UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., **Whitaker Wellness Institute** **4321 Birch Street, Suite 100** **Newport Beach, CA 92623;**	)	
PURE ENCAPSULATIONS, INC., **490 Boston Post Road** **Sudbury, MA 01776;**	)	
DURK PEARSON and SANDY SHAW, **PO Box 2160** **Tonopah, Nevada 89049;**	)	
and the AMERICAN PREVENTIVE MEDICALASSOCIATION, 9912 Georgetown Pike, Suite D2, **Great Falls, VA 22066,**	)	
Plaintiffs,	)	
v.	)	**Civil Action No. _____**
DONNA E. SHALALA, 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;**	)	
JANE E. HENNEY, M.D. **COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane, Room 1471, Rockville, MD 20857;**	)	
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,
AND
INJUNCTIVE RELIEF

Plaintiffs Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; and the American Preventive Medical Association hereby file this Complaint against Defendants Donna E. Shalala, Secretary, United States Department of Health and Human Services; the United States Department of Health and Human Services; Jane E. Henney, M.D., Commissioner of Food and Drugs, Food and Drug Administration; Food and Drug Administration; and the United States of America, seeking review of the December 1, 1999 denial of a health claim petition, declaratory judgment, and preliminary and permanent injunctive relief. The denial is an invalid agency action that has a direct and immediate adverse impact on the Plaintiffs in violation of the First Amendment to the United States Constitution, U.S. CONST. amend. I; the Nutrition Labeling and Education Act, 21 USC § 343(r) *et seq*.; and the Administrative Procedure Act, 5 USC § 706.

The agency action, having the full force and effect of law, unequivocally prevents Plaintiffs for an indefinite future period from communicating on labels and in labeling the scientifically corroborated statement, "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia, and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)."

BRIEF STATEMENT OF THE CASE

1. The Plaintiffs wish to communicate on labels and in the labeling of the saw palmetto-containing dietary supplements that they sell, license for sale, and plan to sell the following statement characterizing the relationship between saw palmetto and benign prostatic hyperplasia: "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia, and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)" (Health Claim).

2. On May 25, 1999, the Plaintiffs filed a petition for approval of the Health Claim (Health Claim Petition) with the Food and Drug Administration (FDA) pursuant to Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FDCA) (21 USC § 343(r)(5)(D)) and Section 101.70 of the Administration's Rules (21 CFR § 101.70).

3. On September 1, 1999, the FDA filed the petition for comprehensive review in accordance with the procedures in Section 101.70(j)(2) of the Administration's Rules (21 CFR § 101.70(j)(2)).

4. On December 1, 1999, the FDA wrote to counsel for Plaintiffs explaining that ninety days had passed since the petition was filed and that FDA had taken no action, thereby causing the petition to be denied by operation of law pursuant to Section 403(r)(4)(A)(i) of the FDCA (21 USC § 343(r)(4)(A)(i)) and Section 101.70(j)(3)(iii) of the Administration's Rules (21 CFR § 101.70(j)(3)(iii)).

5. The FDA explained that it allowed the petition to be denied (and, thus, prohibited the Health Claim) because it deemed the Health Claim not like prior nutrient-disease risk reduction claims it had reviewed, writing: "Because your petition goes beyond risk reduction to claim an effect on an existing disease, the agency has had to

consider seriously whether health claims for foods (including dietary supplements) may encompass this type of claim or whether such a claim is appropriate only on a product that has been shown to meet the safety and efficacy requirements for drugs." The FDA's denial of the Health Claim suppresses the claim immediately and for an indefinite time into the future in violation of the First Amendment to the United States Constitution, U.S. CONST. amend. I; the Nutrition Labeling and Education Act, 21 U.S.C. § 343(r) *et seq.*; and the Administrative Procedure Act, 5 U.S.C. § 706. *See* Attachment A.

JURISDICTION

6. This Court has jurisdiction over this matter pursuant to 5 U.S.C. §§ 702 and 706 (hereinafter the "Administrative Procedure Act") and 28 U.S.C. § 1331 (federal question jurisdiction).

VENUE

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

DESCRIPTION OF THE PARTIES

8. ***Julian M. Whitaker, M.D.*** Julian M. Whitaker, M.D. is one of the parties to the Health Claim Petition that FDA denied. He 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 the 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 *Healthy Healing*, currently the nation's largest single editor health newsletter. In 1998, *Health & Healing* had 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 distribution and sale of several dietary supplements. Two supplement products in which Dr. Whitaker has a direct financial interest contain Saw Palmetto extract. He would like to place the Health Claim on the labels and in the labeling of those Saw Palmetto-containing dietary supplements.

9. ***Pure Encapsulations, Inc.*** Pure Encapsulations, Inc. (Pure) is one of the parties to the Health Claim Petition that FDA denied. Pure is a Massachusetts corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human and companion animal consumption. One of the supplement products manufactured and sold by Pure contains Saw Palmetto extract. Pure offers its saw palmetto product in packages of 60, 120 and 250 capsule bottles. Pure would like to place the Health Claim on the label and in the labeling of its saw palmetto-containing dietary supplement.

10. ***Durk Pearson and Sandy Shaw.*** Durk Pearson and Sandy Shaw are scientists residing in Nevada. They are two of the parties to the Health Claim Petition that FDA denied. 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 have designed a dietary supplement that contains Saw Palmetto extract and wish to license it with the Health Claim on the labels and in the labeling of that supplement.

11. ***American Preventive Medical Association.*** The American Preventive Medical Association (APMA) is a non-profit organization in Great Falls, Virginia. APMA is one of the parties to the Health Claim Petition that FDA denied. 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 information concerning the health benefits of Saw Palmetto extract. Several APMA physicians, including its over 450 physician members and its 14 physician board members, sell dietary supplements that contain the Saw Palmetto extract. APMA and its practitioner members and its practitioner board members along with their hundreds of thousands of patients would benefit from approval of the Health Claim because it would enable them to communicate and receive nonmisleading health information on the labels and in the labeling of their Saw Palmetto-containing dietary supplements.

12. ***Donna E. Shalala, Secretary, United States Department of Health and Human Services; United States Department of Health and Human Services; Jane E. Henney, M.D., Commissioner of Food and Drugs, Food and Drug Administration; Food and Drug Administration; and the United States of America.*** Donna E. Shalala (sued in her official capacity only) is the Secretary of the United States Department of

Health and Human Services, the executive department having jurisdiction over the Food and Drug Administration. Jane E. Henney, M.D. (sued in her official capacity only) is the Commissioner of the Food and Drug Administration, 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 Food and Drug Administration are part of the executive branch of the United States government.

LEGAL BACKGROUND

A. SAW PALMETTO IS A DIETARY SUPPLEMENT

13. Under Section 201 of the FDCA, 21 USC § 321(ff) a "dietary supplement" is defined as "a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A),(B),(C),(D), or (E) . . ."

To be a dietary supplement, the product must in pertinent part be "intended for ingestion;" "not be represented for use as a conventional food or as a sole item of a meal or the diet;" and must be "labeled as a dietary supplement." 21 U.S.C. § 321(ff).

14. The Plaintiffs' Saw Palmetto extract is a dietary supplement within the meaning of 21 USC § 321(ff). It is manufactured in accordance with accepted industry standards and in compliance with USP specifications in the revised United States

Pharmacopoeia (USP) saw palmetto monograph (1997). It meets the definition of a dietary "substance" in 21 CFR § 101.14(a). It is the *n*-hexane lipidosterolic extract of the pulp and seed (fruit) of the dwarf American palm, *Seronoa repens*. It is a mixture of free fatty acids and their esters, small quantities of phytosterols, and various other polyprenic compounds. Plaintiffs' Saw Palmetto extract is thus a botanical extract. It is intended for oral ingestion, and it is labeled and shall be labeled a dietary supplement.

15. For over two decades Saw Palmetto extract has been sold as a dietary supplement in the United States. There is wide agreement among experts on herbal use that there are no known safety risks associated with Saw Palmetto extract.

B. SUBSTANCE-DISEASE RELATIONSHIP CLAIMS ARE AUTHORIZED FOR DIETARY SUPPLEMENTS WITHOUT NEED FOR DRUG APPROVAL

16. Under Section 403 of the FDCA, 21 U.S.C. § 343, a dietary supplement is deemed "misbranded" and an "unapproved new drug," and, thus, may not lawfully be sold and distributed in the United States (21 U.S.C. §§ 331 and 333) if it includes a claim on its label or in its labeling[1] that expressly or by implication "characterizes the relationship of any nutrient . . . to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D)." 21 USC § 343(r)(1)(B).

17. Dietary supplements are subject to 21 USC § 343(r)(5)(D), delegating to the Secretary the authority to promulgate a standard and procedure for the evaluation of "health claims"[2] for dietary supplements.

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[1] "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 USC § 321(k) (1994). "Labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m).

[2] A "health claim" is defined as a "claim made on the label or in the labeling of a . . . dietary supplement that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." 21 CFR § 101.14(a)(1) (1998).

18. FDA requires that health claims be approved by the agency before being added to the label of a dietary supplement. 21 U.S.C. § 343(r)(5)(D); 21 CFR § 101.14. If dietary supplements contain health claims that are not pre-approved they are deemed misbranded and unapproved new drugs within the meaning of 21 U.S.C. § 321(g)(1)(B) and may be seized or enjoined from being sold. 21 U.S.C. §§ 333 and 334.

19. The FDA authorizes a health claim for dietary supplements

> when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 CFR § 101.14(c).

20. FDA authorizes health claims by informal rulemaking under the Administrative Procedure Act. 21 CFR § 101.70; 5 U.S.C. § 553.

FACTUAL BACKGROUND

21. On May 25, 1999, the Plaintiffs filed a health claim petition with the Food and Drug Administration, seeking agency approval of the following claim, "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia, and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)." The petition included all substantive and scientific information needed to permit comprehensive review of its content by the Food and Drug Administration. The FDA therefore accepted the petition for filing for comprehensive review on September 1, 1999. Consistent with *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999), the Plaintiffs requested within their petition that FDA

approve the claim with such disclaimer or disclaimers as the agency reasonably deemed necessary to avoid any potentially misleading connotation.

22. On December 1, 1999, the FDA allowed the petition to be denied by operation of law under 21 U.S.C. § 343(r)(4)(A)(i) and 21 CFR § 101.70(j)(3)(iii), choosing not to take action on it. Denial maintains the existing legal prohibition on the use of the Health Claim. The agency stated that it did not take action on the petition because the Health Claim "goes beyond risk reduction to claim an effect on an existing disease," indicating that the statutory provision for health claims approval of dietary supplements did not embrace the substance-disease claim filed by the Plaintiffs. FDA wrote: ". . . the agency has had to consider seriously whether such a claim is appropriate only on a product that has been shown to meet the safety and efficacy requirements for drugs." FDA then stated an intention to solicit public input at an unspecified future time on the question of whether the claim should only be approved under the statutory regime for new drugs.

23. The agency did not evaluate Plaintiffs' request that the claim be approved with such disclaimer as, or such disclaimers as, would avoid a misleading connotation pursuant to *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999).

24. The Plaintiffs (and, in the case of APMA, its physician members) may not lawfully market the products with the Health Claim on labels and in labeling and will continue to be prevented from communicating the benefits of the proposed Health Claim to sufferers of BPH for an indefinite time into the future.

CAUSE OF ACTION I: VIOLATION OF THE U.S. CONSTITUTION

A. FDA'S DENIAL OF PLAINTIFFS' HEALTH CLAIM PETITION VIOLATES THE FIRST AMENDMENT

25. Plaintiffs reallege and restate paragraphs 1 through 22 and incorporate them herein.

26. The FDA's December 1, 1999 Denial of Plaintiffs' Health Claim petition violates the First Amendment to the United States Constitution. It unconstitutionally suppresses protected commercial speech that conveys factual information important to adult male sufferers of BPH concerning the effects of Saw Palmetto extract on reducing symptoms commonly associated with benign prostatic hyperplasia (BPH).

B. FDA'S DENIAL OF PLAINTIFFS' PETITION UNCONSTITUTIONALLY SUPPRESSES COMMERCIAL SPEECH BY NOT AUTHORIZING THE HEALTH CLAIM WITH A CORRECTIVE DISCLAIMER

27. Plaintiffs reallege and restate paragraphs 1 through 22 and incorporate them herein.

28. The FDA's December 1, 1999 Denial of Plaintiffs' Health Claim petition violates the First Amendment commercial speech doctrine by suppressing Plaintiffs' Health Claim instead of authorizing it with such disclaimer as is, or such disclaimers as are, reasonably necessary to avoid a misleading connotation.

29. For example, if the FDA's concern is to avoid the connotation that Saw Palmetto extract is a substitute for the prescription drug FDA has authorized for the treatment of BPH, finasteride, it could have required that the claim be accompanied by a disclaimer stating, "Those who have symptoms of BPH should consult with their physicians concerning how best to treat the condition. Saw Palmetto extract is not a

substitute for FDA-authorized drug treatments for BPH or for other surgical interventions." Instead, FDA chose to suppress the claim outright.

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

30. Plaintiffs reallege and restate paragraphs 1 through 22 and incorporate them herein.

31. Prior to the adoption of the Nutrition Labeling and Education Act of 1990 (NLEA), health claims could not be made for dietary supplements without obtaining new drug approval for those products, effectively preventing the communication of nutrient-disease health information to consumers at the point of sale. Prior to the NLEA, a dietary supplement could only bear a health claim if the product received approval as a new drug under the provisions of the FDCA governing approval of drug products for marketing, sale, and distribution. 21 U.S.C. § 355.

32. Under the NLEA, however, Congress expressly created an alternative means for making health claims for dietary supplements. It chose to permit dietary supplements to bear health claims on their labels and in their labeling without need for receiving approval of the product as a new drug, provided that the claims themselves were approved following submission of a health claims petition. Under 21 U.S.C. § 343(r)(1)(B), Congress authorized dietary supplements to bear a label or labeling claim that "characterizes the relationship of any nutrient . . . to a disease or a health-related condition" if "the claim is made in accordance with subparagraph (3) or (5)(D)." Congress did not limit to disease risk reduction claims the kinds of claims that relate a nutrient to a disease. Rather, any nutrient-disease claim for a dietary supplement falls within the scope of 21 U.S.C. § 343(r)(1)(B).

33. The plain language of 21 U.S.C. § 343(r) and the legislative history concerning the NLEA plainly reveal that Congress intended for FDA to evaluate every dietary supplement health claim characterizing the relationship of a nutrient to a disease or a health-related condition under the provisions of 21 U.S.C. § 343(r)(1)(B) (pertaining to dietary supplements) and not under the provisions of 21 U.S.C. § 355 (pertaining to drugs).

34. FDA violated the plain language of the NLEA, 21 U.S.C. § 343 (r)(1)(B), and acted in contravention of the legislative history concerning the NLEA, when in its December 1, 1999 Denial of Plaintiffs' Health Claim petition, it refused to review the petition's disease reduction claims on the grounds that such claims should be evaluated under the process for drug approval in 21 U.S.C. § 355.

CAUSE OF ACTION III: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

35. Plaintiffs reallege and restate paragraphs 1 through 22 and incorporate them herein.

36. FDA's December 1, 1999 Denial of Plaintiffs' Health Claim petition is an arbitrary and capricious agency action, an abuse of discretion, and contrary to law in violation of the Administrative Procedure Act, 5 U.S.C. § 706, because it violates 21 U.S.C. §§ 343(r)(4) and (r)(5)(D) by not evaluating the Health Claim petition under the procedure established by Congress for dietary supplements; violates the First Amendment to the United States Constitution by not authorizing the claim with reasonable disclaimers; and violates the FDA's own health claim rules for dietary supplements, 21 CFR.§§ 101.14 and 101.70.

RELIEF REQUESTED

37. The Plaintiffs respectfully request that this Honorable Court declare in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that the FDA's December 1, 1999 denial of the Plaintiffs' Health Claim petition is invalid; in particular, they request that this Court declare:

(a) that the FDA's December 1, 1999 Denial of the Plaintiffs' Health Claim petition violates the First Amendment to the United States Constitution;

(b) that the FDA's December 1, 1999 Denial of the Plaintiffs' Health Claim petition violates the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343(r)(1)(B).

(c) that the FDA's December 1, 1999 Denial of the Plaintiffs' Health Claim petition is an arbitrary and capricious agency action, an abuse of discretion, and is contrary to law in violation of the Administrative Procedure Act, 5 U.S.C. § 706.

38. The Plaintiffs also respectfully request that this Honorable Court order the FDA to evaluate the Plaintiffs' Health Claim petition under the congressionally required scheme for the evaluation of health claims on dietary supplement labels and in dietary supplement labeling in 21 U.S.C. § 343(r)(1)(B).

39. The Plaintiffs also respectfully request that this Honorable Court order the FDA to consider authorizing the claims with such disclaimer as is, or such disclaimers as are, reasonably necessary to avoid a misleading connotation in accordance with the requirements of the First Amendment as mandated by this Court in compliance with the

decision of the United States Court of Appeals for the D.C. Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999).

Respectfully submitted,

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