UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., **Whitaker Wellness Institute** **4321 Birch Street** **Newport Beach, CA 92623;**	)	
PURE ENCAPSULATIONS, INC., **490 Boston Post Road** **Sudbury, MA 01776;**	)	
WELLNESS LIFESTYLES, INC. **d/b/a AMERICAN LONGEVITY** **1151 Bay Blvd. Suite F** **Chula Vista, CA 91911;**	)	
DURK PEARSON and SANDY SHAW, **401 Summa Hills** **Tonopah, NV 89049;**	)	
and the AMERICAN PREVENTIVE **MEDICAL ASSOCIATION,** **9912 Georgetown Pike,** **Suite D2,** **Great Falls, VA 22066,**	)	
Plaintiffs,	)	
v.	)	**Civil Case No. _____**
TOMMY G. THOMPSON, **SECRETARY, UNITED STATES** **DEPARTMENT OF** **HEALTH AND HUMAN SERVICES,** **Sixth Floor, 200 Independence Avenue,** **S.W., Washington, D.C. 20201;**	)	
UNITED STATES DEPARTMENT OF **HEALTH AND HUMAN SERVICES,** **200 Independence Avenue,** **S.W., Washington, D.C. 20201;**	)	
BERNARD A. SCHWETZ, **ACTING PRINCIPAL DEPUTY** **COMMISSIONER,**	)	

FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane,
Room 1471,
Rockville, MD 20857;

JOSEPH A. LEVITT,
DIRECTOR OF THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION,
FOOD AND DRUG ADMINISTRATION,
Federal Building 8, Room 6815,
200 C Street, S.W.,
Washington, D.C. 20204;

CHRISTINE J. LEWIS, Ph.D.,
DIRECTOR, OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane,
Rockville, MD 20857;

and the UNITED STATES OF AMERICA,

Defendants.

COMPLAINT
SEEKING REVIEW OF ADMINISTRATIVE AGENCY ACTION,
DECLARATORY JUDGMENT,
MANDAMUS,
AND
INJUNCTIVE RELIEF

Plaintiffs Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; Wellness Lifestyles, Inc. d/b/a American Longevity; Durk Pearson and Sandy Shaw; and the American Preventive Medical Association hereby file this Complaint against Defendants Tommy G. Thompson, Secretary, the United States Department of Health and Human

Services; United States Department of Health and Human Services (hereinafter "HHS"); Bernard A. Schwetz, Acting Principal Deputy Commissioner of the Food and Drug Administration; the Food and Drug Administration (hereinafter "FDA"); Joseph A. Levitt, Director, FDA Center for Food Safety and Applied Nutrition; Christine J. Lewis, Ph.D., Director, FDA Office of Nutritional Products, Labeling and Dietary Supplements of the Center for Food Safety and Applied Nutrition; and the United States of America, seeking review of the May 4, 2001 denial of a health claim (hereinafter "Antioxidant Vitamin Health Claim Denial"), declaratory judgment, a writ of mandamus (pursuant to 28 U.S.C. § 1361 and 5 U.S.C. § 706(1)), and preliminary and permanent injunctive relief.

The action taken by the agency and the named constitutional officers (sued in their official capacities only): (1) is in contumacious disobedience of three constitutional orders of the Courts (Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999) (hereinafter "Pearson I"); Pearson v. Shalala, 130 F.Supp. 2d 105 (D.D.C. 2001) (hereinafter "Pearson II"); and, Pearson v. Thompson, No.00-2724 (GK), 2001 U.S. Dist. LEXIS 6560, at *18 (D.D.C. May 7, 2001) (hereinafter "Pearson III")); (2) is in violation of the First Amendment rights of the Plaintiffs; (3) is in violation of the Fifth Amendment Due Process rights of the Plaintiffs; (4) is in violation of the oath of office (5 U.S.C. § 3331) for each named constitutional officer; (5) is in violation of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. § 301); (6) is in violation of the Administrative Procedure Act's prohibition on arbitrary, capricious, and unlawful agency action (5 U.S.C. § 706(2)(A)); and (7) is in violation of

the Administrative Procedure Act's prohibition on agency action unlawfully withheld (5 U.S.C.§ 706(1)) .

The Antioxidant Vitamin Health Claim Denial prohibits the Plaintiffs from communicating on labels and in labeling the following scientifically supported statement (hereinafter "Antioxidant Vitamin Health Claim") with or without disclaimers:

> **Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.**

BACKGROUND

1. The Antioxidant Vitamin Health Claim is one of four health claims the United States Court of Appeals for the D.C. Circuit held unconstitutionally suppressed by FDA in violation of the First Amendment rights of the Plaintiffs. See Pearson I, 164 F.3d at 656. The Court held FDA's practice of refusing to authorize health claims with corrective disclaimers suppressive of protected speech in violation of the First Amendment. See id. at 655. The Court ordered FDA to favor disclosure over suppression as its rule of construction, See id. at 658, by relying on corrective disclaimers as a constitutionally required less restrictive alternative to outright suppression. See id. at 657 (hereinafter referred to as the "*Pearson* Disclaimer Requirement"). On the evidence before it, the Court rejected FDA's conclusion that the health claims there in issue, including the Antioxidant Vitamin Health Claim, were "inherently misleading" and, thus, suppressible outright. Indeed, the Court found that contention "almost frivolous." Id. at 655. The Court explained that under commercial speech jurisprudence FDA bears a very heavy burden of proof to justify health claim suppression. See id. at 659. That burden cannot be satisfied without adduction of actual evidence of misleadingness; speculation will not suffice. See id. The Court explained that no claim, except that which cannot be

rendered nonmisleading through the addition of a corrective disclaimer, could be suppressed outright. See id. The Court viewed the absence of *conclusive* proof of a nutrient-disease relationship insufficient to justify banning a health claim so long as there was credible evidence to support the claim. Pearson I, 164 F.3d at 659; Pearson II, 130 F. Supp. 2d at 114; Pearson III, 2001 U.S. Dist. LEXIS 6560 at *14.

2. The Court explained that FDA had reviewed research on the relationship between consumption of foods containing antioxidants (including Vitamins C and E) and risk of cancer. Pearson I, 164 F.3d at 654. Indeed, FDA had approved cancer risk reduction claims for foods low in fat and rich in antioxidants. See 21 C.F.R. § 101.78(e)(1;2) (Approved Model Claim 1: "Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber" and Approved Model Claim 2: "Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C").

3. The Court reasoned FDA's concern that the cancer risk reduction effect "could not be determined with certainty" for the antioxidant component of foods was addressable via "a prominent disclaimer to the label along the following lines: 'The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods.'" Pearson I, 164 F.3d at 658.

4. Following the Court of Appeals' January 15, 1999 decision in Pearson I, FDA chose not to reconsider the Antioxidant Vitamin Health Claim until May 4, 2001 (two years and four months later). All the while FDA suppressed the claim against the protests of the Plaintiffs. In response to correspondence from the Plaintiffs, the FDA refused to set a "date certain" for action. Indeed, the FDA refused to set any "date certain" for action on the Court of Appeals' remand order until after Plaintiffs filed an Application for Preliminary Injunction in Civil Case No. 95-1865 (GK). In its opposition to application. FDA finally announced a "date certain" for action (i.e. October 10, 2000) on April 7, 2000.

5. Since its representation to this Court that it would reevaluate the Antioxidant Vitamin Health Claim by October 10, 2000, FDA has on seven separate occasions (by letters dated October 10, 2000; October 24, 2000; November 30, 2000; December 22, 2000; February 23, 2001; March 30, 2001; and April 20, 2001), established new deadlines for decision (those deadlines were October 24, 2000; November 30, 2000; December 22, 2000; February 23, 2001; March 30, 2001; April 20, 2001; and May 4, 2001)), thereby postponing compliance with the Court of Appeals' order.

6. While on October 2, 2000, FDA announced that it would commence a general health claims rulemaking to codify the requirements of Pearson I, it has not done so despite the passage of 912 days past the Pearson I decision date.

7. While on October 3, 2000, FDA announced that it had revoked the four rules held unconstitutional in Pearson I, it did so in name only, simultaneously announcing that it would continue to enforce the health claim prohibitions contained in

the revoked rules. See 65 Fed. Reg. 58917, 58918; see also Pearson II, 130 F. Supp. 2d at 111.

8. The record is one of persistent and deliberate delay, denial, and avoidance of compliance with the Pearson decisions in willful violation of the First Amendment rights of the Plaintiffs.

9. On February 1, 2001, this Court ruled that FDA's continuing suppression of another of the four original Pearson I claims violated the First Amendment and the Administrative Procedure Act. See Pearson II, 130 F. Supp. 2d at 120. In so doing, the Court stated:

> . . . [I]t is clear that the FDA simply failed to comply with the constitutional guidelines outlined in Pearson. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion.

Id. at 112.

10. The Court enjoined FDA's denial of the claim there in issue and compelled FDA to adhere to *Pearson* Disclaimer Requirement. See Pearson II, 130 F. Supp. 2d at 120. The Court acted in the face of proof (1) that "FDA simply failed to adequately consider the teachings of Pearson: that the agency must shoulder a very heavy burden if it seeks to totally ban a particular health claim," Id. at 118, and (2) that FDA "continually refused to authorize the disclaimers suggested by the Court of Appeals—or any disclaimer, for that matter," Id. at 114.

11. The FDA moved for reconsideration of the Court's February 1, 2001 order. On May 9, 2001, the Court rejected the motion, reiterating:

> In moving for reconsideration, Defendants again seem to ignore the thrust of Pearson I. While that decision might leave certain specific issues to be fleshed out in the course of future litigation, the philosophy underlying Pearson I is

> perfectly clear: that the First Amendment analysis in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557 (1980), applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals.

Pearson III, 2001 U.S. Dist. LEXIS 6560, at *18.

12. This case presents the Court with yet another, now unmistakably deliberate, FDA refusal to abide by the constitutional orders of the Court of Appeals in Pearson I and of this Court in Pearson II and III. By so doing FDA is directly and willfully challenging federal judicial authority over the agency's unconstitutional actions.

13. On May 4, 2001, in the advent of Pearson I and Pearson II, FDA again denied the Antioxidant Vitamin Health Claim without undertaking the First Amendment analysis required of it in those decisions. It did not discuss, let alone establish, whether its chosen means (blanket suppression) directly advanced the FDA's interests in protecting the public health and whether that means bore a reasonable fit to its desired ends. It did not consider, let alone evaluate under Pearson I and II, a single less restrictive alternative to outright suppression. It did not adduce or evaluate any evidence that consumers would actually be misled by the claim or by any potential disclaimer, including the disclaimer recommended by the Court of Appeals ("The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods") before outlawing the claim a second time. Indeed, FDA did not evaluate the actual claim before it but instead assessed scientific evidence not on cancer risk reduction but on cancer prevention and cancer treatment.

14. In its decision, FDA entirely ignored the evidence from Pearson I (and new evidence filed with the agency since then) on the role of antioxidants in reducing oxidants and free radicals that are linked to an increased risk of certain cancers in healthy individuals, i.e., *before cancer initiation*. FDA ignored the generally accepted scientific evidence that links antioxidant vitamins with beneficial physiological effects (trapping, deactivating, and destroying harmful free radicals and reactive oxygen and nitrogen molecules that are linked (e.g., by causing DNA damage) to the initiation of certain kinds of cancer), the very evidence it found persuasive in its evaluation of the cancer risk reduction effects of antioxidant-rich foods (See 56 Fed. Reg. 60624, 60625-60626 (November 27, 1991)).

15. FDA disingenuously raised a safety argument for the first time on reconsideration, never raised in the seven years, in direct contradiction to the year 2000 safety determinations of the Food and Nutrition Board, Institute of Medicine, that Vitamins C and E were safe for human consumption by the general population up to limits of 2,000 mg (vitamin C) and 1,000 iu (vitamin E) and pose no carcinogenic or other risk of injury or illness at those levels. See FOOD AND NUTRITION BOARD, INSTITUTE OF MEDICINE, DIETARY REFERENCE INTAKES FOR VITAMIN C, VITAMIN E, SELENIUM, AND CAROTENOIDS 162, 258 (2000).

16. As noted in Pearson I (and to this day), the Plaintiffs remain fully willing to accept any reasonable disclaimer, including the one recommended by the Court of Appeals in Pearson I making it clear that constituents in fruits and vegetables other than antioxidants may reduce the risk of cancer and ones making it clear that antioxidant vitamins have not been proven effective in the prevention or treatment of cancer.

17. The mandate of this Court, and the Court of Appeals, compelling implementation of the First Amendment analysis prescribed in Pearson I issued on April 20, 1999. Pearson I, Pearson II, and Pearson III are final and binding orders. Because they direct this agency to follow a constitutional mandate, FDA's duty to implement the orders is immediate and omnipresent. That duty may not be delayed, denied, or avoided.

18. Officers of the FDA, like all officers of the Executive Branch, swear an oath of office to support and defend the Constitution of the United States and to well and faithfully execute the duties of their offices. See 5 U.S.C. § 3331. Even were such an oath not required, the Constitution defines the limits of federal power and of the lawful exercise of that power by officers and employees of the Executive Branch. FDA Acting Principal Deputy Commissioner Bernard A. Schwetz; FDA Director of the Center for Food Safety and Applied Nutrition Joseph A. Levitt; and FDA Director of the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition Christine J. Lewis, Ph.D. are the officers directly responsible for the agency's repeated and deliberate failure to implement the orders of this Court and of the Court of Appeals.

19. This Complaint not only asks the Court to declare the agency action unconstitutional, and once again enjoin the agency from prohibiting another Pearson I health claim, but to end FDA's repeated pattern of contumacious conduct through issuance of a mandamus to the agency and to the named FDA officers, holding in reserve authority to impose sanctions on them for contempt if they continue the present pattern of insolence and disobedience of federal court orders. The persistent loss of freedom and the financial costs of repeatedly seeking redress from this Court are directly the result of

FDA and its officers contumacious refusal to be bound by the constitutional orders from the Court of Appeals and this Court. Among the agencies of the federal government, FDA is unique in its refusal to follow the constitutional orders of this Court and the Court of Appeals. The insolence, contempt, and disrespect inherent in that refusal makes prompt and decisive judicial action a necessity.

FACTS

20. The Plaintiffs wish to communicate on labels and in the labeling of their adult formula, antioxidant vitamin-containing, multivitamin dietary supplements (that they sell and license for sale) the following statement characterizing the relationship between antioxidant vitamins and certain types of cancer: "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers" (Antioxidant Vitamin Health Claim).

21. On January 6, 1993, FDA published a final rule in the Federal Register authorizing a health claim regarding the relationship between diets low in fat and high in fruits and vegetables to a reduced risk of cancer (noting that foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C have been shown to reduce the risk of cancer[1]). See 58 Fed. Reg. 2,622 (January 6, 1993).

22. On October 14, 1993, FDA published a proposed rule in the Federal Register announcing its intention not to authorize several health claims (including the Antioxidant Vitamin Health Claim) on the label or in the labeling of dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. See 58 Fed. Reg. 53,296 (October 14, 1993).

23. On December 13, 1993, Plaintiffs filed Joint Comments with FDA arguing that the agency should not promulgate its proposed rule but should instead authorize the Antioxidant Vitamin Health Claim with disclaimers as necessary to avoid potential misleadingness.

24. On January 4, 1994, FDA published a final rule prohibiting the Antioxidant Vitamin Health Claim and summarily rejecting disclaimers. See 59 Fed. Reg. 436 (January 4, 1994); see also 21 C.F.R. §101.71 (2000).

25. On January 15, 1999, the United States Court of Appeals held FDA's final Rule unconstitutional under the First Amendment. See Pearson I, 164 F.3d at 659.

26. On July 19, 1999, counsel for Plaintiffs wrote to the FDA's Chief Counsel, Margaret Jane Porter, and to the CFSAN Director, Joseph A. Levitt, asking when the agency would implement the constitutional mandate of Pearson I.

27. On September 8, 1999, FDA published a notice in the Federal Register requesting scientific data, research study results, and other related information concerning four substance-disease relationships (including the Antioxidant Vitamin Health Claim) as the agency's first step toward implementation of the Court of Appeals' mandate in Pearson I but setting no "date certain" by which FDA would comply with the Pearson I constitutional mandate. See 64 Fed. Reg. 48841, 48841-48842 (September 8, 1999).

28. On September 17, 1999, Joseph A. Levitt of CFSAN wrote to counsel for Plaintiffs demurring on when FDA would comply with the constitutional mandate in Pearson I, not specifying any "date certain" by which the agency would act.

29. On November 22, 1999, Plaintiffs filed Joint Comments before FDA

[1] The agency found evidence that vitamins E, Beta-carotene, and C did have antioxidant effects and were associated with reduced cancer risks, but concluded that proof was "not sufficient" to establish a conclusive

requesting that FDA comply with the decision in Pearson I by defining the term "significant scientific agreement" before taking action on the proposed Antioxidant Vitamin Health Claim. Plaintiffs (and other commenters) presented FDA with a substantial quantity of scientific evidence supporting a direct connection between consumption of antioxidant vitamins and a reduction in the risk of certain kinds of cancer.[2] However, if FDA determined that the scientific evidence in favor of the Antioxidant Vitamin Health Claim did not meet the "significant scientific agreement" standard, Plaintiffs requested that the claim be authorized with such disclaimer or disclaimers as the agency reasonably deemed necessary to avoid a potentially misleading connotation.

30. On December 1, 1999, FDA published a notice in the Federal Register announcing its strategy for implementing the Pearson I decision but setting no "date certain" for compliance. See generally 64 Fed. Reg. 67,289 (December 1, 1999).

31. On January 19, 2000, counsel for Plaintiffs wrote to the FDA's Chief Counsel and to the CFSAN Director again inquiring of a "date certain" by which the agency would act on the Antioxidant Vitamin Health Claim in compliance with the constitutional mandate of Pearson I.

32. On January 26, 2000, FDA announced in the Federal Register that it was

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link between those effects and a reduced risk of cancer. See 58 Fed. Reg. 53,296, 53,298.

[2] The primary mechanism of action is well-accepted. Free radicals and oxidants are by products of normal cell metabolism and a wide variety of chemical insults to the body. They can be carcinogenic because they cause damage at the cellular level and some of that damage is mutagenic in nature. Antioxidants are scavengers of free radicals and oxidants and neutralize the destructive effects of those molecules. See Block, *The Data Support a Role for Antioxidant Vitamins in Reducing Cancer Risk*, 50 NUTR. REV. at 207 (1992).

reopening the comment period for the Antioxidant Vitamin Health Claim and would accept scientific data and written comments submitted before April 3, 2000. See 65 Fed. Reg. 4252 (January 26, 2000).

33. On February 17, 2000, Joseph A. Levitt of CFSAN wrote to counsel for Plaintiffs again demurring on when FDA would comply with the constitutional mandate in Pearson I, not specifying any "date certain" by which the agency would act.

34. On February 18, 2000, counsel for Plaintiffs wrote to Joseph A. Levitt of CFSAN for a third time inquiring of a "date certain" by which the agency would act on the Antioxidant Vitamin Health Claim in compliance with the constitutional mandate of Pearson I.

35. On February 28, 2000, Joseph A. Levitt of CFSAN wrote to counsel for Plaintiffs again demurring on when FDA would comply with the constitutional mandate in Pearson I, not specifying any "date certain" by which the agency would act, but instead soliciting an in-person conference between Mr. Levitt and the Plaintiffs and directing all future correspondence to Patricia J. Kaeding, FDA's Associate Chief Counsel of Enforcement.

36. On February 28, 2000, counsel for Plaintiffs wrote to Patricia J. Kaeding seeking confirmation that the in-person conference initiated by Joseph A. Levitt would result in a "date certain" by which FDA would implement the constitutional mandate of Pearson I and authorization of the four health claims on an interim basis with disclaimers.

37. On March 2, 2000, Patricia J. Kaeding wrote to counsel for Plaintiffs explaining that "the meeting will be a mutual discussion of the issues, rather than a forum to obtain agency commitments." (Letter from Kaeding to Emord of 3/2/00, at 1).

38. On March 3, 2000, counsel for Plaintiffs wrote to Patricia J. Kaeding accepting Joseph A. Levitt's invitation. Again Plaintiffs inquired of a "date certain" by which the agency would act on the Antioxidant Vitamin Health Claim and informed FDA that unless a "date certain" was set by March 30, 2000, Plaintiffs would seek judicial intervention. The parties agreed to a meeting, held it, and agreed to keep the content of the meeting confidential.

39. On April 3, 2000, Plaintiffs filed Supplemental Comments responding to FDA's request for scientific data and information published between 1992 and 2000 concerning the relationship between antioxidants and cancer. Again Plaintiffs urged FDA to interpret "significant scientific agreement" as Congress intended and authorize the Antioxidant Vitamin Health Claim requiring use of the disclaimer crafted by the Court in Pearson I.

40. On April 6, 2000, Joseph A. Levitt wrote to counsel for Plaintiffs stating that FDA's decision regarding the Antioxidant Vitamin Health Claim would be issued no later than October 10, 2000.

41. On August 8, 2000, Plaintiffs filed Supplemental Comments responding to FDA's request for data and information relating to the economic impact of the barriers the agency has erected to communication of truthful, qualified claims. Supported by the economic report of Dr. Paul H. Rubin, Plaintiffs urged FDA to authorize the Antioxidant Vitamin Health Claim requiring use of the disclaimer crafted by the Court in Pearson I.

42. On September 27, 2000, Plaintiffs filed Supplemental Comments before

FDA submitting newly published scientific studies and reviews. Again Plaintiffs urged FDA to authorize the Antioxidant Vitamin Health Claim requiring use of the disclaimer crafted by the Court in Pearson I.

43. On October 2, 2000, FDA published a notice in the Federal Register announcing that the agency would commence a general health claims rulemaking before deciding on the Antioxidant Vitamin Health Claim. See 65 Fed. Reg. 59,855 (October 6, 2000). To this day fully *8 months* later, FDA has not commenced that general health claims rulemaking.

44. On October 6, 2000, Plaintiffs filed Supplemental Comments before FDA wherein the economic report prepared by Dr. Paul H. Rubin concluded that authorization of the Antioxidant Vitamin Health Claim, with an appropriate disclaimer, would improve the public health and welfare.

45. On October 10, 2000, the Director of CFSAN's Office of Nutritional Products, Labeling, and Dietary Supplements, Christine J. Lewis, wrote to counsel for Plaintiffs extending the October 10, 2000 deadline until October 24, 2000.

46. On October 24, 2000, Christine J. Lewis again wrote to counsel for Plaintiffs extending the October 24, 2000 deadline until November 30, 2000.

47. On November 30, 2000, Christine J. Lewis again wrote to counsel for Plaintiffs extending the November 30, 2000 deadline until December 22, 2000.

48. On December 22, 2000, Christine J. Lewis again wrote to counsel for Plaintiffs extending the December 22, 2000 deadline until February 23, 2001.

49. On February 23, 2001, Christine J. Lewis again wrote to counsel for Plaintiffs extending the February 23, 2001 deadline until March 30, 2001.

50. On March 30, 2001, Christine J. Lewis again wrote to counsel for Plaintiffs extending the March 30, 2001 deadline until April 20, 2001.

51. On April 20, 2001, Christine J. Lewis again wrote to counsel for Plaintiffs extending the April 20, 2001 deadline until May 4, 2001.

52. Finally, on May 4, 2001, Christine J. Lewis wrote to counsel for Plaintiffs denying outright the Antioxidant Vitamin Health Claim, failing to evaluate the Plaintiffs' actual claim concerning cancer risk reduction and instead evaluating whether antioxidant vitamins have been proven to prevent or treat cancer; failing to apply the First Amendment standard required by Pearson I and II; and failing to evaluate disclaimers as a less restrictive alternative to outright suppression.

JURISDICTION

53. This Court has jurisdiction over this matter pursuant to 5 U.S.C. §§ 702 and 706 (hereinafter the "Administrative Procedure Act"); 28 U.S.C. § 1331 (federal question jurisdiction); and 28 U.S.C. § 1361 (action to compel an officer of the United States to perform his or her duty).

VENUE

54. This Court has venue over this action pursuant to 28 U.S.C. § 1391(e).

DESCRIPTION OF THE PARTIES

55. ***Julian M. Whitaker, M.D.*** Julian M. Whitaker, M.D. is among those who filed comments with FDA seeking approval of the Antioxidant Vitamin Health Claim. Dr. Whitaker 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. *Health & Healing* has over 500,000 subscribers. Dr. Whitaker consults in the design and distribution of pharmaceutical grade dietary supplements for human consumption. He receives royalties from the sale of several dietary supplements. Thirteen multi-vitamin dietary supplements in which Dr. Whitaker has a direct financial interest each contain antioxidant vitamin C (60-1,500 mg) and antioxidant vitamin E (50-800 iu) that are the subject of this Complaint. The daily dose amounts of vitamin C and vitamin E in those multi-vitamins are beneath the 2,000 mg (vitamin C) and 1,000 iu (synthetic vitamin E) or 1,360 iu (natural vitamin E) amounts set as safe upper limits for the general population by the Institute of Medicine's Food and Nutrition Board. Dr. Whitaker would like to place the Antioxidant Vitamin Health Claim on the labels and in the labeling of those dietary supplements. Dr. Whitaker would accept any reasonable disclaimer to accompany the Antioxidant Vitamin Health Claim, including the disclaimer recommended by the Court of Appeals in Pearson I.

56. ***Pure Encapsulations, Inc.*** Pure Encapsulations, Inc. ("Pure") is among those who filed comments with FDA seeking approval of the Antioxidant Vitamin Health Claim. Pure is a Massachusetts corporation engaged in the business of manufacturing,

distributing, and selling pharmaceutical grade dietary supplements for human and companion animal consumption. Eight of the multi-vitamin dietary supplement products manufactured, distributed, and sold by Pure each contain antioxidant vitamin C (100-1,000 mg) and antioxidant natural vitamin E (100-400 iu) that are the subject of this Complaint. The daily dose amounts of vitamin C and vitamin E in those multi-vitamins are beneath the 2,000 mg (vitamin C) and 1,000 iu (synthetic vitamin E) or 1,360 iu (natural vitamin E) amounts set as safe upper limits for the general population by the Institute of Medicine's Food and Nutrition Board. Pure would like to place the Antioxidant Vitamin Health Claim on the labels and in the labeling of those dietary supplement products. Pure would accept any reasonable disclaimer to accompany the Antioxidant Vitamin Health Claim, including the disclaimer recommended by the Court of Appeals in Pearson I.

57. ***Wellness Lifestyles, Inc. d/b/a American Longevity.*** Wellness Lifestyles, Inc. d/b/a American Longevity (hereinafter "AL") is a California corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human and animal companion consumption. Seven of the multi-vitamin dietary supplement products manufactured, distributed, and sold by AL each contain antioxidant vitamin C (10-1,000 mg) and antioxidant vitamin E (10-300 iu) that are the subject of this Complaint. The daily dose amounts of vitamin C and vitamin E in those multi-vitamins are beneath the 2,000 mg (vitamin C) and 1,000 iu (synthetic vitamin E) or 1,360 iu (natural vitamin E) amounts set as safe upper limits for the general population by the Institute of Medicine's Food and Nutrition Board. AL would like to place the Antioxidant Vitamin Health Claim on the labels and in the labeling of those dietary

supplement products. Wellness would accept any reasonable disclaimer to accompany the Antioxidant Vitamin Health Claim, including the disclaimer recommended by the Court of Appeals in Pearson I.

58. ***Durk Pearson and Sandy Shaw.*** Durk Pearson and Sandy Shaw are scientists residing in Nevada. They are among those who filed comments with FDA seeking approval of the Antioxidant Vitamin Health Claim. They design dietary supplement formulations and license them to manufacturing and retailing companies. They are authors of four books on aging and age-related diseases, including the #1, million plus copy best seller Life Extension: A Practical Scientific Approach (1982). They have also published three other health books, two of which were best sellers: The Life Extension Companion (1984); The Life Extension Weight Loss Program (1986); and Freedom of Informed Choice—FDA Versus Nutrient Supplements (1993). Pearson and Shaw license for sale two multivitamin dietary supplements that each contain antioxidant vitamin C (900-1,076 mg) and antioxidant synthetic vitamin E (200-330 iu) that are the subject of this Complaint. The daily dose amounts of vitamin C and vitamin E in those multi-vitamins are beneath the 2,000 mg (vitamin C) and 1,000 iu (synthetic vitamin E) or 1,360 iu (natural vitamin E) amounts set as safe upper limits for the general population by the Institute of Medicine's Food and Nutrition Board. Pearson and Shaw would like to place the Antioxidant Health Claim on the labels and in the labeling of their Vitamin C and E-containing dietary supplements. Pearson and Shaw would accept any reasonable disclaimer to accompany the Antioxidant Vitamin Health Claim, including the disclaimer recommended by the Court of Appeals in Pearson I.

59. ***American Preventive Medical Association.*** The American Preventive

Medical Association (APMA) is a non-profit organization in Great Falls, Virginia. APMA is among those who filed comments with FDA seeking approval of the Antioxidant Vitamin Health Claim. APMA was founded in October of 1992 and is dedicated to ensuring consumer access to preventive therapies and the rights of health care providers to offer those therapies, including dissemination and receipt of the Antioxidant Vitamin Health Claim that is the subject of this Complaint. Several APMA physicians, including many of its over 450 physician members and several of its 19 physician board members, sell multivitamin dietary supplements that each contain antioxidant vitamin C and antioxidant vitamin E that are the subject of this Complaint. The daily dose amounts of vitamin C and vitamin E in those multi-vitamins are beneath the 2,000 mg (vitamin C) and 1,000 iu (synthetic vitamin E) or 1,360 (natural vitamin E) amounts set as safe upper limits for the general population by the Institute of Medicine's Food and Nutrition Board. APMA and its practitioner members and its practitioner board members would like to place the Antioxidant Vitamin Health Claim on the labels and in the labeling of those dietary supplements and to communicate that information to their patients who purchase those supplements.

60. ***Tommy G. Thompson, Secretary, United States Department of Health and Human Services; United States Department of Health and Human Services; Bernard A. Schwetz, Acting Principal Deputy Commissioner of the FDA; the FDA; Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, FDA; Christine J. Lewis, Ph.D., Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA; and the United States of America.*** Tommy G. Thompson (sued in his official capacity only) is

the Secretary of the United States Department of Health and Human Services, the executive department having jurisdiction over the FDA. Bernard A. Schwetz (sued in his official capacity only) is the Acting Principal Deputy Commissioner of the FDA. Joseph A. Levitt (sued in his official capacity only) is the Director of the Center for Food Safety and Applied Nutrition of the FDA. Christine J. Lewis, Ph.D., is the Director of the Office of Nutritional Products, Labeling and Dietary Supplements at the Center for Food Safety and Applied Nutrition at the FDA. The FDA is that administrative agency granted authority by Congress to regulate the interstate manufacture, sale, and distribution of foods, drugs, cosmetics, biologics, medical devices, and dietary supplements in the United States. The Department of Health and Human Services and the FDA are part of the executive branch of the United States government.

CAUSE OF ACTION I: VIOLATION OF THE FIRST AMENDMENT AND THE COURTS' ORDERS COMMANDING PROTECTION OF FIRST AMENDMENT RIGHTS

61. Plaintiffs reallege and restate paragraphs 1 through 60 and incorporate them herein.

62. FDA's Antioxidant Vitamin Health Claim Denial violates the First Amendment to the United States Constitution and the Pearson I, Pearson II, and Pearson III constitutional orders. That denial unconstitutionally suppresses protected commercial and scientific speech that conveys factual information important to those who seek to reduce their risks of certain kinds of cancers, namely those that can be initiated by the adverse effects of oxidants and free radicals in human tissue.

63. The Antioxidant Vitamin Health Claim is endorsed by the opinion of leading scientists who study antioxidant vitamins, is supported by substantial scientific

evidence, and accurately reflects the current state of scientific information. It is a "may" claim indicating that the evidence in support of it while strong has not yet been proven to a conclusive degree.

64. Government may not suppress either truthful and nonmisleading commercial and scientific speech or potentially misleading commercial and scientific speech. With regard to the latter (including claims backed by scientific evidence that is inconclusive), government must rely on reasonable disclaimers to avoid misleading connotations as a less restrictive alternative to suppression. FDA prohibited the Antioxidant Vitamin Health Claim outright and has refused to rely upon corrective disclaimers as a less restrictive alternative to outright suppression.

THE ANTIOXIDANT VITAMIN HEALTH CLAIM IS NOT INHERENTLY MISLEADING AND MAY NOT BE CONSTITUTIONALLY SUPPRESSED

65. In Pearson I, the United States Court of Appeals for the D.C. Circuit ruled on the record before it that the Antioxidant Vitamin Health Claim was not inherently misleading. Pearson I, 163 F.3d at 659. The Court examined the evidence and found it inconclusive, recommending that the FDA consider use of the following disclaimer to accompany the claim: "The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods."

66. The Antioxidant Vitamin Health Claim is predicated on basic science, cell culture studies, research using laboratory animals, epidemiological studies, and clinical intervention trials spanning four decades and a detailed scientific affidavit endorsing the claim from one of the nation's leading authorities on antioxidant vitamins and cancer,

William Pryor, Ph.D., Professor in the Departments of Chemistry, Biological Sciences, Pharmacology, Physiology & Toxicology, and Biochemistry at the Louisiana State University and the LSU Schools of Medicine and Veterinary Medicine. The record below also reveals that distinguished University of California, Berkeley, Professor Gladys Block, Ph.D. and fifteen other prominent scientists have concluded that the evidence concerning the role of antioxidants in oxidant and free radical quenching strongly supports a cancer risk reduction claim. See generally Gladys Block, Ph.D., et al, *The Data Support a Role for Antioxidant Vitamins in Reducing Cancer Risk*, 50 NUTR. REV. 207-213 (1992).

67. The evidence reveals that antioxidants in combination reduce biological oxidants and free radicals and that oxidants and free radicals increase the risk of the initiation of certain cancers by damaging cells, including, but not limited to, cellular DNA. Vitamin E has also been shown to enhance cell-mediated immune response and phagocyte-derived functions important in reducing the risk of cancer initiation. Antioxidants C and E also block the endogenous formation of carcinogenic nitrosamines. The primary mechanism of action is well-accepted. Oxidants and free radicals are by-products of normal cell metabolism and of a wide variety of chemical insults to the body. Some of the damage they produce is mutagenic in nature. Antioxidants are scavengers of oxidants and free radicals and neutralize destructive effects of oxidants and free radicals. Since 1991, the FDA has accepted that antioxidants function to scavenge oxidants and free radicals and to block the formation of carcinogenic nitrosamines:

> Vitamins C and E . . . are vitamins that function as antioxidants . . . .
> Vitamin C . . . serves as an effective free-radical scavenger to protect cells from damage by oxidants. It is in this capacity that vitamin C may provide protection against adverse effects of potential carcinogens. Vitamin C plays roles in

> maintaining the integrity of intracellular matrices, enhances the immune system, and is necessary for several types of biochemical reactions . . . . The basic biological function of vitamin E in animal tissues is as an antioxidant where it acts as a defense against potentially harmful reactions with oxygen . . . .The antioxidant vitamins are interactive in that they complement each other during situations of biological stress. Vitamin C, most of which is located in the aqueous portion of the cell, spares vitamin E until the vitamin C reserve is depleted. Vitamin E is located in the lipid portions of all membranes, and it deactivates free radicals . . . . Beta-carotene, vitamin C and vitamin E all inhibit damage by oxidative chemicals, including carcinogens. More specifically, beta-carotene traps reactive oxygen molecules, vitamin E and beta-carotene remove free radicals, and vitamin C inhibits oxidative reactions and also removes free radicals . . . . A major effect of vitamin C that could be the basis of protection against cancer is its ability to inhibit nitrosamine formation. Nitrosamines (N-nitroso amines and N-nitroso amides) are types of carcinogens which occur in foods and are produced within the body by the reaction of nitrite with other dietary or endogenous amines and amides. Some nitrite occurs in food, but more is produced from reduction of nitrate by bacteria in the mouth and small intestine. Nitrate occurs in food, and some is produced in the body from L-arginine. The nitrosation reactions occur rapidly in the acid environment of the stomach and upper duodenum. Most nitrosamines tested in experimental animals are carcinogenic, and some are very potent carcinogens affecting multiple sites . . . . [V]itamin C blocks the formation of carcinogenic nitrosamines from nitrates and nitrites in the digestive tract. The combination of evidence from epidemiological studies and evidence from several types of studies with animals which involved administration of carcinogens and carcinogen precursors provides a strong basis on which to postulate that vitamin C reduces the risk of cancer in humans. . . . . Animal studies have demonstrated an inhibitory effect of vitamin E on cancers induced by ultraviolet light and certain chemicals. These studies date back to the earliest days of vitamin E chemistry. More recently, the implications of reactive oxygen molecules in cancer development provide a theoretical basis for the involvement of vitamin E (a strong antioxidant) in the development of cancer, because carcinogens are activated by oxidative processes and oxidation of cell components may contribute to cancer development.

56 Fed. Reg. 60624, 60627-60628 (Nov. 27, 1991).

68. For the past decade to the present other government scientists and agencies have published their acceptance that antioxidant vitamins help reduce the risk of the initiation of certain kinds of cancers by scavenging harmful oxidants and free radicals:

• "Antioxidants such as vitamin E help protect against the damaging effects of free radicals, which may contribute to the development of chronic diseases such as cancer. Vitamin E may also block the formation of nitrosamines, which are carcinogens formed in the stomach from nitrites consumed in the diet. It also may protect against the development of cancers by enhancing immune function." *Facts About Vitamin E*. **http://www.cc.nih.gov/ccc/supplements/vite.html**. National Institutes of Health, Office of Dietary Supplements, Facts About Dietary Supplements, 2001.

• "Antioxidants are thought to help prevent heart attack, stroke, and cancer." Human Nutrition, Agriculture Research Service (a division of the USDA), Quaterly Report, 4th Quarter of 1996.

• "The antioxidant nutrients found in plant foods (e.g. vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their potentially beneficial role in reducing the risk of cancer and certain other chronic diseases." *Nutrition and Your Health: Dietary Guidelines for Americans*, United States Department of Agriculture and Department of Health and Human Services, Fourth Edition, 1995.

• "Antioxidant micronutrients, especially carotenes, vitamin C, and vitamin E, appear to play many important roles in protecting the body against cancer. They block the formation of chemical carcinogens in the stomach, protect DNA and lipid membranes from oxidative damage, and enhance immune function." Byers, Tim and Perry, Geraldine, Centers for Disease Control, Epidemiology Branch, Division of Nutrition, National Center for Chronic Disease Prevention and Health Promotion in "Dietary Carotenes, Vitamin C, and Vitamin E as Protective Antioxidants in Human Cancers," *Annual Review of Nutrition*, 1992, Vol. 12: 139-59.

• "[Antioxidants] may help prevent disease. Antioxidants fight harmful molecules called oxygen free radicals, which are created by the body as cells go about their normal business of producing energy . . . [S]ome studies show that antioxidants may help prevent heart disease, some cancers, cataracts, and other health problems that are more common as people get older." *National Institute on Aging Age Page: Life Extension: Science or Science Fiction?* **http://www.aoa.dhhs.gov/lifextsn.html**. Administration on Aging, 1994.

• "[I]t is likely that certain antioxidants, such as Vitamins C and E, may destroy the oxygen radicals, retard molecular damage, and perhaps slow the rate of aging." *Aging-Causes and Defenses*, National institutes of Aging, Press Release. **http://www.nih.gov/nia/new/press/agingcau.htm**.

69. The Antioxidant Vitamin Health Claim conveys scientific information concerning the potential for antioxidant vitamins in combination to reduce the risk of

certain kinds of cancer. The claim is either truthful and nonmisleading or, at worst, potentially misleading, but it cannot be deemed inherently misleading because a substantial body of scientific evidence from within government and academia supports the role of antioxidants in reducing oxidants and free radicals and blocking the endogenous formation of nitrosamines that are associated with the initiation of certain kinds of cancer.

70. In their pleadings to the agency, the Plaintiffs invited FDA to employ any disclaimer reasonably deemed necessary to avoid a potentially misleading connotation. Contradicting the Pearson I court, FDA has held the claim "inherently misleading" without undertaking the careful First Amendment analysis required of it to make that determination and without evaluating disclaimers as a less restrictive alternative to suppression.

CAUSE OF ACTION II: VIOLATION OF THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT

71. Plaintiffs reallege and restate paragraphs 1 through 60 and incorporate them herein.

72. FDA's Antioxidant Vitamin Health Claim Denial violates the Due Process Clause of the Fifth Amendment to the United States Constitution.

73. ***Plaintiffs' Protected Interest.*** Plaintiffs wish to communicate a statement conveying the relationship between antioxidant vitamins and risk of certain types of cancer on the labels and in the labeling of their dietary supplement products. FDA has prevented Plaintiffs from making such a claim, despite Plaintiffs' willingness to accompany the claim with reasonable disclaimers. In Pearson I, the United States Court

of Appeals for the D.C. Circuit held that FDA's outright denial of the Antioxidant Vitamin Health Claim unconstitutionally suppressed protected commercial speech. See id. at 659. That violation of Plaintiffs' First Amendment right to freedom of speech is a protected liberty interest under the Constitution of the United States.

74. ***Governmental Deprivation of Plaintiffs' Protected Interest.*** The Court in Pearson I remanded the case to FDA and instructed the agency to review the health claims under the First Amendment three-part test in Central Hudson Gas & Electric Corporation and to evaluate disclaimers as less restrictive alternatives to outright suppression. See Pearson I, 164 F.3d at 661. Since that January 15, 1999 decision, FDA has established a long pattern of deliberate noncompliance with the Court of Appeals Order, consequently denying Plaintiffs their First Amendment rights for over two-and-one-half years. Counsel for Plaintiffs repeatedly requested (by letters dated July 19, 1999; January 19, 2000; February 18, 2000; February 28, 2000; and March 3, 2000) that FDA set a "date certain" by which the agency would implement the constitutional mandate of Pearson I. FDA repeatedly refused (by letters dated September 17, 1999; February 17, 2000; February 28, 2000; and March 2, 2000) to commit to a date by which it would comply with the Court's Order and, in its ultimate May 4, 2001 Antioxidant Vitamin Health Claim Denial, it again failed to implement the Constitutional mandate.

75. On July 6, 2000, FDA set October 10, 2000, as the "date certain" by which the agency would issue its decision regarding the Antioxidant Vitamin Health Claim. During that interim period, Plaintiffs submitted numerous supplemental scientific and economic comments to aid FDA in its purported Pearson I review. On the October 10, 2000 deadline, FDA wrote to counsel for Plaintiffs extending the "date certain" until

October 24, 2000. Again on the October 24, 2000 deadline, FDA wrote to counsel for Plaintiffs extending the "date certain" until November 30, 2000. *In toto*, the agency postponed the "date certain" seven times, finally issuing a decision letter denying the Antioxidant Vitamin Health Claim outright on May 4, 2001—*206 days* after its initial deadline. Hence, since the Pearson I decision, Plaintiffs have been denied their constitutionally protected right to freedom of speech for a total of *912 days* past the January 15, 1999 date of that decision. In addition, FDA never performed the Central Hudson review required of it by the Court of Appeals and by this Court and never evaluated disclaimers (including the one recommended by the Court of Appeals) as less restrictive alternatives to claim suppression.

76. ***Deprivation without Procedural Protections.*** FDA's refusal to abide by the Pearson I Court Order is not an isolated incidence, but rather a continued and deliberate strategy. For example, in Pearson II this court issued a preliminary injunction instructing FDA to draft a reasonable disclaimer for Plaintiffs' Folic Acid Health Claim within 60 days because "there [wa]s no question that the agency…acted with less than reasonable speed in this case." See Pearson II, 130 F. Supp. 2d at 120. That preliminary injunction was issued because of the same pattern of intolerable delays and deliberate indifference to court orders that FDA has maintained in its approach to the Antioxidant Vitamin Health Claim.

77. Aside from the blatant tardiness of its Antioxidant Vitamin Health Claim Denial, FDA has refused to evaluate the claim under the constitutional orders of Pearson I and Pearson II. Instead FDA has denied outright Plaintiffs' Antioxidant Vitamin Health Claim, not even considering a reasonable disclaimer. As this court stated in Pearson II,

"it is clear that the FDA simply failed to comply with the constitutional guidelines outlined in Pearson. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion." Id. at 112. At this juncture—after Pearson II—there can be no mistake, FDA's decisions are deliberate acts of disobedience.

78. By rebuffing court orders and prolonging the implementation of the constitutional orders of Pearson I and II, FDA has disregarded the procedural mechanisms required to protect Plaintiffs' liberty interests and has done so without the constitutional process this Court has held due in the evaluation of health claims.

CAUSE OF ACTION III: VIOLATION OF THE OATH OF OFFICE TO SUPPORT AND DEFEND THE CONSTITUTION

79. Plaintiffs reallege and restate paragraphs 1 through 60 and incorporate them herein.

80. Bernard A. Schwetz, FDA Acting Principal Deputy Commissioner; Joseph A. Levitt, FDA Director of the Center for Food Safety and Applied Nutrition; and Christine J. Lewis, Ph.D., Director of the FDA Office of Nutritional Products, Labeling and Dietary Supplements at the FDA Center for Food Safety and Applied Nutrition have each sworn an oath of office, pursuant to 5 U.S.C. § 3331[3], as a condition precedent to civil service in the federal government. Those oaths require them to support and defend

[3] That section reads:

> An individual, except the President, elected or appointed to an office of honor or profit in the civil service or uniformed services, shall take the following oath: "I, AB, do solmenly swear (or affirm) that I will support and defend the Constitution of the United States against all enemies, foreign and domestic; that I will bear true faith and allegiance to the same; that I take this obligation freely, without any mental reservation or purpose of evasion; and that I will well and faithfully discharge the duties of the office on which I am about to enter. So help me God." This section does not affect other oaths required by law.

the Constitution, to bear true faith and allegiance to it, and to discharge the duties of their offices well and faithfully.

81. FDA Acting Commissioner Schwetz, FDA Center Director Levitt, and FDA Office Director Lewis have repeatedly refused to authorize with disclaimers health claims, including the Antioxidant Vitamin Health Claim, against the constitutional orders of the United States Court of Appeals in Pearson I and of the United States District Court in Pearson II. Those acts of disobedience violate their oaths of office.

CAUSE OF ACTION IV: VIOLATION OF THE NUTRITION LABELING AND EDUCATION ACT OF 1990

82. Plaintiffs reallege and restate paragraphs 1 through 60 and incorporate them herein.

83. In its Antioxidant Vitamin Health Claim Denial, FDA demands conclusive proof of a causal nexus between antioxidant vitamins and prevention or treatment of cancers at certain sites in the body.

84. FDA's demand for conclusive proof of prevention or treatment as a condition precedent to approval of Plaintiffs' Antioxidant Vitamin Health Claim is contrary to Congress's express intent for interpretation of "significant scientific agreement" in the Nutrition Labeling and Education Act of 1990 and contrary to the plain meaning of the statute, 21 U.S.C. § 343(r) *et seq.*

85. Congress has repeatedly faulted this agency for applying a more stringent standard than Congress intended. Congress did not intent for there to be a requirement of conclusive proof of a health claim for dietary supplements as a condition precedent to claim approval. Rather, Congress expected health claims to be approved under "significant scientific agreement" "when a significant segment of scientists having

relevant expertise agree, based on relevant scientific evidence, that consumers are reasonably likely to obtain the claimed health benefit." S. Rep. No. 103-410, at 24 (1994). Congress plainly did not contemplate that the drug pre-approval certainty standard would be applied. Rather, Congress defined "NLEA's goal" as that of "assuring that consumers have access on food and dietary supplement labels to health claims that are scientifically supported, without having to wait until the degree of scientific certainty contemplated by the drug standard has been achieved." S. Rep. No. 103-410, at 24 (1994).

86. Congress has severely criticized FDA for harboring an institutional bias against approval of dietary supplement health claims and for interpreting its health claims approval standard in a way that hinders, rather than fosters, the dissemination of scientific information and that limits consumer access to important information on diet and health. See S. Rep. No. 103-410, at 14, 16, 23, 24, 30 (1994); S. Rep. No. 105-43, at 49 (1997); H. Rep. No. 105-306, at 16 (1997).

87. FDA's demand of near conclusive proof of causality between Antioxidant Vitamins and cancer prevention or treatment violates the plain and intended meaning of the NLEA section concerning health claims approval.

CAUSE OF ACTION V: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT'S PROHIBITION ON ARBITRARY AND CAPRICIOUS AGENCY ACTION

88. Plaintiffs reallege and restate paragraphs 1 through 60 and incorporate them herein.

89. In 1993 the Defendants approved cancer risk reduction claims for foods low in fat and rich in antioxidants. See 21 C.F.R. § 101.78; 58 F.R. 2639 (Jan. 6

1993)(Model Claim 1: "Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber." Model Claim 2: "Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.") FDA recognized that antioxidants in fruits and vegetables quenched oxidants and free radicals which it found implicated in carcinogenesis. See 58 Fed. Reg. 2,622 (January 6, 1993).

90. In its May 4, 2001 rejection of Plaintiffs' Antioxidant Vitamin Health Claim Defendants arbitrarily and capriciously ignored scientific evidence on the role of antioxidants in quenching oxidants and free radicals. Defendants applied no consistent scrutiny to the scientific literature reviewed. FDA did not evaluate the actual health claim before it, focusing not on evidence of risk reduction before cancer initiation but on proof of cancer prevention or treatment after cancer initiation FDA did not perform the First Amendment analysis required of it in Pearson I and II, and FDA did not evaluate disclaimers as a less restrictive alternative to outright claim suppression.

91. Defendants' analysis of the scientific literature concerning antioxidants and cancer focused on the effect of antioxidants on prevention and treatment of cancer, a relationship not contemplated by the Plaintiffs' Antioxidant Vitamin Health Claim, and on the effect of single antioxidants instead of antioxidant combinations.

92. Defendants ignored the Pearson I Court's recommended disclaimer: "The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods."

93. Defendants' suppression of Plaintiffs' Antioxidant Vitamin Health Claim is an agency action and conclusion that is arbitrary, capricious, and an abuse of discretion in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2).

CAUSE OF ACTION VI: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT'S PROHIBITION ON AGENCY ACTION UNLAWFULLY WITHHELD AND UNREASONABLY DELAYED

94. Plaintiffs reallege and restate paragraphs 1 through 59 and incorporate them herein.

95. Since January 15, 1999, more than two years ago, Defendants have refused to comply with the constitutional orders of this Court and the United States Court of Appeals in Pearson I, II and III. Defendants have failed to apply the First Amendment analysis of Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557 (1980) and have failed to evaluate disclaimers as less restrictive alternatives to outright suppression. Defendants have thus unlawfully withheld and unreasonably delayed constitutionally mandated agency action.

96. In Pearson II, this Court recognized that the loss of First Amendment freedoms for any length of time results in irreparable injury. Pearson II required the Defendants to cease immediately the abridgement of the Plaintiff's First Amendment rights and to implement the First Amendment analysis of Central Hudson in the Health

Claim petition process. More than two years after Pearson I, the Defendants still refuse to abide by that requirement.

97. The Defendants have a non-discretionary duty to follow Central Hudson and enforce the First Amendment disclaimer requirement mandated by the Court of Appeals in Pearson I and this Court in Pearson II and III. Defendants' May 4th denial of Plaintiff's Antioxidant Vitamin Health Claim without undertaking the First Amendment analysis required by the Pearson decisions violates that duty.

98. The Defendants refusal to comply with the Court of Appeals' absolute requirement to implement the constitutional mandate of Pearson I is an unlawful withholding of and unreasonable delay in implementing, constitutionally required agency action in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1).

RELIEF REQUESTED

99. The Plaintiffs respectfully request that this Honorable Court:

100. **Declare** in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that the FDA's Antioxidant Vitamin Health Claim Denial is invalid; in particular, they request that this Court declare:

(a) that the FDA's Antioxidant Vitamin Health Claim Denial constitutes a willful violation of the First Amendment rights of the Plaintiffs, depriving them of their freedom of speech;

(b) that the FDA's Antioxidant Vitamin Health Claim Denial constitutes a willful violation of the Plaintiffs' right to Due Process of law under the Fifth Amendment, depriving Plaintiffs of the process ordered by the Court of Appeals and this Court for the evaluation of health claims in Pearson I and Pearson II;

(c) that the FDA's Antioxidant Vitamin Health Claim Denial is a violation of the oaths of office, required by 5 U.S.C. § 3331, of Bernard A. Schwetz, FDA Acting Principal Deputy Commissioner; Joseph A. Levitt, FDA Director of the Center for Food Safety and Applied Nutrition; and Christine J. Lewis, Ph.D., Director of the FDA Office of Nutritional Products, Labeling and Dietary Supplements at the FDA Center for Food Safety and Applied Nutrition who have each sworn to support and defend the Constitution, to bear true faith and allegiance to it, and to discharge the duties of their offices well and faithfully;

(d) that the FDA's Antioxidant Vitamin Health Claim Denial is a violation of the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343(r)(1)(B); and

(e) that the FDA's Antioxidant Vitamin Health Claim Denial constitutes arbitrary and capricious agency action, an abuse of discretion, and action contrary to law in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), and agency action unlawfully withheld and unreasonably delayed in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1).

101. **Order** in accordance with Pearson I and Pearson II's constitutional orders and the First Amendment that FDA permit Plaintiffs to place on the labels and in the labeling of their Antioxidant Vitamins the Antioxidant Vitamin Health Claim with one or more short, succinct, and accurate alternative disclaimers drafted by the agency, which may be chosen by Plaintiffs, to accompany the Antioxidant Vitamin Health Claim.

102. **Order** in accordance with 28 U.S.C. § 1361 (to compel an officer of the United States to perform his duty) and 5 U.S.C. § 706(1) that FDA and that FDA's Acting Principal Deputy Commissioner Bernard A. Schwetz; FDA's Director of the

Center for Food Safety and Applied Nutrition Joseph A. Levitt; and Director of the FDA Office of Nutritional Products, Labeling and Dietary Supplements at the FDA Center for Food Safety and Applied Nutrition Christine J. Lewis, Ph.D. come into immediate and full compliance with the Court of Appeals' and this Court's constitutional orders in Pearson I and Pearson II by henceforth evaluating all health claims submitted to FDA under the First Amendment standard prescribed in Pearson I and II and henceforth relying upon short, succinct and accurate disclaimers as less restrictive alternatives to suppression of potentially misleading health claims.

103. **Declare** that any continuing failure to comply with the Court's orders may result in Contempt of Court proceedings pursuant to the Court's inherent judicial authority to ensure that its orders are implemented and pursuant to 18 U.S.C. § 401, and declare that any Defendant found to have caused, aided in, abetted, or countenanced any continued failure to implement immediately, fully, and faithfully the orders of the United States Court of Appeals and this Court in Pearson I, II, and III shall be prosecuted for contempt and may be subjected to monetary penalties for noncompliance.

104. **Order** that the Defendants report to the Court within thirty days of the issuance of this Court's Order explaining the actions they have taken to comply with the Court's Order.

Respectfully submitted,

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