescission or revocation of the Commission's approval."

15. Admit that the Federal Trade Commission is under no obligation to issue warning letters if it changes its position regarding advice previously provided under 16 C.F.R. § 1.1.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel also objects to this request as vague as it fails to define "warning letters" and "changes its position." Subject to and without waiving these objections, Complaint Counsel asserts that the text of 16 C.F.R. § 1.1 speaks for itself and that the regulatory framework governing Advisory Opinions cannot properly be understood except by reference to the framework as a whole which includes not only but §1.1 but §§ 1.2-1.4. Complaint Counsel notes that the text of §§ 1.3(b) and (c) provide that the Commission may reconsider, rescind, or revoke advice given by the Commission or its staff. Section 1.3(b) goes on to provide that "Notice of such rescission or revocation will be given to the requesting party so that he may discontinue the course of action taken pursuant to the Commission's advice. The Commission will not proceed against the requesting party with respect to any action taken in good faith reliance upon the Commission's advice under this section, where all the relevant facts were fully, completely, and accurately presented to the Commission and where such action was promptly discontinued upon notification of rescission or revocation of the Commission's approval."

16. Admit that in 2000, the Federal Trade Commission received a petition to adopt a rule for the pre-screening of dietary supplement advertisements.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that the Federal Trade Commission received a Petition for Rulemaking in 2000 from Jonathan W. Emord, Esq. which is attached and speaks for itself.

17. Admit that in 2000, the Federal Trade Commission denied a petition to adopt a rule for the pre-screening of dietary supplement advertisements.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening" Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a

response. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that the Federal Trade Commission denied a Petition for Rulemaking in 2000 from Jonathan W. Emord, Esq. and the letter denying the Petition was previously produced to Respondents but is also attached and speaks for itself.

18. Admit that in 2000, the Federal Trade Commission denied a petition to adopt a rule for the pre-screening of dietary supplement advertisements because it was impracticable.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that the Federal Trade Commission denied a Petition for Rulemaking in 2000 from Jonathan W. Emord, Esq. and that the bases for the Federal Trade Commission's denial cannot properly be understood except by reference to the letter denying the petition as a whole. The letter denying the Petition was previously produced to Respondents but is also attached and speaks for itself.

19. Admit that the Federal Trade Commission, at one time, had a pre-screening protocol for approving advertisements prior to dissemination.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "at one time" and "pre-screening protocol." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response. Subject to and without waiving these objections, Complaint Counsel denies this Request to the extent that the compliance order procedures, allowing "any respondent to request advice from the Commission as to whether a proposed course of action, if pursued by it, will constitute compliance" with a Commission Order, see 16 C.F.R. §2.41 (d), constitute a "pre-screening protocol." Complaint Counsel also denies this request to the extent that the use of the phrase "at one time" suggests that the procedure set forth in §2.41 (d) is no longer in place. Complaint Counsel lacks sufficient information to either admit or deny the remainder of this request.

20. Admit that the Federal Trade Commission abolished its pre-screening protocol for approving advertisements prior to dissemination.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening protocol." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response. Subject to and without waiving these objections, Complaint Counsel denies this Request to the extent that the compliance order procedures, allowing "any respondent to request advice from the Commission as to whether a proposed course of action, if pursued by it, will constitute compliance" with a Commission Order, see 16 C.F.R. §2.41 (d), constitute a "pre-screening protocol." Complaint Counsel also denies this request to the extent that the use of the phrase "abolished" suggests that the procedure set forth in §2.41 (d) is no longer in place. Complaint Counsel lacks sufficient information to either admit or deny the remainder of this request.

21. Admit that the Federal Trade Commission would pre-screen Respondents' advertisements in the event that a cease and desist order is issued against them.

Response: Complaint Counsel objects to this request because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague as to "pre-screening." Complaint Counsel had sought clarification of this term from Respondent's Counsel but failed to receive a response. Subject to and without waiving these objections, Complaint Counsel admits this Request to the extent that the compliance order procedures, allowing "any respondent to request advice from the Commission as to whether a proposed course of action, if pursued by it, will constitute compliance" with a Commission Order, see 16 C.F.R. §2.41 (d), constitute "pre-screen[ing]." Complaint Counsel denies this Request to the extent that §2.41 (d) provides that such requests for advice are inappropriate under certain circumstances.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as overbroad and because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions.

25. Admit that the Federal Trade Commission coordinated the filing of the Complaint with the Congressional hearings held on June 16, 2004 before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, United States House of Representatives ("the Hearings").

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague and ambiguous as to "coordinated."

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request as vague and ambiguous as to "Congressional representatives."

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further object to this request as vague and overbroad as to Dr. Wexler.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further object to this request as vague and overbroad as to Dr. Wexler.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further object to this request as vague and overbroad as to Dr. Wexler.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further object to this request as vague and overbroad as to Dr. Wexler.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions.

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

Response: Complaint Counsel objects to this request as vague as to "specific type and amount." Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine. Subject to and without waiving these objections, Complaint Counsel admits this Request to the extent that Complaint Counsel contends that its allegations that respondents did not possess and rely upon a reasonable basis that substantiated the claims challenged in the Complaint will be proven at trial. Complaint Counsel's allegations are premised upon a review of Respondents' advertising of the Challenged Products and the substantiation proffered by Respondents to support the claims challenged in the Complaint. Complaint Counsel contends that the substantiation proffered does not constitute competent and reliable scientific evidence for the claims challenged in the Complaint.

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

Response: Complaint Counsel objects to this request as vague, ambiguous and overbroad regarding the "Federal Trade Commission's authority." Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that Complaint Counsel contends that one of the issues for trial will be whether Respondents' had a reasonable basis for making the claims challenged in the Complaint before the claims were disseminated.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions. Subject to and without waiving this objection, Complaint Counsel admits this request to the extent that what constitutes competent and reliable scientific evidence may vary depending upon a number of factors including the type of product, the type of claim being made, and the particular field of science involved based upon the claims and the product.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions. Subject to and without waiving this objection, Complaint Counsel admits this request to the extent that the Federal Trade Commission has defined "competent and reliable scientific evidence" in the Order attached to its Complaint as "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."

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions. Subject to and without waiving this objection, Complaint Counsel admits this request to the extent that the Federal Trade Commission has defined "competent and reliable scientific evidence" in the Order attached to its Complaint as "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."

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

Response: Complaint Counsel objects to this request as vague as to "the state of the science" and overbroad as to "all the representations." Complaint Counsel further objects to this request because it seeks premature disclosure of Complaint Counsel's expert discovery contrary to the timing established in the Court's Scheduling Order and disclosure of information from Complaint Counsel's non-testifying witness[es] which is protected from disclosure under the work product doctrine.

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

Response: Complaint Counsel objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that the Federal Trade Commission typically requires claims about the efficacy or safety of dietary supplements to be supported with competent and reliable scientific evidence.

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

Response: Complaint Counsel objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions. Subject to and without waiving these objections, Complaint Counsel admits this request to the extent that it contends that Respondents needed competent and reliable scientific evidence to support the claims regarding the Challenged Products alleged in its Complaint.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions. Complaint Counsel further objects to this request because it seeks an admission as to a matter of law and hence is not a proper request and exceeds the scope of Rule 3.32 Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions.

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

Response: Complaint Counsel objects to this request to the because it does not seek "an admission of the truth of any matters relevant to the pending proceeding." R. 3.32, Admissions.

Dated: September 24, 2004

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Bureau of Consumer Protection
Federal Trade Commission
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Certificate of Service

I hereby certify that on this 27th day of August, 2004, I caused *COMPLAINT COUNSEL'S RESPONSE TO RESPONDENT BASIC RESEARCH LLC'S FIRST REQUEST FOR ADMISSIONS* to be served and filed as follows:

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

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Before the
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

In Re: Petition for a Rule Requiring the Division of Enforcement, Bureau of Consumer Protection to Abide by the Strictures of the First Amendment in Enforcing the FTCA	)	**Docket No. _____**

PETITION FOR RULEMAKING

The First Amendment Health Freedom Association ("Association"), an industry association comprised of corporate, sole proprietor, and consumer members, by counsel and pursuant to 16 C.F.R. § 1.9 and Section 18 of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. § 57(a)(1)(B), hereby petitions the Federal Trade Commission ("FTC" or "Commission") to reform at the earliest possible moment those enforcement practices and procedures identified herein, used in nonpublic investigations of health benefit advertisers,[1] that violate the First Amendment.

This petition calls for reform in the way FTC communicates with, and acts toward, the subjects of access letters and civil investigative demands.

FTC staff habitually fail, at the outset and throughout nonpublic investigations of health benefit advertising, to fulfill their First Amendment duty of informing the subjects of investigation of precisely which speech they suspect is inherently misleading (and, thus, not protected by the First Amendment) and which they suspect is (at worst) only potentially misleading (and, thus, protected by the First Amendment) and which they suspect does not mislead at all (and, thus, is also protected by the First Amendment). That failure engenders a

broad chilling effect on protected speech because without knowledge of precisely which ad content FTC suspects is inherently misleading (and, thus, unprotected by the First Amendment), advertisers questioned tend to favor overbroad self-censorship in order to reduce the risk of adverse FTC action.

FTC staff habitually fail in resolution of cases (short of trials or hearings on the merits) to inform subjects of nonpublic investigations not only of the precise content they deem inherently misleading but also of the precise scientific grounds they have for suspecting that content is not backed by "competent and reliable scientific evidence." Those failures not only deprive subjects of the process due them in matters as sensitive as government regulation of speech but also constitute an arbitrary and capricious agency practice in violation of the Administrative Procedure Act ("APA"). By not revealing their substantive reasons for suspecting that specific health benefit advertising content lacks supporting competent and reliable scientific evidence, the FTC staff fail to achieve that degree of transparency necessary for the subject (and--upon public notice of a disposition of the case—all others) to discern precisely why it is that certain speech has been deemed deceptive by the FTC. The absence of that transparency makes it extremely difficult, if not impossible, for both the subject, and others similarly situated, to know with reasonable certainty what ad content on the same subject FTC will in future regard as deceptive, leading prudent advertisers to engage in broad self-censorship (of a categorical nature, e.g., dropping entire ads rather than reforming them in ways that may be unobjectionable to FTC).

In particular, the petitioner calls upon the Commission **(1) to require FTC staff before initiating a nonpublic investigation of health benefit adverting to ascertain from scientific experts the competence and reliability of that advertising; (2) to require FTC staff in every**

[1] As used herein, the term "health benefit advertisers" refers to all who advertise that a food, dietary supplement, or drug conveys a health benefit.

nonpublic investigation of health benefit advertising, at the time an access letter or civil investigative demand is served upon the subject (and thereafter upon any change in the staff's position on the point until a final resolution), to notify the subject in unambiguous terms of precisely which ad content the staff suspects is "inherently misleading" (i.e., unprotected under the First Amendment) and the staff's reasons (including its scientific justifications) for so concluding; which ad content the staff suspects is, at worst, only "potentially misleading" (i.e., protected under the First Amendment and capable of being rendered nonmisleading through the addition of a disclaimer) and the staff's reasons therefore; and which ad content the staff does not challenge at all (and, thus, concedes is protected speech). Given the heavy First Amendment onus against government restrictions on commercial speech, the foregoing steps are most certainly that minimum process due a party whose speech the government deigns objectionable on pain of sanction. Moreover, the foregoing steps are an obvious, less speech restrictive alternative to current staff practices and procedures.

The petitioner also calls upon the Commission **(3) to require FTC staff—at the earliest possible moment during the course of a nonpublic investigation of health benefit advertising and, in any event, in advance of agreement upon terms of a consent decree or initiation of FTC litigation--to inform the subject of investigation of the precise scientific grounds the staff has for suspecting that specific health benefit advertising content is not backed by "competent and reliable scientific evidence" and to reveal FTC's scientific justification for concluding that a health benefit claim is inherently misleading.** The freedom to advertise cannot be exercised with confidence unless FTC limits on the exercise of that freedom are well defined and within constitutional bounds. FTC's historic refusal to divulge the scientific basis for its charge of deceptive advertising in nonpublic investigations of health

benefit advertising (in all cases that are resolved short of a decision on the merits) creates considerable ambiguity, preventing advertisers from discerning with sufficient confidence what level, degree, quality, and quantity of scientific evidence FTC expects to back individual health benefit advertising claims. Ultimately, that ambiguity induces broad self-censorship by responsible parties, including Association members, a sacrifice of First Amendment rights and a loss of information that may prove indispensable to the exercise of informed consumer choice in the market.

The petitioner also calls upon the Commission **(4) to require FTC staff to avoid use of compulsory process, including access letters and civil investigative demands, and to rely instead on warning letters and optional disclaimer or qualification language as a primary enforcement mechanism in those instances where health benefit ad content of an advertiser to which the staff objects is, at worst, only potentially misleading (and, thus, protected by the First Amendment). Use of warning letters calling for disclaimers is both a necessary and sufficient means to avoid misleadingness without imposing on the subject the full costs associated with complying with compulsory process, such as the costs of responding to access letters and civil investigative demands, thereby providing an obvious, less speech restrictive alternative to the FTC's current approach.**

At present, FTC staff inform subjects during nonpublic investigations that it suspects their advertising is "deceptive" but routinely fails to fulfill its First Amendment duty of identifying precisely which content in an ad it suspects to be inherently misleading (along with its reasons therefore), which content it suspects to be only potentially misleading (along with its reasons therefore), and which it does not challenge at all. That failure frequently induces responsible parties who are the subject of an investigation to engage in self-censorship of

protected speech within the ads in question. The logical and actual reaction of prudent advertisers is to withdraw entire ads from the market out of fear of adverse FTC action when, in fact, only a part (or no part at all) of those ads may contain speech for which the First Amendment affords no protection.

The First Amendment freedoms sacrificed by FTC's failure to provide subjects the precise notice called for herein are not only those of the health benefit advertisers but also those of consumers who depend upon as much potentially useful information as possible to exercise informed choice in the market. The Commission has long credited itself with adherence to the First Amendment in the conduct of its advertising reviews. See, e.g., Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection and the Office of Policy Planning of the FTC at 12 (September 13, 2002). It is time it brought the anachronistic procedures and practices used in nonpublic investigations of health benefit advertising suspected of containing deceptive content in line with the modern limits on federal power prescribed by the Supreme Court and the United States Courts of Appeal in the commercial speech decisions of the past decade. This petition calls upon FTC to achieve that laudable and, constitutionally required, goal and to afford the Commission an opportunity to reconfirm its adherence to First Amendment strictures (as the FDA has done most recently in its Consumer Health Information for Better Nutrition initiative[2]).

I. DESCRIPTION OF THE PETITIONER AND SUMMARY OF THE ARGUMENT

The Association is a nonprofit organization incorporated under the laws of Nevada. The Association's members are designers, manufacturers, distributors, and consumer purchasers of dietary supplements and functional foods. The Association's purpose is to defend the free flow

[2] http://www.fda.gov/oc/nutritioninitiative/whitepaper.html (last visited March 26, 2003).

of commercial information protected by the First Amendment of the United States Constitution necessary for a consumer to exercise fully informed choice in food and dietary supplement markets. The purpose of the organization is impeded by the FTC staff's current enforcement practices and procedures because the staff routinely challenges entire advertisements without making the above-mentioned constitutionally required distinctions[3], thus unnecessarily burdening ad content that is protected by the First Amendment in the same way that it burdens ad content that it suspects is not protected.[4]

The failure of the staff to inform a subject of the precise content in each ad suspected of being inherently misleading produces the logical and actual effect of causing a prudent subject of such an investigation--not informed by the staff during the investigation of precisely which content within an ad the staff suspects is inherently misleading and which, if any, the staff suspects is, at worst, only potentially misleading--to engage in self-censorship, removing from the market entire ads (or at least unobjectionable content along with the objectionable), in an effort to reduce the risk of, and potential extent of, FTC consumer redress demands and to reduce FTC insistence upon broad fencing in provisions in consent agreements as conditions precedent to pre-trial settlement. Those subjects may refrain from communicating information that FTC may rightly consider unprotected by the First Amendment, but they may also (and, indeed, do) refrain from communicating information that is undoubtedly protected, not knowing precisely which ad content FTC suspects is inherently misleading and which it suspects is, at worst, only potentially misleading or not misleading at all.

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[3] Typical questions in civil investigative demands and access letters call for production of all advertising content concerning the product in question and all related products and the production of all income and cost information for the products advertised.

[4] To the extent that FTC perceives deceptive advertising condemnable under the FTCA, 15 U.S.C. § 45, as more inclusive than protected speech under the First Amendment, it is duty-bound by the Supreme law of the Constitution to make sure that it does not impose undue burdens on protected speech, including potentially misleading commercial speech.

Those subjects, including members of the Association, have engaged in self-censorship out of a reasonable fear of law that is uncertain, because FTC has not required FTC staff in each case to inform subjects precisely which content in each ad it suspects is inherently misleading, which content it suspects is, at worst, only potentially misleading (and, thus, protected by the First Amendment), and which content it does not challenge at all. Because the subjects cannot discern the thoughts of the staff or of the Commission and cannot discern (without being so informed by the staff) the staff's precise position on the merit of specific ad content, that uncertainty combined with reasonable fear of adverse agency action necessarily induces broad self-censorship in lieu of (1) deletion of the precise content FTC actually suspects of being inherently misleading, (2) revision of ad content suspected of being only potentially misleading (i.e., through qualification of the language in issue or through the addition of a disclaimer), and (3) continuation of ad content that is not suspected of being misleading at all. Commission economists have long touted the benefits of accurate information flow to the exercise of consumer choice in a free market. See, e.g., Comments on the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission at 23 (September 13, 2002). The staff's aforementioned lack of requisite specificity disserves the end of keeping information markets as open as possible for the exchange of accurate commercial information. Moreover, the self-censorship induced unnecessarily limits economic opportunity, market entry, and competition, redounding to the detriment not only of consumers but also of industry. The loss of economic liberty and concomitant economic opportunity is particularly devastating to small business (and, most notably, to market entrants).

Because government restriction of commercial speech (both direct and foreseeable) is constitutionally impermissible absent satisfaction of a rather high burden of proof, it is

incumbent upon the Commission to ensure that the tools it uses during nonpublic investigations are carefully and precisely tailored to avoid undue burdens on the exercise of protected speech. The reforms the Petitioner urges the Commission to adopt herein are obvious, less speech restrictive alternatives to current practices and procedures and comport better with the public interest because they achieve FTC's objective of ridding the market of deception without sacrificing the advertiser's and the public's First Amendment rights (and the value of the free flow of accurate information).

The Association and its members find the staff's penchant for commencing nonpublic investigations of health benefit advertisers without first obtaining the counsel of scientific experts as to whether the advertised benefits are backed by scientific evidence unconstitutional because such advance consultation is an obvious, less speech restrictive alternative to current practices and procedures and may avoid or reduce the scope of burdens placed on advertisers and their speech. See Thompson v. Western States Medical Center, 122 S. Ct. 1497, 1506 (2002) (the Supreme Court explained that it has "in previous cases addressing [the] final prong of the Central Hudson test, . . . made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so").

The Association and its members find FTC staff's failure to inform subjects of precisely which ad content it suspects of being inherently misleading (and the reasons therefore, including the scientific justifications), which it suspects of being, at worst, only potentially misleading (and, thus, protected under the First Amendment) and which it suspects of not being objectionable (1) denies those subjects, other advertisers, and the public a clear understanding of legal limits on ad content and (2) leads ineluctably to a pervasive chilling effect, wherein the subject (and others similarly situated who become aware of the action) avoid entire categories of

advertising content, not able to discern with reasonable certainty what specific content FTC finds objectionable and why.

The Association and its members find FTC's failure to rely on warning letters in lieu of compulsory process in nonpublic investigations unnecessarily burdensome when the ad content in issue is, at worst, only potentially misleading and not inherently misleading. In such circumstances, the obvious, less speech restrictive alternative of a warning letter defining why the speech misleads and what disclaimers could be used to avoid misleadingness is both a necessary and sufficient corrective mechanism that is less speech restrictive than the imposition of the extraordinary costs and speech burdens ordinarily associated with compulsory process in FTC nonpublic investigations.

II. STANDING TO PURSUE LEGAL REDRESS

The Association and its individual members are adversely affected by the FTC's failure to ensure adequately that its practices and procedures in nonpublic investigations of health benefit advertising avoid the imposition of undue burdens on advertising content protected by the First Amendment. The Association suffers injury because that failure frustrates its purpose. The Association's for-profit corporate, non-profit corporate, and sole practitioner members are also injured because they include health benefit advertisers who fear adverse FTC action if they communicate certain accurate advertising information[5] but also because they include consumer members injured by their inability to receive such information which they find indispensable to the exercise of informed choice in the market.

As the Supreme Court explained, "[t]here is no question that an association may have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever

rights and immunities the association may enjoy. Moreover, in attempting to secure relief from injury to itself the association may assert the rights of its members, at least so long as the challenged infractions adversely affect its members' associational ties." Warth v. Seldin, 422 U.S. 490, 511 (1975), citing NAACP v. Alabama, 357 U.S. 499, 511 (1958).[6] An organization has standing to pursue legal action for redress of a grievance "if it has been injured as an entity," for example, if the challenged conduct impedes its ability to fulfill its purposes. See, e.g., Association of Community Organizations for Reform Now v. Fowler, 1997 U.S. Dist. LEXIS 20237 at *3 (E.D. La 1997) (citing Havens Realty Corp. v. Coleman, 455 U.S. 363, 379 (1982)). When an organization's purpose is frustrated by acts of government such that the organization cannot obtain protection for constitutional or statutory rights of its members and is forced to devote significant resources to that end, it has alleged a sufficient injury to establish standing to sue. See Truckers Union for Safety, et al. v. Mead, 251 F.3d 183, 188 (D.C. Cir. 2001) (discussing organizational standing and the requirement of cognizable injury to the organization, its activities, or its members).

III. THE UNCONSTITUTIONAL AGENCY PRACTICES AND PROCEDURES IN ISSUE

A. FTC's Current Practices and Procedures Unconstitutionally Vest Broad Discretion in Lay Commission Staff to Determine Whether Scientific Speech May Be Prohibited

The Association understands that the FTC staff's decision whether to initiate compulsory process against health benefit advertisers through either an access letter or a civil investigative

[5] The fear is profound. They also fear retaliation from the Commission if they inform the Commission of who they are. They believe, in the absence of clear criteria, FTC could well initiate nonpublic investigations of their current advertising, without good cause, to punish them for challenging the practices and procedures here in issue.

[6] Although standing is not a requirement to bring a petition before the FTC (or any administrative agency, see generally Sierra Club and Environmental Technology Council, Inc. v. EPA, 292 F.3d 895, 899 (D.C. Cir. 2002), citing Pfizer, Inc. v. Shalala, 182 F.3d 975, 980 (D.C. Cir. 1999) ("An administrative agency . . . is not subject to Article III of the Constitution of the United States")), it is a requirement for any subsequent suit in federal court for

demand is most often predicated not on a scientific expert's assessment but on the lay opinion of FTC legal staff. Before demanding scientific substantiation from health benefit advertisers for allegedly deceptive claims, FTC legal staff rarely, if ever, determine in advance whether their lay opinion of the competence and reliability of the advertising claims mirrors that of scientists expert in the field of science in issue. Based on lay supposition, FTC legal staff frequently impose the high costs of an FTC investigation on subjects without the staff satisfying a threshold burden of ascertaining the relative level of scientific evidence in the publicly available literature supportive of the questioned claims.[7] The determination whether to initiate a costly nonpublic investigation requires, at a minimum, consultation with a qualified scientific expert. The failure to adhere to that reasonable institutional safeguard against the exercise of unbridled discretion over use of compulsory process is a clear violation of the First Amendment. See generally, Forsyth County v. Nationalist Movement, 505 U.S. 123, 132 (1992).

1. Legal Background

It is a well-established legal tenet that "in the area of free expression a...statute placing unbridled discretion in the hands of a government official or agency...may result in censorship." City of Lakewood v. Plain Dealer Publishing Co., 486 U.S. 750, 757 (1988) (citing, e.g. Shuttlesworth v. Birmingham, 394 U.S. 147, 151 (1969); Cox v. Louisiana, 379 U.S. 536 (1965);

FTC's failure to grant the requested relief. We therefore take this opportunity to explain the particularized injury suffered by the petitioner and its members.

[7] The FTC requires advertisers to have scientific substantiation on hand before a health benefit advertisement is published. The First Amendment, however, makes it the Government's burden of proof, not the advertisers, to justify any restriction of commercial speech. The Government must prove speech not protected by the First Amendment. The advertiser has no constitutional duty to prove the contrary proposition. Indeed, all commercial speech is presumptively protected until such time as the government proves it to be inherently misleading. FTC may not constitutionally shift this burden to the advertiser by presuming a health benefit deceptive without proving it to be so, based on nothing more than the advertiser's lack of a substantiation file. It is of course possible that by sheer chance, or by generally derived opinion, an advertiser could make a health benefit advertising claim that was corroborated by science but failed to obtain that corroboration. That truthful speech is no less deserving of full First Amendment protection than the speech of the advertiser who keeps a substantiation file. In both instances, if FTC wishes to challenge the advertising, it must satisfy the First Amendment burden of proof by presenting evidence of deceptiveness; it cannot presume speech deceptive, it must prove it.

Staub v. City of Baxley, 355 U.S. 313, 321-22 (1958). Indeed, the Supreme Court has felt obliged to condemn systems in which the exercise of such authority was not bounded by precise and clear limits. That reasoning has been, simply, that the danger of censorship and of abridgment of our precious First Amendment freedoms is too great to bear when officials have broad discretion over determining which speech is unlawful. See, e.g. Southeastern Promotions, Ltd v. Conrad, 420 U.S. 546, 553 (1975). "Our distaste for censorship—reflecting the natural distaste of a free people—is deep-written in our law." Id. To avoid the exercise of unbridled discretion, adequate procedural safeguards are essential. Id. ("[C]onstitutionally required minimum procedural safeguards" are necessary); See also, Forsyth County v. Nationalist Movement, 505 U.S. 123, 132 (1992) ("[N]arrowly drawn, reasonable and definite standards" guiding officials are necessary before regulating speech). Those standards are required whether the speech in question is protected or not, for the risk of unbridled discretion is the primary constitutional threat. See Southeastern Promotions, Id.; Freedman v. Maryland, 380 U.S. 51, 57 (1965) (In case dealing with prohibition of obscene material, "a state is not free to adopt whatever procedures it pleases for dealing with obscenity...without regard to the possible consequences for constitutionally protected speech" (citing Marcus v. Search Warrant, 367 U.S. 717, 731 (1961).

The law condemning unbridled discretion by government speech police applies equally in cases where official discretion generates a chilling effect on protected commercial speech. That latter circumstance describes present FTC use of compulsory process in the context of health benefit advertising. See generally Lakewood, Id. at 758 (when unbridled discretion is placed in the hands of agency officials, "opportunities for speech are irretrievably lost" (citing Freedman v. Maryland, 380 U.S. 51, 57 (1965); Saia v. New York, 334 U.S. 558, 560 (1948)).

The commercial speech test in Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557, 566 (1980) has been described as "substantially similar" to the test for time, place, and manner restrictions on protected speech.[8] Board of Trustees of the State University of New York v. Fox, 492 U.S. 469, 477 (1989) (citing San Francisco Arts & Athletics, Inc. v. United States Olympic Committee, 483 U.S. 522, 537 n. 16 (1987). The substantive First Amendment purposes served by prohibiting the exercise of unbridled discretion over speech by government officials in time, place, and manner regulation would thus appear to apply equally in the commercial speech regulatory context. See e.g. Lakewood, 486 U.S. at 757 ("It is not merely the sporadic abuse of power by the censor but the pervasive threat inherent in its very existence that constitutes the danger to freedom of discussion" (citing Thornhill v. Alabama, 310 U.S. 88, 97 (1940)). In either context, it is a fundamental tenet under general First Amendment principles that the exercise of unbridled discretion by government officials is forbidden. See, e.g., Lakewood, supra; Shuttlesworth v. City of Birmingham, 394 U.S. 147, 153 (1969) (quoting Kunz v. New York, 340 U.S. 290 (1951); See also, Forsyth County v. Nationalist Movement, 505 U.S. 123 (1992).

[8] Central Hudson established a four-part test for analyzing the legality of restrictions on commercial speech. It held: "At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it must at least concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." Id. 447 U.S. at 566. The time, place, and manner test has been described as: "We have often approved restrictions of that kind [time, place, manner] provided that they are justified without reference to the content of the regulated speech, that they serve a significant governmental interest, and that in doing so they leave open ample alternative channels for communication of the information." Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 771 (1976).

2. FTC's Condonation of the Staff's Failure to Require Scientific Assessment of Health Benefit Advertising Before Imposing the Costs of Compulsory Process Violates the First Amendment

When FTC staff members decide whether to initiate compulsory process against a health benefit advertiser without first ascertaining that a qualified scientist regards the claim as deceptive, the staff proceeds on supposition, preconception, or bias, but not on a competently informed basis. In such a circumstance, the staff has not undertaken reasonably prudent steps to ensure a sound scientific basis for the initiation of costly compulsory process against a health benefit advertiser.[9] That practice directly implicates the major First Amendment risk that the Supreme Court has associated with the exercise of unbridled discretion by government officials: "self censorship by speakers in order to avoid being denied a license to speak." Lakewood, 486 U.S. at 759. While a license to speak is not at issue here, self-censorship in order to avoid risk of future adverse enforcement action is. As explained in the affidavit of the Association's President (Exhibit A), members of the Association have refrained from making certain truthful and nonmisleading health benefit claims in advertising because they cannot, from moment to moment, reliably discern in specific circumstances what FTC regards as deceptive.

FTC staff members must be limited in the exercise of their discretion by adequate procedural safeguards that ensure that each initiation of compulsory process against a health benefit advertiser is predicated on a sound and expert scientific foundation rather than on lay supposition, preconception, or bias. See, Forsyth County v. Nationalist Movement, 505 U.S. 123 at 132 (1992) (In case of whether a parade-permit fee is constitutional, the Supreme Court held that "based on the county's implementation and construction of the

[9] The point is not that lawyers, the proverbial jacks of all trades, who lack formal scientific training, cannot be intelligent interpreters of law and its relation to science. It is, rather, that they cannot reliably determine in the first instance whether an advertising claim of health benefit is scientifically supported without consulting a scientist appropriately educated and experienced in the study of the science in question.

ordinance, it simply cannot be said that there are any narrowly drawn, reasonable and definite standards guiding the hand of the Forsyth County administrator. The decision [of] how much to charge for police protection or administrative time—or even whether to charge at all—is left to the whim of the administrator. There are no articulated standards either in the ordinance or in the county's established practice...The First Amendment prohibits the vesting of such unbridled discretion in a government official"). Without required consults with qualified scientists as a condition precedent to initiation of nonpublic investigations of health benefit advertising, there exists no reasonable procedural safeguard to protect against unscientific bias, supposition, or preconception by staff in the initiation of such investigations. Because the safeguards are reasonable and obvious less speech restrictive alternatives, the Commission violates the First Amendment by not implementing them. Id.; See also Central Hudson, supra, 447 U.S. at 566.

The Association urges FTC to require its staff to ascertain from scientific experts the competence and reliability of health benefit advertising claims before initiating compulsory process against health benefit advertisers. Only when FTC meets that preliminary burden may it constitutionally justify imposing the costs of its compulsory process on a health benefit advertiser (whose commercial speech, under our First Amendment, is presumptively protected against state restriction and undue burden absent government fulfillment of its burden to prove the speech in question inherently misleading).

B. FTC's Staff Violates the First Amendment by Failing to Differentiate Between Inherently and Potentially Misleading Speech in Nonpublic Investigations of Health Benefit Advertising

The FTC (and its Division of Enforcement ("Division") and its Bureau of Consumer Protection ("Bureau")) commence nonpublic investigations of health benefit advertising when the staff suspects that it has discovered evidence of deceptive advertising. That discovery

necessarily entails a preliminary judgment by at least one staff attorney that specific content communicated in a health benefit ad deceives the public. Under the First Amendment, commercial speech is deemed protected if it is potentially misleading (i.e., may convey a misleading connotation that can be eliminated through use of a qualification or disclaimer).[10] Nevertheless, potentially misleading speech is of a kind that fits within the agency's definition of deceptive speech and, so, is actionable under the FTCA.[11] A statement can be "deceptive" even if literally true if it fails to disclose material information. See, e.g., Sterling Drug, Inc. v. FTC, 741 F.2d 1146, 1154 (9th Cir. 1984) ("The failure to disclose material information may cause an advertisement to be deceptive, even if it does not state false facts") (citing Simeon Management Corp. v. FTC, 579 F.2d 1137, 1145 (9th Cir. 1978)). Accordingly, FTC defines as deceptive all advertising content that includes the potential to mislead, yet that content is protected from government restriction and suppression by the First Amendment to the United States Constitution. See, Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing In Re R.M.J., 455 U.S. 191 (1982); Ibanez v. Florida Dep't of Business and Prof'l Regulation, 512 U.S. 136 (1994); and Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91 (1990)).

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[10] Since In re R.M.J., the Supreme Court has consistently drawn a distinction between speech that is *misleading* (by which the Court means inherently misleading) and speech which is at worst only *potentially misleading* (by which the Court means speech that can be rendered nonmisleading through the addition of a reasonable disclaimer, warning statement, or other information). See In Re R.M.J., 455 U.S. 191, 203 (1982); see also Ibanez v. Florida Dep't of Bus. And Prof'l Regulation, 512 U.S. 136, 144-46 (1994); Peel v. Attorney Registration and Disciplinary Comm'n, 496 U.S. 91, 99-111 (1990). If speech is inherently misleading, government may suppress it outright. See Joe Conte Toyota, Inc. v. Louisiana Motor Vehicle Commission, et.al., 24 F.3d 754 (5th Cir. 1994); Pearson I, 164 F.3d at 655. If speech is potentially misleading, government may not suppress it but, if it chooses to regulate the speech, the Court will allow it to require reasonable disclaimers, qualifications, or warning statements as less speech restrictive alternatives to suppression. See Peel, 496 U.S. at 100; In Re R.M.J., 455 U.S. at 207; Shapero v. Kentucky Bar Association, 486 U.S. at 479; Pearson I, 164 F.3d at 655. A reasonable disclaimer is, *inter alia*, one that is succinct and accurate and does not engender a chilling effect on others willingness to communicate the same message. See Zauderer, 471 U.S. at 651; see also Borgner v. Brooks, 284 F.3d 1204 (11th Cir. 2002).

[11] See, e.g., 15 U.S.C. § 45.

The Supreme Court has drawn a distinction between commercial speech that is inherently misleading and that which is potentially misleading. See, e.g., In Re R.M.J., 455 U.S. at 203; note 5 supra. Inherently misleading speech cannot be cured of its misleadingness through any form of qualification or disclaimer, but potentially misleading speech can be so cured. Consequently, the Court has no quarrel with government restriction or suppression of inherently misleading commercial speech but finds restriction or suppression of potentially misleading commercial speech a forbidden exercise of government power that violates the strictures of the First Amendment. Id. ("Inherently misleading advertising may be prohibited entirely. But the States may not place an absolute prohibition on...potentially misleading information...if the information also may be presented in a way that is not deceptive"). The First Amendment burden of proof rests squarely on the government to justify each act which restricts or suppresses protected speech. See Western States Medical Center, 122 S. Ct.. at 1507 ("[i]t is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it,'" Ibanez v. Florida Dep't of Business and Prof'l Reg., 512 U.S. 136, 143 (1994), citing Edenfield v. Fane, 507 U.S. at 770 (quoting Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 71, n.20 (1983)). Thus, when there exists an obvious, less speech restrictive alternative regulatory means, the government cannot ignore it but must implement it.[12]

It is the duty of speech police to re-evaluate the weapons in their arsenal continually and to replace them whenever it becomes apparent that a more precise means would impose less of a restriction on protected speech than the ones then in use. In these comments, the Petitioners define for FTC new methods for use in nonpublic investigations that are far less speech

[12] In Rubin v. Coors, 514 U.S. at 490-91, and again in Western States Medical Center, 122 S. Ct. at 1506-7, the Court evaluated all feasible less speech restrictive alternatives to the means chosen, and it condemned speech restrictions in both cases because they were more extensive restrictions than the alternatives. The Court reminds

restrictive than the old ones now in use. It is therefore constitutionally incumbent upon the Commission to apply the new methods in lieu of the old at the earliest possible moment. See, e.g. Western States Medical Center, 122 S. Ct. at 1506 (the Supreme Court explained that it has "in previous cases addressing this final prong of the Central Hudson test, . . . made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so"). See also, Rubin v. Coors Brewing Co., 514 U.S. 476, 491 (1995)).[13]

When the staff issues an access letter or a civil investigative demand to an advertiser, the staff rarely, if ever, informs the advertiser precisely which content it suspects of being inherently misleading under the First Amendment standard; which it suspects, at worst, of being only potentially misleading; and which it finds unobjectionable. Without so informing the subject of investigation, FTC nevertheless demands a wide array of responses to searching and, oftentimes, intrusive questions calling for the production of documents and the provision of answers. Such questions demand, e.g., (1) sensitive financial information about the compensation of company officers and employees ("State all compensation, payments, and other benefits (whether in the form of cash, loans, real property, or other form) and the time period of such payments made by the company to each current or former officer and director, and the five most highly compensated employees, independent contractors, or consultants"); (2) extremely detailed

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regulators that "[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort." Id. at 1507.

[13] Delay of any sort in rectifying free speech violations is the bane of the First Amendment. See Elrod v. Burns, 427 U.S. 347, 373 (1986)("[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"); see also Jackson v. City of Columbus, 194 F.3d 737, 747 (6th Cir. 1999); Iowa Right to Life Comm., Inc. v. Williams, 187 F.3d 963, 969 (8th Cir. 1999); Brownsburg Area Patrons Affecting Change v. Baldwin, 137 F.3d 503, 507 (7th Cir. 1998); New York Magazine v. Metropolitan Transportation Authority, 136 F.3d 123, 127 (2nd Cir. 1998); Lakewood v. Plain Dealer Publishing Co., 486 U.S. 750, 758 (1988) (noting that "opportunities for speech," if suppressed, "are irretrievably lost"); Washington Free Community v. Wilson, 426 F.2d 1213, 1218 (D.C. Cir. 1969) ("Speakers . . . cannot be made to wait for years before being able to speak with a

information concerning the advertising and promotion of products ("For each item of promotional material...submit a separate, complete dissemination schedule, including the dates, times, and cities of dissemination, number of disseminations, cost of disseminations, media used, and job numbers or descriptions used by each broadcast station, publication, or online service"); (3) sales figures for the product or products at issue and company sales information ("Please provide annual sales figures for [three consecutive years and to date] for the company as a whole and for each of the products identified...above"); and even (4) internal company information concerning the marketing and development of advertising strategies ("For each product...identify and provide a brief description of the roles and responsibilities of all individuals and companies, including but not limited to advertising agencies, marketing firms, public relations firms, or others who participated in: a) the creation, development or preparation of promotional materials for such products; and b) the media placement or dissemination of the promotional materials for such products").

The cost of response can be substantial, ranging (in legal fees alone) from a low of five figures ($25,000 to $75,000) to six figures ($100,000 to $200,000) or more.[14] The aforementioned FTC failure unnecessarily causes all content of the ad in question, including that protected by the First Amendment, to be treated the same as ad content not protected by the First Amendment. The failure leaves the subject to guess about what content FTC actually finds objectionable and about FTC's substantive basis for the objection. Continued use of deceptive advertising content during the investigation phase can (and often does) increase the amount FTC demands for consumer redress and can (and often does) worsen the prospects for pre-trial settlement. Uninformed of precisely what ad content FTC finds objectionable (and, more

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measure of security"); Riley v. National Federation of the Blind, 784 U.S. 781, 793-94 (1988); Pearson v. Shalala, 130 F. Supp. 2d at 119 (D.C. 2001) (applying Elrod and progeny in the health claims context).

particularly, of which content it suspects is inherently misleading, of which is only potentially misleading and curable by disclaimer, and of which is not misleading at all), the prudent advertiser often decides to withdraw entire ads from the market (thus suppressing not only content FTC actually suspects is inherently misleading but also content protected by the First Amendment, i.e., potentially misleading and nonmisleading content). For an advertiser to modify ad content (but to guess wrongly as to what content FTC suspects is deceptive) entails enormous risks for the advertiser because FTC may well find failures to correct content it finds deceptive to warrant greater consumer redress and harsher terms for a consent decree.

In sum, in the absence of word from FTC staff specifically identifying which content the staff suspects is "inherently misleading," which it suspects is "potentially misleading," and which it finds not deceptive, an advertiser must guess at its own peril if it wishes to continue running the ad without what it presumes is the offending content. The ambiguity present creates a pervasive chilling effect that induces self-censorship.[15] The resulting self-censorship not only causes the advertiser to suffer a loss in free speech but also causes the consumer to experience a loss in actually or potentially useful information that may prove indispensable to the rendering of an informed market selection.

Variously in its decision to issue access letters and civil investigative demands; in its pursuit of compulsory process; in its communication with regulatees and their counsel; in the content of its administrative and judicial complaints; and in the content of its consent orders, the

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[14] See Exhibit B.

[15] The enforcement uncertainty created by FTC's practice results in a chilling effect. As the court stated in Grayned, "uncertain meanings inevitably lead citizens to 'steer far wider of the unlawful zone'...than if the boundaries of the forbidden area were clearly marked." Id. at 109, citing Baggett v. Bullitt, 377 U.S. 360, 372 (1964), quoting Speiser v. Randall, 357 U.S. 513, 526 (1958), see also Interstate Circuit v. Dallas, 390 U.S. 676, 684 (1968); Ashton v. Kentucky, 384 U.S. 195, 200-201 (1966); Dombrowski v. Pfister, 380 U.S. 479, 486 (1965); Smith v. California, 361 U.S. 147, 150-152 (1959); Winters v. New York, 333 U.S. 507 (1948); Stromberg v. California, 283 U.S. 359, 369 (1931).

Commission, the Division, and the Bureau violate the First Amendment: (1) by not requiring its staff to ascertain from scientific experts the competence and reliability of health benefit advertising claims before initiating compulsory process; (2) by not evaluating health benefit advertising to discern and explain whether it is inherently or potentially misleading; (3) by not employing obvious less restrictive alternatives to use of compulsory process to protect those who engage in potentially misleading health benefit advertising from the same costs, burdens, and restrictions imposed on those who engage in inherently misleading advertising; (4) by not informing regulatees of precisely why the content of specific health benefit advertising is deemed inherently or potentially misleading by the Bureau, Division, or Commission; (5) by not informing regulatees that they may continue to use potentially misleading health benefit ads if they disclaim or qualify them to avoid misleading connotations; and (6) by not excluding potentially misleading health benefit advertising from consent decrees and orders that impose on advertisers often costly consumer redress, disgorgement, effective injunctions against future use of statements deemed deceptive, reporting, recordkeeping, and consumer notification requirements (collectively referred to herein as "penalties"[16]).

Indeed, the FTC defines any health benefit advertising that does not satisfy its largely subjective and ambiguous "competent and reliable scientific evidence" standard as deceptive and defines those who communicate such advertising as deserving of compulsory process, enforcement, and penalties without any effort to protect potentially misleading health benefit advertising from the costs, burdens, and restrictions of that process. By failing to make accommodations to protect potentially misleading health benefit advertising from the burdens it imposes on inherently misleading health benefit advertising, the FTC's repeated incursions into

[16] We understand that FTC does not regard these requirements as punitive measures but, in point of fact, they affect subjects in the same negative way, regardless of the nomenclature used.

the market generate a chilling effect, causing entire categories of advertising to be viewed by responsible advertisers as too risky and thereby to induce self-censorship.[17] In the end the current process redounds to the detriment of consumers, denying them information on the potential benefits realizable from the use of health enhancing products by unduly restricting what may be said about those products.

There is an obvious and less speech restrictive alternative to the current staff practice and procedure. That alternative is for the staff: (1) to avoid soliciting or compelling any individual or entity to respond to FTC access letters and/or civil investigative demands concerning allegedly deceptive health benefit advertising until the staff has first consulted with a qualified scientist to determine whether the ad claims in question are ones for which supportive publicly available scientific evidence is lacking; (2) to avoid soliciting or compelling any individual or entity to respond to FTC access letters and/or civil investigative demands concerning alleged deceptive health benefit advertising until the staff has written to the subject informing that person or entity of: the precise ad content suspected of being "inherently misleading" and the reasons therefore; the precise ad content suspected of being, at worst, only "potentially misleading" and the reasons therefore; and the precise ad content not questioned by the FTC; (3) to inform the subject of investigation of the precise scientific basis for FTC's conclusion that claims lack "competent and reliable scientific evidence" at the earliest possible moment during a nonpublic investigation of such advertising and, in any event, before entry of a consent decree or commencement of litigation against the subject; and (4) in instances where the content to which FTC objects is potentially, and not inherently, misleading, to use a warning letter[18] instead of compulsory

[17] See Exhibit A.

[18] The warning letter should inform the regulatee of precisely why the FTC has found specific content potentially misleading and inform the regulatee of potential disclaimers or qualifications that could be used to avoid

process to address FTC concerns about that advertising (including, but not limited to, all claims the FTC believes implied by the advertising), reserving the right to use compulsory process if the subject of the warning letter does not qualify or disclaim its potentially misleading content to eliminate misleadingness. The Petitioner urges FTC to adopt these new practices and procedures promptly as a less speech restrictive alternative to the current, more burdensome and costly practices and procedures.

IV. OBVIOUS, LESS SPEECH RESTRICTIVE ALTERNATIVES

Under the First Amendment standard that governs all government restrictions on speech, the practices and procedures here in issue do not directly advance the government's interest in ridding the market of false (i.e., inherently misleading) claims. Moreover, there are obvious, less speech restrictive alternatives to the current practices and procedures. Under Central Hudson Gas & Elec. Corp. v. Public Service Comm'n, 447 U.S. 540, 536 (1980), as modified, the third and fourth prongs of the test are not satisfied by FTC's current practices and procedures. Use of compulsory process, including access letters and civil investigative demands that impose costs upon advertisers without informing those subjects of precisely which content in issue is inherently misleading, which is potentially misleading and which is not neither directly nor materially advances the government's interest in ridding deceptive advertising from the market. Rather, it creates a chilling effect upon advertising. It induces self-censorship by advertisers, causing them to suppress potentially misleading content and nonmisleading content (both of which are First Amendment protected), along with content

misleadingness and afford the regulatee a reasonable time either to alter advertising to include needed disclaimers or qualifications or face compulsory process, including access letters and civil investigative demands.

that may be inherently misleading. It is thus overly inclusive and, thereby, unnecessarily burdensome.

FTC's imposition of costs for compulsory process on advertisers regardless of the form of deceptive advertising (the potentially misleading and the inherently misleading alike) and its failure to inform subjects of investigation of precisely which content it finds inherently misleading and which it does not causes protected speech to be unduly burdened when obvious, less speech restrictive alternatives exist to free that speech from burden: the abovementioned alternatives (1) of informing subjects of the particular content FTC suspects is inherently misleading, potentially misleading, and not misleading at all and the reasons therefore and (2) of relying on warning letters in lieu of compulsory process in nonpublic investigations when the speech in issue is, at worst, only potentially misleading. Reliance on alternative 1 above has the salutary effect of enabling the subject of investigation to discern which speech it can selectively delete from advertising or modify to avoid, in the eyes of the staff, a continuing offense and which speech it can continue to communicate with confidence (knowing that the speech is neither exacerbating the offense nor risking an increase in any ultimate consumer redress demand). The resulting restrictions on speech are thus minimized and the consequential benefit to consumers is maximized because consumers may continue to receive First Amendment protected content that may prove indispensable to them in the exercise of choice in the market. Reliance on alternative 2 above has the salutary effect of relieving those who communicate protected speech (speech that is, at worst, only potentially misleading) of the costs and burdens associated with compulsory process in nonpublic investigations so long as they heed the government's warning and employ requisite qualifications or disclaimers to eliminate perceived misleadingness.

V. FTC'S CURRENT PRACTICES AND PROCEDURES IN NON-PUBLIC INVESTIGATIONS OF HEALTH BENEFIT ADVERTISERS VIOLATE THE ADMINISTRATIVE PROCEDURE ACT

The Administrative Procedure Act declares unlawful Commission action that is arbitrary, capricious and contrary to law. 5 U.S.C. § 706 (2)(A). In matters of speech regulation, clarity and predictability are indispensable for government compliance with the strictures of the First Amendment. The absence of either defines arbitrary and capricious enforcement in the context of speech regulation and suggests, if not reveals, reliance on undisclosed motives. See Public Citizen, Inc. v. FAA, 988 F.2d 186, 197 (D.C. Cir. 1993) ("The requirement that agency action not be arbitrary and capricious includes a requirement that the agency adequately explain its result"); Dickson v. Secretary of Defense, 68 F. 3d 1396, 1404 (D.C. Cir. 1995) ("The arbitrary and capricious standard of the APA 'mandates that an agency take whatever steps it needs to provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision'") (citing Pension Benefit Guaranty Corp. v. LTV Corp., 496 U.S. 633, 654 (1990)); National Treasury Employees Union v. Horner, 854 F.2d 490, 498 (D.C. Cir. 1988) (Agency must examine "the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made'") (citing Motor Vehicle Manufacturer's Ass'n v. State Farm Automobile Ins. Co., 463 U.S. 29, 43 (1983); Pearson v. Shalala, 164 F.3d 650, 660 (D.C. Cir 1999) ("Pearson I") ("We agree with appellants that the APA requires the agency to explain why it rejects their proposed health claims—to do so adequately necessarily implies giving some definitional content to the phrase 'significant scientific agreement'. We think this proposition is squarely rooted in the prohibition under the APA that an agency not engage in arbitrary and capricious action"); Id. ("It simply will not do

for a government agency to declare—without explanation, that a proposed course of private action is not approved");

The constitutional violations mentioned above are also violations of the Administrative Procedure Act, 5 U.S.C. § 551 et. seq. In addition, the use of enforcement power (including investigatory power) against advertising content on allegations of deceptiveness without identifying which statements are inherently misleading; which are, at worst, only potentially misleading; and which are not objectionable, constitutes an arbitrary and capricious action because it fails to take minimum, constitutionally required steps to ensure that protected speech is not unduly burdened. Likewise, the Commission's failure to disclose to the subject of a nonpublic investigation of health benefit advertising the precise scientific reason for its charge that advertising is not backed by "competent and reliable scientific evidence" constitutes arbitrary and capricious decisionmaking because, in matters of speech, precision and clarity in the application of government power is indispensable, a touchstone of constitutionality. See, e.g. Meehan v. Macy, 392 F.2d 822, 834 (D.C. Cir. 1968) ("There is a particular need for clarity and specificity when Government officials are engaged in regulating speech"); Keyishian v. Board of Regents, 385 U.S. 589, 603-604 (1967) ("We emphasize once again that 'precision of regulation must be the touchstone in an area so closely touching our most precious freedoms,' N.A.A.C.P. v. Button, 371 U.S. 415, 438 (1963) 'for standards of permissible statutory vagueness are strict in the area of free expression...Because First Amendment freedoms need breathing space to survive, government may regulate in the area only with narrow specificity.'" Id. at 432). Finally, the FTC's failure to distinguish potentially misleading ad content from inherently misleading ad content, treating both the same as deceptive advertising and imposing the same

regulatory burdens upon the different speech forms, violates the APA too because it inexplicably denigrates protected speech. See Public Citizen, Inc. v. FAA, supra, 988 F.2d 186 at 197.

VI. THE PROPOSED PRACTICE AND PROCEDURE FOR USE IN NONPUBLIC INVESTIGATIONS OF HEALTH BENEFIT ADVERTISING

For the foregoing reasons, the Petitioner respectfully requests that the Commission order, without delay, the adoption of the following practices and procedures for FTC staff in the exercise of nonpublic investigations of health benefit advertisers:

1. That FTC staff, before initiating a nonpublic investigation of health benefit advertising, ascertain from scientific experts the competence and reliability of that advertising.

2. That FTC staff in every nonpublic investigation of health benefit advertising, at the time an access letter or civil investigative demand is served upon the subject (and thereafter upon any change in the staff's position on the point until a final resolution), notify the subject in unambiguous terms of precisely which ad content the staff suspects is "inherently misleading" (i.e., unprotected under the First Amendment) and its reasons (including its scientific justifications) for so concluding; which ad content the staff suspects is, at worst, only "potentially misleading" (i.e., protected under the First Amendment and capable of being rendered nonmisleading through the addition of a disclaimer) and its reasons therefore; and which ad content the staff does not challenge at all.

3. That FTC staff—at the earliest possible moment during the course of a nonpublic investigation of health benefit advertising and, in any event, in advance of agreement upon terms of a consent decree or initiation of FTC litigation—inform the subject of investigation of the precise scientific grounds it has for suspecting that health benefit advertising is not backed by "competent and reliable scientific evidence," i.e., to reveal the staff's scientific justification for concluding that a health benefit claim is inherently misleading.

4. That FTC staff avoid use of compulsory process, including access letters and civil investigative demands, and instead rely on warning letters and optional disclaimer or qualification language as a primary enforcement mechanism in those instances where the health benefit ad content of an advertiser to which the staff objects is, at worst, only potentially misleading (and, thus, protected by the First Amendment).

VII. THE COSTS OF UNDERTAKING THE PROPOSED REFORMS

The costs of undertaking the proposed reforms are minimal and borne entirely by the Commission because they exclusively involve a change in the practices and procedures of Commission staff in the exercise of nonpublic investigations of health benefit advertisers. Moreover, as explained above, the proposed reforms are a constitutional imperative. The ultimate costs associated with enforcing the proposed new practices and procedures will likely be less than those associated with enforcing the current practices and procedures because the increased clarity afforded and the lessened burden experienced by what is proposed should reduce noncompliance and thereby decrease the need for future nonpublic investigations of health benefit advertisers. The agency will benefit from improved industry and public confidence in the Commission's decisionmaking instead of the present Kafkaesque scenario where companies are punished for practices they did not know were unlawful because the government failed to inform the regulated class unambiguously of specific government limits on the exercise of freedom of speech .[19]

[19] See, Franz Kafka, The Trial (Schocken Books 1995).

VIII. CONCLUSION

For the foregoing reasons, the First Amendment Health Freedom Association respectfully requests that the FTC immediately adopt the practices and procedures herein proposed. Because ongoing First Amendment constitutional violations are present, the Petitioner respectfully requests that the Commission act expediously on this petition. See, e.g. Elrod v. Burns, 427 U.S. 347, 373 (1976) ("[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"); Washington Free Community v. Wilson, 426 F.2d 1213, 1218 (D.C. Cir. 1969) ("Speakers...cannot be made to wait for years before being able to speak with a measure of security").

Respectfully submitted,

THE FIRST AMENDMENT HEALTH FREEDOM ASSOCIATION

By _____

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Their Attorneys

Emord & Associates, P.C.
1050 Seventeenth Street, N.W.
Suite 600
Washington, D.C. 20036
202/466-6937

Dated: April 16, 2003

EXHIBITS

AFFIDAVIT OF NORMAN ANDERSON

I, Norman Anderson, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1) I am the President of the First Amendment Health Freedom Association ("Association").

2) The Association's purpose is to defend the free flow of commercial information protected by the First Amendment of the United States Constitution necessary for a consumer to exercise fully informed choice in food and dietary supplement markets.

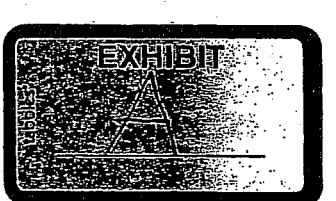
3) The Association's confidential membership base includes both manufacturers and consumers of dietary supplement products.

4) In the course of reviewing statements made and concerns raised by several members, the Association has learned that several companies and individuals routinely engage in self-censorship due to a lack of ascertainable scientific standards and arbitrary enforcement practices of the Federal Trade Commission ("FTC").

5) The Association believes that companies have engaged in self-censorship by refraining from making numerous truthful and nonmisleading claims and refraining from conveying truthful and nonmisleading information concerning their products through television and radio advertising for fear of adverse enforcement action by FTC.

6) The Association also believes that members have not entered the dietary supplement market due to fear of adverse FTC enforcement action.

7) The Association believes that FTC's current enforcement practices have a chilling effect on its members' advertising and marketing practices.



8) This chilling effect is detrimental in that the Association's members wish to both convey and receive information that will assist the American public to help them make informed health care decisions but have not done so in numerous instances due to fear of adverse agency action.

9) FTC's arbitrary enforcement practices directly and substantially frustrate the purpose of the Association and its individual members. As a consequence, I authorize the Association's attorneys to file and prosecute a rulemaking petition with and before the FTC and, as necessary, before the federal courts to bring about reforms of the way in which FTC engages in enforcement action to end the First Amendment violations present.

NORMAN ANDERSON

4-14-03
Dated

AFFIDAVIT OF CHAUNYA BLACKWELL

I, Chaunya Blackwell, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1) I am the business manager at the firm Emord & Associates, P.C., 5282 Lyngate Court, Burke, Virginia 22015.

2) I prepare all final monthly billing statements issued by the firm and review all time entries and descriptions with the firm's principals.

3) Before joining Emord & Associates, I worked from September 2000 to November 2002 as a paraprofessional at the accounting firm of Reznick, Fedder, and Silverman, 7700 Old Georgetown Road, Bethesda, Maryland 20814.

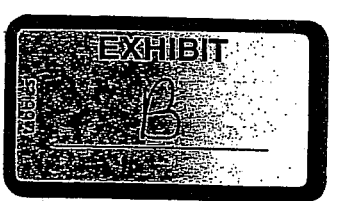
4) In that capacity, I prepared bills for four (4) law firms.

5) Emord & Associates represents companies and sole proprietors that have received access letters and civil investigative demands from FTC concerning allegedly deceptive advertising practices and claims.

6) The attorney time billed includes counseling of clients on federal law governing health benefit advertising; counseling of clients on the meaning, requirements, and legal options available in response to access letters and civil investigative demands; drafting responses to FTC documentary and interrogatory requests on behalf of clients; document production and review; aiding clients in negotiation with FTC; and drafting settlement agreements and/or consent orders.

7) At the request of the firm's principals, I have reviewed bills for several clients to determine the range and extent of legal fees associated with FTC compulsory process. My review covers the period from 2001 to March 2003.

8) The hourly rates charged by this firm range from $165 to $375 and are comparable to other firms in this same practice area.



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FEDERAL TRADE COMMISSION
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DOCUMENT PROCESSING

Before the
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

In Re: Petition for a Rule Authorizing Issuance of Advisory Opinions Concerning Dietary Supplement Structure/Function Claim Advertising or, in the Alternative, Defining the Criteria FTC Uses to Evaluate Scientific Evidence Required in Support of Dietary Supplement Structure/Function Claim Advertising	)	Docket No. P002501

PETITION FOR RULEMAKING

Dr. Julian M. Whitaker; Pure Encapsulations, Inc.; Imagenetix, Inc.; and XCEL Medical Pharmacy, Ltd. (collectively, "Joint Petitioners"), by counsel and pursuant to 16 C.F.R. § 1.9 and Section 18 of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. § 57(a)(1)(B), hereby petition the Federal Trade Commission ("FTC") to promulgate a rule for the issuance of advisory opinions concerning whether an advertiser's scientific corroboration for planned structure/function claim advertising[1] constitutes "competent and reliable scientific evidence" needed to substantiate the claims. In the alternative, the Joint Petitioners petition FTC to promulgate a rule that will make explicit the principles which guide agency action when it evaluates the sufficiency of scientific evidence in support of dietary supplement structure/function claim advertising.

[1] The term "structure/function claim advertising" is meant to refer to those statements which appear in advertising that satisfy the definition of such claims contained in 21 U.S.C. § 343(r):

> [a] statement [that] claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

DESCRIPTION OF THE PARTIES

Dr. Julian M. Whitaker. Julian M. Whitaker, M.D. is a physician licensed to practice medicine in the states of California and Washington. He graduated from Dartmouth College in 1966 with a B.S. degree and from Emory University in 1970 with an M.D. degree. He received additional training in surgery as a resident at the University of California Medical School. From 1975 to 1976 he worked as a physician at the Pritikin Institute in California. Since that time he has been the Clinical Director of the Whitaker Wellness Institute in Newport Beach, California. He is the author of five books: ***Reversing Heart Disease*** (1985), ***Reversing Diabetes*** (1987), ***Reversing Health Risk*** (1989), ***Natural Healing*** (1994), and ***What Your Doctor Won't Tell You About Bypass*** (1995). Since August of 1991 he has been the editor of ***Health & Healing***, currently the nation's largest single editor health newsletter. In 1996, ***Health & Healing*** had over 500,000 subscribers. Dr. Whitaker sells and promotes the sale of his own brand of dietary supplements. He receives royalties from the distribution and sale of several dietary supplements based on formulas he develops and licenses.

Dr. Whitaker would disseminate print advertising containing the following structure/function claims in association with his sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibits A-C) will be regarded by FTC as competent and reliable.

Product Description

Omega-3 Fatty Acid (EPA (360 mg per serving) and DHA (240 mg per serving))

Health Benefit Advertising Claim

Consumption of omega-3 fatty acids supports and promotes cardiovascular health.

Product Description

Saw Palmetto (160 mg per serving)

Health Benefit Advertising Claim

Saw Palmetto extract supports prostate health and healthy urinary function.

Product Description

Folic Acid (800 mcg per serving), Vitamin B6 (25 mcg per serving) and Vitamin B12 (100mcg per serving)

Health Benefit Advertising Claim

Folic Acid when taken in combination with Vitamin B6 and Vitamin B12 supports vascular health.

Pure Encapsulations, Inc. Pure Encapsulations, Inc. (Pure) is a Massachusetts corporation engaged in the business of manufacturing, distributing, and selling over 250 pharmaceutical grade dietary supplements for human and companion animal consumption.

Pure Encapsulations, Inc. would disseminate print advertising containing the following structure/function claims in association with its sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibits A, B and D) will be regarded by FTC as competent and reliable.

Product Description

Saw Palmetto Plus (160 mg per serving)

Health Benefit Advertising Claim

Saw Palmetto extract supports prostate health and healthy urinary flow.

Product Description

Vitamin E (400 I.U. per serving)

Health Benefit Advertising Claim

As a part of a healthy diet low in saturated fat and cholesterol 400 IU/day of Vitamin E promotes cardiovascular health.

Product Description

EPA/DHA (1000 mg per serving)
Flax/Borage Oil (600 mg per serving)

Health Benefit Advertising Claim

Consumption of omega-3 fatty acids as found in our EPA/DHA and Flax/Borage Oil supplement products promote cardiovascular health.

Imagenetix, Inc. Imagenetix, Inc. (Imagenetix) is a California corporation engaged in the business of manufacturing, distributing, and selling multiple pharmaceutical grade dietary supplements for human consumption.

Imagenetix, Inc. would disseminate print advertising containing the following structure/function claims in association with its sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibits B, C, and D) will be regarded by FTC as competent and reliable.

Product Description

Saw Palmetto (160 mg per serving)

Health Benefit Advertising Claim

Saw Palmetto extract supports prostate health and healthy urinary flow.

Product Description

Vitamin E (50 I.U. per serving)

Health Benefit Advertising Claim

As a part of a healthy diet low in saturated fat and cholesterol, Vitamin E supports cardiovascular health.

Product Description

Folic Acid (400 mcg per serving), Vitamin B6 (10 mg per serving), and Vitamin B12 (50 mg per serving)

Health Benefit Advertising Claim

Folic acid when taken in combination with vitamin B6 and Vitamin B12 supports vascular health.

XCEL Medical Pharmacy, Ltd. XCEL Medical Pharmacy, LTD d/b/a XCEL Health Care (XCEL) is a California corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human consumption. XCEL Medical Pharmacy, Ltd. would disseminate print advertising containing the following structure/function claims in association with its sale and promotion of the following dietary supplements but refrains from doing so in light of uncertainty as to whether the science supporting the claims (attached hereto as Exhibit B, D, and E) will be regarded by FTC as competent and reliable.

Product Description

Saw Palmetto (325 mg per serving)

Health Benefit Advertising Claim

Our saw palmetto product includes high quality saw palmetto and is formulated to promote prostate health and support healthy urine flow in men.

Product Description

Vitamin E (400 I.U. per serving)

Health Benefit Advertising Claim

XCEL's Vitamin E dietary supplement contains a-tocopherol and dl-a-tocopherol. This Vitamin E dietary supplement supports cardiovascular health especially when taken as part of a healthy diet low in saturated fat and cholesterol.

Product Description

Antioxidant Vitamin (vitamin A (7,500 I.U. per serving), vitamin C (70 mg per serving), vitamin E (100 mg per serving))

Health Benefit Advertising Claim

XCEL's dietary supplement contains antioxidant vitamins that are formulated to promote cellular structure integrity.

II. THE PROBLEMATIC AGENCY PRACTICE AT ISSUE

The FTC deems a structure/function claim ad deceptive unless it is supported by "competent and reliable scientific evidence." *See, e.g., In the Matter of Western Direct Marketing Group*, 1998 FTC LEXUS 78, (July 28, 1998); *In the Matter of Amerifit*, 123 F.T.C 1454, (1997); *In the Matter of Kave Elahie d/b/a MEK International*, 124 F.T.C. 407 (1997); *In the Matter of Metagenics*, 124 F.T.C. 483 (1997); *In the Matter of Nature's Bounty* 130 F.T.C. 206 (July 21, 1995). In *Thompson Medical Company v. Federal Trade Commission*, the FTC made clear in connection with health claim advertising[2] for drugs (and, presumably, the precedent applies equally well to health claim advertising for dietary supplements) that two well-designed double blind placebo controlled clinical trials are the minimum acceptable corroboration for a claim. 104 F.T.C. 648 (1986), *affirmed*, 791 F.2d 189 (D.C. Cir. 1986), *see also American Home*

[2] The term "health claim advertising" is meant to refer to that advertising which contains "health claims" as that term is understood by the Food and Drug Administration, namely: a "claim . . . that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." As used herein the term "health claim advertising" is distinguishable from "structure/function claim advertising" in that the latter—with the exception of classic nutrient deficiency diseases—associates a nutrient with a body structure or function without reference to a disease or disease condition.

Product Corp., *98* F.T.C. 136 (1981), *modified*, 696 F.2d 681 (3rd Cir. 1983). The lack of a comparable, clear definition for "competent and reliable scientific evidence" as it applies to dietary supplement structure/function claim advertising makes it impossible for the Joint Petitioners to discern what level, degree, quality, quantity, and kind of scientific evidence FTC will consider necessary and sufficient support for any dietary supplement structure/function claim ad. To date, although FTC's Bureau of Consumer Protection issued "Dietary Supplements: An Advertising Guide for Industry" in 1998, that otherwise helpful document does not provide necessarily specific guidance on the level, degree, quality, quantity, and kind of scientific evidence FTC expects to corroborate structure/function claim advertising that the Joint Petitioners must have to discern what FTC expects of them.

Incapable of discerning from FTC precedent what principles guide the agency in making its determinations on the corroborative sufficiency of science supporting dietary supplement structure/function claim advertising, and in light of Commissioner Sheila Anthony's order compelling greater FTC enforcement of its laws and policies against deceptive advertising in the dietary supplement marketplace (see Exhibit F), the Joint Petitioners dare not use the structure/function claim advertising listed above for fear that FTC will second-guess the sufficiency of the science they possess corroborating the claims. Furthermore, the Joint Petitioners cannot otherwise ascertain FTC's position in advance of advertising because FTC has no procedure for rendering advisory opinions as to whether a proposed structure/function claim advertisement is deceptive. Moreover, they cannot determine how best to qualify the claims to address, e.g., any concerns FTC may have about the extent to which the science provides suggestive, rather than

conclusive, evidence of the claimed health benefits. Lacking legally sufficient guidance, the Joint Petitioners now engage in self-censorship because they cannot discern what, if any, meaningful definition or distinguishing principle FTC applies to determine whether structure/function claim advertising is backed by "competent and reliable scientific evidence."

The FTC has never revealed precisely what objective criteria it uses to evaluate scientific evidence submitted to it in response to access letters and civil investigative demands that call into question scientific corroboration for dietary supplement structure/function claim advertising. In its dietary supplement claim decisions and in its consent agreements concerning those claims, the FTC does not explain the content of the staff's scientific evaluations and never reveals the content of the scientific evaluations supplied to it by independent reviewers, thereby denying relevant insight into the process that determines the advertiser's fate. In short, FTC's criteria for evaluating dietary supplement structure/function claims and its weighing of those criteria are hidden from advertisers. Consequently, neither the Joint Petitioners nor any other regulatee can discern, with confidence, in advance of advertising what science will prove adequate to satisfy FTC.[3] The Joint Petitioners thus perceive inherent risk of adverse regulatory action in undertaking advertising of this kind.

The need for definition is particularly essential in the area of structure/function claim advertising because dietary supplements, unlike pharmaceutical drugs, yield substantially less revenue per unit sold than do drug products. In addition most dietary

[3] This problem is compounded by the fact that agency staff attorneys routinely advise that the level of scientific evidence needed to support a structure/function claim ad is generally less than that required to support a health claim ad. In public presentations, FTC representatives have indicated that structure/function claim ads may not need to be supported by two or more double blind placebo controlled

supplements cannot be patented, unlike drugs, and thus do not enjoy monopoly rents needed to finance costly intervention trials. Double blind placebo controlled clinical trials for drug products frequently require expenditures of several hundred million dollars to establish, to FDA's satisfaction, the safety and efficacy of a drug. As a consequence of the foregoing market realities, almost all dietary supplement companies depend upon publicly available scientific evidence, and not commissioned clinical trials, to corroborate structure/function claim advertising.

In the absence of principles to guide them, the Joint Petitioners are entirely at a loss to know whether, if ever, the scientific evidence they possess will satisfy FTC's substantively undefined standard for structure/function claim advertising.

FTC defines "competent and reliable scientific evidence" as:

> Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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, e.g., In the Matter of Western Direct Marketing Group, 1998 FTC LEXUS 78, (July 28, 1998); *In the Matter of Amerifit*, 123 F.T.C 1454, (1997); *In the Matter of Kave Elahie d/b/a MEK International*, 124 F.T.C. 407 (1997); *In the Matter of Metagenics*, 124 F.T.C. 483 (1997); and *In the Matter of Nature's Bounty* 130 F.T.C. 206 (July 21, 1995).

In the context of health claims for drug products and, to some extent, of health claims for dietary supplements, FTC appears to rely upon *Thompson Medical*, 104 F.T.C. 648 (1986), which indicates that two well designed clinical trials will often suffice. No comparable criteria exist in the precedent for dietary supplement structure/function claim ads. The agency's lack of definition for adequate corroboration for dietary supplement

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clinical trials, as is the case under *Thompson Medical*, 104 F.T.C. 648 (1986) for health claims on drug products.

structure/function claim ads begs several questions, the answers for which are essential requisites to an advertiser's comprehension of the requirements imposed by this agency:

(1) What nature, quality, and quantity of tests, analyses, research, studies, or other evidence (collectively "scientific evidence") does FTC require to support a claim? (e.g., Will animal studies suffice or must there be human clinical trials? Will one study suffice or must there be a dozen or more? Will studies on an active ingredient in a product be sufficient or must all ingredients of the product be evaluated? Will studies by independent individuals and entities on the same ingredient used in a product suffice or must the product itself be tested? Are studies in peer-reviewed scientific journals preferred over unpublished clinical trials?)

(2) Upon the expertise of how many professionals in the relevant area must the scientific evidence be based? (e.g., Will two concurring professionals suffice? Will agreement among some minority of professionals in the field suffice or must there be a consensus among all professionals in the relevant area?)

(3) What criteria does FTC employ to determine whether a test, analysis, research, study or other evidence has been conducted and evaluated in an objective manner?

(4) What criteria does FTC employ to determine whether a test, analysis, research, study or other evidence is well-designed?

(5) What criteria does FTC employ to determine whether a person is qualified to conduct and evaluate scientific evidence?

(6) What criteria does FTC employ to determine whether procedures in testing used are generally accepted in the profession to yield accurate and reliable results?

(7) What factors does FTC take into account to determine whether scientific evidence is accurate?

(8) What factors does FTC take into account to determine whether scientific evidence yields reliable results? To what extent must a study otherwise acceptable to FTC be the subject of redundant scientific studies to be deemed "reliable"?

Without answers to the foregoing questions regulatees, including the Joint Petitioners, simply cannot discern what nature, degree, quality, and quantity of scientific evidence they must possess to satisfy FTC. The Joint Petitioners note that FTC

frequently disagrees with regulatees concerning whether the science they have marshaled in support of claims is "competent and reliable." *See, e.g., In the Matter of Schering Corporation*, 118 F.T.C. 1030 (1994); *In the Matter of Metagenics*, 124 F.T.C. 483 (1997); and *In the Matter of Nature's Bounty* 130 F.T.C. 206 (1995).

In 1998, the FTC's Bureau of Consumer Protection published "Dietary Supplements: An Advertising Guide for Industry." While that guidance informs the industry of the need to have substantiation for a claim (pages 8 to 17 therein), it does not do more than recite general considerations advertisers should take into account when developing ads (e.g., the need to evaluate the level of support for a claim, the amount and type of supportive evidence, the quality of the evidence, the totality of the evidence, and the relevance of the evidence to a specific claim). Taking those considerations into account, the prospective advertiser must still be, as indeed the Joint Petitioners are, at a loss to understand precisely what level, degree, quality, quantity, and kind of science FTC expects to be present in advance of structure/function claim advertising.

I. THE STATUTORY AND CONSTITUTIONAL INFIRMITIES OF FTC'S CURRENT PRACTICE AND ITS ADVERSE IMPACT ON THE JOINT COMMENTERS

The FTC's failure to define the criteria it uses to evaluate dietary supplement structure/function claim advertising either case by case, by a separate rule, or by issuance of advisory opinions violates the Administrative Procedure Act's ("APA") prohibition on arbitrary and capricious agency action; the First Amendment's commercial speech standard; and the Fifth Amendment's void for vagueness standard. Accordingly, by failing to define explicitly the criteria it employs the FTC not only deprives the Joint Petitioners of their statutory right to rules that are neither arbitrary nor capricious but also

of their First and Fifth Amendment rights. The violation of the statute and the deprivation of constitutional rights are themselves palpable harms. They are not the only harms, however, that the agency's current practice imposes on the Joint Petitioners. The Joint Petitioners are forced to suffer economic losses equal to the sales that would be derived from purchases attendant to the above-referenced claims that they are not able to make for fear of adverse FTC action.

A. FTC'S CURRENT PRACTICE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

FTC's failure to define either by rule or case by case (including through advisory opinions) the criteria it employs in assessing whether scientific evidence supporting a dietary supplement structure/function claim is competent and reliable violates the Administrative Procedure Act's ("APA") prohibition against arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A) (1994). See *Pearson v. Shalala*, 164 F.3d 650, (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (1999) ("It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved," *citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("[T]he agency must . . . articulate a satisfactory explanation for its action . . . ."). Indeed, in assessing the FDA's refusal to define the criteria it employs in applying its health claims standard, the Court of Appeals for the D.C. Circuit reasoned that "[t]o refuse to define the criteria . . . is equivalent to simply saying no without explanation" and cannot withstand scrutiny under the APA. *Pearson*, 164 at 660.

B. THE FTC'S CURRENT PRACTICE VIOLATES THE FIRST AMENDMENT

Dietary supplement structure/function claim advertising is protected by the First Amendment to the United States Constitution as commercial speech so long as it is not inherently misleading. *See Bolger v. Youngs Drugs Products, Corp.*,463 U.S. 60, 67-68 (1983); *Rubin v. Coors Brewing Company*, 514 U.S. 476 (1995). Under the First Amendment commercial speech standard, only inherently misleading claims may be suppressed outright. By contrast, potentially misleading claims must be permitted with reasonable disclaimers designed to eliminate the misleading connotation. *See In re RMJ*, 455 U.S. 191, 203 (1982); *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 144-46; *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 99-111 (1990).

The claims here in issue are ones for which scientific evidence provides support. Thus, they convey information. They therefore cannot be inherently misleading but must either be nonmisleading or potentially misleading. While the Joint Petitioners believe them to be the former, FTC may think them the latter, depending upon how it evaluates the scientific evidence supporting them. If it found them potentially misleading, its constitutional remedy would be to compel use of appropriate disclaimers, not to suppress the claims. *In re R. M. J.*, 455 U.S. 191 (1982). The issue is whether the scientific evidence supporting the claim rises to the level of "competent and reliable scientific evidence" sufficient to satisfy FTC that the claim is not deceptive. That standard must be defined by this agency in a manner consistent with existing First Amendment precedent which would not allow suppression or punishment of parties who communicate potentially misleading claims; rather, such claims may only be required to carry

corrective disclaimers. *Peel*, 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206; *Shapero*, 486 U.S. at 478.

In the absence of clear criteria for discerning whether a dietary supplement structure/function claim is backed by competent and reliable scientific evidence and in the absence of any system for providing FTC advisory opinions on proposed claims, the Joint Petitioners cannot reasonably anticipate whether FTC will agree with them that their science is adequate support for a claim and cannot know whether any particular disclaimer could eliminate FTC concerns that would otherwise arise. They thus refrain from communicating the structure/function information above for fear that doing so will subject them to adverse regulatory action.

Indeed, when FTC calls into question the scientific support for a claim, it commences a process that imposes significant costs on the advertiser (legal fees, search costs, revised marketing and advertising costs) including on those, such as the Joint Petitioners, who possess science they reasonably believe corroborates their claims. In the first instance, agency officials issue either an access letter or a civil investigative demand (requesting or compelling the production of all corroborative science possessed by the advertiser). Then the information is evaluated but the agency does not disclose the criteria used for the evaluation and does not disclose the scientists who have advised it, the scientific reports it receives from those scientists, or even the precise content of, or reasons for its scientific findings. Thereafter, if the agency's undisclosed evaluation yields a determination that the scientific evidence is not "competent and reliable," it sends the advertiser a draft complaint and consent agreement stating that proposition in a conclusory manner. It thereby commences the first step in its prosecution of the

advertiser. The complaint and consent agreement do not reveal the agency's evaluation or the criteria used to assess the ads but include conclusory charges of statutory violations based on a purported lack of "competent and reliable scientific evidence," defined only as quoted above. In the absence of clear criteria that conform with the requirements of the First Amendment, these regulatory acts impose upon those who would communicate dietary supplement structure/function claims significant and unconstitutional burdens of a financial and regulatory nature. FTC causes those burdens to be imposed regardless of whether the speech in issue is inherently misleading or potentially misleading. If the agency's criteria were revealed and adequately defined, and if those criteria comported with the requirements of the First Amendment, the Joint Petitioners would be able to discern the circumstances in which FTC would regard their dietary supplement structure/function claims as adequately supported and the circumstances in which otherwise inadequately supported ads could be rendered unobjectionable through use of appropriate disclaimers. The Joint Petitioners are not able to discern those circumstances given current precedent.

Thus, in the absence of defined criteria, the agency's entire system for evaluating dietary supplement structure/function claim advertising violates the First Amendment's commercial speech standard. Accordingly, to avoid further violation of the First Amendment, FTC must explain with particularity the criteria it uses in evaluating dietary supplement structure/function claims or, in the alternative, authorize the issuance of advisory opinions to guide the Joint Petitioners and all regulatees on a case by case basis. The agency's criteria must distinguish potentially from inherently misleading claims and must permit use of disclaimers in association with potentially misleading claims as an

alternative to outright suppression. Finally, the comparative weight of its evaluative criteria must be explained either case by case or in a general rule.

C. THE FTC'S CURRENT PRACTICE VIOLATES THE FIFTH AMENDMENT

Under the Fifth Amendment, a law is unconstitutionally vague if it does not provide regulatees with sufficient information to discern how to conform their conduct to the requirements of the law. *See, Grayned v. Rockford*, 408 U.S. 105 (1972) and *Zauderer v. Ohio*, 471 U.S. 626 (1985). The absence of defined criteria creates just such a constitutional violation. The Joint Commenters are effectively deprived of their liberty and property rights in their chosen commercial speech and advertising because they cannot discern through the exercise of reason what FTC will and will not accept as scientific corroboration for a dietary supplement structure/function claim, and thus, must refrain from advertising *ab initio* to avoid the risk of law violation.

II. THE PROPOSED RULE

The Joint Petitioners respectfully request that the FTC promulgate a proposed rule that will either (1) authorize the issuance of advisory opinions concerning whether dietary supplement structure/function claim advertising satisfies its competent and reliable scientific evidence requirement or (2) make express all of the criteria that it applies to evaluating scientific evidence under its "competent and reliable scientific evidence" standard for dietary supplement structure/function claim advertising, elucidating the nature, degree, quality, quantity, and kind of scientific corroboration it expects in support of dietary supplement structure/function claim advertising. In particular, if the agency chooses the second option, the Joint Petitioners ask that it promulgate a proposed rule that will articulate all criteria used by FTC to evaluate

scientific evidence, define the comparative weight of each criterion, and explain the principles that guide the agency in reaching decisions as to whether scientific evidence corroborates a dietary supplement structure/function advertising claim. In addition, the Joint Petitioners ask the agency to explain when and how disclaimers may be appropriately used to correct potentially misleading speech.

III. THE COSTS OF UNDERTAKING THE PROPOSED RULE

The costs of undertaking the proposed rule are entirely administrative and are minimal. Moreover, as explained above, commencement of the proposed rulemaking is a statutory and constitutional imperative. The ultimate costs associated with enforcing the proposed rule will likely be less than those associated with enforcing the current rule because regulatees informed of the criteria the agency employs to assess "competent and reliable scientific evidence" for structure/function claims will be able, for the first time, to determine whether the scientific evidence they possess for a claim is sufficient corroboration for the claim. In turn, the agency should experience a reduction in the need to prosecute cases of this kind because the regulated class will perceive the principles that guide agency action.

IV. CONCLUSION

For the foregoing reasons, the Joint Petitioners respectfully request that the FTC Commence a rulemaking to adopt the rule proposed herein. Because First and Fifth Amendment constitutional violations are present, the Joint Petitioners respectfully request

that the agency expedite action on this petition.

Sincerely,

DR. JULIAN M. WHITAKER;
PURE ENCAPSULATIONS, INC.;
IMAGENETIX, INC.; and
XCEL MEDICAL PHARMACY, LTD.,

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